Anhang 4-G: Ergänzende Daten zu den in Abschnitt 4.3.1.3 gezeigten Ergebnissen für die Studie RATIONALE 302

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Table 14.1.1.2.1.b:
Patient Disposition and Reasons for Discontinuation
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139) n (%)	ICC (N = 138) n (%)	Total (N = 277) n (%)
Number of Patients Randomized	139 (100.0)	138 (100.0)	277 (100.0)
Patients Randomized, but Not Treated	0 (0.0)	9 (6.5)	9 (3.2)
Primary Reason for Not Treated			
Adverse Event	0 (0.0)	2 (1.4)	2 (0.7)
Withdrawal by Subject	0 (0.0)	6 (4.3)	6 (2.2)
Other	0 (0.0)	1 (0.7)	1 (0.4)
Number of Patients Treated	139 (100.0)	129 (93.5)	268 (96.8)

Source: Listing 16.2.1.3, 16.2.1.4. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
[a] Study follow-up duration is defined as the duration from the randomization date to the study discontinuation date (due to death, consent withdrawal, lost to follow-up etc.)
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Table 14.1.1.2.1.b:
Patient Disposition and Reasons for Discontinuation
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139) n (%)	ICC (N = 138) n (%)	Total (N = 277) n (%)
Number of Patients Discontinued From Treatment	128 (92.1)	128 (92.8)	256 (92.4)
Primary Reason for Study Drug Discontinuation			
Radiographic Progression	98 (70.5)	82 (59.4)	180 (65.0)
Adverse Event	17 (12.2)	19 (13.8)	36 (13.0)
Related to COVID-19	0 (0.0)	0 (0.0)	0 (0.0)
Clinical Progression	9 (6.5)	10 (7.2)	19 (6.9)
Related to COVID-19	0 (0.0)	0 (0.0)	0 (0.0)
Withdrawal by Subject	2 (1.4)	12 (8.7)	14 (5.1)
Physician Decision	0 (0.0)	4 (2.9)	4 (1.4)
Other	2 (1.4)	1 (0.7)	3 (1.1)
Related to COVID-19	0 (0.0)	0 (0.0)	0 (0.0)
Number of Patients Remained on Treatment	11 (7.9)	1 (0.7)	12 (4.3)

Source: Listing 16.2.1.3, 16.2.1.4. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
[a] Study follow-up duration is defined as the duration from the randomization date to the study discontinuation date (due to death, consent withdrawal, lost to follow-up etc.)
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Table 14.1.1.2.1.b:
Patient Disposition and Reasons for Discontinuation
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139) n (%)	ICC (N = 138) n (%)	Total (N = 277) n (%)
Number of Patients Discontinued From Study	109 (78.4)	121 (87.7)	230 (83.0)
Primary Reason for Study Discontinuation			
Subject Death	105 (75.5)	112 (81.2)	217 (78.3)
Related to COVID-19	0 (0.0)	0 (0.0)	0 (0.0)
Voluntary Withdrawal by Subject	4 (2.9)	7 (5.1)	11 (4.0)
Subject Lost to Follow-up	0 (0.0)	2 (1.4)	2 (0.7)
Related to COVID-19	0 (0.0)	0 (0.0)	0 (0.0)
Number of Patients Remained on Study	30 (21.6)	17 (12.3)	47 (17.0)
Study Follow-up Duration (months) [a]			
n	139	138	277
Mean (SD)	9.98 (7.171)	8.17 (6.338)	9.08 (6.817)
Median	8.61	6.54	7.39
Q1, Q3	3.91, 14.19	3.29, 10.97	3.68, 12.65
Min, Max	0.4, 31.7	0.1, 30.8	0.1, 31.7

Source: Listing 16.2.1.3, 16.2.1.4. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
[a] Study follow-up duration is defined as the duration from the randomization date to the study discontinuation date (due to death, consent withdrawal, lost to follow-up etc.)
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Table 14.1.2.1:
Summary of Demographics and Baseline Characteristics
ITT Analysis Set

Parameter	Tislelizumab (N = 256)	ICC (N = 256)	Total (N = 512)
Age (years)			
n	256	256	512
Mean (SD)	61.4 (8.43)	61.6 (8.01)	61.5 (8.21)
Median	62.0	63.0	62.0
Q1, Q3	55.0, 67.0	55.0, 66.0	55.0, 67.0
Min, Max	40, 86	35, 81	35, 86
Age Group, n (%)			
<65 years	157 (61.3)	161 (62.9)	318 (62.1)
>=65 years	99 (38.7)	95 (37.1)	194 (37.9)
Gender, n (%)			
Female	39 (15.2)	41 (16.0)	80 (15.6)
Male	217 (84.8)	215 (84.0)	432 (84.4)

Source: Listing 16.2.4.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; BMI = Body Mass Index; ECOG = Eastern Cooperative Oncology Group; vCPS = visually-estimated combined positive score.
Percentages were based on N.
PD-L1 positive is defined as vCPS >= 10%, PD-L1 negative is defined as vCPS < 10%, PD-L1 missing refers to the patients without sample collection, not evaluable at baseline, or scored with unqualified sample.
[a] 3 patients refused to report race and were entered with race of "unknown" by the site.
[b] 3 patients refused to report ethnicity and were entered with ethnicity of "unknown" by the site.
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Table 14.1.2.1:
Summary of Demographics and Baseline Characteristics
ITT Analysis Set

Parameter	Tislelizumab (N = 256)	ICC (N = 256)	Total (N = 512)
Race, n (%)			
Asian	201 (78.5)	207 (80.9)	408 (79.7)
Chinese	161 (62.9)	163 (63.7)	324 (63.3)
Japanese	25 (9.8)	25 (9.8)	50 (9.8)
Korean	15 (5.9)	16 (6.3)	31 (6.1)
Asian Indian	0 (0.0)	3 (1.2)	3 (0.6)
White or Caucasian	53 (20.7)	44 (17.2)	97 (18.9)
Not Reported [a]	1 (0.4)	0 (0.0)	1 (0.2)
Unknown	1 (0.4)	2 (0.8)	3 (0.6)
Black or African American	0 (0.0)	2 (0.8)	2 (0.4)
Other	0 (0.0)	1 (0.4)	1 (0.2)
Ethnicity, n (%)			
Not Hispanic or Latino	252 (98.4)	252 (98.4)	504 (98.4)
Hispanic or Latino	2 (0.8)	2 (0.8)	4 (0.8)
Not Reported [b]	1 (0.4)	0 (0.0)	1 (0.2)
Unknown	1 (0.4)	2 (0.8)	3 (0.6)

Source: Listing 16.2.4.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; BMI = Body Mass Index; ECOG = Eastern Cooperative Oncology Group; vCPS = visually-estimated combined positive score.

Percentages were based on N.

PD-L1 positive is defined as vCPS >= 10%, PD-L1 negative is defined as vCPS < 10%, PD-L1 missing refers to the patients without sample collection, not evaluable at baseline, or scored with unqualified sample.

[a] 3 patients refused to report race and were entered with race of "unknown" by the site.

[b] 3 patients refused to report ethnicity and were entered with ethnicity of "unknown" by the site.

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Table 14.1.2.1:
Summary of Demographics and Baseline Characteristics
ITT Analysis Set

Parameter	Tislelizumab (N = 256)	ICC (N = 256)	Total (N = 512)
ECOG Status, n (%)			
0	66 (25.8)	60 (23.4)	126 (24.6)
1	190 (74.2)	196 (76.6)	386 (75.4)
Height (cm)			
n	254	256	510
Mean (SD)	166.89 (6.862)	166.56 (7.842)	166.72 (7.365)
Median	168.00	167.00	168.00
Q1, Q3	163.00, 172.00	162.00, 172.00	162.50, 172.00
Min, Max	147.0, 182.9	140.0, 189.0	140.0, 189.0
Weight (kg)			
n	256	256	512
Mean (SD)	59.32 (10.275)	60.15 (11.745)	59.73 (11.032)
Median	58.85	59.55	59.00
Q1, Q3	52.25, 66.00	52.00, 67.00	52.00, 66.10
Min, Max	37.5, 99.0	37.2, 105.0	37.2, 105.0

Source: Listing 16.2.4.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; BMI = Body Mass Index; ECOG = Eastern Cooperative Oncology Group; vCPS = visually-estimated combined positive score.
Percentages were based on N.
PD-L1 positive is defined as vCPS >= 10%, PD-L1 negative is defined as vCPS < 10%, PD-L1 missing refers to the patients without sample collection, not evaluable at baseline, or scored with unqualified sample.
[a] 3 patients refused to report race and were entered with race of "unknown" by the site.
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Table 14.1.2.1:
Summary of Demographics and Baseline Characteristics
ITT Analysis Set

Parameter	Tislelizumab (N = 256)	ICC (N = 256)	Total (N = 512)
BMI (kg/m^2)			
n	254	256	510
Mean (SD)	21.27 (3.393)	21.62 (3.569)	21.45 (3.483)
Median	21.06	21.15	21.10
Q1, Q3	18.75, 23.18	18.85, 23.89	18.83, 23.48
Min, Max	14.0, 37.7	14.3, 33.1	14.0, 37.7
PD-L1 Status, n (%)			
vCPS >= 10%	80 (31.3)	62 (24.2)	142 (27.7)
vCPS < 10%	100 (39.1)	122 (47.7)	222 (43.4)
Missing	76 (29.7)	72 (28.1)	148 (28.9)
Smoking Status, n (%)			
Never	68 (26.6)	63 (24.6)	131 (25.6)
Former	162 (63.3)	159 (62.1)	321 (62.7)
Current	26 (10.2)	33 (12.9)	59 (11.5)
Missing	0 (0.0)	1 (0.4)	1 (0.2)

Source: Listing 16.2.4.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; BMI = Body Mass Index; ECOG = Eastern Cooperative Oncology Group; vCPS = visually-estimated combined positive score.
Percentages were based on N.
PD-L1 positive is defined as vCPS >= 10%, PD-L1 negative is defined as vCPS < 10%, PD-L1 missing refers to the patients without sample collection, not evaluable at baseline, or scored with unqualified sample.
[a] 3 patients refused to report race and were entered with race of "unknown" by the site.
[b] 3 patients refused to report ethnicity and were entered with ethnicity of "unknown" by the site.
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Table 14.1.2.1:
Summary of Demographics and Baseline Characteristics
ITT Analysis Set

Parameter	Tislelizumab (N = 256)	ICC (N = 256)	Total (N = 512)
Alcohol Consumption, n (%)			
Never	75 (29.3)	73 (28.5)	148 (28.9)
Former	146 (57.0)	151 (59.0)	297 (58.0)
Current	34 (13.3)	31 (12.1)	65 (12.7)
Missing	1 (0.4)	1 (0.4)	2 (0.4)
ICC Options, n (%)			
Paclitaxel	83 (32.4)	85 (33.2)	168 (32.8)
Docetaxel	56 (21.9)	53 (20.7)	109 (21.3)
Irinotecan	117 (45.7)	118 (46.1)	235 (45.9)
Region #1, n (%)			
Asia	201 (78.5)	203 (79.3)	404 (78.9)
Europe/North America	55 (21.5)	53 (20.7)	108 (21.1)

Source: Listing 16.2.4.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; BMI = Body Mass Index; ECOG = Eastern Cooperative Oncology Group; vCPS = visually-estimated combined positive score.
Percentages were based on N.
PD-L1 positive is defined as vCPS >= 10%, PD-L1 negative is defined as vCPS < 10%, PD-L1 missing refers to the patients without sample collection, not evaluable at baseline, or scored with unqualified sample.
[a] 3 patients refused to report race and were entered with race of "unknown" by the site.
[b] 3 patients refused to report ethnicity and were entered with ethnicity of "unknown" by the site.
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Table 14.1.2.1:
Summary of Demographics and Baseline Characteristics
ITT Analysis Set

Parameter	Tislelizumab (N = 256)	ICC (N = 256)	Total (N = 512)
Region #2, n (%)			
Asia (excluding Japan)	176 (68.8)	178 (69.5)	354 (69.1)
Japan	25 (9.8)	25 (9.8)	50 (9.8)
Europe/North America	55 (21.5)	53 (20.7)	108 (21.1)

Source: Listing 16.2.4.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; BMI = Body Mass Index; ECOG = Eastern Cooperative Oncology Group; vCPS = visually-estimated combined positive score.

Percentages were based on N.

PD-L1 positive is defined as vCPS >= 10%, PD-L1 negative is defined as vCPS < 10%, PD-L1 missing refers to the patients without sample collection, not evaluable at baseline, or scored with unqualified sample.

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[b] 3 patients refused to report ethnicity and were entered with ethnicity of "unknown" by the site.

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Table 14.1.2.1.b:
Summary of Demographics and Baseline Characteristics
ITT Analysis Set - Subpopulation without Irinotecan

Parameter	Tislelizumab (N = 139)	ICC (N = 138)	Total (N = 277)
Age (years)			
n	139	138	277
Mean (SD)	61.8 (9.11)	62.7 (8.40)	62.3 (8.76)
Median	63.0	63.5	63.0
Q1, Q3	55.0, 68.0	57.0, 68.0	55.0, 68.0
Min, Max	40, 83	35, 81	35, 83
Age Group, n (%)			
<65 years	77 (55.4)	77 (55.8)	154 (55.6)
>=65 years	62 (44.6)	61 (44.2)	123 (44.4)
Gender, n (%)			
Female	21 (15.1)	27 (19.6)	48 (17.3)
Male	118 (84.9)	111 (80.4)	229 (82.7)

Source: Listing 16.2.4.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; BMI = Body Mass Index; ECOG = Eastern Cooperative Oncology Group; vCPS = visually-estimated combined positive score.
Percentages were based on N.
PD-L1 positive is defined as vCPS >= 10%, PD-L1 negative is defined as vCPS < 10%, PD-L1 missing refers to the patients without sample collection, not evaluable at baseline, or scored with unqualified sample.
[a] 3 patients refused to report race and were entered with race of "unknown" by the site.
[b] 3 patients refused to report ethnicity and were entered with ethnicity of "unknown" by the site.
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Table 14.1.2.1.b:
Summary of Demographics and Baseline Characteristics
ITT Analysis Set - Subpopulation without Irinotecan

Parameter	Tislelizumab (N = 139)	ICC (N = 138)	Total (N = 277)
Race, n (%)			
Asian	103 (74.1)	109 (79.0)	212 (76.5)
Chinese	66 (47.5)	66 (47.8)	132 (47.7)
Japanese	25 (18.0)	25 (18.1)	50 (18.1)
Korean	12 (8.6)	15 (10.9)	27 (9.7)
Asian Indian	0 (0.0)	3 (2.2)	3 (1.1)
White or Caucasian	34 (24.5)	24 (17.4)	58 (20.9)
Not Reported [a]	1 (0.7)	0 (0.0)	1 (0.4)
Unknown	1 (0.7)	2 (1.4)	3 (1.1)
Black or African American	0 (0.0)	2 (1.4)	2 (0.7)
Other	0 (0.0)	1 (0.7)	1 (0.4)
Ethnicity, n (%)			
Not Hispanic or Latino	135 (97.1)	134 (97.1)	269 (97.1)
Hispanic or Latino	2 (1.4)	2 (1.4)	4 (1.4)
Not Reported [b]	1 (0.7)	0 (0.0)	1 (0.4)
Unknown	1 (0.7)	2 (1.4)	3 (1.1)

Source: Listing 16.2.4.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; BMI = Body Mass Index; ECOG = Eastern Cooperative Oncology Group; vCPS = visually-estimated combined positive score.

Percentages were based on N.

PD-L1 positive is defined as vCPS >= 10%, PD-L1 negative is defined as vCPS < 10%, PD-L1 missing refers to the patients without sample collection, not evaluable at baseline, or scored with unqualified sample.

[a] 3 patients refused to report race and were entered with race of "unknown" by the site.

[b] 3 patients refused to report ethnicity and were entered with ethnicity of "unknown" by the site.

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Table 14.1.2.1.b:
Summary of Demographics and Baseline Characteristics
ITT Analysis Set - Subpopulation without Irinotecan

Parameter	Tislelizumab (N = 139)	ICC (N = 138)	Total (N = 277)
ECOG Status, n (%)			
0	44 (31.7)	39 (28.3)	83 (30.0)
1	95 (68.3)	99 (71.7)	194 (70.0)
Height (cm)			
n	139	138	277
Mean (SD)	166.59 (6.813)	165.84 (7.904)	166.22 (7.373)
Median	167.00	167.00	167.00
Q1, Q3	163.00, 171.50	160.00, 170.30	162.00, 171.00
Min, Max	149.0, 182.9	140.0, 189.0	140.0, 189.0
Weight (kg)			
n	139	138	277
Mean (SD)	59.03 (10.402)	58.98 (11.154)	59.00 (10.764)
Median	58.00	58.70	58.00
Q1, Q3	52.50, 66.00	50.40, 67.00	51.80, 66.00
Min, Max	38.4, 99.0	37.2, 101.3	37.2, 101.3

Source: Listing 16.2.4.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; BMI = Body Mass Index; ECOG = Eastern Cooperative Oncology Group; vCPS = visually-estimated combined positive score.
Percentages were based on N.
PD-L1 positive is defined as vCPS >= 10%, PD-L1 negative is defined as vCPS < 10%, PD-L1 missing refers to the patients without sample collection, not evaluable at baseline, or scored with unqualified sample.
[a] 3 patients refused to report race and were entered with race of "unknown" by the site.
[b] 3 patients refused to report ethnicity and were entered with ethnicity of "unknown" by the site.
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Table 14.1.2.1.b:
Summary of Demographics and Baseline Characteristics
ITT Analysis Set - Subpopulation without Irinotecan

Parameter	Tislelizumab (N = 139)	ICC (N = 138)	Total (N = 277)
BMI (kg/m^2)			
n	139	138	277
Mean (SD)	21.26 (3.499)	21.40 (3.542)	21.33 (3.515)
Median	21.08	21.12	21.11
Q1, Q3	18.82, 23.05	18.66, 24.02	18.80, 23.47
Min, Max	14.2, 37.7	14.3, 32.1	14.2, 37.7
PD-L1 Status, n (%)			
vCPS >= 10%	45 (32.4)	34 (24.6)	79 (28.5)
vCPS < 10%	53 (38.1)	56 (40.6)	109 (39.4)
Missing	41 (29.5)	48 (34.8)	89 (32.1)
Smoking Status, n (%)			
Never	35 (25.2)	33 (23.9)	68 (24.5)
Former	86 (61.9)	90 (65.2)	176 (63.5)
Current	18 (12.9)	15 (10.9)	33 (11.9)

Source: Listing 16.2.4.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; BMI = Body Mass Index; ECOG = Eastern Cooperative Oncology Group; vCPS = visually-estimated combined positive score.

Percentages were based on N.

PD-L1 positive is defined as vCPS >= 10%, PD-L1 negative is defined as vCPS < 10%, PD-L1 missing refers to the patients without sample collection, not evaluable at baseline, or scored with unqualified sample.

[a] 3 patients refused to report race and were entered with race of "unknown" by the site.

[b] 3 patients refused to report ethnicity and were entered with ethnicity of "unknown" by the site.

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Table 14.1.2.1.b:
Summary of Demographics and Baseline Characteristics
ITT Analysis Set - Subpopulation without Irinotecan

Parameter	Tislelizumab (N = 139)	ICC (N = 138)	Total (N = 277)
Alcohol Consumption, n (%)			
Never	35 (25.2)	30 (21.7)	65 (23.5)
Former	80 (57.6)	88 (63.8)	168 (60.6)
Current	23 (16.5)	19 (13.8)	42 (15.2)
Missing	1 (0.7)	1 (0.7)	2 (0.7)
ICC Options, n (%)			
Paclitaxel	83 (59.7)	85 (61.6)	168 (60.6)
Docetaxel	56 (40.3)	53 (38.4)	109 (39.4)
Region #1, n (%)			
Asia	103 (74.1)	105 (76.1)	208 (75.1)
Europe/North America	36 (25.9)	33 (23.9)	69 (24.9)

Source: Listing 16.2.4.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; BMI = Body Mass Index; ECOG = Eastern Cooperative Oncology Group; vCPS = visually-estimated combined positive score.

Percentages were based on N.

PD-L1 positive is defined as vCPS >= 10%, PD-L1 negative is defined as vCPS < 10%, PD-L1 missing refers to the patients without sample collection, not evaluable at baseline, or scored with unqualified sample.

[a] 3 patients refused to report race and were entered with race of "unknown" by the site.

[b] 3 patients refused to report ethnicity and were entered with ethnicity of "unknown" by the site.

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Table 14.1.2.1.b:
Summary of Demographics and Baseline Characteristics
ITT Analysis Set - Subpopulation without Irinotecan

Parameter	Tislelizumab (N = 139)	ICC (N = 138)	Total (N = 277)
Region #2, n (%)			
Asia (excluding Japan)	78 (56.1)	80 (58.0)	158 (57.0)
Japan	25 (18.0)	25 (18.1)	50 (18.1)
Europe/North America	36 (25.9)	33 (23.9)	69 (24.9)

Source: Listing 16.2.4.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; BMI = Body Mass Index; ECOG = Eastern Cooperative Oncology Group; vCPS = visually-estimated combined positive score.

Percentages were based on N.

PD-L1 positive is defined as vCPS >= 10%, PD-L1 negative is defined as vCPS < 10%, PD-L1 missing refers to the patients without sample collection, not evaluable at baseline, or scored with unqualified sample.

[a] 3 patients refused to report race and were entered with race of "unknown" by the site.

[b] 3 patients refused to report ethnicity and were entered with ethnicity of "unknown" by the site.

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Table 14.1.3.1:
Disease History and Characteristics at Study Entry
ITT Analysis Set

Description	Tislelizumab (N = 256)	ICC (N = 256)	Total (N = 512)
Number of Patient With Metastatic Diagnosis at Study Entry, n (%)			
Yes	251 (98.0)	236 (92.2)	487 (95.1)
No	5 (2.0)	20 (7.8)	25 (4.9)
Time from Metastatic Diagnosis to Study Entry (months)			
n	251	236	487
Mean (SD)	6.66 (6.585)	7.09 (6.791)	6.87 (6.682)
Median	5.26	5.37	5.36
Q1, Q3	1.18, 9.86	1.95, 10.00	1.54, 9.92
Min, Max	0.2, 43.5	0.2, 53.0	0.2, 53.0
Prior Systemic Therapy, n (%)			
Chemotherapy	94 (36.7)	101 (39.5)	195 (38.1)
Chemo-Radiotherapy	161 (62.9)	155 (60.5)	316 (61.7)
Other *	1 (0.4)	0 (0.0)	1 (0.2)

Source: Listing 16.2.4.4. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Percentages were based on N.
Study Entry date referred to randomization date in this study.
[a] A patient was counted only once within each category, but may be counted in multiple categories.
* Other was the combination of chemotherapy and a monoclonal antibody of epidermal growth factor receptor.
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Table 14.1.3.1:
Disease History and Characteristics at Study Entry
ITT Analysis Set

Description	Tislelizumab (N = 256)	ICC (N = 256)	Total (N = 512)
Primary Site of Esophageal Cancer at Diagnosis, n (%)			
Cervical	6 (2.3)	4 (1.6)	10 (2.0)
Upper	42 (16.4)	49 (19.1)	91 (17.8)
Middle	107 (41.8)	86 (33.6)	193 (37.7)
Lower	68 (26.6)	86 (33.6)	154 (30.1)
Overlapping Lesions	11 (4.3)	9 (3.5)	20 (3.9)
Esophagus NOS	22 (8.6)	22 (8.6)	44 (8.6)
Histologic Grade at Diagnosis, n (%)			
Gx - Grade cannot be assessed	19 (7.4)	14 (5.5)	33 (6.4)
G1 - Well differentiated	23 (9.0)	16 (6.3)	39 (7.6)
G2 - Moderately differentiated	86 (33.6)	97 (37.9)	183 (35.7)
G3 - Poorly differentiated	49 (19.1)	58 (22.7)	107 (20.9)
Not Done	79 (30.9)	71 (27.7)	150 (29.3)

Source: Listing 16.2.4.4. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Percentages were based on N.
Study Entry date referred to randomization date in this study.
[a] A patient was counted only once within each category, but may be counted in multiple categories.
* Other was the combination of chemotherapy and a monoclonal antibody of epidermal growth factor receptor.
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Table 14.1.3.1:
Disease History and Characteristics at Study Entry
ITT Analysis Set

Description	Tislelizumab (N = 256)	ICC (N = 256)	Total (N = 512)
Target Lesions Sum of Diameter by Investigator (mm)			
n	237	246	483
Mean (SD)	49.30 (32.325)	49.35 (32.307)	49.33 (32.282)
Median	42.00	42.00	42.00
Q1, Q3	25.70, 66.20	23.00, 66.00	24.60, 66.00
Min, Max	10.0, 261.0	10.0, 238.0	10.0, 261.0

Source: Listing 16.2.4.4. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Percentages were based on N.
Study Entry date referred to randomization date in this study.
[a] A patient was counted only once within each category, but may be counted in multiple categories.
* Other was the combination of chemotherapy and a monoclonal antibody of epidermal growth factor receptor.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-dh.sas 22APR2024 22:38 t-14-01-03-01-dh-itt-fa.rtf

Table 14.1.3.1:
Disease History and Characteristics at Study Entry
ITT Analysis Set

Description	Tislelizumab (N = 256)	ICC (N = 256)	Total (N = 512)
Target/Non-Target Lesion Location at Study Entry, n (%) [a]			
Lymph nodes	186 (72.7)	192 (75.0)	378 (73.8)
Lung	116 (45.3)	119 (46.5)	235 (45.9)
Esophagus	109 (42.6)	107 (41.8)	216 (42.2)
Liver	76 (29.7)	69 (27.0)	145 (28.3)
Pleura	32 (12.5)	24 (9.4)	56 (10.9)
Bone	30 (11.7)	32 (12.5)	62 (12.1)
Peritoneum	16 (6.3)	9 (3.5)	25 (4.9)
Adrenal gland	11 (4.3)	11 (4.3)	22 (4.3)
Gastroesophageal Junction	7 (2.7)	5 (2.0)	12 (2.3)
Soft tissue	4 (1.6)	4 (1.6)	8 (1.6)
Brain	3 (1.2)	0 (0.0)	3 (0.6)
Muscle	1 (0.4)	1 (0.4)	2 (0.4)
Skin	1 (0.4)	1 (0.4)	2 (0.4)
Other	39 (15.2)	50 (19.5)	89 (17.4)

Source: Listing 16.2.4.4. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Percentages were based on N.
Study Entry date referred to randomization date in this study.
[a] A patient was counted only once within each category, but may be counted in multiple categories.
* Other was the combination of chemotherapy and a monoclonal antibody of epidermal growth factor receptor.
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Table 14.1.3.1:
Disease History and Characteristics at Study Entry
ITT Analysis Set

Description	Tislelizumab (N = 256)	ICC (N = 256)	Total (N = 512)
Time from Initial Cancer Diagnosis to Study Entry (months)			
n	256	256	512
Mean (SD)	14.51 (14.224)	16.15 (17.319)	15.33 (15.853)
Median	10.12	10.14	10.12
Q1, Q3	6.80, 15.49	6.62, 19.19	6.72, 17.72
Min, Max	2.0, 119.8	2.1, 170.5	2.0, 170.5

Source: Listing 16.2.4.4. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Percentages were based on N.
Study Entry date referred to randomization date in this study.
[a] A patient was counted only once within each category, but may be counted in multiple categories.
* Other was the combination of chemotherapy and a monoclonal antibody of epidermal growth factor receptor.
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Table 14.1.3.1.b:
Disease History and Characteristics at Study Entry
ITT Analysis Set - Subpopulation without Irinotecan

Description	Tislelizumab (N = 139)	ICC (N = 138)	Total (N = 277)
Number of Patient With Metastatic Diagnosis at Study Entry, n (%)			
Yes	137 (98.6)	125 (90.6)	262 (94.6)
No	2 (1.4)	13 (9.4)	15 (5.4)
Time from Metastatic Diagnosis to Study Entry (months)			
n	137	125	262
Mean (SD)	6.15 (5.301)	7.36 (6.789)	6.73 (6.075)
Median	4.99	6.21	5.29
Q1, Q3	1.41, 9.56	1.64, 10.32	1.45, 9.92
Min, Max	0.3, 26.5	0.2, 34.4	0.2, 34.4
Prior Systemic Therapy, n (%)			
Chemotherapy	49 (35.3)	61 (44.2)	110 (39.7)
Chemo-Radiotherapy	90 (64.7)	77 (55.8)	167 (60.3)

Source: Listing 16.2.4.4. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Study Entry date referred to randomization date in this study.
[a] A patient was counted only once within each category, but may be counted in multiple categories.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-dh.sas 22APR2024 22:38 t-14-01-03-01-b-dh-itts-fa.rtf

Table 14.1.3.1.b:
Disease History and Characteristics at Study Entry
ITT Analysis Set - Subpopulation without Irinotecan

Description	Tislelizumab (N = 139)	ICC (N = 138)	Total (N = 277)
Primary Site of Esophageal Cancer at Diagnosis, n (%)			
Cervical	4 (2.9)	3 (2.2)	7 (2.5)
Upper	22 (15.8)	26 (18.8)	48 (17.3)
Middle	59 (42.4)	42 (30.4)	101 (36.5)
Lower	35 (25.2)	49 (35.5)	84 (30.3)
Overlapping Lesions	6 (4.3)	4 (2.9)	10 (3.6)
Esophagus NOS	13 (9.4)	14 (10.1)	27 (9.7)
Histologic Grade at Diagnosis, n (%)			
Gx - Grade cannot be assessed	16 (11.5)	12 (8.7)	28 (10.1)
G1 - Well differentiated	15 (10.8)	9 (6.5)	24 (8.7)
G2 - Moderately differentiated	48 (34.5)	56 (40.6)	104 (37.5)
G3 - Poorly differentiated	26 (18.7)	32 (23.2)	58 (20.9)
Not Done	34 (24.5)	29 (21.0)	63 (22.7)

Source: Listing 16.2.4.4. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Study Entry date referred to randomization date in this study.
[a] A patient was counted only once within each category, but may be counted in multiple categories.
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Table 14.1.3.1.b:
Disease History and Characteristics at Study Entry
ITT Analysis Set - Subpopulation without Irinotecan

Description	Tislelizumab (N = 139)	ICC (N = 138)	Total (N = 277)
Target Lesions Sum of Diameter by Investigator (mm)			
n	125	131	256
Mean (SD)	49.24 (35.087)	51.01 (36.609)	50.14 (35.815)
Median	41.40	41.00	41.20
Q1, Q3	23.00, 66.90	21.40, 66.00	22.00, 66.45
Min, Max	10.0, 261.0	12.0, 238.0	10.0, 261.0

Source: Listing 16.2.4.4. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Study Entry date referred to randomization date in this study.
[a] A patient was counted only once within each category, but may be counted in multiple categories.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-dh.sas 22APR2024 22:38 t-14-01-03-01-b-dh-itts-fa.rtf

Table 14.1.3.1.b:
Disease History and Characteristics at Study Entry
ITT Analysis Set - Subpopulation without Irinotecan

Description	Tislelizumab (N = 139)	ICC (N = 138)	Total (N = 277)
Target/Non-Target Lesion Location at Study Entry, n (%) [a]			
Lymph nodes	100 (71.9)	99 (71.7)	199 (71.8)
Esophagus	66 (47.5)	59 (42.8)	125 (45.1)
Lung	62 (44.6)	61 (44.2)	123 (44.4)
Liver	34 (24.5)	40 (29.0)	74 (26.7)
Pleura	19 (13.7)	14 (10.1)	33 (11.9)
Bone	15 (10.8)	16 (11.6)	31 (11.2)
Peritoneum	9 (6.5)	6 (4.3)	15 (5.4)
Adrenal gland	6 (4.3)	5 (3.6)	11 (4.0)
Gastroesophageal Junction	4 (2.9)	3 (2.2)	7 (2.5)
Soft tissue	4 (2.9)	2 (1.4)	6 (2.2)
Brain	2 (1.4)	0 (0.0)	2 (0.7)
Skin	1 (0.7)	0 (0.0)	1 (0.4)
Muscle	0 (0.0)	1 (0.7)	1 (0.4)
Other	21 (15.1)	24 (17.4)	45 (16.2)

Source: Listing 16.2.4.4. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Study Entry date referred to randomization date in this study.
[a] A patient was counted only once within each category, but may be counted in multiple categories.
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Table 14.1.3.1.b:
Disease History and Characteristics at Study Entry
ITT Analysis Set - Subpopulation without Irinotecan

Description	Tislelizumab (N = 139)	ICC (N = 138)	Total (N = 277)
Time from Initial Cancer Diagnosis to Study Entry (months)			
n	139	138	277
Mean (SD)	15.26 (16.413)	15.06 (14.170)	15.16 (15.309)
Median	10.12	10.02	10.12
Q1, Q3	6.87, 15.57	6.34, 18.33	6.67, 17.25
Min, Max	2.0, 119.8	2.1, 79.4	2.0, 119.8

Source: Listing 16.2.4.4. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Study Entry date referred to randomization date in this study.
[a] A patient was counted only once within each category, but may be counted in multiple categories.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-dh.sas 22APR2024 22:38 t-14-01-03-01-b-dh-itts-fa.rtf

Table 14.1.5.1.b:
Prior Anti-Cancer Systemic Therapy
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)	ICC (N = 138)	Total (N = 277)
Patients With at Least One Prior Systemic Therapy, n (%)	139 (100.0)	138 (100.0)	277 (100.0)
Patients With Prior Line of Platinum-based Systemic Therapy [a], n (%)	131 (94.2)	135 (97.8)	266 (96.0)
Number of Prior Line of Systemic Therapies [b], n (%)			
0	0 (0.0)	1 (0.7)	1 (0.4)
1	139 (100.0)	137 (99.3)	276 (99.6)
Prior Neo-Adjuvant/Adjuvant Treatment or Definitive Chemoradiotherapy as First Line Systemic Therapies [c], n (%)			
Neo-Adjuvant/Adjuvant Treatment	27 (19.4)	16 (11.6)	43 (15.5)
Definitive Chemoradiotherapy	16 (11.5)	21 (15.2)	37 (13.4)

Source: Listing 16.2.4.7. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
[a] Platinum-based regimen in the first-line systemic therapy was requested for enrollment eligibility since Protocol Amendment version 3.0.
[b] Based on protocol deviation of inclusion criteria #4 and exclusion criteria #1 identified in the study.
[c] Neoadjuvant/adjuvant chemotherapy or chemoradiotherapy, or definitive chemoradiotherapy received by patients who had disease progression during treatment or <= 6 months (180 days) of cessation of treatment was counted as one prior line. Definitive chemoradiotherapy data were provided based on medical review on relevant data collected in the EDC.
[d] Study Entry date referred to randomization date in this study.
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Table 14.1.5.1.b:
Prior Anti-Cancer Systemic Therapy
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)	ICC (N = 138)	Total (N = 277)
Duration of Last Prior Anti-Cancer Systemic Therapy (months)			
n	139	138	277
Mean (SD)	3.35 (3.203)	3.51 (3.723)	3.43 (3.467)
Median	2.73	2.68	2.69
Q1, Q3	1.12, 4.50	1.05, 4.70	1.12, 4.63
Min, Max	0.0, 17.1	0.0, 28.8	0.0, 28.8
Time From End of Last Prior Anti-Cancer Systemic Therapy to Study Entry [d] (months)			
n	139	138	277
Mean (SD)	4.33 (3.551)	4.09 (4.271)	4.21 (3.921)
Median	3.42	2.43	2.73
Q1, Q3	1.58, 6.21	1.45, 5.45	1.48, 5.78
Min, Max	0.6, 18.5	0.5, 30.4	0.5, 30.4

Source: Listing 16.2.4.7. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

Percentages were based on N.

[a] Platinum-based regimen in the first-line systemic therapy was requested for enrollment eligibility since Protocol Amendment version 3.0.

[b] Based on protocol deviation of inclusion criteria #4 and exclusion criteria #1 identified in the study.

[c] Neoadjuvant/adjuvant chemotherapy or chemoradiotherapy, or definitive chemoradiotherapy received by patients who had disease progression during treatment or <= 6 months (180 days) of cessation of treatment was counted as one prior line. Definitive chemoradiotherapy data were provided based on medical review on relevant data collected in the EDC.

[d] Study Entry date referred to randomization date in this study.

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Table 14.1.5.1.4.b:
Last Prior Anti-Cancer Systemic Therapy Before Study Entry
ITT Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 138) n (%)	Total (N = 277) n (%)
Platinum Compounds	131 (94.2)	135 (97.8)	266 (96.0)
Cisplatin	75 (54.0)	85 (61.6)	160 (57.8)
Nedaplatin	28 (20.1)	18 (13.0)	46 (16.6)
Oxaliplatin	20 (14.4)	25 (18.1)	45 (16.2)
Carboplatin	8 (5.8)	7 (5.1)	15 (5.4)
Lobaplatin	3 (2.2)	5 (3.6)	8 (2.9)
Pyrimidine Analogues	103 (74.1)	111 (80.4)	214 (77.3)
Fluorouracil	80 (57.6)	75 (54.3)	155 (56.0)
Capecitabine	13 (9.4)	19 (13.8)	32 (11.6)
Tegafur	8 (5.8)	5 (3.6)	13 (4.7)
Gimeracil;oteracil Potassium;tegafur	3 (2.2)	10 (7.2)	13 (4.7)
Tegafur;uracil	3 (2.2)	2 (1.4)	5 (1.8)
Gemcitabine	0 (0.0)	2 (1.4)	2 (0.7)

Source: Listing 16.2.4.7. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.5.1.4.b:
Last Prior Anti-Cancer Systemic Therapy Before Study Entry
ITT Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 138) n (%)	Total (N = 277) n (%)
Taxanes	43 (30.9)	34 (24.6)	77 (27.8)
Paclitaxel	21 (15.1)	17 (12.3)	38 (13.7)
Docetaxel	17 (12.2)	14 (10.1)	31 (11.2)
Paclitaxel Liposome	5 (3.6)	2 (1.4)	7 (2.5)
Paclitaxel Albumin	0 (0.0)	1 (0.7)	1 (0.4)
Detoxifying Agents For Antineoplastic Treatment	19 (13.7)	15 (10.9)	34 (12.3)
Folinic Acid	14 (10.1)	12 (8.7)	26 (9.4)
Calcium Folinate	2 (1.4)	2 (1.4)	4 (1.4)
Levofolinic Acid	2 (1.4)	0 (0.0)	2 (0.7)
Calcium Levofolinate	1 (0.7)	1 (0.7)	2 (0.7)
Anthracyclines And Related Substances	2 (1.4)	2 (1.4)	4 (1.4)
Epirubicin	2 (1.4)	2 (1.4)	4 (1.4)
Folic Acid Analogues	2 (1.4)	3 (2.2)	5 (1.8)
Raltitrexed	2 (1.4)	3 (2.2)	5 (1.8)

Source: Listing 16.2.4.7. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.5.1.4.b:
Last Prior Anti-Cancer Systemic Therapy Before Study Entry
ITT Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 138) n (%)	Total (N = 277) n (%)
Other Antineoplastic Agents	2 (1.4)	2 (1.4)	4 (1.4)
Irinotecan	2 (1.4)	1 (0.7)	3 (1.1)
Endostatin	0 (0.0)	1 (0.7)	1 (0.4)
Protein Kinase Inhibitors	2 (1.4)	1 (0.7)	3 (1.1)
Apatinib Mesylate	1 (0.7)	0 (0.0)	1 (0.4)
Oteracil Potassium	1 (0.7)	1 (0.7)	2 (0.7)
Antimetabolites	1 (0.7)	1 (0.7)	2 (0.7)
Gimeracil	1 (0.7)	1 (0.7)	2 (0.7)
Combinations Of Antineoplastic Agents	1 (0.7)	0 (0.0)	1 (0.4)
Calcium Folinate;fluorouracil;oxaliplatin	1 (0.7)	0 (0.0)	1 (0.4)
Nitrogen Mustard Analogues	1 (0.7)	0 (0.0)	1 (0.4)
Cyclophosphamide	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing 16.2.4.7. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.5.1.4.b:
Last Prior Anti-Cancer Systemic Therapy Before Study Entry
ITT Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 138) n (%)	Total (N = 277) n (%)
Monoclonal Antibodies	0 (0.0)	4 (2.9)	4 (1.4)
Cetuximab	0 (0.0)	1 (0.7)	1 (0.4)
Nimotuzumab	0 (0.0)	3 (2.2)	3 (1.1)
Other Cytotoxic Antibiotics	0 (0.0)	1 (0.7)	1 (0.4)
Bleomycin	0 (0.0)	1 (0.7)	1 (0.4)
Various	0 (0.0)	2 (1.4)	2 (0.7)
Blinded Therapy	0 (0.0)	2 (1.4)	2 (0.7)

Source: Listing 16.2.4.7. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-prlst.sas 22APR2024 22:41 t-14-01-05-01-04-b-prlst-itts-fa.rtf

Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Patients With at Least One Prior Medication	62 (44.6)	74 (57.4)	136 (50.7)
Proton Pump Inhibitors	12 (8.6)	18 (14.0)	30 (11.2)
Pantoprazole	4 (2.9)	3 (2.3)	7 (2.6)
Rabeprazole Sodium	3 (2.2)	1 (0.8)	4 (1.5)
Lansoprazole	2 (1.4)	3 (2.3)	5 (1.9)
Omeprazole	2 (1.4)	2 (1.6)	4 (1.5)
Pantoprazole Sodium Sesquihydrate	2 (1.4)	0 (0.0)	2 (0.7)
Ilaprazole	1 (0.7)	0 (0.0)	1 (0.4)
Omeprazole Sodium	1 (0.7)	5 (3.9)	6 (2.2)
Esomeprazole	0 (0.0)	3 (2.3)	3 (1.1)
Esomeprazole Magnesium	0 (0.0)	1 (0.8)	1 (0.4)
Vonoprazan Fumarate	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Glucocorticoids	11 (7.9)	16 (12.4)	27 (10.1)
Dexamethasone	10 (7.2)	15 (11.6)	25 (9.3)
Prednisone	2 (1.4)	0 (0.0)	2 (0.7)
Hydrocortisone	1 (0.7)	0 (0.0)	1 (0.4)
Prednisolone	0 (0.0)	1 (0.8)	1 (0.4)
Solutions For Parenteral Nutrition	8 (5.8)	8 (6.2)	16 (6.0)
Glucose	3 (2.2)	0 (0.0)	3 (1.1)
Alanine;arginine;calcium Chloride Dihydrate;fish Oil;glucose Monohydrate;glycine;glycine Max Oil;histidine;isoleucine;leucine;lysine Hydrochloride;magnesium Sulfate Heptahydrate;medium-Chain Triglycerides;methionine;olea Europaea Oil;phenylalanine;potassium Chloride;proline;serine;sodium Acetate Trihydrate;sodium Glycerophosphate;threonine;tryptophan, L-;tyrosine;valine;zinc Sulfate Heptahydrate	2 (1.4)	1 (0.8)	3 (1.1)
Amino Acids Nos	1 (0.7)	3 (2.3)	4 (1.5)
Amino Acids Nos;copper;electrolytes Nos;glucose;iodine;iron;manganese;vitamins Nos;zinc	1 (0.7)	0 (0.0)	1 (0.4)
Fats Nos	1 (0.7)	1 (0.8)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Glycerol;glycine Max Seed Oil;medium-Chain Triglycerides;phospholipids Egg	1 (0.7)	0 (0.0)	1 (0.4)
Alanine;arginine;aspartic Acid;calcium Chloride Dihydrate;glucose Monohydrate;glutamic Acid;glycine;glycine Max Oil;histidine;isoleucine;leucine;lysine Acetate;magnesium Chloride Hexahydrate;methionine;olea Europaea Oil;phenylalanine;potassium Chloride;proline;serine;sodium Acetate;sodium Glycerophosphate;threonine;tryptophan, L-;tyrosine;valine	0 (0.0)	1 (0.8)	1 (0.4)
Alanine;arginine;aspartic Acid;calcium Chloride;glucose Monohydrate;glutamic Acid;glycine;glycine Max Seed Oil;histidine Hydrochloride;isoleucine;leucine;lysine Hydrochloride;magnesium Acetate Tetrahydrate;medium-Chain Triglycerides;methionine;phenylalanine;potassium Acetate;proline;serine;sodium Acetate;sodium Chloride;sodium Hydroxide;sodium Phosphate Monobasic (Dihydrate);threonine;tryptophan, L-;valine;zinc Acetate Dihydrate	0 (0.0)	1 (0.8)	1 (0.4)
Alanine;arginine;aspartic Acid;cysteine;glutamic Acid;glycine;histidine;isoleucine;leucine;lysine Acetate;methionine;phenylalanine;proline;serine;threonine;tryptophan, L-;tyrosine;valine	0 (0.0)	1 (0.8)	1 (0.4)
Alanine;arginine;aspartic Acid;cystine;glutamic Acid;glycine;histidine;isoleucine;leucine;lysine Acetate;methionine;phenylalanine;proline;serine;threonine;tryptophan, L-;tyrosine;valine	0 (0.0)	2 (1.6)	2 (0.7)
Alanine;arginine;calcium Chloride Dihydrate;fish Oil;glucose Monohydrate;glycine;glycine Max Seed Oil;histidine;isoleucine;leucine;lysine Acetate;magnesium Sulfate Heptahydrate;methionine;olea Europaea Oil;phenylalanine;potassium Chloride;proline;serine;sodium Acetate Trihydrate;sodium Glycerophosphate;taurine;threonine;triglycerides;tryptophan, L-;tyrosine;valine;zinc Sulfate Heptahydrate	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Alanine;arginine;calcium Chloride;fish Oil;glucose Monohydrate;glycine;glycine Max Seed Oil;histidine;isoleucine;leucine;lysine Acetate;magnesium Sulfate;medium-Chain Triglycerides;methionine;olea Europaea Oil;phenylalanine;potassium Chloride;proline;serine;sodium Acetate;sodium Glycerophosphate;taurine;threonine;tryptophan, L-;tyrosine;valine;zinc Sulfate	0 (0.0)	1 (0.8)	1 (0.4)
Amino Acids Nos;carbohydrates Nos;minerals Nos;vitamins Nos	0 (0.0)	1 (0.8)	1 (0.4)
Fish Oil;glycine Max Seed Oil;olea Europaea Oil;triglycerides	0 (0.0)	1 (0.8)	1 (0.4)
Glycerol;glycine Max Seed Oil;lecithin;medium-Chain Triglycerides	0 (0.0)	1 (0.8)	1 (0.4)
Glycine Max Seed Oil;lecithin	0 (0.0)	2 (1.6)	2 (0.7)
Electrolyte Solutions	7 (5.0)	6 (4.7)	13 (4.9)
Potassium Chloride	6 (4.3)	5 (3.9)	11 (4.1)
Sodium Chloride	1 (0.7)	2 (1.6)	3 (1.1)
Magnesium Sulfate	0 (0.0)	2 (1.6)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Natural Opium Alkaloids	7 (5.0)	6 (4.7)	13 (4.9)
Morphine Hydrochloride	3 (2.2)	3 (2.3)	6 (2.2)
Oxycodone Hydrochloride	3 (2.2)	2 (1.6)	5 (1.9)
Hydromorphone Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Morphine Sulfate	1 (0.7)	1 (0.8)	2 (0.7)
Oxycodone	1 (0.7)	1 (0.8)	2 (0.7)
Unspecified Herbal And Traditional Medicine	7 (5.0)	15 (11.6)	22 (8.2)
Unspecified Herbal And Traditional Medicine	3 (2.2)	3 (2.3)	6 (2.2)
Agaricus Blazei;centella Asiatica Leaf;citrus Aurantium Peel;citrus Reticulata Peel;cordyceps Sinensis;cuminum Cyminum;curcuma Longa Rhizome;cymbopogon Citratus;elettaria Cardamomum Fruit;foeniculum Vulgare Seed;illicium Verum Oil;pimpinella Anisum Seed;salvia Officinalis Leaf;syzygium Aromaticum;zingiber Officinale Root	1 (0.7)	0 (0.0)	1 (0.4)
Astragalus Mongholicus Root;oxymatrine;panax Ginseng Dry Extract	1 (0.7)	0 (0.0)	1 (0.4)
Astragalus Spp. Root;cantharidin;eleutherococcus Senticosus Root With Rhizome;panax Ginseng Root	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Bupleurum Chinense, Root;citrus Reticulata Peel;glycyrrhiza Uralensis Root With Rhizome;paeonia Lactiflora Sun Dried Root;saposhnikovia Divaricata Root;zingiber Officinale Rhizome	1 (0.7)	0 (0.0)	1 (0.4)
Ganoderma Capense	1 (0.7)	1 (0.8)	2 (0.7)
Hericium Erinaceus	1 (0.7)	0 (0.0)	1 (0.4)
Panax Notoginseng	1 (0.7)	1 (0.8)	2 (0.7)
Panax Notoginseng Root Total Saponin Extract	1 (0.7)	0 (0.0)	1 (0.4)
Angelica Dahurica Var. Formosana Root;arisaema Consanguineum Rhizome;atractylodes Lancea Rhizome;citrus Reticulata Peel;curcuma Longa Rhizome;glycyrrhiza Uralensis Root With Rhizome;magnolia Officinalis Bark;phellodendron Amurense Bark;rheum Palmatum Root With Rhizome;trichosanthes Kirilowii Root	0 (0.0)	1 (0.8)	1 (0.4)
Arctium Lappa Fruit;cicada Slough;ephedra Spp. Herb;eriobotrya Japonica Leaf;perilla Frutescens Fruit;perilla Frutescens Leaf;peucedanum Praeruptorum Root;pheretima Spp.;schisandra Chinensis Fruit	0 (0.0)	1 (0.8)	1 (0.4)
Arisaema Spp. Tuber;coptis Spp. Rhizome;fritillaria Cirrhosa Bulb;herbal Nos;rheum Spp. Root With Rhizome	0 (0.0)	1 (0.8)	1 (0.4)
Astragalus Mongholicus Root;codonopsis Pilosula Root	0 (0.0)	3 (2.3)	3 (1.1)
Baicalin;buffalo Horn;cholic Acid;concha Margaritifera;gardenia Jasminoides Fruit;hyodeoxycholic Acid;isatis Indigotica Root;lonicera Japonica Flower	0 (0.0)	1 (0.8)	1 (0.4)
Benzoic Acid;camphor;glycyrrhiza Uralensis Root With Rhizome;illicium Verum Oil;papaver Somniferum Tincture	0 (0.0)	1 (0.8)	1 (0.4)
Bidens Biternata;caffeine;chlorphenamine Maleate;chrysanthemum Indicum Flower;ilex Asprella Root;melicope Pteleifolia;mentha Canadensis Oil;paracetamol	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Calcium Sulfate Dihydrate;dryopteris Crassirhizoma Rhizome;ephedra Spp. Herb;forsythia Suspensa;glycyrrhiza Glabra Root;houttuynia Cordata Herb;isatis Tinctoria Root;lonicera Japonica Flower;menthol;pogostemon Cablin Herb;prunus Spp. Seed;rheum Spp.;rhodiola Crenulata	0 (0.0)	1 (0.8)	1 (0.4)
Marsdenia Tenacissima Stem	0 (0.0)	1 (0.8)	1 (0.4)
Papaver Somniferum Tincture	0 (0.0)	1 (0.8)	1 (0.4)
Periplaneta Americana	0 (0.0)	1 (0.8)	1 (0.4)
Smilax Binchuanensis Root;sophora Flavescens Root	0 (0.0)	1 (0.8)	1 (0.4)
Ulmus Spp.	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Propionic Acid Derivatives	6 (4.3)	4 (3.1)	10 (3.7)
Flurbiprofen Axetil	2 (1.4)	0 (0.0)	2 (0.7)
Apronal;caffeine;ibuprofen	1 (0.7)	0 (0.0)	1 (0.4)
Arginine Hydrochloride;ibuprofen	1 (0.7)	0 (0.0)	1 (0.4)
Flurbiprofen	1 (0.7)	0 (0.0)	1 (0.4)
Ibuprofen	1 (0.7)	1 (0.8)	2 (0.7)
Loxoprofen Sodium	1 (0.7)	2 (1.6)	3 (1.1)
Loxoprofen	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Propulsives	6 (4.3)	10 (7.8)	16 (6.0)
Metoclopramide	3 (2.2)	3 (2.3)	6 (2.2)
Itopride Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Metoclopramide Hydrochloride	1 (0.7)	2 (1.6)	3 (1.1)
Mosapride	1 (0.7)	0 (0.0)	1 (0.4)
Mosapride Citrate	1 (0.7)	4 (3.1)	5 (1.9)
Metoclopramide Dihydrochloride	0 (0.0)	2 (1.6)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Solutions Affecting The Electrolyte Balance	6 (4.3)	10 (7.8)	16 (6.0)
Glucose;sodium Chloride	2 (1.4)	3 (2.3)	5 (1.9)
Sodium Chloride	2 (1.4)	2 (1.6)	4 (1.5)
Electrolytes Nos;glucose	1 (0.7)	3 (2.3)	4 (1.5)
Fructose;glucose;magnesium Chloride;potassium Chloride;sodium Chloride;sodium Lactate;sodium Phosphate Monobasic	1 (0.7)	0 (0.0)	1 (0.4)
Calcium Chloride;potassium Chloride;sodium Chloride;sodium Lactate;sorbitol	0 (0.0)	2 (1.6)	2 (0.7)
Potassium Chloride;sodium Chloride	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 22APR2024 22:37 t-14-01-06-b-cm-prmed-safetys-fa.rtf

Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Third-Generation Cephalosporins	6 (4.3)	2 (1.6)	8 (3.0)
Cefoperazone Sodium;sulbactam Sodium	2 (1.4)	0 (0.0)	2 (0.7)
Cefotaxime	1 (0.7)	0 (0.0)	1 (0.4)
Ceftazidime	1 (0.7)	0 (0.0)	1 (0.4)
Ceftriaxone	1 (0.7)	2 (1.6)	3 (1.1)
Ceftriaxone Sodium	1 (0.7)	0 (0.0)	1 (0.4)
Cefixime	0 (0.0)	1 (0.8)	1 (0.4)
Contact Laxatives	5 (3.6)	4 (3.1)	9 (3.4)
Bisacodyl	2 (1.4)	1 (0.8)	3 (1.1)
Senna Alexandrina Leaf	2 (1.4)	1 (0.8)	3 (1.1)
Sennoside A+b	1 (0.7)	0 (0.0)	1 (0.4)
Ricinus Communis Oil	0 (0.0)	1 (0.8)	1 (0.4)
Sennoside A+b Calcium	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 22APR2024 22:37 t-14-01-06-b-cm-prmed-safetys-fa.rtf

Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (Gord)	5 (3.6)	3 (2.3)	8 (3.0)
Calcium Carbonate;sodium Alginate;sodium Bicarbonate	2 (1.4)	0 (0.0)	2 (0.7)
Polaprezinc	1 (0.7)	0 (0.0)	1 (0.4)
Rebamipide	1 (0.7)	1 (0.8)	2 (0.7)
Sodium Alginate	1 (0.7)	1 (0.8)	2 (0.7)
Sucralfate	1 (0.7)	1 (0.8)	2 (0.7)
Other Plain Vitamin Preparations	5 (3.6)	5 (3.9)	10 (3.7)
Pyridoxine Hydrochloride	4 (2.9)	5 (3.9)	9 (3.4)
Panthenol	1 (0.7)	0 (0.0)	1 (0.4)
Substituted Alkylamines	5 (3.6)	1 (0.8)	6 (2.2)
Chlorphenamine Maleate	5 (3.6)	0 (0.0)	5 (1.9)
Chlorphenamine	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Acetic Acid Derivatives And Related Substances	4 (2.9)	1 (0.8)	5 (1.9)
Aceclofenac	1 (0.7)	0 (0.0)	1 (0.4)
Diclofenac	1 (0.7)	1 (0.8)	2 (0.7)
Diclofenac Potassium	1 (0.7)	0 (0.0)	1 (0.4)
Indometacin	1 (0.7)	0 (0.0)	1 (0.4)
Amides	4 (2.9)	7 (5.4)	11 (4.1)
Lidocaine	2 (1.4)	2 (1.6)	4 (1.5)
Lidocaine Hydrochloride	2 (1.4)	5 (3.9)	7 (2.6)
Lidocaine Hydrochloride;menthol	0 (0.0)	1 (0.8)	1 (0.4)
Anilides	4 (2.9)	5 (3.9)	9 (3.4)
Paracetamol	3 (2.2)	4 (3.1)	7 (2.6)
Diclofenac Sodium;paracetamol	1 (0.7)	0 (0.0)	1 (0.4)
Propacetamol Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Ascorbic Acid (Vitamin C), Plain	4 (2.9)	5 (3.9)	9 (3.4)
Ascorbic Acid	4 (2.9)	5 (3.9)	9 (3.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Fluoroquinolones	4 (2.9)	6 (4.7)	10 (3.7)
Levofloxacin	2 (1.4)	3 (2.3)	5 (1.9)
Levofloxacin Hydrochloride	1 (0.7)	1 (0.8)	2 (0.7)
Levofloxacin Lactate	1 (0.7)	1 (0.8)	2 (0.7)
Moxifloxacin	0 (0.0)	1 (0.8)	1 (0.4)
Moxifloxacin Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Heparin Group	4 (2.9)	3 (2.3)	7 (2.6)
Enoxaparin Sodium	2 (1.4)	1 (0.8)	3 (1.1)
Heparin Calcium	1 (0.7)	0 (0.0)	1 (0.4)
Heparin Sodium	1 (0.7)	2 (1.6)	3 (1.1)
Opioids In Combination With Non-Opioid Analgesics	4 (2.9)	2 (1.6)	6 (2.2)
Paracetamol;tramadol Hydrochloride	2 (1.4)	1 (0.8)	3 (1.1)
Codeine Phosphate;ibuprofen	1 (0.7)	1 (0.8)	2 (0.7)
Codeine Phosphate;paracetamol	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Osmotically Acting Laxatives	4 (2.9)	6 (4.7)	10 (3.7)
Mannitol	2 (1.4)	3 (2.3)	5 (1.9)
Lactulose	1 (0.7)	0 (0.0)	1 (0.4)
Macrogol 4000;potassium Chloride;sodium Bicarbonate;sodium Chloride;sodium Sulfate	1 (0.7)	0 (0.0)	1 (0.4)
Magnesium Oxide	1 (0.7)	0 (0.0)	1 (0.4)
Macrogol	0 (0.0)	1 (0.8)	1 (0.4)
Macrogol 3350;potassium Chloride;sodium Bicarbonate;sodium Chloride	0 (0.0)	1 (0.8)	1 (0.4)
Macrogol 4000;potassium Chloride;sodium Bicarbonate;sodium Chloride;sodium Sulfate Anhydrous	0 (0.0)	1 (0.8)	1 (0.4)
Other Opioids	4 (2.9)	3 (2.3)	7 (2.6)
Tramadol Hydrochloride	2 (1.4)	2 (1.6)	4 (1.5)
Bucinnazine Hydrochloride	1 (0.7)	1 (0.8)	2 (0.7)
Tramadol	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Serotonin (5ht3) Antagonists	4 (2.9)	9 (7.0)	13 (4.9)
Granisetron	1 (0.7)	0 (0.0)	1 (0.4)
Palonosetron	1 (0.7)	2 (1.6)	3 (1.1)
Sodium Chloride;tropisetron	1 (0.7)	0 (0.0)	1 (0.4)
Tropisetron	1 (0.7)	1 (0.8)	2 (0.7)
Dolasetron Mesilate	0 (0.0)	1 (0.8)	1 (0.4)
Granisetron Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Ondansetron	0 (0.0)	1 (0.8)	1 (0.4)
Ondansetron Hydrochloride;sodium Chloride	0 (0.0)	1 (0.8)	1 (0.4)
Palonosetron Hydrochloride	0 (0.0)	2 (1.6)	2 (0.7)
Tropisetron Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Sulfonamides, Plain	4 (2.9)	5 (3.9)	9 (3.4)
Furosemide	4 (2.9)	4 (3.1)	8 (3.0)
Torasemide	0 (0.0)	2 (1.6)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Amino Acids	3 (2.2)	4 (3.1)	7 (2.6)
Tranexamic Acid	2 (1.4)	1 (0.8)	3 (1.1)
Aminomethylbenzoic Acid	1 (0.7)	0 (0.0)	1 (0.4)
Alanyl Glutamine	0 (0.0)	2 (1.6)	2 (0.7)
Sodium Chloride;tranexamic Acid	0 (0.0)	1 (0.8)	1 (0.4)
Benzodiazepine Derivatives	3 (2.2)	4 (3.1)	7 (2.6)
Alprazolam	1 (0.7)	0 (0.0)	1 (0.4)
Diazepam	1 (0.7)	1 (0.8)	2 (0.7)
Lorazepam	1 (0.7)	0 (0.0)	1 (0.4)
Midazolam	1 (0.7)	1 (0.8)	2 (0.7)
Estazolam	0 (0.0)	1 (0.8)	1 (0.4)
Oxazepam	0 (0.0)	1 (0.8)	1 (0.4)
Colony Stimulating Factors	3 (2.2)	2 (1.6)	5 (1.9)
Granulocyte Colony Stimulating Factor	3 (2.2)	2 (1.6)	5 (1.9)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Combinations Of Penicillins, Incl. Beta-Lactamase Inhibitors	3 (2.2)	2 (1.6)	5 (1.9)
Amoxicillin;clavulanic Acid	1 (0.7)	1 (0.8)	2 (0.7)
Ampicillin Sodium;sulbactam Sodium	1 (0.7)	0 (0.0)	1 (0.4)
Mezlocillin;sulbactam	1 (0.7)	0 (0.0)	1 (0.4)
Piperacillin Sodium;tazobactam Sodium	0 (0.0)	1 (0.8)	1 (0.4)
H2-Receptor Antagonists	3 (2.2)	4 (3.1)	7 (2.6)
Famotidine	3 (2.2)	2 (1.6)	5 (1.9)
Cimetidine	0 (0.0)	2 (1.6)	2 (0.7)
Other General Anesthetics	3 (2.2)	0 (0.0)	3 (1.1)
Propofol	3 (2.2)	0 (0.0)	3 (1.1)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Phenylpiperidine Derivatives	3 (2.2)	4 (3.1)	7 (2.6)
Fentanyl	3 (2.2)	0 (0.0)	3 (1.1)
Fentanyl Citrate	0 (0.0)	1 (0.8)	1 (0.4)
Pethidine	0 (0.0)	1 (0.8)	1 (0.4)
Pethidine Hydrochloride	0 (0.0)	2 (1.6)	2 (0.7)
Piperazine Derivatives	3 (2.2)	0 (0.0)	3 (1.1)
Levocetirizine	2 (1.4)	0 (0.0)	2 (0.7)
Cetirizine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Antiinfectives And Antiseptics For Local Oral Treatment	2 (1.4)	0 (0.0)	2 (0.7)
Nystatin	2 (1.4)	0 (0.0)	2 (0.7)
Neomycin	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Combinations And Complexes Of Aluminium, Calcium And Magnesium Compounds	2 (1.4)	0 (0.0)	2 (0.7)
Aluminium Hydroxide Gel, Dried;magnesium Carbonate	1 (0.7)	0 (0.0)	1 (0.4)
Hydrotalcite	1 (0.7)	0 (0.0)	1 (0.4)
Corticosteroids For Local Oral Treatment	2 (1.4)	0 (0.0)	2 (0.7)
Dexamethasone	1 (0.7)	0 (0.0)	1 (0.4)
Triamcinolone	1 (0.7)	0 (0.0)	1 (0.4)
Diazepines, Oxazepines, Thiazepines And Oxepines	2 (1.4)	1 (0.8)	3 (1.1)
Olanzapine	2 (1.4)	1 (0.8)	3 (1.1)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Enemas	2 (1.4)	1 (0.8)	3 (1.1)
Sodium Chloride	1 (0.7)	0 (0.0)	1 (0.4)
Sodium Phosphate Dibasic;sodium Phosphate Monobasic	1 (0.7)	0 (0.0)	1 (0.4)
Soft Soap	1 (0.7)	1 (0.8)	2 (0.7)
Glycerol	0 (0.0)	1 (0.8)	1 (0.4)
Insulins And Analogues For Injection, Fast-Acting	2 (1.4)	2 (1.6)	4 (1.5)
Insulin	2 (1.4)	1 (0.8)	3 (1.1)
Insulin Human	0 (0.0)	1 (0.8)	1 (0.4)
Macrolides	2 (1.4)	0 (0.0)	2 (0.7)
Clarithromycin	1 (0.7)	0 (0.0)	1 (0.4)
Spiramycin	1 (0.7)	0 (0.0)	1 (0.4)
Medical Gases	2 (1.4)	0 (0.0)	2 (0.7)
Oxygen	2 (1.4)	0 (0.0)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Mucolytics	2 (1.4)	4 (3.1)	6 (2.2)
Ambroxol Acefyllinate	1 (0.7)	0 (0.0)	1 (0.4)
Bromhexine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Ambroxol Hydrochloride	0 (0.0)	4 (3.1)	4 (1.5)
Opium Alkaloids And Derivatives	2 (1.4)	2 (1.6)	4 (1.5)
Codeine	1 (0.7)	0 (0.0)	1 (0.4)
Dextromethorphan	1 (0.7)	0 (0.0)	1 (0.4)
Dextromethorphan Hydrobromide	0 (0.0)	2 (1.6)	2 (0.7)
Other Blood Products	2 (1.4)	3 (2.3)	5 (1.9)
Red Blood Cells, Concentrated	2 (1.4)	0 (0.0)	2 (0.7)
Blood, Whole	0 (0.0)	2 (1.6)	2 (0.7)
Red Blood Cells	0 (0.0)	1 (0.8)	1 (0.4)
Peripheral Opioid Receptor Antagonists	2 (1.4)	0 (0.0)	2 (0.7)
Naldemedine Tosilate	1 (0.7)	0 (0.0)	1 (0.4)
Naloxegol	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Watersoluble, Nephrotropic, Low Osmolar X-Ray Contrast Media	2 (1.4)	1 (0.8)	3 (1.1)
Iohexol	2 (1.4)	1 (0.8)	3 (1.1)
Ioversol	1 (0.7)	0 (0.0)	1 (0.4)
Alpha-Adrenoreceptor Antagonists	1 (0.7)	0 (0.0)	1 (0.4)
Tamsulosin Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Amino Acids/Carbohydrates/Minerals/Vitamins, Combinations	1 (0.7)	0 (0.0)	1 (0.4)
Amino Acids Nos;carbohydrates Nos;fats Nos;minerals Nos;vitamins Nos	1 (0.7)	0 (0.0)	1 (0.4)
Aminoalkyl Ethers	1 (0.7)	2 (1.6)	3 (1.1)
Diphenhydramine	1 (0.7)	1 (0.8)	2 (0.7)
Diphenhydramine Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Anesthetics, Local	1 (0.7)	0 (0.0)	1 (0.4)
Lidocaine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 22APR2024 22:37 t-14-01-06-b-cm-prmed-safetys-fa.rtf

Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Angiotensin Ii Receptor Blockers (Arbs), Plain	1 (0.7)	1 (0.8)	2 (0.7)
Valsartan	1 (0.7)	0 (0.0)	1 (0.4)
Losartan	0 (0.0)	1 (0.8)	1 (0.4)
Antidiarrheal Microorganisms	1 (0.7)	2 (1.6)	3 (1.1)
Bifidobacterium Longum;enterococcus Faecalis;lactobacillus Acidophilus	1 (0.7)	0 (0.0)	1 (0.4)
Bacillus Mesentericus;clostridium Butyricum;enterococcus Faecalis	0 (0.0)	1 (0.8)	1 (0.4)
Bacillus Subtilis;enterococcus Faecalis;lactobacillus Acidophilus	0 (0.0)	1 (0.8)	1 (0.4)
Antihemorrhagics	1 (0.7)	0 (0.0)	1 (0.4)
Antihemorrhagics	1 (0.7)	0 (0.0)	1 (0.4)
Antiinfectives For Systemic Use	1 (0.7)	1 (0.8)	2 (0.7)
Andrographolide	1 (0.7)	1 (0.8)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 22APR2024 22:37 t-14-01-06-b-cm-prmed-safetys-fa.rtf

Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Appetite Stimulants	1 (0.7)	3 (2.3)	4 (1.5)
Carnitine Hydrochloride;cyanocobalamin;cyproheptadine Orotate;lysine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Megestrol Acetate	1 (0.7)	2 (1.6)	3 (1.1)
Megestrol	0 (0.0)	1 (0.8)	1 (0.4)
Belladonna Alkaloids, Semisynthetic, Quaternary Ammonium Compounds	1 (0.7)	1 (0.8)	2 (0.7)
Cimetropium Bromide	1 (0.7)	1 (0.8)	2 (0.7)
Benzothiazepine Derivatives	1 (0.7)	0 (0.0)	1 (0.4)
Diltiazem Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Beta-Lactamase Resistant Penicillins	1 (0.7)	0 (0.0)	1 (0.4)
Dicloxacillin Sodium Monohydrate	1 (0.7)	0 (0.0)	1 (0.4)
Bile Acids And Derivatives	1 (0.7)	0 (0.0)	1 (0.4)
Ursodeoxycholic Acid	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
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unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 22APR2024 22:37 t-14-01-06-b-cm-prmed-safetys-fa.rtf

Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Bisphosphonates	1 (0.7)	1 (0.8)	2 (0.7)
Zoledronic Acid	1 (0.7)	1 (0.8)	2 (0.7)
Blood And Related Products	1 (0.7)	1 (0.8)	2 (0.7)
Blood, Calf, Deprot., Lmw Portion	1 (0.7)	1 (0.8)	2 (0.7)
Combinations Of Sulfonamides And Trimethoprim, Incl. Derivatives	1 (0.7)	1 (0.8)	2 (0.7)
Sulfamethoxazole;trimethoprim	1 (0.7)	1 (0.8)	2 (0.7)
Coxibs	1 (0.7)	0 (0.0)	1 (0.4)
Celecoxib	1 (0.7)	0 (0.0)	1 (0.4)
Detoxifying Agents For Antineoplastic Treatment	1 (0.7)	0 (0.0)	1 (0.4)
Amifostine	1 (0.7)	0 (0.0)	1 (0.4)
Dihydropyridine Derivatives	1 (0.7)	1 (0.8)	2 (0.7)
Amlodipine Besilate	1 (0.7)	0 (0.0)	1 (0.4)
Lercanidipine Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Diphenylmethane Derivatives	1 (0.7)	0 (0.0)	1 (0.4)
Hydroxyzine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Enzyme Preparations	1 (0.7)	1 (0.8)	2 (0.7)
Pancreatin	1 (0.7)	0 (0.0)	1 (0.4)
Azintamide;cellulase;dimeticone;pancreatin	0 (0.0)	1 (0.8)	1 (0.4)
Enzymes	1 (0.7)	0 (0.0)	1 (0.4)
Pronase	1 (0.7)	0 (0.0)	1 (0.4)
First-Generation Cephalosporins	1 (0.7)	1 (0.8)	2 (0.7)
Cefadroxil	1 (0.7)	0 (0.0)	1 (0.4)
Cefazolin Sodium	0 (0.0)	1 (0.8)	1 (0.4)
Folic Acid And Derivatives	1 (0.7)	0 (0.0)	1 (0.4)
Folinic Acid	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
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Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
I.V. Solution Additives	1 (0.7)	0 (0.0)	1 (0.4)
Calcium Chloride Dihydrate;glucose;potassium Chloride;sodium Acetate;sodium Chloride	1 (0.7)	0 (0.0)	1 (0.4)
Insulins And Analogues For Injection, Intermediate-Acting	1 (0.7)	0 (0.0)	1 (0.4)
Insulin Human Injection, Isophane	1 (0.7)	0 (0.0)	1 (0.4)
Iron, Parenteral Preparations	1 (0.7)	1 (0.8)	2 (0.7)
Saccharated Iron Oxide	1 (0.7)	1 (0.8)	2 (0.7)
Liver Therapy, Lipotropics	1 (0.7)	0 (0.0)	1 (0.4)
Diisopropylamine Dichloroacetate;gluconate Sodium	1 (0.7)	0 (0.0)	1 (0.4)
Opium Derivatives And Expectorants	1 (0.7)	2 (1.6)	3 (1.1)
Opium Derivatives And Expectorants	1 (0.7)	1 (0.8)	2 (0.7)
Camphor;glycyrrhiza Glabra;illicium Verum Oil;papaver Somniferum;sodium Benzoate	0 (0.0)	1 (0.8)	1 (0.4)
Other Agents For Local Oral Treatment	1 (0.7)	0 (0.0)	1 (0.4)
Lidocaine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Aminoglycosides	1 (0.7)	1 (0.8)	2 (0.7)
Gentamicin;procaine	1 (0.7)	0 (0.0)	1 (0.4)
Etimicin Sulfate	0 (0.0)	1 (0.8)	1 (0.4)
Other Antianemic Preparations	1 (0.7)	1 (0.8)	2 (0.7)
Erythropoietin Human	1 (0.7)	1 (0.8)	2 (0.7)
Other Antibiotics For Topical Use	1 (0.7)	0 (0.0)	1 (0.4)
Neomycin;tyrothricin	1 (0.7)	0 (0.0)	1 (0.4)
Other Antiemetics	1 (0.7)	2 (1.6)	3 (1.1)
Hydroxyzine	1 (0.7)	0 (0.0)	1 (0.4)
Difenidol	0 (0.0)	1 (0.8)	1 (0.4)
Fosaprepitant	0 (0.0)	1 (0.8)	1 (0.4)
Other Antihistamines For Systemic Use	1 (0.7)	0 (0.0)	1 (0.4)
Cyproheptadine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Cough Suppressants	1 (0.7)	0 (0.0)	1 (0.4)
Tipepidine Hibenzate	1 (0.7)	0 (0.0)	1 (0.4)
Other Drugs For Functional Gastrointestinal Disorders	1 (0.7)	1 (0.8)	2 (0.7)
Simeticone	1 (0.7)	0 (0.0)	1 (0.4)
Flopropione	0 (0.0)	1 (0.8)	1 (0.4)
Other Immunostimulants	1 (0.7)	1 (0.8)	2 (0.7)
Agaricus Blazei;ascorbic Acid;cordyceps Sinensis;glutathione;zinc Sulfate	1 (0.7)	0 (0.0)	1 (0.4)
Peptides Nos;thymalfasin	0 (0.0)	1 (0.8)	1 (0.4)
Other Ophthalmologicals	1 (0.7)	1 (0.8)	2 (0.7)
Cyanocobalamin	1 (0.7)	0 (0.0)	1 (0.4)
Urogastrone	0 (0.0)	1 (0.8)	1 (0.4)
Other Systemic Hemostatics	1 (0.7)	0 (0.0)	1 (0.4)
Etamsilate	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Penicillins With Extended Spectrum	1 (0.7)	2 (1.6)	3 (1.1)
Amoxicillin	1 (0.7)	1 (0.8)	2 (0.7)
Piperacillin	0 (0.0)	1 (0.8)	1 (0.4)
Progestogens	1 (0.7)	0 (0.0)	1 (0.4)
Medroxyprogesterone	1 (0.7)	0 (0.0)	1 (0.4)
Pyrazolones	1 (0.7)	1 (0.8)	2 (0.7)
Aminophenazone;barbital;phenazone	1 (0.7)	1 (0.8)	2 (0.7)
Rauwolfia Alkaloids And Diuretics In Combination	1 (0.7)	0 (0.0)	1 (0.4)
Dihydralazine Sulfate;hydrochlorothiazide;reserpine;triamterene	1 (0.7)	0 (0.0)	1 (0.4)
Selective Beta-2-Adrenoreceptor Agonists	1 (0.7)	1 (0.8)	2 (0.7)
Terbutaline	1 (0.7)	0 (0.0)	1 (0.4)
Terbutaline Sulfate	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Sulfonamides	1 (0.7)	0 (0.0)	1 (0.4)
Sulfamethoxazole	1 (0.7)	0 (0.0)	1 (0.4)
Sympathomimetics	1 (0.7)	0 (0.0)	1 (0.4)
Ebastine;pseudoephedrine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Synthetic Anticholinergics, Esters With Tertiary Amino Group	1 (0.7)	0 (0.0)	1 (0.4)
Dicycloverine	1 (0.7)	0 (0.0)	1 (0.4)
Testosterone-5-Alpha Reductase Inhibitors	1 (0.7)	0 (0.0)	1 (0.4)
Finasteride	1 (0.7)	0 (0.0)	1 (0.4)
Various Alimentary Tract And Metabolism Products	1 (0.7)	0 (0.0)	1 (0.4)
Morinda Citrifolia;selenium	1 (0.7)	0 (0.0)	1 (0.4)
Vitamin B1, Plain	1 (0.7)	0 (0.0)	1 (0.4)
Thiamine	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Watersoluble, Nephrotropic, High Osmolar X-Ray Contrast Media	1 (0.7)	0 (0.0)	1 (0.4)
Meglumine Amidotrizoate;sodium Amidotrizoate	1 (0.7)	0 (0.0)	1 (0.4)
Xanthines And Adrenergics	1 (0.7)	0 (0.0)	1 (0.4)
Aminophylline;chlorphenamine Maleate;methoxyphenamine Hydrochloride;noscapine	1 (0.7)	0 (0.0)	1 (0.4)
Antibiotics	0 (0.0)	1 (0.8)	1 (0.4)
Tobramycin	0 (0.0)	1 (0.8)	1 (0.4)
Anticholinergics	0 (0.0)	1 (0.8)	1 (0.4)
Phenylephrine Hydrochloride;tropicamide	0 (0.0)	1 (0.8)	1 (0.4)
Antidotes	0 (0.0)	1 (0.8)	1 (0.4)
Glutathione	0 (0.0)	1 (0.8)	1 (0.4)
Antiinflammatory Preparations, Non-Steroids For Topical Use	0 (0.0)	1 (0.8)	1 (0.4)
Ketoprofen	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Beta Blocking Agents	0 (0.0)	1 (0.8)	1 (0.4)
Carteolol Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Beta Blocking Agents, Selective	0 (0.0)	1 (0.8)	1 (0.4)
Metoprolol	0 (0.0)	1 (0.8)	1 (0.4)
Bile And Liver Therapy	0 (0.0)	2 (1.6)	2 (0.7)
Bicyclol	0 (0.0)	2 (1.6)	2 (0.7)
Blood Substitutes And Plasma Protein Fractions	0 (0.0)	1 (0.8)	1 (0.4)
Albumin Human	0 (0.0)	1 (0.8)	1 (0.4)
Calcium, Combinations With Vitamin D And/Or Other Drugs	0 (0.0)	1 (0.8)	1 (0.4)
Calcium Carbonate;colecalciferol	0 (0.0)	1 (0.8)	1 (0.4)
Carbapenems	0 (0.0)	1 (0.8)	1 (0.4)
Meropenem	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Colouring Agents	0 (0.0)	1 (0.8)	1 (0.4)
Fluorescein Sodium	0 (0.0)	1 (0.8)	1 (0.4)
Combinations Of Vitamins	0 (0.0)	1 (0.8)	1 (0.4)
Combinations Of Vitamins	0 (0.0)	1 (0.8)	1 (0.4)
Corticosteroids	0 (0.0)	1 (0.8)	1 (0.4)
Budesonide	0 (0.0)	1 (0.8)	1 (0.4)
Diuretics	0 (0.0)	1 (0.8)	1 (0.4)
Mannitol	0 (0.0)	1 (0.8)	1 (0.4)
Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (Gord)	0 (0.0)	1 (0.8)	1 (0.4)
Teprenone	0 (0.0)	1 (0.8)	1 (0.4)
Esters Of Aminobenzoic Acid	0 (0.0)	1 (0.8)	1 (0.4)
Tetracaine Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Expectorants	0 (0.0)	1 (0.8)	1 (0.4)
Fudosteine	0 (0.0)	1 (0.8)	1 (0.4)
Fat/Carbohydrates/Proteins/Minerals/Vitamins, Combinations	0 (0.0)	2 (1.6)	2 (0.7)
Ascorbic Acid;biotin;calcium Citrate;calcium Pantothenate;cyanocobalamin;ferrous Sulfate;fibre, Dietary;folic Acid;glycine Max Seed Oil;magnesium Carbonate;maltodextrin;nicotinamide;potassium Citrate;proteins Nos;pyridoxine Hydrochloride;retinol;riboflavin;sodium Chloride;sucrose;thiamine Hydrochloride;tocopheryl Acetate;whey Protein;zea Mays Starch	0 (0.0)	1 (0.8)	1 (0.4)
Casein;fats Nos;fibre, Dietary;maltodextrin;minerals Nos;vitamins Nos	0 (0.0)	1 (0.8)	1 (0.4)
Imidazole Derivatives	0 (0.0)	2 (1.6)	2 (0.7)
Metronidazole	0 (0.0)	1 (0.8)	1 (0.4)
Ornidazole	0 (0.0)	1 (0.8)	1 (0.4)
Insulins And Analogues For Injection, Long-Acting	0 (0.0)	1 (0.8)	1 (0.4)
Insulin Glargine	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Liver Therapy	0 (0.0)	5 (3.9)	5 (1.9)
Magnesium Isoglycyrrhizinate	0 (0.0)	5 (3.9)	5 (1.9)
Local Anesthetics	0 (0.0)	1 (0.8)	1 (0.4)
Cinchocaine Hydrochloride;policresulen	0 (0.0)	1 (0.8)	1 (0.4)
Nucleoside And Nucleotide Reverse Transcriptase Inhibitors	0 (0.0)	2 (1.6)	2 (0.7)
Entecavir	0 (0.0)	1 (0.8)	1 (0.4)
Tenofovir Disoproxil Fumarate	0 (0.0)	1 (0.8)	1 (0.4)
Other Analgesics And Antipyretics	0 (0.0)	2 (1.6)	2 (0.7)
Gabapentin	0 (0.0)	1 (0.8)	1 (0.4)
Pregabalin	0 (0.0)	1 (0.8)	1 (0.4)
Other Cicatrizants	0 (0.0)	1 (0.8)	1 (0.4)
Trafermin	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Diagnostic Agents	0 (0.0)	1 (0.8)	1 (0.4)
Indocyanine Green	0 (0.0)	1 (0.8)	1 (0.4)
Other Drugs Affecting Bone Structure And Mineralization	0 (0.0)	1 (0.8)	1 (0.4)
Denosumab	0 (0.0)	1 (0.8)	1 (0.4)
Other Drugs For Constipation	0 (0.0)	1 (0.8)	1 (0.4)
Prucalopride	0 (0.0)	1 (0.8)	1 (0.4)
Other Intestinal Adsorbents	0 (0.0)	1 (0.8)	1 (0.4)
Montmorillonite	0 (0.0)	1 (0.8)	1 (0.4)
Other Mineral Products	0 (0.0)	1 (0.8)	1 (0.4)
Magnesium Aspartate;potassium Aspartate	0 (0.0)	1 (0.8)	1 (0.4)
Other Plant Alkaloids And Natural Products	0 (0.0)	1 (0.8)	1 (0.4)
Ginsenoside Rg3	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 22APR2024 22:37 t-14-01-06-b-cm-prmed-safetys-fa.rtf

Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Urologicals	0 (0.0)	1 (0.8)	1 (0.4)
Tiopronin	0 (0.0)	1 (0.8)	1 (0.4)
Phenothiazines With Aliphatic Side-Chain	0 (0.0)	1 (0.8)	1 (0.4)
Chlorpromazine	0 (0.0)	1 (0.8)	1 (0.4)
Phenylalkylamine Derivatives	0 (0.0)	1 (0.8)	1 (0.4)
Verapamil Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Phosphodiesterase Inhibitors	0 (0.0)	1 (0.8)	1 (0.4)
Bucladesine Calcium	0 (0.0)	1 (0.8)	1 (0.4)
Platinum Compounds	0 (0.0)	1 (0.8)	1 (0.4)
Cisplatin	0 (0.0)	1 (0.8)	1 (0.4)
Potassium	0 (0.0)	3 (2.3)	3 (1.1)
Potassium Chloride	0 (0.0)	2 (1.6)	2 (0.7)
Potassium Gluconate	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 22APR2024 22:37 t-14-01-06-b-cm-prmed-safetys-fa.rtf

Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Pyrimidine Analogues	0 (0.0)	1 (0.8)	1 (0.4)
Gemcitabine Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Second-Generation Cephalosporins	0 (0.0)	2 (1.6)	2 (0.7)
Cefmetazole Sodium	0 (0.0)	1 (0.8)	1 (0.4)
Cefuroxime	0 (0.0)	1 (0.8)	1 (0.4)
Solutions Producing Osmotic Diuresis	0 (0.0)	1 (0.8)	1 (0.4)
Mannitol	0 (0.0)	1 (0.8)	1 (0.4)
Vasopressin Antagonists	0 (0.0)	1 (0.8)	1 (0.4)
Tolvaptan	0 (0.0)	1 (0.8)	1 (0.4)
Vitamin B-Complex, Plain	0 (0.0)	1 (0.8)	1 (0.4)
Vitamin B Complex	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 22APR2024 22:37 t-14-01-06-b-cm-prmed-safetys-fa.rtf

Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Vitamins	0 (0.0)	2 (1.6)	2 (0.7)
Fat Soluble Vitamins Nos	0 (0.0)	1 (0.8)	1 (0.4)
Vitamins Nos	0 (0.0)	1 (0.8)	1 (0.4)
Vitamins With Minerals	0 (0.0)	1 (0.8)	1 (0.4)
Minerals Nos;vitamins Nos	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Patients With at Least One Concomitant Medication	135 (97.1)	127 (98.4)	262 (97.8)
Proton Pump Inhibitors	81 (58.3)	91 (70.5)	172 (64.2)
Lansoprazole	20 (14.4)	23 (17.8)	43 (16.0)
Omeprazole	17 (12.2)	21 (16.3)	38 (14.2)
Esomeprazole	16 (11.5)	16 (12.4)	32 (11.9)
Pantoprazole Sodium Sesquihydrate	12 (8.6)	21 (16.3)	33 (12.3)
Pantoprazole	8 (5.8)	12 (9.3)	20 (7.5)
Vonoprazan Fumarate	8 (5.8)	6 (4.7)	14 (5.2)
Rabeprazole Sodium	7 (5.0)	8 (6.2)	15 (5.6)
Esomeprazole Magnesium	6 (4.3)	7 (5.4)	13 (4.9)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Omeprazole Sodium	6 (4.3)	9 (7.0)	15 (5.6)
Esomeprazole Sodium	3 (2.2)	5 (3.9)	8 (3.0)
Rabeprazole	2 (1.4)	0 (0.0)	2 (0.7)
Dexlansoprazole	1 (0.7)	1 (0.8)	2 (0.7)
Ilaprazole	1 (0.7)	4 (3.1)	5 (1.9)
Omeprazole Magnesium	1 (0.7)	2 (1.6)	3 (1.1)
Glucocorticoids	54 (38.8)	114 (88.4)	168 (62.7)
Dexamethasone	24 (17.3)	104 (80.6)	128 (47.8)
Prednisolone	18 (12.9)	8 (6.2)	26 (9.7)
Methylprednisolone	13 (9.4)	8 (6.2)	21 (7.8)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Hydrocortisone	9 (6.5)	10 (7.8)	19 (7.1)
Budesonide	6 (4.3)	4 (3.1)	10 (3.7)
Prednisone	6 (4.3)	2 (1.6)	8 (3.0)
Cortisone	4 (2.9)	1 (0.8)	5 (1.9)
Betamethasone	2 (1.4)	6 (4.7)	8 (3.0)
Methylprednisolone Sodium Succinate	1 (0.7)	1 (0.8)	2 (0.7)
Beclometasone Dipropionate	0 (0.0)	1 (0.8)	1 (0.4)
Betamethasone Sodium Phosphate	0 (0.0)	2 (1.6)	2 (0.7)
Dexamethasone Sodium Phosphate	0 (0.0)	1 (0.8)	1 (0.4)
Hydrocortisone Sodium Succinate	0 (0.0)	2 (1.6)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Anilides	52 (37.4)	42 (32.6)	94 (35.1)
Paracetamol	49 (35.3)	38 (29.5)	87 (32.5)
Amantadine Hydrochloride;caffeine;chlorphenamine Maleate;cow Bezoar;paracetamol	1 (0.7)	1 (0.8)	2 (0.7)
Chlorphenamine Maleate;dextromethorphan;paracetamol;pseudoephedrine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Propacetamol Hydrochloride	1 (0.7)	3 (2.3)	4 (1.5)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Natural Opium Alkaloids	50 (36.0)	39 (30.2)	89 (33.2)
Oxycodone Hydrochloride	22 (15.8)	21 (16.3)	43 (16.0)
Morphine	12 (8.6)	6 (4.7)	18 (6.7)
Morphine Hydrochloride	11 (7.9)	10 (7.8)	21 (7.8)
Morphine Sulfate	8 (5.8)	5 (3.9)	13 (4.9)
Oxycodone	7 (5.0)	4 (3.1)	11 (4.1)
Naloxone Hydrochloride;oxycodone Hydrochloride	4 (2.9)	3 (2.3)	7 (2.6)
Hydromorphone Hydrochloride	3 (2.2)	1 (0.8)	4 (1.5)
Codeine	1 (0.7)	0 (0.0)	1 (0.4)
Codeine Phosphate	1 (0.7)	0 (0.0)	1 (0.4)
Dihydrocodeine Bitartrate	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
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Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Naloxone;oxycodone	1 (0.7)	0 (0.0)	1 (0.4)
Osmotically Acting Laxatives	43 (30.9)	31 (24.0)	74 (27.6)
Magnesium Oxide	21 (15.1)	13 (10.1)	34 (12.7)
Lactulose	15 (10.8)	8 (6.2)	23 (8.6)
Macrogol 3350;potassium Chloride;sodium Bicarbonate;sodium Chloride	6 (4.3)	8 (6.2)	14 (5.2)
Macrogol	3 (2.2)	1 (0.8)	4 (1.5)
Macrogol 4000	1 (0.7)	2 (1.6)	3 (1.1)
Sodium Phosphate	1 (0.7)	0 (0.0)	1 (0.4)
Magnesium Hydroxide	0 (0.0)	1 (0.8)	1 (0.4)
Mannitol	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Propulsives	39 (28.1)	46 (35.7)	85 (31.7)
Metoclopramide	14 (10.1)	17 (13.2)	31 (11.6)
Metoclopramide Hydrochloride	13 (9.4)	9 (7.0)	22 (8.2)
Mosapride Citrate	11 (7.9)	7 (5.4)	18 (6.7)
Domperidone	8 (5.8)	10 (7.8)	18 (6.7)
Levosulpiride	2 (1.4)	2 (1.6)	4 (1.5)
Mosapride	2 (1.4)	0 (0.0)	2 (0.7)
Metoclopramide Dihydrochloride	1 (0.7)	10 (7.8)	11 (4.1)
Alizapride Hydrochloride	0 (0.0)	3 (2.3)	3 (1.1)
Domperidone Maleate	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 22APR2024 22:37 t-14-01-07-01-b-cm-gen-safetys-fa.rtf

Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Unspecified Herbal And Traditional Medicine	34 (24.5)	29 (22.5)	63 (23.5)
Unspecified Herbal And Traditional Medicine	9 (6.5)	7 (5.4)	16 (6.0)
Astragalus Propinquus Root;cibotium Barometz Rhizome;eclipta Prostrata Herb;fallopia Multiflora Root Tuber;ligustrum Lucidum Fruit;morus Alba Fruit;paeonia Lactiflora Root	5 (3.6)	3 (2.3)	8 (3.0)
Periplaneta Americana	3 (2.2)	0 (0.0)	3 (1.1)
Sanguisorba Officinalis	3 (2.2)	3 (2.3)	6 (2.2)
Alisma Plantago-Aquatica Var. Orient. Tuber;angelica Sinensis Root;asarum Spp. Root With Rhizome;astragalus Spp. Root;cuscuta Spp. Seed;deer Horn;gastrodia Elata Tuber;lycium Barbarum Fruit;panax Ginseng Root;rehmannia Glutinosa Root Tuber;senna Obtusifolia Seed	2 (1.4)	0 (0.0)	2 (0.7)
Astragalus Mongholicus Root;oxymatrine;panax Ginseng Dry Extract	2 (1.4)	1 (0.8)	3 (1.1)
Cinnamomum Cassia Bark;ferrous Sulfate;juglans Regia Kernel;panax Quinquefolius;ziziphus Jujuba Fruit	2 (1.4)	0 (0.0)	2 (0.7)
Coix Lacryma-Jobi Subsp. Ma-Yuen Seed	2 (1.4)	0 (0.0)	2 (0.7)
Ophiopogon Japonicus Root Tuber;panax Ginseng	2 (1.4)	0 (0.0)	2 (0.7)
Panax Notoginseng	2 (1.4)	2 (1.6)	4 (1.5)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Abelmoschus Manihot Flower	1 (0.7)	0 (0.0)	1 (0.4)
Aconitum Carmichaelii Root;panax Ginseng Root	1 (0.7)	1 (0.8)	2 (0.7)
Aconitum Kusnezoffii Root;herbal Nos	1 (0.7)	0 (0.0)	1 (0.4)
Agrimonia Pilosa Herb;forsythia Suspensa Fruit;glycyrrhiza Spp. Root With Rhizome;indigo;paeonia X Suffruticosa Root Bark	1 (0.7)	0 (0.0)	1 (0.4)
Anemarrhena Asphodeloides Rhizome;angelica Sinensis Root;animal Bone Marrow;arachis Hypogaea;asini Corii Colla;astragalus Spp. Root;atractylodes Macrocephala, Rhizoma;blood, Deer;chicken's Gizzard-Membrane;codonopsis Spp. Root;crataegus Pinnatifida Fruit;deer Horn;hordeum Vulgare Malt;paeonia Lactiflora Root;placenta;polygonatum Multiflorum Root;poria Cocos Sclerotium;rehmannia Glutinosa Root;rheum Spp. Root With Rhizome;turtle Carapace;ziziphus Jujuba Fruit	1 (0.7)	0 (0.0)	1 (0.4)
Angelica Sinensis Root;asini Corii Colla;astragalus Mongholicus Root;epimedium Brevicornu Herb;lespedeza Buergeri;sophora Flavescens Root;ziziphus Jujuba Fruit	1 (0.7)	1 (0.8)	2 (0.7)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Arctium Lappa Fruit;cicada Slough;ephedra Spp. Herb;eriobotrya Japonica Leaf;perilla Frutescens Fruit;perilla Frutescens Leaf;peucedanum Praeruptorum Root;pheretima Spp.;schisandra Chinensis Fruit	1 (0.7)	1 (0.8)	2 (0.7)
Arisaema Spp. Tuber;coptis Spp. Rhizome;fritillaria Cirrhosa Bulb;herbal Nos;rheum Spp. Root With Rhizome	1 (0.7)	0 (0.0)	1 (0.4)
Artemisia Annua Herb;gardenia Jasminoides Fruit;lonicera Japonica Flower Bud	1 (0.7)	0 (0.0)	1 (0.4)
Artemisia Spp. Herb;bupleurum Chinense, Root;isatis Indigotica Root;schisandra Chinensis Fruit;swine Bile;vigna Radiata	1 (0.7)	0 (0.0)	1 (0.4)
Aster Ageratoides Herb;firmiana Simplex Root;gentiana Rhodantha Herb With Root;peucedanum Praeruptorum Root;scleromitrion Diffusum Herb;scutellaria Baicalensis Root;stemona Sessilifolia Root Tuber	1 (0.7)	0 (0.0)	1 (0.4)
Astragalus Spp. Root;blood, Pig;ziziphus Jujuba Fruit	1 (0.7)	0 (0.0)	1 (0.4)
Astragalus Spp. Root;cantharidin;eleutherococcus Senticosus Root With Rhizome;panax Ginseng Root	1 (0.7)	0 (0.0)	1 (0.4)
Aucklandia Costus Root;citrus Aurantium Unripe Fruit;magnolia Officinalis Bark;rheum Palmatum Rhizome	1 (0.7)	0 (0.0)	1 (0.4)
Benzoic Acid;camphor;glycyrrhiza Uralensis Root With Rhizome;illicium Verum Oil;papaver Somniferum Tincture	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Bidens Biternata;caffeine;chlorphenamine Maleate;chrysanthemum Indicum Flower;ilex Asprella Root;melicope Pteleifolia;mentha Canadensis Oil;paracetamol	1 (0.7)	1 (0.8)	2 (0.7)
Cinnamomum Camphora Root;euphorbia Spp. Herb;exallage Chrysotricha;liquidambar Formosana Leaf;mosla Chinensis Herb	1 (0.7)	0 (0.0)	1 (0.4)
Coptis Spp. Rhizome;hedera Helix Leaf	1 (0.7)	0 (0.0)	1 (0.4)
Corydalis Yanhusuo Tuber;ipomoea Nil Seed	1 (0.7)	1 (0.8)	2 (0.7)
Cynanchum Stauntonii Root With Rhizome;eriobotrya Japonica Leaf;menthol;morus Alba Root Bark;papaver Somniferum Peel;platycodon Grandiflorus Root;stemona Sessilifolia Root Tuber	1 (0.7)	1 (0.8)	2 (0.7)
Ganoderma Lucidum	1 (0.7)	0 (0.0)	1 (0.4)
Ginseng Nos	1 (0.7)	0 (0.0)	1 (0.4)
Glycyrrhiza Glabra Extract	1 (0.7)	0 (0.0)	1 (0.4)
Glycyrrhiza Spp. Root;rheum Spp. Rhizome	1 (0.7)	0 (0.0)	1 (0.4)
Isatis Indigotica Root	1 (0.7)	0 (0.0)	1 (0.4)
Panax Ginseng Root;zanthoxylum Piperitum Pericarp;zingiber Officinale Processed Rhizome	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Panax Notoginseng Leaf Total Saponin Extract	1 (0.7)	1 (0.8)	2 (0.7)
Panax Notoginseng Root Total Saponin Extract	1 (0.7)	1 (0.8)	2 (0.7)
Platycodon Grandiflorus	1 (0.7)	1 (0.8)	2 (0.7)
Sesamum Indicum Seed Oil	1 (0.7)	0 (0.0)	1 (0.4)
Sophora Flavescens Root	1 (0.7)	0 (0.0)	1 (0.4)
Achyranthes Bidentata Root;angelica Sinensis Root;astragalus Spp. Root;boswellia Sacra;carthamus Tinctorius Flower;cinnamomum Cassia Twig;commiphora Myrrha Resin;leech Extract;ligusticum Chuanxiong Rhizome;mesobuthus Martensii;morus Alba Twig;paeonia Rubra Root;pheretima Spp.;prunus Persica Seed;salvia Miltiorrhiza Root With Rhizome;spatholobus Suberectus Stem	0 (0.0)	1 (0.8)	1 (0.4)
Aloe Spp.	0 (0.0)	1 (0.8)	1 (0.4)
Angelica Dahurica Var. Formosana Root;arisaema Consanguineum Rhizome;atractylodes Lancea Rhizome;citrus Reticulata Peel;curcuma Longa Rhizome;glycyrrhiza Uralensis Root With Rhizome;magnolia Officinalis Bark;phellodendron Amurense Bark;rheum Palmatum Root With Rhizome;trichosanthes Kirilowii Root	0 (0.0)	3 (2.3)	3 (1.1)
Angelica Sinensis Root;carthamus Tinctorius Flower;ligusticum Chuanxiong Rhizome;paeonia Lactiflora Sun Dried Root;salvia Miltiorrhiza Root	0 (0.0)	1 (0.8)	1 (0.4)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Angelica Sinensis Root;cistanche Deserticola Stem;senna Alexandrina Leaf	0 (0.0)	1 (0.8)	1 (0.4)
Arachis Hypogaea	0 (0.0)	1 (0.8)	1 (0.4)
Arctium Lappa Fruit;forsythia Suspensa Fruit;glycine Max Fermented Seed;glycyrrhiza Uralensis Root With Rhizome;lonicera Japonica Flower Bud;lophatherum Gracile Herb;mentha Canadensis Herb;platycodon Grandiflorus Root;schizonepeta Tenuifolia Herb	0 (0.0)	1 (0.8)	1 (0.4)
Areca Catechu Seed;aucklandia Costus Root;citrus Aurantium Unripe Fruit;lindera Aggregata Root	0 (0.0)	1 (0.8)	1 (0.4)
Artemisia Argyi	0 (0.0)	1 (0.8)	1 (0.4)
Asini Corii Colla	0 (0.0)	1 (0.8)	1 (0.4)
Astragalus Mongholicus Root;codonopsis Pilosula Root	0 (0.0)	1 (0.8)	1 (0.4)
Atractylodes Lancea Rhizome;citrus Reticulata Peel;glycyrrhiza Spp. Root;panax Ginseng Root;pinellia Ternata Tuber;poria Cocos Sclerotium;zingiber Officinale Rhizome;ziziphus Jujuba Var. Inermis Fruit	0 (0.0)	1 (0.8)	1 (0.4)
Atractylodes Macrocephala, Rhizoma;glycyrrhiza Spp. Root With Rhizome;levoglutamide;panax Ginseng Root;poria Cocos Sclerotium	0 (0.0)	1 (0.8)	1 (0.4)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Baicalin;buffalo Horn;cholic Acid;concha Margaritifera;gardenia Jasminoides Fruit;hyodeoxycholic Acid;isatis Indigotica Root;lonicera Japonica Flower	0 (0.0)	1 (0.8)	1 (0.4)
Bioflavonoids Nos;d-Mannose;vaccinium Macrocarpon	0 (0.0)	1 (0.8)	1 (0.4)
Bupleurum Spp. Root	0 (0.0)	1 (0.8)	1 (0.4)
Calcium Sulfate Dihydrate;dryopteris Crassirhizoma Rhizome;ephedra Spp. Herb;forsythia Suspensa;glycyrrhiza Glabra Root;houttuynia Cordata Herb;isatis Tinctoria Root;lonicera Japonica Flower;menthol;pogostemon Cablin Herb;prunus Spp. Seed;rheum Spp.;rhodiola Crenulata	0 (0.0)	1 (0.8)	1 (0.4)
Cannabis Sativa Fruit;citrus Aurantium Unripe Fruit;magnolia Officinalis Bark;paeonia Lactiflora Root;prunus Spp. Seed;rheum Spp. Root With Rhizome	0 (0.0)	1 (0.8)	1 (0.4)
Ficus Carica	0 (0.0)	1 (0.8)	1 (0.4)
Pelargonium Sidoides Root Ethanol Extract	0 (0.0)	1 (0.8)	1 (0.4)
Senecio Cannabifolius Herb	0 (0.0)	1 (0.8)	1 (0.4)
Smilax Glabra Rhizome;sophora Flavescens Root	0 (0.0)	1 (0.8)	1 (0.4)

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Concomitant Medication
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Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Vitis Vinifera Extract	0 (0.0)	1 (0.8)	1 (0.4)
Solutions For Parenteral Nutrition	31 (22.3)	28 (21.7)	59 (22.0)
Amino Acids Nos	11 (7.9)	5 (3.9)	16 (6.0)
Glucose	10 (7.2)	7 (5.4)	17 (6.3)
Fats Nos	7 (5.0)	7 (5.4)	14 (5.2)
Amino Acids Nos;electrolytes Nos;glucose;thiamine Hydrochloride	5 (3.6)	5 (3.9)	10 (3.7)
Alanine;arginine;aspartic Acid;cysteine;glutamic Acid;glycine;histidine;isoleucine;leucine;lysine Acetate;methionine;phenylalanine;proline;serine;threonine;tryptophan, L-;tyrosine;valine	3 (2.2)	0 (0.0)	3 (1.1)
Alanine;arginine;calcium Chloride;fish Oil;glucose Monohydrate;glycine;glycine Max Seed Oil;histidine;isoleucine;leucine;lysine Acetate;magnesium Sulfate;medium-Chain Triglycerides;methionine;olea Europaea Oil;phenylalanine;potassium Chloride;proline;serine;sodium Acetate;sodium Glycerophosphate;taurine;threonine;tryptophan, L-;tyrosine;valine;zinc Sulfate	3 (2.2)	1 (0.8)	4 (1.5)
Amino Acids Nos;fats Nos;glucose	3 (2.2)	0 (0.0)	3 (1.1)

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Table 14.1.7.1.b:
Concomitant Medication
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Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Alanine;arginine;calcium Chloride Dihydrate;fish Oil;glucose Monohydrate;glycine;glycine Max Oil;histidine;isoleucine;leucine;lysine Hydrochloride;magnesium Sulfate Heptahydrate;medium-Chain Triglycerides;methionine;olea Europaea Oil;phenylalanine;potassium Chloride;proline;serine;sodium Acetate Trihydrate;sodium Glycerophosphate;threonine;tryptophan, L-;tyrosine;valine;zinc Sulfate Heptahydrate	2 (1.4)	1 (0.8)	3 (1.1)
Amino Acids Nos;copper;electrolytes Nos;glucose;iodine;iron;manganese;vitamins Nos;zinc	2 (1.4)	1 (0.8)	3 (1.1)
Solutions For Parenteral Nutrition	2 (1.4)	1 (0.8)	3 (1.1)
Acetic Acid;alanine;arginine;aspartic Acid;calcium;calcium Chloride;chloride;glucose;glutamate Sodium;glycerol;glycine;glycine Max Seed Oil;histidine;isoleucine;lecithin;leucine;lysine Hydrochloride;magnesium;magnesium Sulfate;methionine;phenylalanine;phosphorus;potassium;potassium Chloride;proline;serine;sodium;sodium Acetate;sodium Glycerophosphate;sodium Hydroxide;threonine;tryptophan, L-;tyrosine;valine	1 (0.7)	1 (0.8)	2 (0.7)
Acetylcysteine;alanine;arginine;ascorbic Acid;aspartic Acid;biotin;calcium Chloride Dihydrate;cyanocobalamin;folic Acid;glucose;glutamic Acid;glycine;histidine;isoleucine;leucine;lysine Hydrochloride;magnesium Sulfate Heptahydrate;methionine;nicotinamide;panthenol;phenylalanine;potassium Phosphate Dibasic;proline;pyridoxine Hydrochloride;riboflavin Sodium Phosphate;serine;sodium Chloride;sodium Lactate;thiamine Hydrochloride;threonine;tryptophan, L-;tyrosine;valine;zinc Sulfate Heptahydrate	1 (0.7)	0 (0.0)	1 (0.4)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Alanine;arginine;aspartic Acid;calcium Chloride Dihydrate;glucose;glutamic Acid;glycerol;glycine;glycine Max Seed Oil;histidine;isoleucine;leucine;lysine Hydrochloride;magnesium Sulfate Heptahydrate;methionine;phenylalanine;phospholipids Egg;potassium Chloride;proline;serine;sodium Acetate Trihydrate;sodium Glycerophosphate;threonine;tryptophan, L-;tyrosine;valine	1 (0.7)	0 (0.0)	1 (0.4)
Amino Acids Nos;carbohydrates Nos;electrolytes Nos	1 (0.7)	0 (0.0)	1 (0.4)
Amino Acids Nos;electrolytes Nos;glucose	1 (0.7)	0 (0.0)	1 (0.4)
Amino Acids Nos;electrolytes Nos;glucose;lipids Nos	1 (0.7)	0 (0.0)	1 (0.4)
Amino Acids Nos;glucose	1 (0.7)	0 (0.0)	1 (0.4)
Amino Acids Nos;xylitol	1 (0.7)	0 (0.0)	1 (0.4)
Fish Oil;glycine Max Seed Oil;olea Europaea Oil;triglycerides	1 (0.7)	1 (0.8)	2 (0.7)
Glycerol;glycine Max Seed Oil;lecithin	1 (0.7)	0 (0.0)	1 (0.4)
Glycerol;glycine Max Seed Oil;lecithin;medium-Chain Triglycerides	1 (0.7)	0 (0.0)	1 (0.4)
Glycerol;glycine Max Seed Oil;medium-Chain Triglycerides;phospholipids Egg	1 (0.7)	1 (0.8)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Glycine Max Seed Oil;lecithin	1 (0.7)	0 (0.0)	1 (0.4)
Triglycerides	1 (0.7)	0 (0.0)	1 (0.4)
Alanine;arginine Hydrochloride;aspartic Acid;calcium Gluconate;cysteine;glucose;glutamic Acid;glycine;histidine;isoleucine;leucine;lysine Hydrochloride;magnesium Sulfate;methionine;phenylalanine;potassium Phosphate Dibasic;proline;serine;sodium Chloride;sodium Lactate;threonine;tryptophan, L-;tyrosine;valine;zinc Sulfate	0 (0.0)	1 (0.8)	1 (0.4)
Alanine;arginine Hydrochloride;aspartic Acid;cysteine;glutamic Acid;glycine;histidine Hydrochloride;isoleucine;leucine;lysine Hydrochloride;methionine;phenylalanine;proline;serine;threonine;tryptophan, L-;tyrosine;valine	0 (0.0)	1 (0.8)	1 (0.4)
Alanine;arginine;aspartic Acid;calcium Chloride Dihydrate;glucose Monohydrate;glutamic Acid;glycine;glycine Max Oil;histidine;isoleucine;leucine;lysine Acetate;magnesium Chloride Hexahydrate;methionine;olea Europaea Oil;phenylalanine;potassium Chloride;proline;serine;sodium Acetate;sodium Glycerophosphate;threonine;tryptophan, L-;tyrosine;valine	0 (0.0)	1 (0.8)	1 (0.4)
Amino Acids Nos;electrolytes Nos;fatty Acid Glycerides;glucose	0 (0.0)	1 (0.8)	1 (0.4)
Carbohydrates Nos;electrolytes Nos	0 (0.0)	2 (1.6)	2 (0.7)
Cysteine;glycine;glycyrrhizic Acid	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Fructose	0 (0.0)	2 (1.6)	2 (0.7)
Invert Sugar	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Fluoroquinolones	30 (21.6)	29 (22.5)	59 (22.0)
Levofloxacin	21 (15.1)	14 (10.9)	35 (13.1)
Levofloxacin Hydrochloride	5 (3.6)	4 (3.1)	9 (3.4)
Ciprofloxacin	2 (1.4)	1 (0.8)	3 (1.1)
Levofloxacin Lactate	2 (1.4)	1 (0.8)	3 (1.1)
Moxifloxacin Hydrochloride	2 (1.4)	5 (3.9)	7 (2.6)
Ofloxacin	2 (1.4)	2 (1.6)	4 (1.5)
Enoxacin Gluconate	1 (0.7)	0 (0.0)	1 (0.4)
Moxifloxacin	1 (0.7)	2 (1.6)	3 (1.1)
Ciprofloxacin Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Norfloxacin	0 (0.0)	1 (0.8)	1 (0.4)
Phenylpiperidine Derivatives	29 (20.9)	21 (16.3)	50 (18.7)
Fentanyl	20 (14.4)	16 (12.4)	36 (13.4)
Fentanyl Citrate	13 (9.4)	9 (7.0)	22 (8.2)
Pethidine	1 (0.7)	0 (0.0)	1 (0.4)
Pethidine Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Benzodiazepine Derivatives	28 (20.1)	28 (21.7)	56 (20.9)
Alprazolam	8 (5.8)	6 (4.7)	14 (5.2)
Lorazepam	5 (3.6)	4 (3.1)	9 (3.4)
Midazolam	5 (3.6)	5 (3.9)	10 (3.7)
Brotizolam	3 (2.2)	4 (3.1)	7 (2.6)
Diazepam	3 (2.2)	4 (3.1)	7 (2.6)
Flunitrazepam	3 (2.2)	0 (0.0)	3 (1.1)
Clonazepam	2 (1.4)	1 (0.8)	3 (1.1)
Estazolam	2 (1.4)	4 (3.1)	6 (2.2)
Oxazepam	2 (1.4)	1 (0.8)	3 (1.1)
Bromazepam	1 (0.7)	0 (0.0)	1 (0.4)
Etizolam	0 (0.0)	2 (1.6)	2 (0.7)
Lormetazepam	0 (0.0)	3 (2.3)	3 (1.1)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
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Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Prazepam	0 (0.0)	2 (1.6)	2 (0.7)
Solutions Affecting The Electrolyte Balance	27 (19.4)	36 (27.9)	63 (23.5)
Sodium Chloride	13 (9.4)	7 (5.4)	20 (7.5)
Glucose;sodium Chloride	5 (3.6)	5 (3.9)	10 (3.7)
Electrolytes Nos;glucose	4 (2.9)	7 (5.4)	11 (4.1)
Calcium Chloride Dihydrate;potassium Chloride;sodium Chloride;sodium Lactate	3 (2.2)	4 (3.1)	7 (2.6)
Calcium Chloride;potassium Chloride;sodium Chloride;sodium Lactate;sorbitol	3 (2.2)	3 (2.3)	6 (2.2)
Fructose;glucose;magnesium Chloride;potassium Chloride;sodium Chloride;sodium Lactate;sodium Phosphate Monobasic	2 (1.4)	5 (3.9)	7 (2.6)
Solutions Affecting The Electrolyte Balance	2 (1.4)	1 (0.8)	3 (1.1)
Calcium Chloride Dihydrate;maltose Monohydrate;potassium Chloride;sodium Chloride;sodium Lactate	1 (0.7)	1 (0.8)	2 (0.7)
Calcium Chloride Dihydrate;potassium Chloride;sodium Acetate Trihydrate;sodium Chloride	1 (0.7)	1 (0.8)	2 (0.7)
Calcium Chloride;glucose	1 (0.7)	0 (0.0)	1 (0.4)
Calcium Gluconate Monohydrate;glucose;magnesium Chloride Hexahydrate;potassium Chloride;sodium Acetate;sodium Chloride;sodium Citrate Dihydrate	1 (0.7)	1 (0.8)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Electrolytes Nos	1 (0.7)	2 (1.6)	3 (1.1)
Glucose;potassium Chloride	1 (0.7)	0 (0.0)	1 (0.4)
Glucose;potassium Chloride;sodium Chloride;sodium Lactate	1 (0.7)	2 (1.6)	3 (1.1)
Glucose;sodium Chloride;sodium Lactate	1 (0.7)	2 (1.6)	3 (1.1)
Potassium Chloride;sodium Chloride	1 (0.7)	0 (0.0)	1 (0.4)
Calcium Chloride Dihydrate;glucose;potassium Chloride;sodium Acetate	0 (0.0)	1 (0.8)	1 (0.4)
Calcium Chloride;potassium Chloride;sodium Acetate;sodium Chloride	0 (0.0)	1 (0.8)	1 (0.4)
Fructose;glucose;magnesium Chloride;potassium Chloride;sodium Bisulfite;sodium Chloride;sodium Lactate;sodium Phosphate Monobasic	0 (0.0)	1 (0.8)	1 (0.4)
Potassium Chloride;sodium Chloride;sodium Lactate	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Combinations Of Penicillins, Incl. Beta-Lactamase Inhibitors	25 (18.0)	23 (17.8)	48 (17.9)
Piperacillin Sodium;tazobactam Sodium	10 (7.2)	5 (3.9)	15 (5.6)
Amoxicillin;clavulanic Acid	8 (5.8)	11 (8.5)	19 (7.1)
Ampicillin Sodium;sulbactam Sodium	4 (2.9)	4 (3.1)	8 (3.0)
Amoxicillin;clavulanate Potassium	2 (1.4)	3 (2.3)	5 (1.9)
Amoxicillin Trihydrate;clavulanate Potassium	1 (0.7)	1 (0.8)	2 (0.7)
Mezlocillin;sulbactam	1 (0.7)	0 (0.0)	1 (0.4)
Piperacillin Sodium;sulbactam Sodium	1 (0.7)	0 (0.0)	1 (0.4)
Piperacillin Sodium;tazobactam	1 (0.7)	0 (0.0)	1 (0.4)
Piperacillin;tazobactam	1 (0.7)	4 (3.1)	5 (1.9)
Sultamicillin	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Mucolytics	25 (18.0)	25 (19.4)	50 (18.7)
Ambroxol Hydrochloride	10 (7.2)	9 (7.0)	19 (7.1)
Acetylcysteine	7 (5.0)	9 (7.0)	16 (6.0)
Carbocisteine	6 (4.3)	3 (2.3)	9 (3.4)
Bromhexine	3 (2.2)	0 (0.0)	3 (1.1)
Bromhexine Hydrochloride	3 (2.2)	1 (0.8)	4 (1.5)
Ambroxol	2 (1.4)	1 (0.8)	3 (1.1)
Erdosteine	2 (1.4)	4 (3.1)	6 (2.2)
Ambroxol Hydrochloride;sodium Chloride	1 (0.7)	2 (1.6)	3 (1.1)
Chymotrypsin	1 (0.7)	0 (0.0)	1 (0.4)
Mesna	1 (0.7)	0 (0.0)	1 (0.4)
Sodium Chloride	1 (0.7)	0 (0.0)	1 (0.4)
Ambroxol Hydrochloride;glucose	0 (0.0)	1 (0.8)	1 (0.4)
L-Carbocysteine	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Electrolyte Solutions	24 (17.3)	19 (14.7)	43 (16.0)
Potassium Chloride	19 (13.7)	14 (10.9)	33 (12.3)
Calcium Gluconate	7 (5.0)	2 (1.6)	9 (3.4)
Magnesium Sulfate	6 (4.3)	2 (1.6)	8 (3.0)
Sodium Chloride	5 (3.6)	3 (2.3)	8 (3.0)
Potassium Chloride;sodium Chloride	2 (1.4)	0 (0.0)	2 (0.7)
Sodium Glycerophosphate	2 (1.4)	0 (0.0)	2 (0.7)
Potassium Phosphate Monobasic	1 (0.7)	0 (0.0)	1 (0.4)
Sodium Bicarbonate	1 (0.7)	2 (1.6)	3 (1.1)
Calcium Chloride;potassium Chloride	0 (0.0)	1 (0.8)	1 (0.4)
Calcium Chloride;potassium Chloride;sodium Chloride	0 (0.0)	1 (0.8)	1 (0.4)
Calcium Gluconate;calcium Saccharate	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Chromic Chloride Hexahydrate;copper Chloride Dihydrate;ferric Chloride Hexahydrate;manganese Chloride Tetrahydrate;potassium Iodide;sodium Fluoride;sodium Molybdate Dihydrate;sodium Selenite Pentahydrate;zinc Chloride	0 (0.0)	1 (0.8)	1 (0.4)
Potassium	0 (0.0)	1 (0.8)	1 (0.4)
Potassium Phosphate Dibasic;potassium Phosphate Monobasic	0 (0.0)	2 (1.6)	2 (0.7)
Contact Laxatives	22 (15.8)	13 (10.1)	35 (13.1)
Bisacodyl	8 (5.8)	4 (3.1)	12 (4.5)
Sennoside A+b	7 (5.0)	0 (0.0)	7 (2.6)
Sennoside A+b Calcium	5 (3.6)	5 (3.9)	10 (3.7)
Senna Alexandrina Leaf	2 (1.4)	0 (0.0)	2 (0.7)
Sodium Picosulfate	2 (1.4)	3 (2.3)	5 (1.9)
Ricinus Communis Oil	1 (0.7)	0 (0.0)	1 (0.4)
Senna Alexandrina	0 (0.0)	2 (1.6)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Third-Generation Cephalosporins	22 (15.8)	19 (14.7)	41 (15.3)
Cefoperazone Sodium;sulbactam Sodium	5 (3.6)	5 (3.9)	10 (3.7)
Ceftazidime	4 (2.9)	5 (3.9)	9 (3.4)
Cefcapene Pivoxil Hydrochloride	3 (2.2)	2 (1.6)	5 (1.9)
Ceftriaxone Sodium	3 (2.2)	7 (5.4)	10 (3.7)
Cefoperazone Sodium;tazobactam Sodium	2 (1.4)	0 (0.0)	2 (0.7)
Ceftriaxone	2 (1.4)	0 (0.0)	2 (0.7)
Cefixime	1 (0.7)	0 (0.0)	1 (0.4)
Cefotaxime	1 (0.7)	1 (0.8)	2 (0.7)
Cefpodoxime Proxetil	1 (0.7)	0 (0.0)	1 (0.4)
Ceftriaxone Sodium Sesquaterhydrate	1 (0.7)	0 (0.0)	1 (0.4)
Cefditoren Pivoxil	0 (0.0)	1 (0.8)	1 (0.4)
Cefotaxime Sodium	0 (0.0)	2 (1.6)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 22APR2024 22:37 t-14-01-07-01-b-cm-gen-safetys-fa.rtf

Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Thyroid Hormones	22 (15.8)	4 (3.1)	26 (9.7)
Levothyroxine Sodium	15 (10.8)	4 (3.1)	19 (7.1)
Levothyroxine	6 (4.3)	0 (0.0)	6 (2.2)
Thyroid	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
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unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 22APR2024 22:37 t-14-01-07-01-b-cm-gen-safetys-fa.rtf

Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
H2-Receptor Antagonists	20 (14.4)	71 (55.0)	91 (34.0)
Famotidine	10 (7.2)	24 (18.6)	34 (12.7)
Ranitidine	5 (3.6)	14 (10.9)	19 (7.1)
Cimetidine	3 (2.2)	25 (19.4)	28 (10.4)
Ranitidine Hydrochloride	3 (2.2)	12 (9.3)	15 (5.6)
Nizatidine	0 (0.0)	1 (0.8)	1 (0.4)
Ranitidine Bismuth Citrate	0 (0.0)	1 (0.8)	1 (0.4)
Roxatidine Acetate	0 (0.0)	1 (0.8)	1 (0.4)
Roxatidine Acetate Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
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Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Opioids	19 (13.7)	17 (13.2)	36 (13.4)
Tramadol Hydrochloride	12 (8.6)	9 (7.0)	21 (7.8)
Tramadol	4 (2.9)	3 (2.3)	7 (2.6)
Dezocine	2 (1.4)	2 (1.6)	4 (1.5)
Bucinnazine Hydrochloride	1 (0.7)	1 (0.8)	2 (0.7)
Naloxone;tilidine	0 (0.0)	1 (0.8)	1 (0.4)
Tapentadol Hydrochloride	0 (0.0)	2 (1.6)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 22APR2024 22:37 t-14-01-07-01-b-cm-gen-safetys-fa.rtf

Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Opium Alkaloids And Derivatives	18 (12.9)	22 (17.1)	40 (14.9)
Codeine Phosphate	8 (5.8)	10 (7.8)	18 (6.7)
Codeine	4 (2.9)	3 (2.3)	7 (2.6)
Dextromethorphan Hydrobromide	4 (2.9)	5 (3.9)	9 (3.4)
Dextromethorphan	2 (1.4)	0 (0.0)	2 (0.7)
Chlorphenamine Maleate;dihydrocodeine Phosphate;methylephedrine Hydrochloride-Dl	1 (0.7)	1 (0.8)	2 (0.7)
Dextromethorphan Hydrobromide;lysozyme Hydrochloride;potassium Cresolsulfonate	1 (0.7)	0 (0.0)	1 (0.4)
Dihydrocodeine	1 (0.7)	1 (0.8)	2 (0.7)
Ammonium Chloride;chlorphenamine Maleate;dihydrocodeine Bitartrate;methylephedrine Hydrochloride-Dl	0 (0.0)	4 (3.1)	4 (1.5)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Analgesics And Antipyretics	18 (12.9)	17 (13.2)	35 (13.1)
Pregabalin	10 (7.2)	10 (7.8)	20 (7.5)
Gabapentin	4 (2.9)	6 (4.7)	10 (3.7)
Nefopam Hydrochloride	2 (1.4)	0 (0.0)	2 (0.7)
Mirogabalin Besilate	1 (0.7)	1 (0.8)	2 (0.7)
Nefopam	1 (0.7)	0 (0.0)	1 (0.4)
Clonidine Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Duloxetine	0 (0.0)	1 (0.8)	1 (0.4)
Duloxetine Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Amino Acids	17 (12.2)	12 (9.3)	29 (10.8)
Tranexamic Acid	12 (8.6)	7 (5.4)	19 (7.1)
Alanyl Glutamine	4 (2.9)	3 (2.3)	7 (2.6)
Aminomethylbenzoic Acid	3 (2.2)	1 (0.8)	4 (1.5)
Sodium Chloride;tranexamic Acid	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Opioids In Combination With Non-Opioid Analgesics	17 (12.2)	27 (20.9)	44 (16.4)
Paracetamol;tramadol Hydrochloride	9 (6.5)	14 (10.9)	23 (8.6)
Codeine Phosphate;ibuprofen	3 (2.2)	1 (0.8)	4 (1.5)
Codeine Phosphate;ibuprofen;paracetamol	3 (2.2)	4 (3.1)	7 (2.6)
Oxycodone;paracetamol	3 (2.2)	1 (0.8)	4 (1.5)
Codeine Phosphate;paracetamol	0 (0.0)	2 (1.6)	2 (0.7)
Codeine;paracetamol	0 (0.0)	1 (0.8)	1 (0.4)
Dihydrocodeine Bitartrate;paracetamol	0 (0.0)	3 (2.3)	3 (1.1)
Oxycodone Hydrochloride;paracetamol	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Propionic Acid Derivatives	17 (12.2)	22 (17.1)	39 (14.6)
Ibuprofen	5 (3.6)	6 (4.7)	11 (4.1)
Loxoprofen Sodium Dihydrate	5 (3.6)	4 (3.1)	9 (3.4)
Naproxen	3 (2.2)	4 (3.1)	7 (2.6)
Dexketoprofen	2 (1.4)	0 (0.0)	2 (0.7)
Loxoprofen Sodium	2 (1.4)	6 (4.7)	8 (3.0)
Dexketoprofen Trometamol	1 (0.7)	0 (0.0)	1 (0.4)
Flurbiprofen Axetil	1 (0.7)	4 (3.1)	5 (1.9)
Loxoprofen	1 (0.7)	1 (0.8)	2 (0.7)
Chlorphenamine Maleate;ibuprofen;zinc Gluconate	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Appetite Stimulants	16 (11.5)	10 (7.8)	26 (9.7)
Megestrol Acetate	10 (7.2)	6 (4.7)	16 (6.0)
Megestrol	5 (3.6)	4 (3.1)	9 (3.4)
Carnitine Hydrochloride;cyanocobalamin;cyproheptadine Orotate;lysine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Sulfonamides, Plain	16 (11.5)	19 (14.7)	35 (13.1)
Furosemide	15 (10.8)	16 (12.4)	31 (11.6)
Azosemide	1 (0.7)	0 (0.0)	1 (0.4)
Indapamide	0 (0.0)	1 (0.8)	1 (0.4)
Torasemide	0 (0.0)	3 (2.3)	3 (1.1)
Serotonin (5ht3) Antagonists	15 (10.8)	68 (52.7)	83 (31.0)
Ondansetron	5 (3.6)	5 (3.9)	10 (3.7)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Palonosetron	3 (2.2)	8 (6.2)	11 (4.1)
Granisetron Hydrochloride	2 (1.4)	9 (7.0)	11 (4.1)
Tropisetron	2 (1.4)	4 (3.1)	6 (2.2)
Azasetron Hydrochloride	1 (0.7)	2 (1.6)	3 (1.1)
Glucose;granisetron Hydrochloride	1 (0.7)	1 (0.8)	2 (0.7)
Ondansetron Hydrochloride	1 (0.7)	5 (3.9)	6 (2.2)
Palonosetron Hydrochloride	1 (0.7)	19 (14.7)	20 (7.5)
Tropisetron Hydrochloride	1 (0.7)	14 (10.9)	15 (5.6)
Dolasetron	0 (0.0)	1 (0.8)	1 (0.4)
Dolasetron Mesilate	0 (0.0)	9 (7.0)	9 (3.4)
Granisetron	0 (0.0)	3 (2.3)	3 (1.1)
Ramosetron	0 (0.0)	3 (2.3)	3 (1.1)
Ramosetron Hydrochloride	0 (0.0)	2 (1.6)	2 (0.7)
Sodium Chloride;tropisetron Hydrochloride	0 (0.0)	2 (1.6)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Tropisetron Mesylate	0 (0.0)	1 (0.8)	1 (0.4)
Benzodiazepine Related Drugs	14 (10.1)	9 (7.0)	23 (8.6)
Zopiclone	6 (4.3)	3 (2.3)	9 (3.4)
Zolpidem Tartrate	5 (3.6)	5 (3.9)	10 (3.7)
Zolpidem	2 (1.4)	2 (1.6)	4 (1.5)
Eszopiclone	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (Gord)	14 (10.1)	17 (13.2)	31 (11.6)
Sucralfate	4 (2.9)	4 (3.1)	8 (3.0)
Rebamipide	3 (2.2)	4 (3.1)	7 (2.6)
Sodium Alginate	3 (2.2)	1 (0.8)	4 (1.5)
Alginic Acid;aluminium Hydroxide;magnesium Carbonate;silicon Dioxide	1 (0.7)	0 (0.0)	1 (0.4)
Calcium Carbonate;sodium Alginate;sodium Bicarbonate	1 (0.7)	1 (0.8)	2 (0.7)
Eupatilin	1 (0.7)	0 (0.0)	1 (0.4)
Irsogladine Maleate	1 (0.7)	0 (0.0)	1 (0.4)
Levoglutamide;sodium Gualenate	1 (0.7)	2 (1.6)	3 (1.1)
Other Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (Gord)	1 (0.7)	0 (0.0)	1 (0.4)
Polaprezinc	1 (0.7)	4 (3.1)	5 (1.9)
Sodium Gualenate	1 (0.7)	1 (0.8)	2 (0.7)
Bismuth Pectin	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 22APR2024 22:37 t-14-01-07-01-b-cm-gen-safetys-fa.rtf

Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Fat/Carbohydrates/Proteins/Minerals/Vitamins, Combinations	13 (9.4)	17 (13.2)	30 (11.2)
Ascorbic Acid;biotin;calcium;carbohydrates Nos;chloride;colecalciferol;copper;cyanocobalamin;fats Nos;folic Acid;iron;magnesium;manganese;nicotinamide;pantothenic Acid;phosphorus;potassium;proteins Nos;pyridoxine;retinol;riboflavin;sodium;thiamine;tocopherol;zinc	3 (2.2)	5 (3.9)	8 (3.0)
Casein;herbal Oil Nos;maltodextrin;minerals Nos;trace Elements Nos;vitamins Nos	3 (2.2)	1 (0.8)	4 (1.5)
Nutrients Nos	3 (2.2)	4 (3.1)	7 (2.6)
Ascorbic Acid;biotin;calcium Citrate;calcium Pantothenate;cyanocobalamin;ferrous Sulfate;fibre, Dietary;folic Acid;glycine Max Seed Oil;magnesium Carbonate;maltodextrin;nicotinamide;potassium Citrate;proteins Nos;pyridoxine Hydrochloride;retinol;riboflavin;sodium Chloride;sucrose;thiamine Hydrochloride;tocopheryl Acetate;whey Protein;zea Mays Starch	2 (1.4)	3 (2.3)	5 (1.9)
Carbohydrates Nos;electrolytes Nos;lipids Nos;proteins Nos;vitamins Nos	2 (1.4)	2 (1.6)	4 (1.5)
Fat/Carbohydrates/Proteins/Minerals/Vitamins, Combinations	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
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unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 22APR2024 22:37 t-14-01-07-01-b-cm-gen-safetys-fa.rtf

Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Ascorbic Acid;biotin;calcium;carbohydrates Nos;chlorine;choline;chromium;copper;fats Nos;folic Acid;fructooligosaccharides;iron;levocarnitine;magnesium;manganese;molybdenum;nicotinic Acid;pantothenic Acid;phosphorus;potassium;proteins Nos;pyridoxine Hydrochloride;retinol;riboflavin;selenium;sodium;turin;vitamin B1 Nos;vitamin B12 Nos;vitamin D Nos;vitamin E Nos;vitamin K Nos;zinc	0 (0.0)	1 (0.8)	1 (0.4)
Carbohydrates Nos;fats Nos;minerals Nos;proteins Nos;vitamins Nos	0 (0.0)	1 (0.8)	1 (0.4)
Carbohydrates Nos;fatty Acids Nos;minerals Nos;proteins Nos;vitamins Nos	0 (0.0)	1 (0.8)	1 (0.4)
Casein;fats Nos;fibre, Dietary;maltodextrin;minerals Nos;vitamins Nos	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
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unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 22APR2024 22:37 t-14-01-07-01-b-cm-gen-safetys-fa.rtf

Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Heparin Group	13 (9.4)	7 (5.4)	20 (7.5)
Tinzaparin Sodium	3 (2.2)	1 (0.8)	4 (1.5)
Enoxaparin	2 (1.4)	1 (0.8)	3 (1.1)
Heparin	2 (1.4)	1 (0.8)	3 (1.1)
Heparin Sodium	2 (1.4)	1 (0.8)	3 (1.1)
Dalteparin Sodium	1 (0.7)	0 (0.0)	1 (0.4)
Heparin Calcium	1 (0.7)	0 (0.0)	1 (0.4)
Sulodexide	1 (0.7)	0 (0.0)	1 (0.4)
Tinzaparin	1 (0.7)	0 (0.0)	1 (0.4)
Enoxaparin Sodium	0 (0.0)	1 (0.8)	1 (0.4)
Nadroparin Calcium	0 (0.0)	2 (1.6)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
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unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 22APR2024 22:37 t-14-01-07-01-b-cm-gen-safetys-fa.rtf

Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Insulins And Analogues For Injection, Fast-Acting	13 (9.4)	4 (3.1)	17 (6.3)
Insulin	8 (5.8)	3 (2.3)	11 (4.1)
Insulin Aspart	4 (2.9)	0 (0.0)	4 (1.5)
Insulin Human	3 (2.2)	0 (0.0)	3 (1.1)
Insulin Lispro	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Antihistamines For Systemic Use	13 (9.4)	10 (7.8)	23 (8.6)
Desloratadine	3 (2.2)	1 (0.8)	4 (1.5)
Fexofenadine Hydrochloride	3 (2.2)	4 (3.1)	7 (2.6)
Azelastine	2 (1.4)	0 (0.0)	2 (0.7)
Bepotastine Besilate	2 (1.4)	0 (0.0)	2 (0.7)
Bilastine	2 (1.4)	1 (0.8)	3 (1.1)
Cyproheptadine Hydrochloride	2 (1.4)	0 (0.0)	2 (0.7)
Loratadine	2 (1.4)	2 (1.6)	4 (1.5)
Epinastine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Fexofenadine	1 (0.7)	2 (1.6)	3 (1.1)
Ketotifen	1 (0.7)	0 (0.0)	1 (0.4)
Mebhydrolin	1 (0.7)	0 (0.0)	1 (0.4)
Ebastine	0 (0.0)	2 (1.6)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Liver Therapy	12 (8.6)	9 (7.0)	21 (7.8)
Magnesium Isoglycyrrhizinate	4 (2.9)	3 (2.3)	7 (2.6)
Cysteine;glycine;glycyrrhizic Acid	3 (2.2)	2 (1.6)	5 (1.9)
Polyene Phosphatidylcholine	3 (2.2)	1 (0.8)	4 (1.5)
Cysteine Hydrochloride;glycine;glycyrrhizic Acid, Ammonium Salt	2 (1.4)	1 (0.8)	3 (1.1)
Diammonium Glycyrrhizinate	2 (1.4)	2 (1.6)	4 (1.5)
Glycine;glycyrrhizic Acid;methionine	1 (0.7)	1 (0.8)	2 (0.7)
Ornithine Aspartate	1 (0.7)	0 (0.0)	1 (0.4)
Tiopronin	1 (0.7)	0 (0.0)	1 (0.4)
Diisopropylamine Dichloroacetate	0 (0.0)	1 (0.8)	1 (0.4)
Inosine	0 (0.0)	1 (0.8)	1 (0.4)
Liver Therapy	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Platelet Aggregation Inhibitors Excl. Heparin	12 (8.6)	8 (6.2)	20 (7.5)
Acetylsalicylic Acid	6 (4.3)	4 (3.1)	10 (3.7)
Acetylsalicylate Lysine	2 (1.4)	2 (1.6)	4 (1.5)
Clopidogrel Bisulfate	2 (1.4)	2 (1.6)	4 (1.5)
Alprostadil	1 (0.7)	0 (0.0)	1 (0.4)
Cilostazol	1 (0.7)	0 (0.0)	1 (0.4)
Clopidogrel	1 (0.7)	0 (0.0)	1 (0.4)
Antidotes	11 (7.9)	13 (10.1)	24 (9.0)
Glutathione	7 (5.0)	12 (9.3)	19 (7.1)
Flumazenil	2 (1.4)	0 (0.0)	2 (0.7)
Acetylcysteine	1 (0.7)	1 (0.8)	2 (0.7)
Glutathione Sodium	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Antiinflammatory Preparations, Non-Steroids For Topical Use	11 (7.9)	8 (6.2)	19 (7.1)
Ketoprofen	4 (2.9)	1 (0.8)	5 (1.9)
Flurbiprofen	2 (1.4)	0 (0.0)	2 (0.7)
Loxoprofen Sodium	2 (1.4)	0 (0.0)	2 (0.7)
Loxoprofen Sodium Dihydrate	2 (1.4)	3 (2.3)	5 (1.9)
Esflurbiprofen;mentha Spp. Oil	1 (0.7)	0 (0.0)	1 (0.4)
Etofenamate	1 (0.7)	0 (0.0)	1 (0.4)
Diclofenac Diethylamine	0 (0.0)	1 (0.8)	1 (0.4)
Diclofenac Sodium	0 (0.0)	1 (0.8)	1 (0.4)
Indometacin	0 (0.0)	2 (1.6)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Blood Substitutes And Plasma Protein Fractions	11 (7.9)	6 (4.7)	17 (6.3)
Albumin Human	7 (5.0)	4 (3.1)	11 (4.1)
Albumin Nos	5 (3.6)	2 (1.6)	7 (2.6)
Dextran	1 (0.7)	0 (0.0)	1 (0.4)
Succinylated Gelatin	0 (0.0)	1 (0.8)	1 (0.4)
Combinations And Complexes Of Aluminium, Calcium And Magnesium Compounds	11 (7.9)	13 (10.1)	24 (9.0)
Hydrotalcite	5 (3.6)	3 (2.3)	8 (3.0)
Almagate	4 (2.9)	3 (2.3)	7 (2.6)
Aluminium Hydroxide;calcium Carbonate;magnesium Carbonate;oxetacaine	1 (0.7)	0 (0.0)	1 (0.4)
Aluminium;magnesium	1 (0.7)	7 (5.4)	8 (3.0)
Magaldrate	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Corticosteroids, Potent (Group Iii)	11 (7.9)	10 (7.8)	21 (7.8)
Betamethasone Valerate	4 (2.9)	1 (0.8)	5 (1.9)
Diflucortolone Valerate	3 (2.2)	2 (1.6)	5 (1.9)
Betamethasone	2 (1.4)	1 (0.8)	3 (1.1)
Betamethasone Dipropionate	1 (0.7)	1 (0.8)	2 (0.7)
Difluprednate	1 (0.7)	1 (0.8)	2 (0.7)
Fluocinonide	1 (0.7)	0 (0.0)	1 (0.4)
Mometasone Furoate	1 (0.7)	1 (0.8)	2 (0.7)
Betamethasone Butyrate Propionate	0 (0.0)	1 (0.8)	1 (0.4)
Diflucortolone	0 (0.0)	1 (0.8)	1 (0.4)
Hydrocortisone	0 (0.0)	1 (0.8)	1 (0.4)

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Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Coxibs	11 (7.9)	8 (6.2)	19 (7.1)
Celecoxib	9 (6.5)	7 (5.4)	16 (6.0)
Etoricoxib	1 (0.7)	0 (0.0)	1 (0.4)
Imrecoxib	1 (0.7)	1 (0.8)	2 (0.7)
Hmg Coa Reductase Inhibitors	11 (7.9)	7 (5.4)	18 (6.7)
Atorvastatin	4 (2.9)	1 (0.8)	5 (1.9)
Atorvastatin Calcium	2 (1.4)	1 (0.8)	3 (1.1)
Rosuvastatin Calcium	2 (1.4)	1 (0.8)	3 (1.1)
Simvastatin	2 (1.4)	2 (1.6)	4 (1.5)
Pitavastatin	1 (0.7)	0 (0.0)	1 (0.4)
Pitavastatin Calcium	1 (0.7)	0 (0.0)	1 (0.4)
Pravastatin	0 (0.0)	1 (0.8)	1 (0.4)
Rosuvastatin	0 (0.0)	1 (0.8)	1 (0.4)

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Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Plain Vitamin Preparations	11 (7.9)	16 (12.4)	27 (10.1)
Pyridoxine Hydrochloride	11 (7.9)	15 (11.6)	26 (9.7)
Riboflavin	1 (0.7)	0 (0.0)	1 (0.4)
Riboflavin Sodium Phosphate	1 (0.7)	0 (0.0)	1 (0.4)
Vitamin B Nos	0 (0.0)	1 (0.8)	1 (0.4)
Selective Beta-2-Adrenoreceptor Agonists	11 (7.9)	4 (3.1)	15 (5.6)
Salbutamol	6 (4.3)	1 (0.8)	7 (2.6)
Terbutaline	2 (1.4)	0 (0.0)	2 (0.7)
Tulobuterol	2 (1.4)	0 (0.0)	2 (0.7)
Terbutaline Sulfate	1 (0.7)	2 (1.6)	3 (1.1)
Procaterol Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Acetic Acid Derivatives And Related Substances	10 (7.2)	9 (7.0)	19 (7.1)
Diclofenac Potassium	3 (2.2)	1 (0.8)	4 (1.5)
Diclofenac Sodium	2 (1.4)	3 (2.3)	5 (1.9)
Aceclofenac	1 (0.7)	1 (0.8)	2 (0.7)
Acemetacin	1 (0.7)	1 (0.8)	2 (0.7)
Diclofenac	1 (0.7)	1 (0.8)	2 (0.7)
Indometacin	1 (0.7)	2 (1.6)	3 (1.1)
Ketorolac Tromethamine	1 (0.7)	1 (0.8)	2 (0.7)
Ascorbic Acid (Vitamin C), Plain	10 (7.2)	10 (7.8)	20 (7.5)
Ascorbic Acid	10 (7.2)	10 (7.8)	20 (7.5)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Opium Derivatives And Expectorants	10 (7.2)	4 (3.1)	14 (5.2)
Ammonia;benzoic Acid;camphor;glycerol;glycyrrhiza Spp. Root With Rhizome;guaifenesin;illicium Verum Oil;papaver Somniferum Tincture	4 (2.9)	1 (0.8)	5 (1.9)
Chlorphenamine Maleate;codeine Phosphate;glycyrrhizic Acid;methylephedrine Hydrochloride-Dl	2 (1.4)	0 (0.0)	2 (0.7)
Opium Derivatives And Expectorants	2 (1.4)	0 (0.0)	2 (0.7)
Dextromethorphan;guaifenesin;phenylephrine	1 (0.7)	0 (0.0)	1 (0.4)
Ephedrine Hydrochloride;guaifenesin;pholcodine	1 (0.7)	0 (0.0)	1 (0.4)
Camphor;glycyrrhiza Glabra;illicium Verum Oil;papaver Somniferum;sodium Benzoate	0 (0.0)	1 (0.8)	1 (0.4)
Chlorphenamine Maleate;dihydrocodeine Bitartrate;guaifenesin;methylephedrine Hydrochloride-Dl	0 (0.0)	1 (0.8)	1 (0.4)
Papaver Somniferum Powder;platycodon Grandiflorus;potassium Sulfate	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Antiemetics	10 (7.2)	11 (8.5)	21 (7.8)
Prochlorperazine Maleate	4 (2.9)	1 (0.8)	5 (1.9)
Metopimazine	3 (2.2)	0 (0.0)	3 (1.1)
Aprepitant	1 (0.7)	3 (2.3)	4 (1.5)
Difenidol	1 (0.7)	0 (0.0)	1 (0.4)
Promethazine	1 (0.7)	0 (0.0)	1 (0.4)
Azasetron Hydrochloride;sodium Chloride	0 (0.0)	1 (0.8)	1 (0.4)
Dimenhydrinate	0 (0.0)	1 (0.8)	1 (0.4)
Diphenhydramine	0 (0.0)	1 (0.8)	1 (0.4)
Diphenhydramine Hydrochloride	0 (0.0)	2 (1.6)	2 (0.7)
Fosaprepitant Meglumine	0 (0.0)	1 (0.8)	1 (0.4)
Hyoscine Hydrobromide	0 (0.0)	1 (0.8)	1 (0.4)
Promethazine Hydrochloride	0 (0.0)	2 (1.6)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Blood Products	10 (7.2)	12 (9.3)	22 (8.2)
Blood, Whole	4 (2.9)	1 (0.8)	5 (1.9)
Plasma	3 (2.2)	0 (0.0)	3 (1.1)
Red Blood Cells, Concentrated	2 (1.4)	5 (3.9)	7 (2.6)
Platelets	1 (0.7)	0 (0.0)	1 (0.4)
Red Blood Cells	1 (0.7)	6 (4.7)	7 (2.6)
Red Blood Cells, Leucocyte Depleted	1 (0.7)	0 (0.0)	1 (0.4)
Other Systemic Hemostatics	10 (7.2)	4 (3.1)	14 (5.2)
Haemocoagulase	5 (3.6)	2 (1.6)	7 (2.6)
Etamsilate	4 (2.9)	1 (0.8)	5 (1.9)
Recombinant Human Thrombopoietin	2 (1.4)	0 (0.0)	2 (0.7)
Carbazochrome	1 (0.7)	0 (0.0)	1 (0.4)
Carbazochrome Sodium Sulfonate	1 (0.7)	2 (1.6)	3 (1.1)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Substituted Alkylamines	10 (7.2)	35 (27.1)	45 (16.8)
Chlorphenamine	4 (2.9)	13 (10.1)	17 (6.3)
Chlorphenamine Maleate	4 (2.9)	5 (3.9)	9 (3.4)
Dexchlorpheniramine Maleate	2 (1.4)	14 (10.9)	16 (6.0)
Dexchlorpheniramine	0 (0.0)	2 (1.6)	2 (0.7)
Pheniramine	0 (0.0)	2 (1.6)	2 (0.7)
Carbapenems	9 (6.5)	5 (3.9)	14 (5.2)
Meropenem	5 (3.6)	2 (1.6)	7 (2.6)
Meropenem Trihydrate	3 (2.2)	2 (1.6)	5 (1.9)
Cilastatin Sodium;imipenem	1 (0.7)	0 (0.0)	1 (0.4)
Imipenem	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
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Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Cough Suppressants	9 (6.5)	1 (0.8)	10 (3.7)
Tipepidine Hibenzate	6 (4.3)	0 (0.0)	6 (2.2)
Benzonatate	1 (0.7)	1 (0.8)	2 (0.7)
Cloperastine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Helicidine	1 (0.7)	0 (0.0)	1 (0.4)
Alpha-Adrenoreceptor Antagonists	8 (5.8)	6 (4.7)	14 (5.2)
Tamsulosin Hydrochloride	6 (4.3)	3 (2.3)	9 (3.4)
Alfuzosin	1 (0.7)	0 (0.0)	1 (0.4)
Tamsulosin	1 (0.7)	1 (0.8)	2 (0.7)
Terazosin Hydrochloride	1 (0.7)	1 (0.8)	2 (0.7)
Doxazosin	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Antidiarrheal Microorganisms	8 (5.8)	8 (6.2)	16 (6.0)
Bacillus Subtilis;enterococcus Faecalis;lactobacillus Acidophilus	2 (1.4)	0 (0.0)	2 (0.7)
Bifidobacterium Bifidum;bifidobacterium Infantis	2 (1.4)	1 (0.8)	3 (1.1)
Bifidobacterium Nos	1 (0.7)	0 (0.0)	1 (0.4)
Enterococcus Faecalis	1 (0.7)	1 (0.8)	2 (0.7)
Lactobacillus Nos	1 (0.7)	0 (0.0)	1 (0.4)
Saccharomyces Boulardii	1 (0.7)	0 (0.0)	1 (0.4)
Antidiarrheal Microorganisms	0 (0.0)	1 (0.8)	1 (0.4)
Bacillus Lichenformis	0 (0.0)	1 (0.8)	1 (0.4)
Bacillus Mesentericus;clostridium Butyricum;enterococcus Faecalis	0 (0.0)	1 (0.8)	1 (0.4)
Bifidobacterium Longum;enterococcus Faecalis;lactobacillus Acidophilus	0 (0.0)	2 (1.6)	2 (0.7)
Bifidobacterium Longum;lactobacillus Bulgaricus;streptococcus Thermophilus	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Beta Blocking Agents, Selective	8 (5.8)	11 (8.5)	19 (7.1)
Bisoprolol	4 (2.9)	4 (3.1)	8 (3.0)
Bisoprolol Fumarate	2 (1.4)	1 (0.8)	3 (1.1)
Atenolol	1 (0.7)	1 (0.8)	2 (0.7)
Metoprolol Tartrate	1 (0.7)	2 (1.6)	3 (1.1)
Acebutolol	0 (0.0)	1 (0.8)	1 (0.4)
Esmolol Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Metoprolol	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Bisphosphonates	8 (5.8)	10 (7.8)	18 (6.7)
Zoledronic Acid	6 (4.3)	9 (7.0)	15 (5.6)
Clodronate Disodium	1 (0.7)	0 (0.0)	1 (0.4)
Glucose;pamidronate Disodium	1 (0.7)	0 (0.0)	1 (0.4)
Ibandronate Monosodium Monohydrate	1 (0.7)	0 (0.0)	1 (0.4)
Ibandronate Sodium	1 (0.7)	0 (0.0)	1 (0.4)
Disodium Incadronate	0 (0.0)	1 (0.8)	1 (0.4)
Corticosteroids, Moderately Potent (Group Ii)	8 (5.8)	2 (1.6)	10 (3.7)
Desonide	4 (2.9)	1 (0.8)	5 (1.9)
Hydrocortisone Butyrate	3 (2.2)	0 (0.0)	3 (1.1)
Dexamethasone	1 (0.7)	0 (0.0)	1 (0.4)
Dexamethasone Sodium Phosphate	0 (0.0)	1 (0.8)	1 (0.4)

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Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Direct Factor Xa Inhibitors	8 (5.8)	5 (3.9)	13 (4.9)
Apixaban	5 (3.6)	4 (3.1)	9 (3.4)
Edoxaban	2 (1.4)	0 (0.0)	2 (0.7)
Edoxaban Tosilate	2 (1.4)	0 (0.0)	2 (0.7)
Rivaroxaban	2 (1.4)	2 (1.6)	4 (1.5)
Medical Gases	8 (5.8)	8 (6.2)	16 (6.0)
Oxygen	8 (5.8)	8 (6.2)	16 (6.0)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Agents For Local Oral Treatment	8 (5.8)	7 (5.4)	15 (5.6)
Lidocaine	3 (2.2)	2 (1.6)	5 (1.9)
Sodium Gualenate Hydrate	3 (2.2)	2 (1.6)	5 (1.9)
Benzydamine	1 (0.7)	0 (0.0)	1 (0.4)
Calcium Chloride;carmellose Sodium;magnesium Chloride;potassium Chloride;potassium Phosphate Dibasic;sodium Chloride;sorbitol	1 (0.7)	0 (0.0)	1 (0.4)
Sucralfate	1 (0.7)	0 (0.0)	1 (0.4)
Benzydamine Hydrochloride	0 (0.0)	2 (1.6)	2 (0.7)
Cetylpyridinium Chloride	0 (0.0)	1 (0.8)	1 (0.4)
Lidocaine Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Other Aminoglycosides	8 (5.8)	1 (0.8)	9 (3.4)
Amikacin	5 (3.6)	0 (0.0)	5 (1.9)
Gentamicin	2 (1.4)	1 (0.8)	3 (1.1)
Gentamicin Sulfate;procaine Hydrochloride;vitamin B12 Nos	1 (0.7)	0 (0.0)	1 (0.4)

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Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Emollients And Protectives	8 (5.8)	2 (1.6)	10 (3.7)
Heparinoid	4 (2.9)	0 (0.0)	4 (1.5)
Mucopolysaccharide Polysulfuric Acid Ester	2 (1.4)	1 (0.8)	3 (1.1)
Ceramide;fatty Acids Nos;methyl Caprooyl Tyrosinate;phytosterols Nos;squalene;stearic Acid	1 (0.7)	0 (0.0)	1 (0.4)
Glycerol;paraffin, Liquid;white Soft Paraffin	1 (0.7)	1 (0.8)	2 (0.7)
Other Ophthalmologicals	8 (5.8)	3 (2.3)	11 (4.1)
Pirenoxine	4 (2.9)	0 (0.0)	4 (1.5)
Cyanocobalamin	3 (2.2)	0 (0.0)	3 (1.1)
Hyaluronate Sodium	1 (0.7)	2 (1.6)	3 (1.1)
Hypromellose	1 (0.7)	0 (0.0)	1 (0.4)
Potassium Iodide;sodium Iodide	1 (0.7)	0 (0.0)	1 (0.4)
Rebamipide	1 (0.7)	0 (0.0)	1 (0.4)
Trehalose	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Piperazine Derivatives	8 (5.8)	10 (7.8)	18 (6.7)
Cetirizine Hydrochloride	3 (2.2)	2 (1.6)	5 (1.9)
Levocetirizine Dihydrochloride	3 (2.2)	3 (2.3)	6 (2.2)
Buclizine Hydrochloride	1 (0.7)	1 (0.8)	2 (0.7)
Hydroxyzine	1 (0.7)	0 (0.0)	1 (0.4)
Hydroxyzine Hydrochloride	1 (0.7)	1 (0.8)	2 (0.7)
Levocetirizine	1 (0.7)	2 (1.6)	3 (1.1)
Cetirizine	0 (0.0)	1 (0.8)	1 (0.4)
Second-Generation Cephalosporins	8 (5.8)	2 (1.6)	10 (3.7)
Cefaclor	3 (2.2)	1 (0.8)	4 (1.5)
Cefuroxime Sodium	3 (2.2)	0 (0.0)	3 (1.1)
Cefmetazole Sodium	1 (0.7)	1 (0.8)	2 (0.7)
Cefonicid Sodium	1 (0.7)	0 (0.0)	1 (0.4)
Cefoxitin Sodium	0 (0.0)	1 (0.8)	1 (0.4)

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Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Anticholinergics	7 (5.0)	3 (2.3)	10 (3.7)
Ipratropium Bromide	2 (1.4)	0 (0.0)	2 (0.7)
Ipratropium	1 (0.7)	0 (0.0)	1 (0.4)
Phenylephrine Hydrochloride;tropicamide	1 (0.7)	0 (0.0)	1 (0.4)
Tiotropium	1 (0.7)	1 (0.8)	2 (0.7)
Tropicamide	1 (0.7)	0 (0.0)	1 (0.4)
Umeclidinium Bromide	1 (0.7)	0 (0.0)	1 (0.4)
Ipratropium Bromide Monohydrate	0 (0.0)	1 (0.8)	1 (0.4)
Tiotropium Bromide	0 (0.0)	1 (0.8)	1 (0.4)
Biguanides	7 (5.0)	3 (2.3)	10 (3.7)
Metformin Hydrochloride	4 (2.9)	2 (1.6)	6 (2.2)
Metformin	3 (2.2)	2 (1.6)	5 (1.9)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Diazepines, Oxazepines, Thiazepines And Oxepines	7 (5.0)	6 (4.7)	13 (4.9)
Olanzapine	4 (2.9)	2 (1.6)	6 (2.2)
Quetiapine Fumarate	2 (1.4)	1 (0.8)	3 (1.1)
Quetiapine	1 (0.7)	2 (1.6)	3 (1.1)
Asenapine Maleate	0 (0.0)	1 (0.8)	1 (0.4)
Enemas	7 (5.0)	6 (4.7)	13 (4.9)
Glycerol	6 (4.3)	6 (4.7)	12 (4.5)
Sodium Chloride	1 (0.7)	1 (0.8)	2 (0.7)
Soft Soap	1 (0.7)	0 (0.0)	1 (0.4)
Enemas	0 (0.0)	1 (0.8)	1 (0.4)
Peripheral Opioid Receptor Antagonists	7 (5.0)	0 (0.0)	7 (2.6)
Naldemedine Tosilate	6 (4.3)	0 (0.0)	6 (2.2)
Naloxegol	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
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Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Xanthines	7 (5.0)	4 (3.1)	11 (4.1)
Doxofylline	4 (2.9)	1 (0.8)	5 (1.9)
Diprophylline	2 (1.4)	1 (0.8)	3 (1.1)
Theobromine	1 (0.7)	0 (0.0)	1 (0.4)
Theophylline	1 (0.7)	0 (0.0)	1 (0.4)
Aminophylline	0 (0.0)	2 (1.6)	2 (0.7)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Adrenergic And Dopaminergic Agents	6 (4.3)	6 (4.7)	12 (4.5)
Norepinephrine	3 (2.2)	1 (0.8)	4 (1.5)
Midodrine Hydrochloride	2 (1.4)	1 (0.8)	3 (1.1)
Norepinephrine Bitartrate	2 (1.4)	1 (0.8)	3 (1.1)
Dopamine	1 (0.7)	0 (0.0)	1 (0.4)
Epinephrine	1 (0.7)	3 (2.3)	4 (1.5)
Metaraminol Tartrate	1 (0.7)	0 (0.0)	1 (0.4)
Dopamine Hydrochloride	0 (0.0)	2 (1.6)	2 (0.7)
Etilefrine Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Norepinephrine Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Adrenergics In Combinations With Anticholinergics Incl. Triple Combinations With Corticosteroids	6 (4.3)	1 (0.8)	7 (2.6)
Beclometasone Dipropionate;formoterol Fumarate;glycopyrronium Bromide	1 (0.7)	0 (0.0)	1 (0.4)
Fenoterol Hydrobromide;ipratropium Bromide	1 (0.7)	1 (0.8)	2 (0.7)
Ipratropium Bromide;salbutamol	1 (0.7)	0 (0.0)	1 (0.4)
Ipratropium Bromide;salbutamol Sulfate	1 (0.7)	0 (0.0)	1 (0.4)
Ipratropium;salbutamol	1 (0.7)	0 (0.0)	1 (0.4)
Olodaterol Hydrochloride;tiotropium Bromide Monohydrate	1 (0.7)	0 (0.0)	1 (0.4)
Antipropulsives	6 (4.3)	13 (10.1)	19 (7.1)
Loperamide	4 (2.9)	4 (3.1)	8 (3.0)
Loperamide Hydrochloride	2 (1.4)	9 (7.0)	11 (4.1)
General Nutrients	6 (4.3)	6 (4.7)	12 (4.5)
General Nutrients	3 (2.2)	5 (3.9)	8 (3.0)
Trace Elements Nos	3 (2.2)	1 (0.8)	4 (1.5)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Iron Bivalent, Oral Preparations	6 (4.3)	7 (5.4)	13 (4.9)
Ferrous Sulfate	3 (2.2)	2 (1.6)	5 (1.9)
Ferrous Glycine Sulfate	1 (0.7)	0 (0.0)	1 (0.4)
Ferrous Sodium Citrate	1 (0.7)	1 (0.8)	2 (0.7)
Ferrous Succinate	1 (0.7)	1 (0.8)	2 (0.7)
Ferrous Fumarate	0 (0.0)	2 (1.6)	2 (0.7)
Ferrous Gluconate	0 (0.0)	1 (0.8)	1 (0.4)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Cardiac Preparations	6 (4.3)	8 (6.2)	14 (5.2)
Adenosine	2 (1.4)	0 (0.0)	2 (0.7)
Ivabradine	1 (0.7)	0 (0.0)	1 (0.4)
Levocarnitine	1 (0.7)	2 (1.6)	3 (1.1)
Magnesium Tanshinoate B	1 (0.7)	0 (0.0)	1 (0.4)
Meglumine Adenosine Cyclophosphate	1 (0.7)	0 (0.0)	1 (0.4)
Phosphocreatine Sodium	0 (0.0)	4 (3.1)	4 (1.5)
Tanshinone Iia Sodium Sulfonate	0 (0.0)	1 (0.8)	1 (0.4)
Ubidecarenone	0 (0.0)	1 (0.8)	1 (0.4)

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Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Immunostimulants	6 (4.3)	7 (5.4)	13 (4.9)
Leucogen	2 (1.4)	2 (1.6)	4 (1.5)
Lentinan	1 (0.7)	0 (0.0)	1 (0.4)
Mannatide	1 (0.7)	0 (0.0)	1 (0.4)
Polypeptide	1 (0.7)	1 (0.8)	2 (0.7)
Thymopentin	1 (0.7)	1 (0.8)	2 (0.7)
Amino Acids Nos;nucleic Acid Nos;polysaccharides Nos	0 (0.0)	1 (0.8)	1 (0.4)
Deoxyribonucleotide Sodium	0 (0.0)	1 (0.8)	1 (0.4)
Nucleotides Nos;polypeptide	0 (0.0)	1 (0.8)	1 (0.4)
Thymalfasin	0 (0.0)	2 (1.6)	2 (0.7)

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Concomitant Medication
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Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Phenothiazine Derivatives	6 (4.3)	13 (10.1)	19 (7.1)
Alimemazine Tartrate	2 (1.4)	0 (0.0)	2 (0.7)
Mequitazine	2 (1.4)	0 (0.0)	2 (0.7)
Promethazine Hydrochloride	2 (1.4)	11 (8.5)	13 (4.9)
Promethazine	0 (0.0)	3 (2.3)	3 (1.1)
Vitamins	6 (4.3)	1 (0.8)	7 (2.6)
Vitamins Nos	5 (3.6)	1 (0.8)	6 (2.2)
Fat Soluble Vitamins Nos	1 (0.7)	0 (0.0)	1 (0.4)
Adrenergics In Combination With Corticosteroids Or Other Drugs, Excl. Anticholinergics	5 (3.6)	0 (0.0)	5 (1.9)
Beclometasone Dipropionate;formoterol Fumarate	2 (1.4)	0 (0.0)	2 (0.7)
Fluticasone Furoate;vilanterol Trifenatate	1 (0.7)	0 (0.0)	1 (0.4)
Fluticasone Propionate;salmeterol Xinafoate	1 (0.7)	0 (0.0)	1 (0.4)
Fluticasone;salmeterol	1 (0.7)	0 (0.0)	1 (0.4)

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Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Amides	5 (3.6)	15 (11.6)	20 (7.5)
Lidocaine	3 (2.2)	5 (3.9)	8 (3.0)
Lidocaine;prilocaine	2 (1.4)	0 (0.0)	2 (0.7)
Lidocaine Hydrochloride	1 (0.7)	7 (5.4)	8 (3.0)
Ropivacaine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Bupivacaine	0 (0.0)	1 (0.8)	1 (0.4)
Epinephrine;lidocaine	0 (0.0)	1 (0.8)	1 (0.4)
Lidocaine Hydrochloride;menthol	0 (0.0)	1 (0.8)	1 (0.4)
Aminoalkyl Ethers	5 (3.6)	19 (14.7)	24 (9.0)
Diphenhydramine Hydrochloride	3 (2.2)	15 (11.6)	18 (6.7)
Diphenhydramine	2 (1.4)	4 (3.1)	6 (2.2)
Dimenhydrinate	0 (0.0)	1 (0.8)	1 (0.4)
Piprinhydrinate	0 (0.0)	1 (0.8)	1 (0.4)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Antibiotics	5 (3.6)	2 (1.6)	7 (2.6)
Nystatin	2 (1.4)	0 (0.0)	2 (0.7)
Amphotericin B	1 (0.7)	0 (0.0)	1 (0.4)
Erythromycin	1 (0.7)	0 (0.0)	1 (0.4)
Tetracycline Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Chloramphenicol	0 (0.0)	1 (0.8)	1 (0.4)
Tetracycline	0 (0.0)	1 (0.8)	1 (0.4)
Belladonna Alkaloids, Semisynthetic, Quaternary Ammonium Compounds	5 (3.6)	6 (4.7)	11 (4.1)
Hyoscine	3 (2.2)	1 (0.8)	4 (1.5)
Hyoscine Butylbromide	2 (1.4)	3 (2.3)	5 (1.9)
Butylscopolamine	0 (0.0)	1 (0.8)	1 (0.4)
Cimetropium Bromide	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Bile Acids And Derivatives	5 (3.6)	3 (2.3)	8 (3.0)
Ursodeoxycholic Acid	5 (3.6)	3 (2.3)	8 (3.0)
Bile And Liver Therapy	5 (3.6)	2 (1.6)	7 (2.6)
Bicyclol	5 (3.6)	2 (1.6)	7 (2.6)
Calcium, Combinations With Vitamin D And/Or Other Drugs	5 (3.6)	4 (3.1)	9 (3.4)
Calcium Carbonate;colecalciferol	3 (2.2)	2 (1.6)	5 (1.9)
Calcium Carbonate;colecalciferol;magnesium Carbonate	1 (0.7)	2 (1.6)	3 (1.1)
Calcium;colecalciferol	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Colony Stimulating Factors	5 (3.6)	50 (38.8)	55 (20.5)
Granulocyte Colony Stimulating Factor	4 (2.9)	32 (24.8)	36 (13.4)
Granulocyte Macrophage Colony Stim Factor	1 (0.7)	2 (1.6)	3 (1.1)
Peg Granulocyte Colony Stimulating Factor	1 (0.7)	5 (3.9)	6 (2.2)
Filgrastim	0 (0.0)	16 (12.4)	16 (6.0)
Lenograstim	0 (0.0)	4 (3.1)	4 (1.5)
Pegfilgrastim	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Enzyme Preparations	5 (3.6)	2 (1.6)	7 (2.6)
Azintamide;cellulase;dimeticone;pancreatin	1 (0.7)	1 (0.8)	2 (0.7)
Enzymes Nos;pancreatin	1 (0.7)	0 (0.0)	1 (0.4)
Pancreatin	1 (0.7)	0 (0.0)	1 (0.4)
Pancrelipase	1 (0.7)	0 (0.0)	1 (0.4)
Pepsin	1 (0.7)	0 (0.0)	1 (0.4)
Enzymes Nos	0 (0.0)	1 (0.8)	1 (0.4)
Glycopeptide Antibacterials	5 (3.6)	4 (3.1)	9 (3.4)
Teicoplanin	3 (2.2)	1 (0.8)	4 (1.5)
Vancomycin	2 (1.4)	1 (0.8)	3 (1.1)
Vancomycin Hydrochloride	0 (0.0)	2 (1.6)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Antibiotics For Topical Use	5 (3.6)	8 (6.2)	13 (4.9)
Mupirocin	2 (1.4)	2 (1.6)	4 (1.5)
Fusidate Sodium	1 (0.7)	0 (0.0)	1 (0.4)
Gentamicin	1 (0.7)	1 (0.8)	2 (0.7)
Neomycin	1 (0.7)	0 (0.0)	1 (0.4)
Bacitracin;neomycin Sulfate;polymyxin B Sulfate	0 (0.0)	1 (0.8)	1 (0.4)
Fusidic Acid	0 (0.0)	4 (3.1)	4 (1.5)
Gentamicin Sulfate	0 (0.0)	1 (0.8)	1 (0.4)
Other Drugs For Functional Gastrointestinal Disorders	5 (3.6)	2 (1.6)	7 (2.6)
Dimeticone	2 (1.4)	2 (1.6)	4 (1.5)
Simeticone	2 (1.4)	0 (0.0)	2 (0.7)
Phloroglucinol	1 (0.7)	0 (0.0)	1 (0.4)
Phloroglucinol;trimethylphloroglucinol	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Mineral Products	5 (3.6)	3 (2.3)	8 (3.0)
Magnesium Aspartate;potassium Aspartate	2 (1.4)	2 (1.6)	4 (1.5)
Phosphoric Acid;sodium Phosphate Dibasic	1 (0.7)	0 (0.0)	1 (0.4)
Sodium Phosphate	1 (0.7)	0 (0.0)	1 (0.4)
Sodium Phosphate Monobasic (Anhydrous)	1 (0.7)	0 (0.0)	1 (0.4)
Calcium Phosphate Monobasic;magnesium Glycerophosphate;phosphoric Acid;sodium Phosphate Dibasic	0 (0.0)	1 (0.8)	1 (0.4)
Penicillins With Extended Spectrum	5 (3.6)	7 (5.4)	12 (4.5)
Amoxicillin	3 (2.2)	6 (4.7)	9 (3.4)
Amoxicillin Trihydrate	1 (0.7)	2 (1.6)	3 (1.1)
Ampicillin	1 (0.7)	0 (0.0)	1 (0.4)
Piperacillin	1 (0.7)	1 (0.8)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Potassium	5 (3.6)	5 (3.9)	10 (3.7)
Potassium Chloride	3 (2.2)	2 (1.6)	5 (1.9)
Magnesium;potassium Aspartate	1 (0.7)	0 (0.0)	1 (0.4)
Potassium Gluconate	1 (0.7)	1 (0.8)	2 (0.7)
Potassium Magnesium Aspartate	1 (0.7)	0 (0.0)	1 (0.4)
Potassium Aspartate	0 (0.0)	1 (0.8)	1 (0.4)
Potassium Citrate	0 (0.0)	1 (0.8)	1 (0.4)
Pyrazolones	5 (3.6)	5 (3.9)	10 (3.7)
Aminophenazone;barbital;phenazone	3 (2.2)	2 (1.6)	5 (1.9)
Metamizole	2 (1.4)	1 (0.8)	3 (1.1)
Metamizole Sodium	0 (0.0)	2 (1.6)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Various Alimentary Tract And Metabolism Products	5 (3.6)	4 (3.1)	9 (3.4)
Adenosine;coenzyme A;nadide	1 (0.7)	2 (1.6)	3 (1.1)
Glucurolactone	1 (0.7)	0 (0.0)	1 (0.4)
Probiotics Nos	1 (0.7)	0 (0.0)	1 (0.4)
Sodium Bicarbonate	1 (0.7)	0 (0.0)	1 (0.4)
Thioctic Acid Tromethamine	1 (0.7)	0 (0.0)	1 (0.4)
Acetylcarnitine;citicoline;pantothenic Acid;pyridoxine Hydrochloride;riboflavin;thioctic Acid;vitamin B1 Nos;vitamin B12 Nos	0 (0.0)	1 (0.8)	1 (0.4)
Zinc Acetate Dihydrate	0 (0.0)	1 (0.8)	1 (0.4)
Aldosterone Antagonists	4 (2.9)	2 (1.6)	6 (2.2)
Spironolactone	4 (2.9)	2 (1.6)	6 (2.2)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Angiotensin Ii Receptor Blockers (Arbs), Plain	4 (2.9)	6 (4.7)	10 (3.7)
Candesartan	1 (0.7)	1 (0.8)	2 (0.7)
Candesartan Cilexetil	1 (0.7)	0 (0.0)	1 (0.4)
Olmesartan Medoxomil	1 (0.7)	0 (0.0)	1 (0.4)
Telmisartan	1 (0.7)	0 (0.0)	1 (0.4)
Azilsartan	0 (0.0)	1 (0.8)	1 (0.4)
Losartan	0 (0.0)	1 (0.8)	1 (0.4)
Losartan Potassium	0 (0.0)	1 (0.8)	1 (0.4)
Valsartan	0 (0.0)	2 (1.6)	2 (0.7)
Butyrophenone Derivatives	4 (2.9)	3 (2.3)	7 (2.6)
Haloperidol	4 (2.9)	3 (2.3)	7 (2.6)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Combinations Of Sulfonamides And Trimethoprim, Incl. Derivatives	4 (2.9)	3 (2.3)	7 (2.6)
Sulfamethoxazole;trimethoprim	4 (2.9)	3 (2.3)	7 (2.6)
Corticosteroids	4 (2.9)	1 (0.8)	5 (1.9)
Aluminium Acetate;hydrocortisone Acetate;lidocaine;zinc Oxide	1 (0.7)	0 (0.0)	1 (0.4)
Beclometasone Dipropionate	1 (0.7)	0 (0.0)	1 (0.4)
Fluticasone Furoate	1 (0.7)	0 (0.0)	1 (0.4)
Triamcinolone	1 (0.7)	0 (0.0)	1 (0.4)
Escherichia Coli;hydrocortisone	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Dihydropyridine Derivatives	4 (2.9)	12 (9.3)	16 (6.0)
Amlodipine	1 (0.7)	5 (3.9)	6 (2.2)
Amlodipine Besilate	1 (0.7)	1 (0.8)	2 (0.7)
Lercanidipine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Nifedipine	1 (0.7)	4 (3.1)	5 (1.9)
Felodipine	0 (0.0)	1 (0.8)	1 (0.4)
Lacidipine	0 (0.0)	1 (0.8)	1 (0.4)
Expectorants	4 (2.9)	0 (0.0)	4 (1.5)
Fudosteine	3 (2.2)	0 (0.0)	3 (1.1)
Ammonium Chloride;glycyrrhiza Glabra	1 (0.7)	0 (0.0)	1 (0.4)

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Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
First-Generation Cephalosporins	4 (2.9)	2 (1.6)	6 (2.2)
Cefazolin Sodium	2 (1.4)	2 (1.6)	4 (1.5)
Cefazedone	1 (0.7)	0 (0.0)	1 (0.4)
Cefazolin Sodium Pentahydrate	1 (0.7)	0 (0.0)	1 (0.4)
Influenza Vaccines	4 (2.9)	1 (0.8)	5 (1.9)
Influenza Vaccine	4 (2.9)	1 (0.8)	5 (1.9)
Insulins And Analogues For Injection, Long-Acting	4 (2.9)	2 (1.6)	6 (2.2)
Insulin Glargine	4 (2.9)	1 (0.8)	5 (1.9)
Insulin Glargine Biosimilar 1	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
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Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Macrolides	4 (2.9)	5 (3.9)	9 (3.4)
Azithromycin	3 (2.2)	2 (1.6)	5 (1.9)
Roxithromycin	1 (0.7)	0 (0.0)	1 (0.4)
Clarithromycin	0 (0.0)	3 (2.3)	3 (1.1)
Nucleoside And Nucleotide Reverse Transcriptase Inhibitors	4 (2.9)	7 (5.4)	11 (4.1)
Entecavir	3 (2.2)	3 (2.3)	6 (2.2)
Tenofovir	1 (0.7)	2 (1.6)	3 (1.1)
Lamivudine	0 (0.0)	1 (0.8)	1 (0.4)
Tenofovir Disoproxil Fumarate	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
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Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 22APR2024 22:37 t-14-01-07-01-b-cm-gen-safetys-fa.rtf

Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Centrally Acting Agents	4 (2.9)	2 (1.6)	6 (2.2)
Eperisone Hydrochloride	3 (2.2)	1 (0.8)	4 (1.5)
Baclofen	1 (0.7)	1 (0.8)	2 (0.7)
Other Drugs For Constipation	4 (2.9)	2 (1.6)	6 (2.2)
Lubiprostone	3 (2.2)	0 (0.0)	3 (1.1)
Linaclotide	1 (0.7)	0 (0.0)	1 (0.4)
Sodium Bicarbonate;sodium Phosphate Monobasic (Anhydrous)	0 (0.0)	2 (1.6)	2 (0.7)
Sodium	4 (2.9)	4 (3.1)	8 (3.0)
Sodium Chloride	4 (2.9)	4 (3.1)	8 (3.0)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Sulfonylureas	4 (2.9)	1 (0.8)	5 (1.9)
Glimepiride	3 (2.2)	0 (0.0)	3 (1.1)
Glipizide	1 (0.7)	1 (0.8)	2 (0.7)
Triazole Derivatives	4 (2.9)	2 (1.6)	6 (2.2)
Fluconazole	3 (2.2)	2 (1.6)	5 (1.9)
Voriconazole	1 (0.7)	0 (0.0)	1 (0.4)
Vitamin B12 (Cyanocobalamin And Analogues)	4 (2.9)	8 (6.2)	12 (4.5)
Mecobalamin	4 (2.9)	7 (5.4)	11 (4.1)
Cyanocobalamin	0 (0.0)	1 (0.8)	1 (0.4)
Vitamin B12 Nos	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
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Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Watersoluble, Nephrotropic, Low Osmolar X-Ray Contrast Media	4 (2.9)	0 (0.0)	4 (1.5)
Ioversol	2 (1.4)	0 (0.0)	2 (0.7)
Iodixanol	1 (0.7)	0 (0.0)	1 (0.4)
Iohexol	1 (0.7)	0 (0.0)	1 (0.4)
Ace Inhibitors, Plain	3 (2.2)	4 (3.1)	7 (2.6)
Ramipril	2 (1.4)	1 (0.8)	3 (1.1)
Captopril	1 (0.7)	2 (1.6)	3 (1.1)
Enalapril	1 (0.7)	1 (0.8)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Alpha- And Beta-Adrenoreceptor Agonists	3 (2.2)	0 (0.0)	3 (1.1)
Epinephrine	2 (1.4)	0 (0.0)	2 (0.7)
Ephedrine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Amino Acids And Derivatives	3 (2.2)	2 (1.6)	5 (1.9)
Ademetionine 1,4-Butanedisulfonate	2 (1.4)	1 (0.8)	3 (1.1)
Ademetionine	1 (0.7)	0 (0.0)	1 (0.4)
Levoglutamide	1 (0.7)	1 (0.8)	2 (0.7)
Anesthetics, Local	3 (2.2)	2 (1.6)	5 (1.9)
Lidocaine	3 (2.2)	1 (0.8)	4 (1.5)
Dyclonine Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Antiinfectives And Antiseptics For Local Oral Treatment	3 (2.2)	5 (3.9)	8 (3.0)
Amphotericin B	1 (0.7)	1 (0.8)	2 (0.7)
Chlorhexidine Gluconate	1 (0.7)	1 (0.8)	2 (0.7)
Nystatin	1 (0.7)	2 (1.6)	3 (1.1)
Cetylpyridinium Chloride;chlorhexidine Gluconate	0 (0.0)	1 (0.8)	1 (0.4)
Chlorhexidine	0 (0.0)	1 (0.8)	1 (0.4)
Antiinfectives For Systemic Use	3 (2.2)	1 (0.8)	4 (1.5)
Andrographolide	3 (2.2)	1 (0.8)	4 (1.5)
Corticosteroids, Plain	3 (2.2)	0 (0.0)	3 (1.1)
Fluorometholone	2 (1.4)	0 (0.0)	2 (0.7)
Prednisolone	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Corticosteroids, Very Potent (Group Iv)	3 (2.2)	1 (0.8)	4 (1.5)
Clobetasol Propionate	2 (1.4)	1 (0.8)	3 (1.1)
Clobetasol	1 (0.7)	0 (0.0)	1 (0.4)
Diphenylmethane Derivatives	3 (2.2)	2 (1.6)	5 (1.9)
Hydroxyzine Hydrochloride	2 (1.4)	2 (1.6)	4 (1.5)
Hydroxyzine	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Imidazole And Triazole Derivatives	3 (2.2)	1 (0.8)	4 (1.5)
Econazole Nitrate;triamcinolone Acetonide	2 (1.4)	0 (0.0)	2 (0.7)
Bifonazole	1 (0.7)	0 (0.0)	1 (0.4)
Clobetasol Propionate;ketoconazole	1 (0.7)	0 (0.0)	1 (0.4)
Isoconazole Nitrate	1 (0.7)	0 (0.0)	1 (0.4)
Miconazole	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Imidazole Derivatives	3 (2.2)	3 (2.3)	6 (2.2)
Econazole	1 (0.7)	0 (0.0)	1 (0.4)
Econazole Nitrate	1 (0.7)	0 (0.0)	1 (0.4)
Metronidazole	1 (0.7)	1 (0.8)	2 (0.7)
Sertaconazole	1 (0.7)	0 (0.0)	1 (0.4)
Tinidazole	1 (0.7)	0 (0.0)	1 (0.4)
Ornidazole	0 (0.0)	2 (1.6)	2 (0.7)
Opioid Anesthetics	3 (2.2)	3 (2.3)	6 (2.2)
Fentanyl	3 (2.2)	0 (0.0)	3 (1.1)
Remifentanil Hydrochloride	1 (0.7)	1 (0.8)	2 (0.7)
Sufentanil Citrate	0 (0.0)	2 (1.6)	2 (0.7)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Organic Nitrates	3 (2.2)	2 (1.6)	5 (1.9)
Glyceryl Trinitrate	2 (1.4)	2 (1.6)	4 (1.5)
Isosorbide Mononitrate	1 (0.7)	0 (0.0)	1 (0.4)
Other Antianemic Preparations	3 (2.2)	6 (4.7)	9 (3.4)
Erythropoietin Human	2 (1.4)	3 (2.3)	5 (1.9)
Darbepoetin Alfa	1 (0.7)	1 (0.8)	2 (0.7)
Epoetin Alfa	0 (0.0)	2 (1.6)	2 (0.7)
Epoetin Nos	0 (0.0)	1 (0.8)	1 (0.4)
Other Antivirals	3 (2.2)	1 (0.8)	4 (1.5)
Lysozyme Chloride	2 (1.4)	0 (0.0)	2 (0.7)
Dehydroandrographolide Succinate K Na	1 (0.7)	1 (0.8)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Dermatologicals	3 (2.2)	3 (2.3)	6 (2.2)
Guaiazulene	3 (2.2)	2 (1.6)	5 (1.9)
Magnesium Sulfate	0 (0.0)	1 (0.8)	1 (0.4)
Other General Anesthetics	3 (2.2)	3 (2.3)	6 (2.2)
Propofol	3 (2.2)	2 (1.6)	5 (1.9)
Etomidate	1 (0.7)	1 (0.8)	2 (0.7)
Oxazol, Thiazine, And Triazine Derivatives	3 (2.2)	0 (0.0)	3 (1.1)
Chlorzoxazone	3 (2.2)	0 (0.0)	3 (1.1)
Phosphodiesterase Inhibitors	3 (2.2)	3 (2.3)	6 (2.2)
Bucladesine Calcium	3 (2.2)	3 (2.3)	6 (2.2)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Protein Supplements	3 (2.2)	1 (0.8)	4 (1.5)
Protein Hydrolysate	2 (1.4)	0 (0.0)	2 (0.7)
Proteins Nos	1 (0.7)	1 (0.8)	2 (0.7)
Whey Protein	0 (0.0)	1 (0.8)	1 (0.4)
Selective Serotonin Reuptake Inhibitors	3 (2.2)	0 (0.0)	3 (1.1)
Citalopram	2 (1.4)	0 (0.0)	2 (0.7)
Sertraline	1 (0.7)	0 (0.0)	1 (0.4)
Softeners, Emollients	3 (2.2)	1 (0.8)	4 (1.5)
Paraffin, Liquid	2 (1.4)	0 (0.0)	2 (0.7)
Paraffin;sodium Picosulfate	1 (0.7)	0 (0.0)	1 (0.4)
Glycerol;paraffin, Liquid	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
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Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Somatostatin And Analogues	3 (2.2)	2 (1.6)	5 (1.9)
Octreotide Acetate	2 (1.4)	1 (0.8)	3 (1.1)
Somatostatin	1 (0.7)	1 (0.8)	2 (0.7)
Stomatological Preparations	3 (2.2)	2 (1.6)	5 (1.9)
Sodium Bicarbonate	3 (2.2)	2 (1.6)	5 (1.9)
Sulfonamides	3 (2.2)	2 (1.6)	5 (1.9)
Sulfamethoxazole	3 (2.2)	2 (1.6)	5 (1.9)
Vitamin K	3 (2.2)	2 (1.6)	5 (1.9)
Phytomenadione	3 (2.2)	2 (1.6)	5 (1.9)
Alpha Glucosidase Inhibitors	2 (1.4)	0 (0.0)	2 (0.7)
Acarbose	2 (1.4)	0 (0.0)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Angiotensin Ii Receptor Blockers (Arbs) And Calcium Channel Blockers	2 (1.4)	2 (1.6)	4 (1.5)
Amlodipine Besilate;olmesartan Medoxomil	1 (0.7)	0 (0.0)	1 (0.4)
Amlodipine;valsartan	1 (0.7)	0 (0.0)	1 (0.4)
Amlodipine;losartan Potassium	0 (0.0)	1 (0.8)	1 (0.4)
Lercanidipine;valsartan	0 (0.0)	1 (0.8)	1 (0.4)
Angiotensin Ii Receptor Blockers (Arbs) And Diuretics	2 (1.4)	0 (0.0)	2 (0.7)
Hydrochlorothiazide;irbesartan	1 (0.7)	0 (0.0)	1 (0.4)
Hydrochlorothiazide;valsartan	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 22APR2024 22:37 t-14-01-07-01-b-cm-gen-safetys-fa.rtf

Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Antiarrhythmics, Class Iii	2 (1.4)	4 (3.1)	6 (2.2)
Amiodarone Hydrochloride	2 (1.4)	2 (1.6)	4 (1.5)
Amiodarone	0 (0.0)	2 (1.6)	2 (0.7)
Benzomorphan Derivatives	2 (1.4)	1 (0.8)	3 (1.1)
Pentazocine	2 (1.4)	1 (0.8)	3 (1.1)
Benzothiazepine Derivatives	2 (1.4)	0 (0.0)	2 (0.7)
Diltiazem Hydrochloride	2 (1.4)	0 (0.0)	2 (0.7)
Beta Blocking Agents	2 (1.4)	0 (0.0)	2 (0.7)
Carteolol Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Timolol Maleate	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Calcitonin Preparations	2 (1.4)	0 (0.0)	2 (0.7)
Calcitonin	1 (0.7)	0 (0.0)	1 (0.4)
Elcatonin	1 (0.7)	0 (0.0)	1 (0.4)
Corticosteroids, Moderately Potent, Other Combinations	2 (1.4)	0 (0.0)	2 (0.7)
Camphor;dexamethasone Acetate;menthol	2 (1.4)	0 (0.0)	2 (0.7)
Dipeptidyl Peptidase 4 (Dpp-4) Inhibitors	2 (1.4)	1 (0.8)	3 (1.1)
Sitagliptin	1 (0.7)	0 (0.0)	1 (0.4)
Vildagliptin	1 (0.7)	0 (0.0)	1 (0.4)
Linagliptin	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Drugs For Constipation	2 (1.4)	1 (0.8)	3 (1.1)
Drugs For Constipation	2 (1.4)	1 (0.8)	3 (1.1)
Drugs For Treatment Of Hyperkalemia And Hyperphosphatemia	2 (1.4)	0 (0.0)	2 (0.7)
Calcium Polystyrene Sulfonate	2 (1.4)	0 (0.0)	2 (0.7)
Drugs For Urinary Frequency And Incontinence	2 (1.4)	1 (0.8)	3 (1.1)
Solifenacin Succinate	1 (0.7)	0 (0.0)	1 (0.4)
Trospium Chloride	1 (0.7)	0 (0.0)	1 (0.4)
Vibegron	1 (0.7)	0 (0.0)	1 (0.4)
Mirabegron	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 22APR2024 22:37 t-14-01-07-01-b-cm-gen-safetys-fa.rtf

Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Enzymes	2 (1.4)	2 (1.6)	4 (1.5)
Bromelains;cysteine	1 (0.7)	0 (0.0)	1 (0.4)
Kallidinogenase	1 (0.7)	0 (0.0)	1 (0.4)
Bromelains;trypsin	0 (0.0)	1 (0.8)	1 (0.4)
Hyaluronidase	0 (0.0)	1 (0.8)	1 (0.4)
Iron, Parenteral Preparations	2 (1.4)	4 (3.1)	6 (2.2)
Ferric Carboxymaltose	1 (0.7)	1 (0.8)	2 (0.7)
Saccharated Iron Oxide	1 (0.7)	3 (2.3)	4 (1.5)
Mineralocorticoids	2 (1.4)	0 (0.0)	2 (0.7)
Fludrocortisone Acetate	2 (1.4)	0 (0.0)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Nucleosides And Nucleotides Excl. Reverse Transcriptase Inhibitors	2 (1.4)	3 (2.3)	5 (1.9)
Ganciclovir	1 (0.7)	1 (0.8)	2 (0.7)
Valaciclovir Hydrochloride	1 (0.7)	1 (0.8)	2 (0.7)
Vidarabine	1 (0.7)	0 (0.0)	1 (0.4)
Aciclovir	0 (0.0)	1 (0.8)	1 (0.4)
Valaciclovir	0 (0.0)	1 (0.8)	1 (0.4)
Other Alimentary Tract And Metabolism Products	2 (1.4)	1 (0.8)	3 (1.1)
Clostridium Butyricum	2 (1.4)	1 (0.8)	3 (1.1)
Other Antibacterials	2 (1.4)	1 (0.8)	3 (1.1)
Fosfomycin Sodium	1 (0.7)	0 (0.0)	1 (0.4)
Linezolid	1 (0.7)	0 (0.0)	1 (0.4)
Fosfomycin	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Antidepressants	2 (1.4)	7 (5.4)	9 (3.4)
Duloxetine Hydrochloride	1 (0.7)	1 (0.8)	2 (0.7)
Mirtazapine	1 (0.7)	0 (0.0)	1 (0.4)
Trazodone	1 (0.7)	3 (2.3)	4 (1.5)
Mianserin	0 (0.0)	1 (0.8)	1 (0.4)
Trazodone Hydrochloride	0 (0.0)	2 (1.6)	2 (0.7)
Other Antidiarrheals	2 (1.4)	0 (0.0)	2 (0.7)
Racecadotril	2 (1.4)	0 (0.0)	2 (0.7)
Other Antifungals For Topical Use	2 (1.4)	0 (0.0)	2 (0.7)
Methyl Salicylate;tolnaftate	1 (0.7)	0 (0.0)	1 (0.4)
Selenium Sulfide	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Antiinflammatory And Antirheumatic Agents, Non-Steroids	2 (1.4)	0 (0.0)	2 (0.7)
Benzydamine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Rabbit Vaccinia Extract	1 (0.7)	0 (0.0)	1 (0.4)
Other Antipruritics	2 (1.4)	1 (0.8)	3 (1.1)
Doxepin	2 (1.4)	0 (0.0)	2 (0.7)
Calamine	0 (0.0)	1 (0.8)	1 (0.4)
Other Antipsoriatics For Topical Use	2 (1.4)	0 (0.0)	2 (0.7)
Betamethasone;calcipotriol	2 (1.4)	0 (0.0)	2 (0.7)
Other Capillary Stabilizing Agents	2 (1.4)	0 (0.0)	2 (0.7)
Escin Sodium	2 (1.4)	0 (0.0)	2 (0.7)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Cardiac Combination Products	2 (1.4)	1 (0.8)	3 (1.1)
Ligustrazine Hydrochloride;salvia Miltiorrhiza Root With Rhizome	2 (1.4)	0 (0.0)	2 (0.7)
Ligustrazine;salvia Miltiorrhiza	1 (0.7)	0 (0.0)	1 (0.4)
Magnesium Aspartate;potassium Aspartate	0 (0.0)	1 (0.8)	1 (0.4)
Other Hypnotics And Sedatives	2 (1.4)	5 (3.9)	7 (2.6)
Suvorexant	2 (1.4)	2 (1.6)	4 (1.5)
Clomethiazole	0 (0.0)	1 (0.8)	1 (0.4)
Dexmedetomidine Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Hyoscine	0 (0.0)	1 (0.8)	1 (0.4)
Other Intestinal Adsorbents	2 (1.4)	9 (7.0)	11 (4.1)
Diosmectite	1 (0.7)	2 (1.6)	3 (1.1)
Montmorillonite	1 (0.7)	7 (5.4)	8 (3.0)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Local Anesthetics	2 (1.4)	0 (0.0)	2 (0.7)
Dyclonine	1 (0.7)	0 (0.0)	1 (0.4)
Dyclonine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Oxicams	2 (1.4)	0 (0.0)	2 (0.7)
Meloxicam	2 (1.4)	0 (0.0)	2 (0.7)
Parasympathomimetics	2 (1.4)	0 (0.0)	2 (0.7)
Carbachol	1 (0.7)	0 (0.0)	1 (0.4)
Neostigmine	1 (0.7)	0 (0.0)	1 (0.4)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Phenothiazines With Aliphatic Side-Chain	2 (1.4)	1 (0.8)	3 (1.1)
Chlorpromazine	1 (0.7)	1 (0.8)	2 (0.7)
Chlorpromazine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Progestogens	2 (1.4)	0 (0.0)	2 (0.7)
Medroxyprogesterone Acetate	2 (1.4)	0 (0.0)	2 (0.7)
Solutions Producing Osmotic Diuresis	2 (1.4)	4 (3.1)	6 (2.2)
Mannitol	2 (1.4)	1 (0.8)	3 (1.1)
Fructose;glycerol	0 (0.0)	1 (0.8)	1 (0.4)
Glucose;mannitol;sodium Chloride	0 (0.0)	2 (1.6)	2 (0.7)
Synthetic Anticholinergics, Esters With Tertiary Amino Group	2 (1.4)	0 (0.0)	2 (0.7)
Trimebutine Maleate	2 (1.4)	0 (0.0)	2 (0.7)

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Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Taxanes	2 (1.4)	0 (0.0)	2 (0.7)
Paclitaxel	2 (1.4)	0 (0.0)	2 (0.7)
Testosterone-5-Alpha Reductase Inhibitors	2 (1.4)	0 (0.0)	2 (0.7)
Dutasteride	1 (0.7)	0 (0.0)	1 (0.4)
Finasteride	1 (0.7)	0 (0.0)	1 (0.4)
Tetanus Vaccines	2 (1.4)	0 (0.0)	2 (0.7)
Tetanus Vaccine	1 (0.7)	0 (0.0)	1 (0.4)
Tetanus Vaccine Toxoid	1 (0.7)	0 (0.0)	1 (0.4)
Tetracyclines	2 (1.4)	1 (0.8)	3 (1.1)
Minocycline Hydrochloride	1 (0.7)	1 (0.8)	2 (0.7)
Tigecycline	1 (0.7)	0 (0.0)	1 (0.4)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Thiazides, Plain	2 (1.4)	2 (1.6)	4 (1.5)
Hydrochlorothiazide	2 (1.4)	1 (0.8)	3 (1.1)
Bendroflumethiazide	0 (0.0)	1 (0.8)	1 (0.4)
Vitamin B-Complex, Incl. Combinations	2 (1.4)	2 (1.6)	4 (1.5)
Vitamin B-Complex, Incl. Combinations	2 (1.4)	2 (1.6)	4 (1.5)
Vitamin B1 In Combination With Vitamin B6 And/Or Vitamin B12	2 (1.4)	2 (1.6)	4 (1.5)
Cyanocobalamin;pyridoxine Hydrochloride;riboflavin;thiamine Mononitrate	1 (0.7)	0 (0.0)	1 (0.4)
Cyanocobalamin;pyridoxine Hydrochloride;thiamine Disulfide	1 (0.7)	2 (1.6)	3 (1.1)
Vitamin B1, Plain	2 (1.4)	1 (0.8)	3 (1.1)
Thiamine	1 (0.7)	1 (0.8)	2 (0.7)
Thiamine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)

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Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
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Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Xanthines And Adrenergics	2 (1.4)	1 (0.8)	3 (1.1)
Aminophylline;chlorphenamine Maleate;methoxyphenamine Hydrochloride;noscapine	2 (1.4)	1 (0.8)	3 (1.1)
Zinc Products	2 (1.4)	0 (0.0)	2 (0.7)
Zinc Oxide	2 (1.4)	0 (0.0)	2 (0.7)
Ace Inhibitors And Calcium Channel Blockers	1 (0.7)	1 (0.8)	2 (0.7)
Amlodipine Besilate;perindopril Arginine	1 (0.7)	1 (0.8)	2 (0.7)
Alpha And Beta Blocking Agents	1 (0.7)	0 (0.0)	1 (0.4)
Carvedilol	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
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unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 22APR2024 22:37 t-14-01-07-01-b-cm-gen-safetys-fa.rtf

Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Amino Acids/Carbohydrates/Minerals/Vitamins, Combinations	1 (0.7)	0 (0.0)	1 (0.4)
Amino Acids Nos;carbohydrates Nos;fats Nos;minerals Nos;vitamins Nos	1 (0.7)	0 (0.0)	1 (0.4)
Anesthetics For Topical Use	1 (0.7)	1 (0.8)	2 (0.7)
Benzocaine;chlorphenamine Maleate	1 (0.7)	1 (0.8)	2 (0.7)
Cinchocaine Hydrochloride;diphenhydramine;zinc Oxide	1 (0.7)	0 (0.0)	1 (0.4)
Angiotensin Ii Receptor Blockers (Arbs), Other Combinations	1 (0.7)	0 (0.0)	1 (0.4)
Amlodipine Besilate;hydrochlorothiazide;valsartan	1 (0.7)	0 (0.0)	1 (0.4)
Antacids With Antiflatulents	1 (0.7)	0 (0.0)	1 (0.4)
Aluminium Hydroxide Gel, Dried;magnesium Hydroxide;simeticone	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
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unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 22APR2024 22:37 t-14-01-07-01-b-cm-gen-safetys-fa.rtf

Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Antacids With Sodium Bicarbonate	1 (0.7)	1 (0.8)	2 (0.7)
Sodium Alginate;sodium Bicarbonate	1 (0.7)	0 (0.0)	1 (0.4)
Antacids With Sodium Bicarbonate	0 (0.0)	1 (0.8)	1 (0.4)
Antacids, Other Combinations	1 (0.7)	0 (0.0)	1 (0.4)
Aluminium Hydroxide-Magnesium Carbonate;lidocaine Hydrochloride;magnesium Hydroxide;magnesium Trisilicate	1 (0.7)	0 (0.0)	1 (0.4)
Antiarrhythmics, Class Ic	1 (0.7)	2 (1.6)	3 (1.1)
Pilsicainide Hydrochloride	1 (0.7)	1 (0.8)	2 (0.7)
Flecainide	0 (0.0)	1 (0.8)	1 (0.4)
Antibacterials For Systemic Use	1 (0.7)	1 (0.8)	2 (0.7)
Antibiotics	1 (0.7)	1 (0.8)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Antihistamines For Topical Use	1 (0.7)	1 (0.8)	2 (0.7)
Diphenhydramine	1 (0.7)	1 (0.8)	2 (0.7)
Antiinflammatory Agents, Non-Steroids	1 (0.7)	0 (0.0)	1 (0.4)
Bromfenac Sodium	1 (0.7)	0 (0.0)	1 (0.4)
Antiinflammatory And Antirheumatic Products, Non-Steroids	1 (0.7)	0 (0.0)	1 (0.4)
Nsaids	1 (0.7)	0 (0.0)	1 (0.4)
Antiseptics	1 (0.7)	1 (0.8)	2 (0.7)
Azulene	1 (0.7)	0 (0.0)	1 (0.4)
Sodium Bicarbonate;sodium Gualenate	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Antivirals	1 (0.7)	5 (3.9)	6 (2.2)
Ganciclovir	1 (0.7)	1 (0.8)	2 (0.7)
Aciclovir	0 (0.0)	4 (3.1)	4 (1.5)
Beta Blocking Agents, Non-Selective	1 (0.7)	0 (0.0)	1 (0.4)
Propranolol	1 (0.7)	0 (0.0)	1 (0.4)
Beta-Lactamase Inhibitors	1 (0.7)	1 (0.8)	2 (0.7)
Sulbactam	1 (0.7)	0 (0.0)	1 (0.4)
Clavulanic Acid	0 (0.0)	1 (0.8)	1 (0.4)
Biguanides And Amidines	1 (0.7)	0 (0.0)	1 (0.4)
Chlorhexidine Gluconate	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Bioflavonoids	1 (0.7)	1 (0.8)	2 (0.7)
Scutellarein Glucuronide	1 (0.7)	1 (0.8)	2 (0.7)
Blood And Related Products	1 (0.7)	2 (1.6)	3 (1.1)
Blood, Calf, Deprot., Lmw Portion	1 (0.7)	2 (1.6)	3 (1.1)
Blood Coagulation Factors	1 (0.7)	0 (0.0)	1 (0.4)
Thrombin	1 (0.7)	0 (0.0)	1 (0.4)
Blood Substitutes And Perfusion Solutions	1 (0.7)	2 (1.6)	3 (1.1)
Carbohydrates Nos;potassium Chloride;sodium Chloride;sodium Lactate	1 (0.7)	2 (1.6)	3 (1.1)
Carbamide Products	1 (0.7)	0 (0.0)	1 (0.4)
Urea	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Carbohydrates	1 (0.7)	1 (0.8)	2 (0.7)
Glucose	1 (0.7)	1 (0.8)	2 (0.7)
Choline Esters	1 (0.7)	2 (1.6)	3 (1.1)
Bethanechol Chloride	1 (0.7)	2 (1.6)	3 (1.1)
Corticosteroids And Antiinfectives In Combination	1 (0.7)	1 (0.8)	2 (0.7)
Betamethasone Sodium Phosphate;neomycin Sulfate	1 (0.7)	0 (0.0)	1 (0.4)
Betamethasone Sodium Phosphate;neomycin	0 (0.0)	1 (0.8)	1 (0.4)
Corticosteroids For Local Oral Treatment	1 (0.7)	7 (5.4)	8 (3.0)
Triamcinolone	1 (0.7)	0 (0.0)	1 (0.4)
Dexamethasone	0 (0.0)	3 (2.3)	3 (1.1)
Triamcinolone Acetonide	0 (0.0)	4 (3.1)	4 (1.5)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Corticosteroids For Systemic Use	1 (0.7)	0 (0.0)	1 (0.4)
Corticosteroids	1 (0.7)	0 (0.0)	1 (0.4)
Corticosteroids, Potent, Combinations With Antibiotics	1 (0.7)	1 (0.8)	2 (0.7)
Betamethasone;gentamicin	1 (0.7)	1 (0.8)	2 (0.7)
Corticosteroids, Potent, Other Combinations	1 (0.7)	0 (0.0)	1 (0.4)
Betamethasone Dipropionate;salicylic Acid	1 (0.7)	0 (0.0)	1 (0.4)
Corticosteroids, Weak, Other Combinations	1 (0.7)	1 (0.8)	2 (0.7)
Crotamiton;hydrocortisone	1 (0.7)	1 (0.8)	2 (0.7)
Detoxifying Agents For Antineoplastic Treatment	1 (0.7)	0 (0.0)	1 (0.4)
Calcium Folinate	1 (0.7)	0 (0.0)	1 (0.4)

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Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (Gord)	1 (0.7)	3 (2.3)	4 (1.5)
Teprenone	1 (0.7)	2 (1.6)	3 (1.1)
Montmorillonite	0 (0.0)	1 (0.8)	1 (0.4)
Emollients And Protectives	1 (0.7)	1 (0.8)	2 (0.7)
Emollients And Protectives	1 (0.7)	1 (0.8)	2 (0.7)
Fibrates	1 (0.7)	1 (0.8)	2 (0.7)
Fenofibrate	1 (0.7)	0 (0.0)	1 (0.4)
Bezafibrate	0 (0.0)	1 (0.8)	1 (0.4)
Fourth-Generation Cephalosporins	1 (0.7)	2 (1.6)	3 (1.1)
Cefepime	1 (0.7)	0 (0.0)	1 (0.4)
Cefepime Hydrochloride	0 (0.0)	2 (1.6)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Imidazoline Receptor Agonists In Combination With Diuretics	1 (0.7)	0 (0.0)	1 (0.4)
Clonidine Hydrochloride;dihydralazine Sulfate;hydrochlorothiazide	1 (0.7)	0 (0.0)	1 (0.4)
Immunoglobulins, Normal Human	1 (0.7)	0 (0.0)	1 (0.4)
Immunoglobulin Human Normal	1 (0.7)	0 (0.0)	1 (0.4)
Insulins And Analogues For Injection, Intermediate- Or Long-Acting Combined With Fast-Acting	1 (0.7)	0 (0.0)	1 (0.4)
Insulin Aspart;insulin Degludec	1 (0.7)	0 (0.0)	1 (0.4)
Insulins And Analogues For Injection, Intermediate-Acting	1 (0.7)	0 (0.0)	1 (0.4)
Insulin Human Injection, Isophane	1 (0.7)	0 (0.0)	1 (0.4)
Interleukin Inhibitors	1 (0.7)	0 (0.0)	1 (0.4)
Tocilizumab	1 (0.7)	0 (0.0)	1 (0.4)

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Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Interleukins	1 (0.7)	1 (0.8)	2 (0.7)
Oprelvekin	1 (0.7)	1 (0.8)	2 (0.7)
Iron In Other Combinations	1 (0.7)	0 (0.0)	1 (0.4)
Ascorbic Acid;ferric Pyrophosphate	1 (0.7)	0 (0.0)	1 (0.4)
Iron Preparations	1 (0.7)	0 (0.0)	1 (0.4)
Iron	1 (0.7)	0 (0.0)	1 (0.4)
Leukotriene Receptor Antagonists	1 (0.7)	0 (0.0)	1 (0.4)
Montelukast Sodium	1 (0.7)	0 (0.0)	1 (0.4)
Lincosamides	1 (0.7)	2 (1.6)	3 (1.1)
Clindamycin Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Clindamycin Phosphate	0 (0.0)	2 (1.6)	2 (0.7)

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Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Local Anesthetics	1 (0.7)	1 (0.8)	2 (0.7)
Proxymetacaine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Benzocaine;bismuth Subgallate;diphenhydramine Hydrochloride;zinc Oxide	0 (0.0)	1 (0.8)	1 (0.4)
Magnesium	1 (0.7)	0 (0.0)	1 (0.4)
Magnesium Aspartate	1 (0.7)	0 (0.0)	1 (0.4)
Magnesium Compounds	1 (0.7)	0 (0.0)	1 (0.4)
Magnesium Oxide	1 (0.7)	0 (0.0)	1 (0.4)
Morphinan Derivatives	1 (0.7)	0 (0.0)	1 (0.4)
Butorphanol	1 (0.7)	0 (0.0)	1 (0.4)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Multivitamins, Plain	1 (0.7)	3 (2.3)	4 (1.5)
Ascorbic Acid;biotin;colecalciferol;dexpanthenol;folic Acid;nicotinamide;pyridoxine Hydrochloride;retinol Palmitate;riboflavin Sodium Phosphate;tocopherol;vitamin B1 Nos;vitamin B12 Nos	1 (0.7)	3 (2.3)	4 (1.5)
Neuraminidase Inhibitors	1 (0.7)	1 (0.8)	2 (0.7)
Oseltamivir Phosphate	1 (0.7)	1 (0.8)	2 (0.7)
Other Antiallergics	1 (0.7)	0 (0.0)	1 (0.4)
Ketotifen Fumarate	1 (0.7)	0 (0.0)	1 (0.4)
Other Antiepileptics	1 (0.7)	1 (0.8)	2 (0.7)
Levetiracetam	1 (0.7)	1 (0.8)	2 (0.7)
Other Antimycotics For Systemic Use	1 (0.7)	0 (0.0)	1 (0.4)
Anidulafungin	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Cephalosporins And Penems	1 (0.7)	0 (0.0)	1 (0.4)
Faropenem Sodium	1 (0.7)	0 (0.0)	1 (0.4)
Other Combinations Of Nutrients	1 (0.7)	0 (0.0)	1 (0.4)
Carbohydrates Nos;fats Nos;fibre, Dietary;minerals Nos;proteins Nos;vitamins Nos	1 (0.7)	0 (0.0)	1 (0.4)
Other Drugs Affecting Bone Structure And Mineralization	1 (0.7)	1 (0.8)	2 (0.7)
Denosumab	1 (0.7)	1 (0.8)	2 (0.7)
Other Intestinal Antiinfectives	1 (0.7)	0 (0.0)	1 (0.4)
Berberine Tannate;scopolia Spp.	1 (0.7)	0 (0.0)	1 (0.4)
Other Nervous System Drugs	1 (0.7)	0 (0.0)	1 (0.4)
Edaravone	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Nutrients	1 (0.7)	2 (1.6)	3 (1.1)
Other Nutrients	1 (0.7)	2 (1.6)	3 (1.1)
Other Parasympathomimetics	1 (0.7)	0 (0.0)	1 (0.4)
Choline Alfoscerate	1 (0.7)	0 (0.0)	1 (0.4)
Other Psychostimulants And Nootropics	1 (0.7)	0 (0.0)	1 (0.4)
Oxiracetam	1 (0.7)	0 (0.0)	1 (0.4)
Other Quaternary Ammonium Compounds	1 (0.7)	1 (0.8)	2 (0.7)
Rocuronium Bromide	1 (0.7)	0 (0.0)	1 (0.4)
Atracurium Besilate	0 (0.0)	1 (0.8)	1 (0.4)
Other Sclerosing Agents	1 (0.7)	0 (0.0)	1 (0.4)
Talc	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Surgical Aids	1 (0.7)	0 (0.0)	1 (0.4)
Calcium Chloride Dihydrate;magnesium Chloride Hexahydrate;potassium Chloride;sodium Acetate Trihydrate;sodium Chloride;sodium Citrate Dihydrate	1 (0.7)	0 (0.0)	1 (0.4)
Other Systemic Drugs For Obstructive Airway Diseases	1 (0.7)	0 (0.0)	1 (0.4)
Asarone	1 (0.7)	0 (0.0)	1 (0.4)
Other Topical Products For Joint And Muscular Pain	1 (0.7)	0 (0.0)	1 (0.4)
Apis Mellifica	1 (0.7)	0 (0.0)	1 (0.4)
Other Vasodilators Used In Cardiac Diseases	1 (0.7)	0 (0.0)	1 (0.4)
Nicorandil	1 (0.7)	0 (0.0)	1 (0.4)
Piperazine And Derivatives	1 (0.7)	0 (0.0)	1 (0.4)
Piperazine Ferulate	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Polymyxins	1 (0.7)	0 (0.0)	1 (0.4)
Colistin	1 (0.7)	0 (0.0)	1 (0.4)
Preparations Inhibiting Uric Acid Production	1 (0.7)	4 (3.1)	5 (1.9)
Febuxostat	1 (0.7)	2 (1.6)	3 (1.1)
Allopurinol	0 (0.0)	2 (1.6)	2 (0.7)
Proteinase Inhibitors	1 (0.7)	0 (0.0)	1 (0.4)
Ulinastatin	1 (0.7)	0 (0.0)	1 (0.4)
Quinoline Derivatives And Related Substances	1 (0.7)	0 (0.0)	1 (0.4)
Praziquantel	1 (0.7)	0 (0.0)	1 (0.4)
Rabies Vaccines	1 (0.7)	0 (0.0)	1 (0.4)
Rabies Vaccine	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Salicylic Acid And Derivatives	1 (0.7)	0 (0.0)	1 (0.4)
Acetylsalicylate Lysine	1 (0.7)	0 (0.0)	1 (0.4)
Selective Serotonin (5ht1) Agonists	1 (0.7)	0 (0.0)	1 (0.4)
Eletriptan	1 (0.7)	0 (0.0)	1 (0.4)
Silver Compounds	1 (0.7)	0 (0.0)	1 (0.4)
Silver Compounds	1 (0.7)	0 (0.0)	1 (0.4)
Soft Paraffin And Fat Products	1 (0.7)	1 (0.8)	2 (0.7)
White Soft Paraffin	1 (0.7)	1 (0.8)	2 (0.7)
Steroid Antibacterials	1 (0.7)	0 (0.0)	1 (0.4)
Fusidic Acid	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
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Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Streptogramins	1 (0.7)	0 (0.0)	1 (0.4)
Pristinamycin	1 (0.7)	0 (0.0)	1 (0.4)
Sympathomimetics	1 (0.7)	1 (0.8)	2 (0.7)
Loratadine;pseudoephedrine Sulfate	1 (0.7)	0 (0.0)	1 (0.4)
Pseudoephedrine Hydrochloride;triprolidine Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Tests For Allergic Diseases	1 (0.7)	2 (1.6)	3 (1.1)
Antibacterial Skin Test	1 (0.7)	2 (1.6)	3 (1.1)
Tetracycline And Derivatives	1 (0.7)	1 (0.8)	2 (0.7)
Oxytetracycline Hydrochloride;polymyxin B Sulfate	1 (0.7)	0 (0.0)	1 (0.4)
Tetracycline Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
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Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Viscoelastic Substances	1 (0.7)	0 (0.0)	1 (0.4)
Hyaluronate Sodium	1 (0.7)	0 (0.0)	1 (0.4)
Vitamin B-Complex With Vitamin C	1 (0.7)	0 (0.0)	1 (0.4)
Ascorbic Acid;vitamin B Complex	1 (0.7)	0 (0.0)	1 (0.4)
Vitamin B-Complex, Plain	1 (0.7)	0 (0.0)	1 (0.4)
Vitamin B Complex	1 (0.7)	0 (0.0)	1 (0.4)
Vitamin D And Analogues	1 (0.7)	4 (3.1)	5 (1.9)
Calcifediol	1 (0.7)	0 (0.0)	1 (0.4)
Alfacalcidol	0 (0.0)	1 (0.8)	1 (0.4)
Colecalciferol	0 (0.0)	3 (2.3)	3 (1.1)

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Percentages were based on N.
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(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Vitamins With Minerals	1 (0.7)	2 (1.6)	3 (1.1)
Minerals Nos;vitamins Nos	1 (0.7)	2 (1.6)	3 (1.1)
All Other Therapeutic Products	0 (0.0)	1 (0.8)	1 (0.4)
All Other Therapeutic Products	0 (0.0)	1 (0.8)	1 (0.4)
Aluminium Compounds	0 (0.0)	5 (3.9)	5 (1.9)
Aluminium Phosphate Gel	0 (0.0)	5 (3.9)	5 (1.9)
Anticholinergic Agents	0 (0.0)	2 (1.6)	2 (0.7)
Anisodamine Hydrochloride	0 (0.0)	2 (1.6)	2 (0.7)
Antipruritics, Incl. Antihistamines, Anesthetics, Etc.	0 (0.0)	1 (0.8)	1 (0.4)
Camphor;chlorphenamine Maleate;hexachlorophene;lidocaine Hydrochloride;menthol;methyl Salicylate	0 (0.0)	1 (0.8)	1 (0.4)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Belladonna Alkaloids, Tertiary Amines	0 (0.0)	4 (3.1)	4 (1.5)
Atropine	0 (0.0)	3 (2.3)	3 (1.1)
Atropine Sulfate	0 (0.0)	1 (0.8)	1 (0.4)
Beta-Lactam Antibacterials, Penicillins	0 (0.0)	1 (0.8)	1 (0.4)
Penicillin Nos	0 (0.0)	1 (0.8)	1 (0.4)
Beta-Lactamase Sensitive Penicillins	0 (0.0)	2 (1.6)	2 (0.7)
Benzylpenicillin Sodium	0 (0.0)	2 (1.6)	2 (0.7)
Bulk-Forming Laxatives	0 (0.0)	1 (0.8)	1 (0.4)
Plantago Spp.	0 (0.0)	1 (0.8)	1 (0.4)
Calcium	0 (0.0)	1 (0.8)	1 (0.4)
Calcium Carbonate	0 (0.0)	1 (0.8)	1 (0.4)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Carbamic Acid Esters	0 (0.0)	1 (0.8)	1 (0.4)
Methocarbamol	0 (0.0)	1 (0.8)	1 (0.4)
Carboxamide Derivatives	0 (0.0)	1 (0.8)	1 (0.4)
Carbamazepine	0 (0.0)	1 (0.8)	1 (0.4)
Combinations Of Vitamins	0 (0.0)	2 (1.6)	2 (0.7)
Ergocalciferol;phytomenadione;retinol;vitamin E Nos	0 (0.0)	2 (1.6)	2 (0.7)
Digitalis Glycosides	0 (0.0)	2 (1.6)	2 (0.7)
Deslanoside	0 (0.0)	2 (1.6)	2 (0.7)
Diphenylpropylamine Derivatives	0 (0.0)	1 (0.8)	1 (0.4)
Methadone Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Drugs Used In Erectile Dysfunction	0 (0.0)	1 (0.8)	1 (0.4)
Sildenafil Citrate	0 (0.0)	1 (0.8)	1 (0.4)
Drugs Used In Nicotine Dependence	0 (0.0)	2 (1.6)	2 (0.7)
Nicotine	0 (0.0)	1 (0.8)	1 (0.4)
Varenicline	0 (0.0)	1 (0.8)	1 (0.4)
Fenamates	0 (0.0)	1 (0.8)	1 (0.4)
Mefenamic Acid	0 (0.0)	1 (0.8)	1 (0.4)
Folic Acid And Derivatives	0 (0.0)	1 (0.8)	1 (0.4)
Folinic Acid	0 (0.0)	1 (0.8)	1 (0.4)
Heparins Or Heparinoids For Topical Use	0 (0.0)	1 (0.8)	1 (0.4)
Mucopolysaccharide Polysulfuric Acid Ester	0 (0.0)	1 (0.8)	1 (0.4)

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Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Homeopathic Preparation	0 (0.0)	1 (0.8)	1 (0.4)
Achillea Millefolium;aconitum Napellus;arnica Montana;atropa Belladonna;bellis Perennis;calcium Sulfide;calendula Officinalis;echinacea Angustifolia;echinacea Purpurea;hamamelis Virginiana;hypericum Perforatum;matricaria Recutita;mercurius Solubilis Hahnemanni;symphytum Officinale	0 (0.0)	1 (0.8)	1 (0.4)
Hypnotics And Sedatives	0 (0.0)	1 (0.8)	1 (0.4)
Promethazine Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
I.V. Solution Additives	0 (0.0)	1 (0.8)	1 (0.4)
Calcium Chloride Dihydrate;glucose;potassium Chloride;sodium Acetate;sodium Chloride	0 (0.0)	1 (0.8)	1 (0.4)
Iodine Products	0 (0.0)	1 (0.8)	1 (0.4)
Iodine	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Iodine Therapy	0 (0.0)	1 (0.8)	1 (0.4)
Potassium Iodide	0 (0.0)	1 (0.8)	1 (0.4)
Liver Therapy, Lipotropics	0 (0.0)	2 (1.6)	2 (0.7)
Diisopropylamine Dichloroacetate;gluconate Sodium	0 (0.0)	2 (1.6)	2 (0.7)
Local Hemostatics	0 (0.0)	1 (0.8)	1 (0.4)
Epinephrine Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Low-Ceiling Diuretics And Potassium-Sparing Agents	0 (0.0)	1 (0.8)	1 (0.4)
Amiloride Hydrochloride;hydrochlorothiazide	0 (0.0)	1 (0.8)	1 (0.4)
Melatonin Receptor Agonists	0 (0.0)	1 (0.8)	1 (0.4)
Ramelteon	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Multivitamins, Other Combinations	0 (0.0)	1 (0.8)	1 (0.4)
Biotin;cyanocobalamin;ergocalciferol;folic Acid;glycine;nicotinamide;pantothenate Sodium;phytomenadione;pyridoxine Hydrochloride;retinol;riboflavin Sodium Phosphate;sodium Ascorbate;thiamine Mononitrate;vitamin E Nos	0 (0.0)	1 (0.8)	1 (0.4)
Nitroferricyanide Derivatives	0 (0.0)	1 (0.8)	1 (0.4)
Nitroprusside Sodium	0 (0.0)	1 (0.8)	1 (0.4)
Non-Selective Monoamine Reuptake Inhibitors	0 (0.0)	3 (2.3)	3 (1.1)
Amitriptyline	0 (0.0)	1 (0.8)	1 (0.4)
Amitriptyline Hydrochloride	0 (0.0)	2 (1.6)	2 (0.7)
Oripavine Derivatives	0 (0.0)	1 (0.8)	1 (0.4)
Buprenorphine	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Antineoplastic Agents	0 (0.0)	1 (0.8)	1 (0.4)
Disodium Cantharidinate;pyridoxine Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Other Antipsychotics	0 (0.0)	1 (0.8)	1 (0.4)
Prothipendyl Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Other Antithrombotic Agents	0 (0.0)	1 (0.8)	1 (0.4)
Fondaparinux	0 (0.0)	1 (0.8)	1 (0.4)
Other Anxiolytics	0 (0.0)	2 (1.6)	2 (0.7)
Paroxetine Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Pregabalin	0 (0.0)	1 (0.8)	1 (0.4)
Other Cicatrizants	0 (0.0)	1 (0.8)	1 (0.4)
Trafermin	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Therapeutic Products	0 (0.0)	1 (0.8)	1 (0.4)
Inosine	0 (0.0)	1 (0.8)	1 (0.4)
Other Throat Preparations	0 (0.0)	1 (0.8)	1 (0.4)
Other Throat Preparations	0 (0.0)	1 (0.8)	1 (0.4)
Perchlorates	0 (0.0)	1 (0.8)	1 (0.4)
Sodium Perchlorate	0 (0.0)	1 (0.8)	1 (0.4)
Phenylalkylamine Derivatives	0 (0.0)	1 (0.8)	1 (0.4)
Verapamil Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Preparations With No Effect On Uric Acid Metabolism	0 (0.0)	1 (0.8)	1 (0.4)
Colchicine	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 22APR2024 22:37 t-14-01-07-01-b-cm-gen-safetys-fa.rtf

Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Prostaglandin Analogues	0 (0.0)	1 (0.8)	1 (0.4)
Latanoprost	0 (0.0)	1 (0.8)	1 (0.4)
Prostaglandins	0 (0.0)	1 (0.8)	1 (0.4)
Misoprostol	0 (0.0)	1 (0.8)	1 (0.4)
Protein Kinase Inhibitors	0 (0.0)	1 (0.8)	1 (0.4)
Anlotinib Dihydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Sulfur-Containing Imidazole Derivatives	0 (0.0)	3 (2.3)	3 (1.1)
Carbimazole	0 (0.0)	1 (0.8)	1 (0.4)
Thiamazole	0 (0.0)	2 (1.6)	2 (0.7)
Sympathomimetics In Glaucoma Therapy	0 (0.0)	1 (0.8)	1 (0.4)
Brimonidine Tartrate	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Sympathomimetics Used As Decongestants	0 (0.0)	1 (0.8)	1 (0.4)
Chlorphenamine Maleate;chondroitin Sulfate Sodium;neostigmine Metilsulfate;potassium Aspartate;pyridoxine Hydrochloride;retinol Palmitate;taurine;tetryzoline Hydrochloride;tocopheryl Acetate	0 (0.0)	1 (0.8)	1 (0.4)
Thiazolidinediones	0 (0.0)	1 (0.8)	1 (0.4)
Pioglitazone Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Topical Products For Joint And Muscular Pain	0 (0.0)	1 (0.8)	1 (0.4)
Achyranthes Bidentata Root;aconitum Carmichaelii Root;aconitum Kusnezoffii Root;angelica Pubescens Root;angelica Sinensis;aralia Chinensis Stem Bark;aucklandia Costus;borneol;boswellia Spp. Resin;caesalpinia Sappan Heartwood;carthamus Tinctorius Flower;cinnamomum Camphora;cinnamomum Cassia Essential Oil;clematis Spp. Root;commiphora Myrrha Resin;corydalis Yanhusuo Tuber;daemonorops Draco Fruit Resin;ephedra Spp.;eucalyptus Globulus Essential Oil;lindera Aggregata Root;menthol;methyl Salicylate;musk;ocimum Gratissimum Oil;periploca Sepium Root Bark;piper Kadsura Stem;rehmannia Glutinosa Root Tuber	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Vasopressin And Analogues	0 (0.0)	1 (0.8)	1 (0.4)
Vasopressin	0 (0.0)	1 (0.8)	1 (0.4)
Vitamins, Other Combinations	0 (0.0)	2 (1.6)	2 (0.7)
Herbal Nos;minerals Nos;vitamins Nos	0 (0.0)	1 (0.8)	1 (0.4)
Vitamins, Other Combinations	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.8.1:
Summary of Follow-up Time by Efficacy-related Endpoint
ITT Analysis Set

Endpoint (Months)	Tislelizumab (N = 256)	ICC (N = 256)	Total (N = 512)
Overall Survival [a]			
n	256	256	512
Mean (SD)	10.09 (7.42)	7.57 (6.17)	8.83 (6.93)
Median	8.49	5.68	6.88
Q1, Q3	3.93, 14.90	2.81, 10.86	3.43, 12.65
Min, Max	0.2, 31.7	0.0, 30.8	0.0, 31.7
Progression-Free Survival [b]			
n	256	256	512
Mean (SD)	4.13 (5.03)	2.34 (2.61)	3.24 (4.11)
Median	1.64	1.45	1.48
Q1, Q3	1.31, 4.22	0.92, 2.81	1.22, 3.58
Min, Max	0.0, 24.2	0.0, 18.1	0.0, 24.2

Source: ADSL, ADQS, ADEFPRE. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

[a] Time from randomization to death or censoring date.

[b] Time from randomization to the last progression-free survival event or censoring date.

[c] Time from randomization to the last tumor assessment by investigator per RECIST 1.1. For patients without post-baseline tumor assessment, their last tumor assessment is considered as on date of randomization. Post-baseline tumor assessment after the initiation of new anti-cancer therapy were not considered.

[d] Time from randomization to the last adequate PRO assessment. For patients without baseline or post-baseline PRO assessment, their last PRO assessment is considered as on date of randomization.

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Table 14.1.8.1:
Summary of Follow-up Time by Efficacy-related Endpoint
ITT Analysis Set

Endpoint (Months)	Tislelizumab (N = 256)	ICC (N = 256)	Total (N = 512)
Investigator Tumor Assessment [c]			
n	256	256	512
Mean (SD)	4.77 (5.36)	2.23 (2.77)	3.50 (4.45)
Median	2.73	1.41	1.64
Q1, Q3	1.38, 5.80	0.66, 2.79	1.18, 4.11
Min, Max	0.0, 28.3	0.0, 20.1	0.0, 28.3
EORTC-QLQ-C30 [d]			
n	256	256	512
Mean (SD)	3.54 (4.02)	2.13 (2.32)	2.83 (3.36)
Median	2.79	1.54	1.87
Q1, Q3	1.41, 3.68	0.72, 2.83	0.79, 3.52
Min, Max	0.0, 28.8	0.0, 12.2	0.0, 28.8

Source: ADSL, ADQS, ADEFPRE. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

[a] Time from randomization to death or censoring date.

[b] Time from randomization to the last progression-free survival event or censoring date.

[c] Time from randomization to the last tumor assessment by investigator per RECIST 1.1. For patients without post-baseline tumor assessment, their last tumor assessment is considered as on date of randomization. Post-baseline tumor assessment after the initiation of new anti-cancer therapy were not considered.

[d] Time from randomization to the last adequate PRO assessment. For patients without baseline or post-baseline PRO assessment, their last PRO assessment is considered as on date of randomization.

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Table 14.1.8.1:
Summary of Follow-up Time by Efficacy-related Endpoint
ITT Analysis Set

Endpoint (Months)	Tislelizumab (N = 256)	ICC (N = 256)	Total (N = 512)
EORTC-QLQ-OES18 [d]			
n	256	256	512
Mean (SD)	3.53 (4.03)	2.12 (2.33)	2.82 (3.36)
Median	2.79	1.54	1.87
Q1, Q3	1.41, 3.68	0.72, 2.83	0.76, 3.52
Min, Max	0.0, 28.8	0.0, 12.2	0.0, 28.8
EQ-5D-VAS [d]			
n	256	256	512
Mean (SD)	3.53 (4.03)	2.09 (2.32)	2.81 (3.36)
Median	2.79	1.54	1.87
Q1, Q3	1.41, 3.68	0.57, 2.83	0.76, 3.52
Min, Max	0.0, 28.8	0.0, 12.2	0.0, 28.8

Source: ADSL, ADQS, ADEFPRE. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

[a] Time from randomization to death or censoring date.

[b] Time from randomization to the last progression-free survival event or censoring date.

[c] Time from randomization to the last tumor assessment by investigator per RECIST 1.1. For patients without post-baseline tumor assessment, their last tumor assessment is considered as on date of randomization. Post-baseline tumor assessment after the initiation of new anti-cancer therapy were not considered.

[d] Time from randomization to the last adequate PRO assessment. For patients without baseline or post-baseline PRO assessment, their last PRO assessment is considered as on date of randomization.

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Table 14.1.8.1.b:
Summary of Follow-up Time by Efficacy-related Endpoint
ITT Analysis Set - Subpopulation without Irinotecan

Endpoint (Months)	Tislelizumab (N = 139)	ICC (N = 138)	Total (N = 277)
Overall Survival [a]			
n	139	138	277
Mean (SD)	9.97 (7.17)	8.15 (6.35)	9.06 (6.82)
Median	8.61	6.54	7.39
Q1, Q3	3.91, 14.19	3.29, 10.97	3.68, 12.65
Min, Max	0.4, 31.7	0.0, 30.8	0.0, 31.7
Progression-Free Survival [b]			
n	139	138	277
Mean (SD)	4.45 (5.24)	2.77 (2.84)	3.61 (4.30)
Median	1.87	1.53	1.64
Q1, Q3	1.35, 5.52	1.18, 3.61	1.31, 4.07
Min, Max	0.0, 24.2	0.0, 18.1	0.0, 24.2

Source: ADSL, ADQS, ADEFPRE. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

[a] Time from randomization to death or censoring date.

[b] Time from randomization to the last progression-free survival event or censoring date.

[c] Time from randomization to the last tumor assessment by investigator per RECIST 1.1. For patients without post-baseline tumor assessment, their last tumor assessment is considered as on date of randomization. Post-baseline tumor assessment after the initiation of new anti-cancer therapy were not considered.

[d] Time from randomization to the last adequate PRO assessment. For patients without baseline or post-baseline PRO assessment, their last PRO assessment is considered as on date of randomization.

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Table 14.1.8.1.b:
Summary of Follow-up Time by Efficacy-related Endpoint
ITT Analysis Set - Subpopulation without Irinotecan

Endpoint (Months)	Tislelizumab (N = 139)	ICC (N = 138)	Total (N = 277)
Investigator Tumor Assessment [c]			
n	139	138	277
Mean (SD)	4.94 (5.33)	2.68 (2.88)	3.81 (4.43)
Median	2.73	1.51	2.30
Q1, Q3	1.38, 7.10	1.12, 3.29	1.35, 4.21
Min, Max	0.0, 24.2	0.0, 18.1	0.0, 24.2
EORTC-QLQ-C30 [d]			
n	139	138	277
Mean (SD)	3.32 (3.64)	2.58 (2.56)	2.95 (3.17)
Median	2.20	1.87	1.91
Q1, Q3	1.41, 3.61	0.89, 3.48	1.08, 3.52
Min, Max	0.0, 21.7	0.0, 12.2	0.0, 21.7

Source: ADSL, ADQS, ADEFPRE. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

[a] Time from randomization to death or censoring date.

[b] Time from randomization to the last progression-free survival event or censoring date.

[c] Time from randomization to the last tumor assessment by investigator per RECIST 1.1. For patients without post-baseline tumor assessment, their last tumor assessment is considered as on date of randomization. Post-baseline tumor assessment after the initiation of new anti-cancer therapy were not considered.

[d] Time from randomization to the last adequate PRO assessment. For patients without baseline or post-baseline PRO assessment, their last PRO assessment is considered as on date of randomization.

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Table 14.1.8.1.b:
Summary of Follow-up Time by Efficacy-related Endpoint
ITT Analysis Set - Subpopulation without Irinotecan

Endpoint (Months)	Tislelizumab (N = 139)	ICC (N = 138)	Total (N = 277)
EORTC-QLQ-OES18 [d]			
n	139	138	277
Mean (SD)	3.31 (3.65)	2.58 (2.56)	2.95 (3.17)
Median	2.20	1.87	1.91
Q1, Q3	1.41, 3.61	0.85, 3.48	1.08, 3.52
Min, Max	0.0, 21.7	0.0, 12.2	0.0, 21.7
EQ-5D-VAS [d]			
n	139	138	277
Mean (SD)	3.32 (3.64)	2.57 (2.57)	2.95 (3.17)
Median	2.20	1.87	1.91
Q1, Q3	1.41, 3.61	0.82, 3.48	1.05, 3.52
Min, Max	0.0, 21.7	0.0, 12.2	0.0, 21.7

Source: ADSL, ADQS, ADEFPRE. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
[a] Time from randomization to death or censoring date.
[b] Time from randomization to the last progression-free survival event or censoring date.
[c] Time from randomization to the last tumor assessment by investigator per RECIST 1.1. For patients without post-baseline tumor assessment, their last tumor assessment is considered as on date of randomization. Post-baseline tumor assessment after the initiation of new anti-cancer therapy were not considered.
[d] Time from randomization to the last adequate PRO assessment. For patients without baseline or post-baseline PRO assessment, their last PRO assessment is considered as on date of randomization.
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Table 14.1.8.2:
Summary of Follow-up Time by Safety-related Endpoint
Safety Analysis Set

Endpoint (Months)	Tislelizumab (N = 255)	ICC (N = 240)	Total (N = 495)
Safety for TEAEs except imAE [a]			
n	255	240	495
Mean (SD)	5.20 (5.44)	2.88 (2.53)	4.07 (4.43)
Median	3.02	1.94	2.43
Q1, Q3	1.71, 6.57	1.38, 3.37	1.61, 4.50
Min, Max	0.2, 28.6	0.2, 19.2	0.2, 28.6
Safety for imAEs [b]			
n	255	240	495
Mean (SD)	6.65 (5.36)	4.42 (2.71)	5.57 (4.42)
Median	5.06	3.81	4.17
Q1, Q3	3.65, 7.95	2.99, 5.29	3.15, 6.44
Min, Max	0.2, 28.8	0.2, 19.2	0.2, 28.8

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; imAE = immune-mediated adverse event.

[a] The time from the first dose date to the earliest date among the date of death, study discontinuation date, cut-off date, last date of study treatment + 30 days, and the date of the initiation of new anticancer therapy.

[b] The time from the first dose date to the earliest date among the date of death, study discontinuation date, cut-off date, last date of study treatment + 90 days.

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Table 14.1.8.2.b:
Summary of Follow-up Time by Safety-related Endpoint
Safety Analysis Set - Subpopulation without Irinotecan

Endpoint (Months)	Tislelizumab (N = 139)	ICC (N = 129)	Total (N = 268)
Safety for TEAEs except imAE [a]			
n	139	129	268
Mean (SD)	5.35 (5.43)	3.37 (2.86)	4.40 (4.49)
Median	3.02	2.40	2.71
Q1, Q3	1.71, 7.75	1.71, 4.21	1.71, 4.94
Min, Max	0.3, 25.6	0.2, 19.2	0.2, 25.6
Safety for imAEs [b]			
n	139	129	268
Mean (SD)	6.80 (5.32)	4.89 (3.03)	5.88 (4.47)
Median	4.99	4.11	4.37
Q1, Q3	3.65, 9.26	3.19, 5.78	3.45, 6.83
Min, Max	0.3, 25.6	0.2, 19.2	0.2, 25.6

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; imAE = immune-mediated adverse event.
[a] The time from the first dose date to the earliest date among the date of death, study discontinuation date, cut-off date, last date of study treatment + 30 days, and the date of the initiation of new anticancer therapy.
[b] The time from the first dose date to the earliest date among the date of death, study discontinuation date, cut-off date, last date of study treatment + 90 days.
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Table 14.2.1.1:
Overall Survival (OS)
ITT Analysis Set

	Tislelizumab (N = 256)	ICC (N = 256)
Number of Patients		
Death, n (%)	197 (77.0)	213 (83.2)
Censored, n (%)	59 (23.0)	43 (16.8)
Ongoing Without Event	54 (21.1)	27 (10.5)
Lost to Follow-up	0 (0.0)	2 (0.8)
Withdrew Consent	5 (2.0)	14 (5.5)
Two-Sided Stratified Log-Rank Test P-value [a]	0.0003	--
Stratified Hazard Ratio (95% CI) [b]	0.695 (0.571, 0.846)	--
Unstratified Hazard Ratio (95% CI) [c]	0.695 (0.572, 0.844)	--
Overall Survival (months)		
Median (95% CI)	8.6 (7.5, 10.4)	6.3 (5.3, 7.0)
1st Quartile (95% CI)	4.0 (3.5, 4.6)	3.3 (2.6, 4.0)
3rd Quartile (95% CI)	18.0 (14.7, 21.0)	11.4 (10.6, 12.9)

Source: Listing 16.2.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE=Not Evaluable.

Percentages were based on N.

In absence of death on or before data cut-off, patients will be censored either at the date that the patient was last known to be alive or the date of data cut-off, whichever comes earlier.

Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley.

Overall Survival rates (cumulative probability of OS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula.

Median follow-up time was estimated by the reverse Kaplan-Meier method.

[a] Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option.

[b] Hazard ratio (Tislelizumab vs. ICC) was based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] Hazard ratio (Tislelizumab vs. ICC) was based on unstratified Cox regression model only including treatment arm as a factor.

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Table 14.2.1.1:
Overall Survival (OS)
ITT Analysis Set

	Tislelizumab (N = 256)	ICC (N = 256)
Overall Survival Rate at, % (95% CI)		
3 Months (95% CI)	84.0 (78.8, 87.9)	78.0 (72.3, 82.7)
6 Months (95% CI)	62.3 (56.0, 67.9)	51.8 (45.3, 57.9)
9 Months (95% CI)	48.7 (42.4, 54.7)	35.0 (29.0, 41.1)
12 Months (95% CI)	37.4 (31.4, 43.4)	23.7 (18.5, 29.3)
Follow-up Time (months)		
Median (95% CI)	20.8 (19.5, 22.4)	21.1 (19.3, 22.8)

Source: Listing 16.2.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE=Not Evaluable.

Percentages were based on N.

In absence of death on or before data cut-off, patients will be censored either at the date that the patient was last known to be alive or the date of data cut-off, whichever comes earlier.

Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley.

Overall Survival rates (cumulative probability of OS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula.

Median follow-up time was estimated by the reverse Kaplan-Meier method.

[a] Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option.

[b] Hazard ratio (Tislelizumab vs. ICC) was based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] Hazard ratio (Tislelizumab vs. ICC) was based on unstratified Cox regression model only including treatment arm as a factor.

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Table 14.2.1.1.b:
Overall Survival (OS)
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)	ICC (N = 138)
Number of Patients		
Death, n (%)	105 (75.5)	112 (81.2)
Censored, n (%)	34 (24.5)	26 (18.8)
Ongoing Without Event	30 (21.6)	17 (12.3)
Lost to Follow-up	0 (0.0)	2 (1.4)
Withdrew Consent	4 (2.9)	7 (5.1)
Two-Sided Stratified Log-Rank Test P-value [a]	0.0455	--
Stratified Hazard Ratio (95% CI) [b]	0.761 (0.582, 0.996)	--
Unstratified Hazard Ratio (95% CI) [c]	0.757 (0.579, 0.989)	--
Overall Survival (months)		
Median (95% CI)	9.7 (7.0, 11.4)	7.0 (5.8, 8.6)
1st Quartile (95% CI)	4.0 (3.5, 5.2)	3.7 (2.7, 4.6)
3rd Quartile (95% CI)	17.0 (13.2, 28.9)	12.6 (10.6, 15.8)

Source: Listing 16.2.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

Percentages were based on N.

In absence of death on or before data cut-off, patients will be censored either at the date that the patient was last known to be alive or the date of data cut-off, whichever comes earlier.

Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley.

Overall Survival rates (cumulative probability of OS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula.

Median follow-up time was estimated by the reverse Kaplan-Meier method.

[a] Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.

[b] Hazard ratio (Tislelizumab vs. ICC) was based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] Hazard ratio (Tislelizumab vs. ICC) was based on unstratified Cox regression model only including treatment arm as a factor.

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Table 14.2.1.1.b:
Overall Survival (OS)
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)	ICC (N = 138)
Overall Survival Rate at, % (95% CI)		
3 Months (95% CI)	85.5 (78.5, 90.4)	82.0 (74.4, 87.6)
6 Months (95% CI)	63.6 (55.0, 71.0)	57.3 (48.4, 65.3)
9 Months (95% CI)	50.3 (41.6, 58.3)	38.6 (30.2, 46.9)
12 Months (95% CI)	38.3 (30.0, 46.5)	27.2 (19.7, 35.1)
Follow-up Time (months)		
Median (95% CI)	20.0 (18.4, 21.8)	20.3 (19.3, 22.8)

Source: Listing 16.2.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

Percentages were based on N.

In absence of death on or before data cut-off, patients will be censored either at the date that the patient was last known to be alive or the date of data cut-off, whichever comes earlier.

Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley.

Overall Survival rates (cumulative probability of OS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula.

Median follow-up time was estimated by the reverse Kaplan-Meier method.

[a] Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.

[b] Hazard ratio (Tislelizumab vs. ICC) was based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] Hazard ratio (Tislelizumab vs. ICC) was based on unstratified Cox regression model only including treatment arm as a factor.

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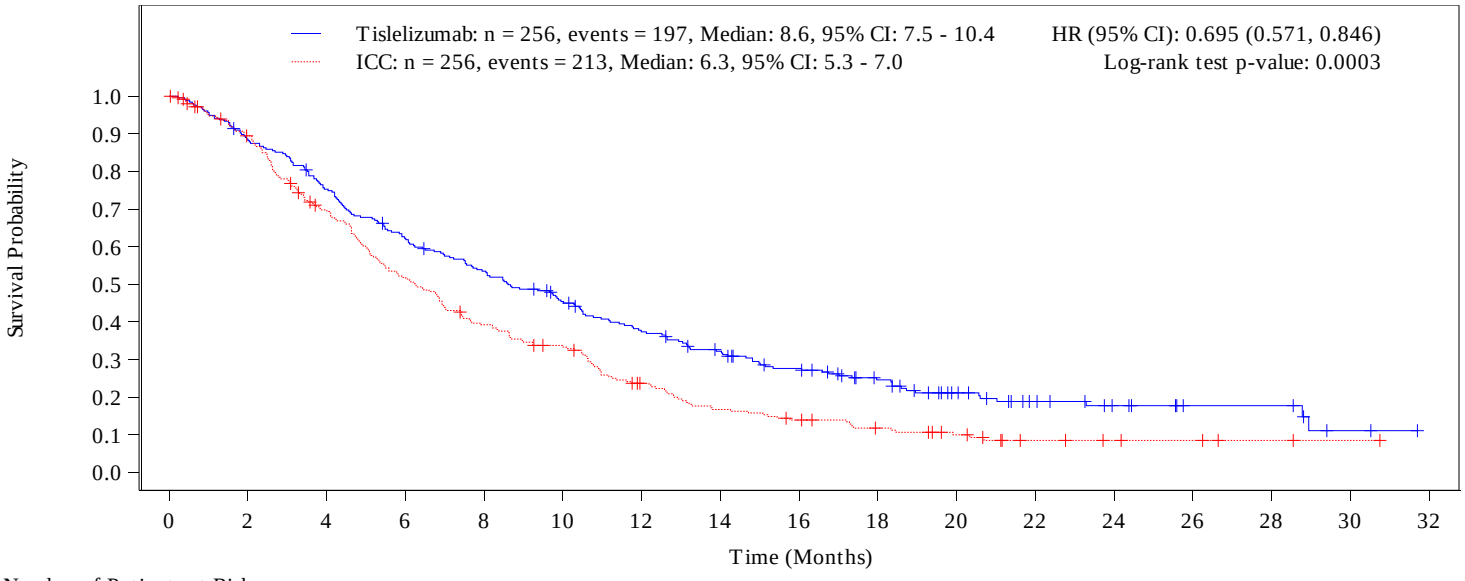
Figure 14.2.1.1:
Kaplan-Meier Plot of Overall Survival (OS)
ITT Analysis Set



Number of Patients at Risk:

Time:	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32
Tislelizumab	256	245	226	214	191	172	157	144	134	122	110	96	88	81	73	63	59	52	44	35	30	25	20	18	13	11	8	8	8	3	2	1	0
ICC	256	235	219	191	167	143	124	105	93	83	77	59	51	42	36	34	29	26	21	19	15	11	7	6	5	4	4	2	2	1	1	0	0

Source: Listing 16.2.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option.
Hazard ratio was based on Cox regression model including treatment as covariate stratified by ECOG status and ICC option.
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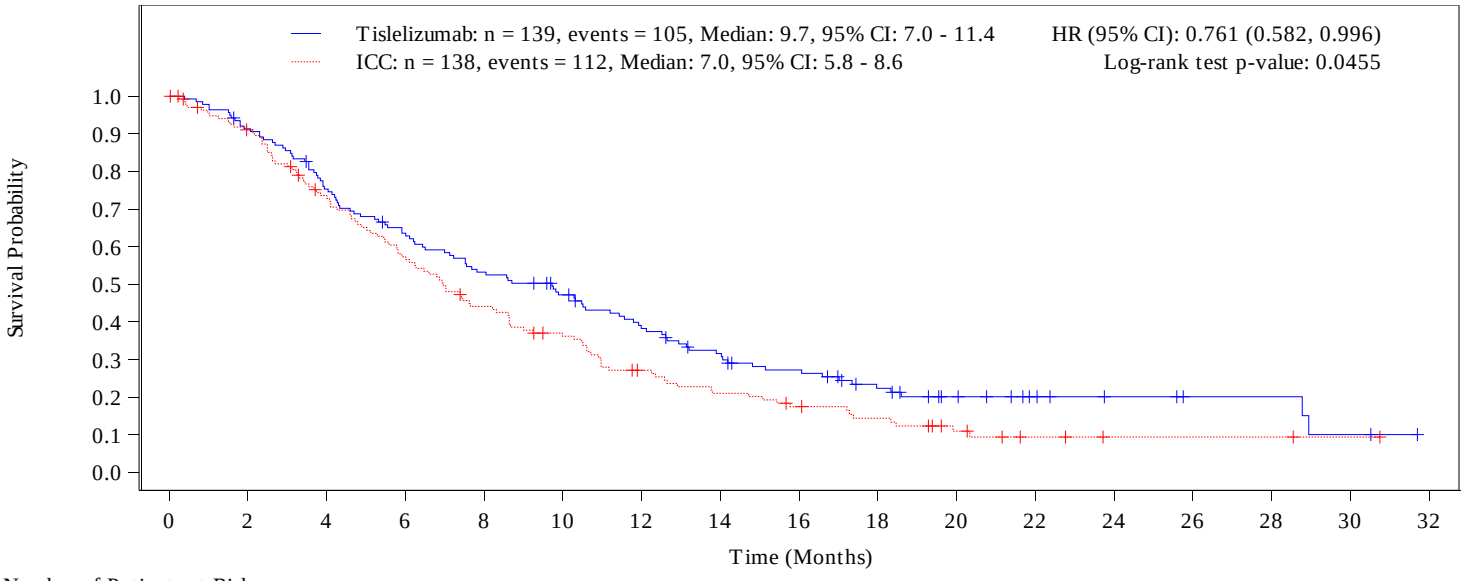
Figure 14.2.1.1.b:
Kaplan-Meier Plot of Overall Survival (OS)
ITT Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32
Tislelizumab	139	136	126	118	103	93	86	79	72	68	61	53	47	41	37	31	30	26	21	17	14	12	9	7	6	6	4	4	4	2	2	1	0
ICC	138	128	121	109	95	84	74	64	56	49	44	34	31	26	24	23	19	17	14	12	8	6	4	3	2	2	2	2	2	1	1	0	0

Source: Listing 16.2.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
Hazard ratio was based on Cox regression model including treatment as covariate stratified by ECOG status and ICC option.
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Table 14.2.1.1.s:
Overall Survival (OS) - Subgroup Analysis
ITT Analysis Set

Subgroup	Tislelizumab (N = 256) Total No. of Patients	Tislelizumab (N = 256) Patients with events n (%)	Tislelizumab (N = 256) Median time to event (95% CI) [a]	ICC (N = 256) Total No. of Patients	ICC (N = 256) Patients with events n (%)	ICC (N = 256) Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	128 (81.5)	8.1 (6.0, 10.0)	161	133 (82.6)	5.4 (4.7, 6.4)	0.730 (0.572, 0.933)	0.0113
>= 65 Years	99	69 (69.7)	9.9 (7.7, 13.1)	95	80 (84.2)	7.0 (6.2, 10.0)	0.643 (0.465, 0.888)	0.0069
Interaction								0.7036
Gender								
Male	217	171 (78.8)	8.5 (6.9, 10.3)	215	178 (82.8)	6.3 (5.4, 7.0)	0.742 (0.601, 0.916)	0.0053
Female	39	26 (66.7)	11.2 (5.5, 18.4)	41	35 (85.4)	5.5 (3.7, 9.0)	0.468 (0.275, 0.798)	0.0043
Interaction								0.1114
Smoking Status								
Former/Current Smoker	188	139 (73.9)	7.8 (6.4, 10.0)	192	161 (83.9)	6.1 (5.1, 6.9)	0.672 (0.535, 0.844)	0.0006
Non-Smoker	68	58 (85.3)	10.5 (8.1, 12.6)	63	52 (82.5)	7.0 (4.9, 10.5)	0.749 (0.511, 1.096)	0.1344
Interaction								0.4551

Source: ADSL, ADTTE. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.1.1.s:
Overall Survival (OS) - Subgroup Analysis
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	59 (71.1)	8.7 (6.0, 11.8)	85	68 (80.0)	7.6 (5.9, 10.3)	0.731 (0.514, 1.038)	0.0779
Docetaxel	56	46 (82.1)	9.8 (6.2, 12.1)	53	44 (83.0)	6.2 (4.7, 8.6)	0.792 (0.523, 1.199)	0.2677
Irinotecan	117	92 (78.6)	8.5 (6.1, 10.4)	118	101 (85.6)	5.2 (4.6, 6.8)	0.632 (0.475, 0.841)	0.0015
Interaction								0.5507
ECOG Performance Score								
0	64	45 (70.3)	12.0 (8.0, 14.8)	63	45 (71.4)	8.2 (5.9, 10.8)	0.731 (0.483, 1.108)	0.1379
1	192	152 (79.2)	8.1 (6.2, 9.9)	193	168 (87.0)	5.5 (4.8, 6.8)	0.686 (0.550, 0.856)	0.0008
Interaction								0.6600

Source: ADSL, ADTTE. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.1.1.s:
Overall Survival (OS) - Subgroup Analysis
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #1								
Asia	201	162 (80.6)	8.5 (7.1, 10.3)	203	171 (84.2)	6.3 (5.3, 7.4)	0.727 (0.586, 0.903)	0.0037
Europe/North America	55	35 (63.6)	11.2 (5.9, 14.8)	53	42 (79.2)	6.3 (4.6, 7.7)	0.547 (0.346, 0.865)	0.0088
Interaction								0.3299
Region #2								
Asia (excluding Japan)	176	143 (81.3)	8.1 (6.2, 10.3)	178	151 (84.8)	6.0 (5.1, 7.4)	0.751 (0.597, 0.946)	0.0144
Japan	25	19 (76.0)	9.8 (7.5, 17.3)	25	20 (80.0)	7.6 (4.1, 10.5)	0.594 (0.315, 1.121)	0.1044
Europe/North America	55	35 (63.6)	11.2 (5.9, 14.8)	53	42 (79.2)	6.3 (4.6, 7.7)	0.547 (0.346, 0.865)	0.0088
Interaction								0.5064

Source: ADSL, ADTTE. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.1.1.s:
Overall Survival (OS) - Subgroup Analysis
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	164 (80.8)	8.5 (7.0, 10.0)	212	179 (84.4)	6.1 (5.2, 7.0)	0.725 (0.586, 0.897)	0.0029
White	53	33 (62.3)	11.2 (6.4, 14.8)	44	34 (77.3)	6.5 (4.7, 9.2)	0.529 (0.323, 0.866)	0.0101
Interaction								0.3869
Baseline PD-L1 Status								
vCPS >= 10%	80	54 (67.5)	10.0 (8.5, 15.1)	62	53 (85.5)	5.1 (3.8, 8.2)	0.518 (0.353, 0.760)	0.0006
vCPS < 10%	100	83 (83.0)	7.5 (5.5, 8.9)	122	106 (86.9)	5.8 (4.8, 6.9)	0.856 (0.641, 1.142)	0.2881
Missing	76	60 (78.9)	8.5 (6.2, 12.1)	72	54 (75.0)	7.0 (5.8, 8.6)	0.715 (0.492, 1.040)	0.0775
Interaction								0.1077

Source: ADSL, ADTTE. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.1.1.b.s:
Overall Survival (OS) - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	61 (79.2)	7.5 (5.6, 10.6)	77	61 (79.2)	6.9 (5.0, 8.7)	0.837 (0.586, 1.196)	0.3271
>= 65 Years	62	44 (71.0)	10.3 (7.0, 13.2)	61	51 (83.6)	7.0 (5.8, 10.0)	0.653 (0.435, 0.980)	0.0378
Interaction								0.4185
Gender								
Male	118	92 (78.0)	8.6 (6.2, 11.2)	111	91 (82.0)	7.0 (5.8, 8.6)	0.824 (0.617, 1.102)	0.1905
Female	21	13 (61.9)	11.9 (5.5, NE)	27	21 (77.8)	6.9 (3.2, 10.6)	0.506 (0.249, 1.029)	0.0547
Interaction								0.1513
Smoking Status								
Former/Current Smoker	104	77 (74.0)	7.6 (6.1, 10.6)	105	88 (83.8)	6.8 (5.8, 8.6)	0.737 (0.542, 1.002)	0.0500
Non-Smoker	35	28 (80.0)	11.8 (8.6, 12.9)	33	24 (72.7)	7.7 (4.6, 10.9)	0.805 (0.461, 1.405)	0.4431
Interaction								0.6418

Source: ADSL, ADTTE. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.1.1.b.s:
Overall Survival (OS) - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	59 (71.1)	8.7 (6.0, 11.8)	85	68 (80.0)	7.6 (5.9, 10.3)	0.731 (0.514, 1.038)	0.0779
Docetaxel	56	46 (82.1)	9.8 (6.2, 12.1)	53	44 (83.0)	6.2 (4.7, 8.6)	0.792 (0.523, 1.199)	0.2677
Interaction								0.7661
ECOG Performance Score								
0	43	29 (67.4)	12.1 (8.0, 15.1)	42	30 (71.4)	9.2 (5.9, 10.9)	0.658 (0.394, 1.099)	0.1064
1	96	76 (79.2)	7.2 (5.2, 10.3)	96	82 (85.4)	6.3 (5.0, 7.4)	0.804 (0.588, 1.099)	0.1694
Interaction								0.6720
Region #1								
Asia	103	82 (79.6)	8.7 (6.2, 11.4)	105	86 (81.9)	6.9 (5.6, 8.6)	0.796 (0.587, 1.078)	0.1379
Europe/North America	36	23 (63.9)	9.7 (4.0, 13.1)	33	26 (78.8)	7.0 (5.1, 10.0)	0.602 (0.340, 1.068)	0.0793
Interaction								0.5022

Source: ADSL, ADTTE. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.1.1.b.s:
Overall Survival (OS) - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	63 (80.8)	7.7 (5.9, 11.4)	80	66 (82.5)	6.9 (5.0, 8.6)	0.876 (0.620, 1.239)	0.4539
Japan	25	19 (76.0)	9.8 (7.5, 17.3)	25	20 (80.0)	7.6 (4.1, 10.5)	0.594 (0.315, 1.121)	0.1044
Europe/North America	36	23 (63.9)	9.7 (4.0, 13.1)	33	26 (78.8)	7.0 (5.1, 10.0)	0.602 (0.340, 1.068)	0.0793
Interaction								0.4656
Race								
Asian and other	105	84 (80.0)	8.6 (6.2, 10.6)	114	94 (82.5)	6.9 (5.5, 8.6)	0.784 (0.584, 1.054)	0.1053
White	34	21 (61.8)	11.2 (5.9, 14.8)	24	18 (75.0)	7.7 (6.2, 10.9)	0.582 (0.302, 1.124)	0.1029
Interaction								0.6876

Source: ADSL, ADTTE. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.1.1.b.s:
Overall Survival (OS) - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	30 (66.7)	9.9 (4.6, 15.1)	34	27 (79.4)	6.8 (3.5, 11.0)	0.702 (0.417, 1.182)	0.1802
vCPS < 10%	53	41 (77.4)	8.0 (5.9, 11.9)	56	49 (87.5)	6.2 (5.1, 8.6)	0.782 (0.514, 1.189)	0.2478
Missing	41	34 (82.9)	9.8 (6.1, 12.1)	48	36 (75.0)	7.6 (6.0, 10.5)	0.787 (0.488, 1.268)	0.3225
Interaction								0.8989

Source: ADSL, ADTTE. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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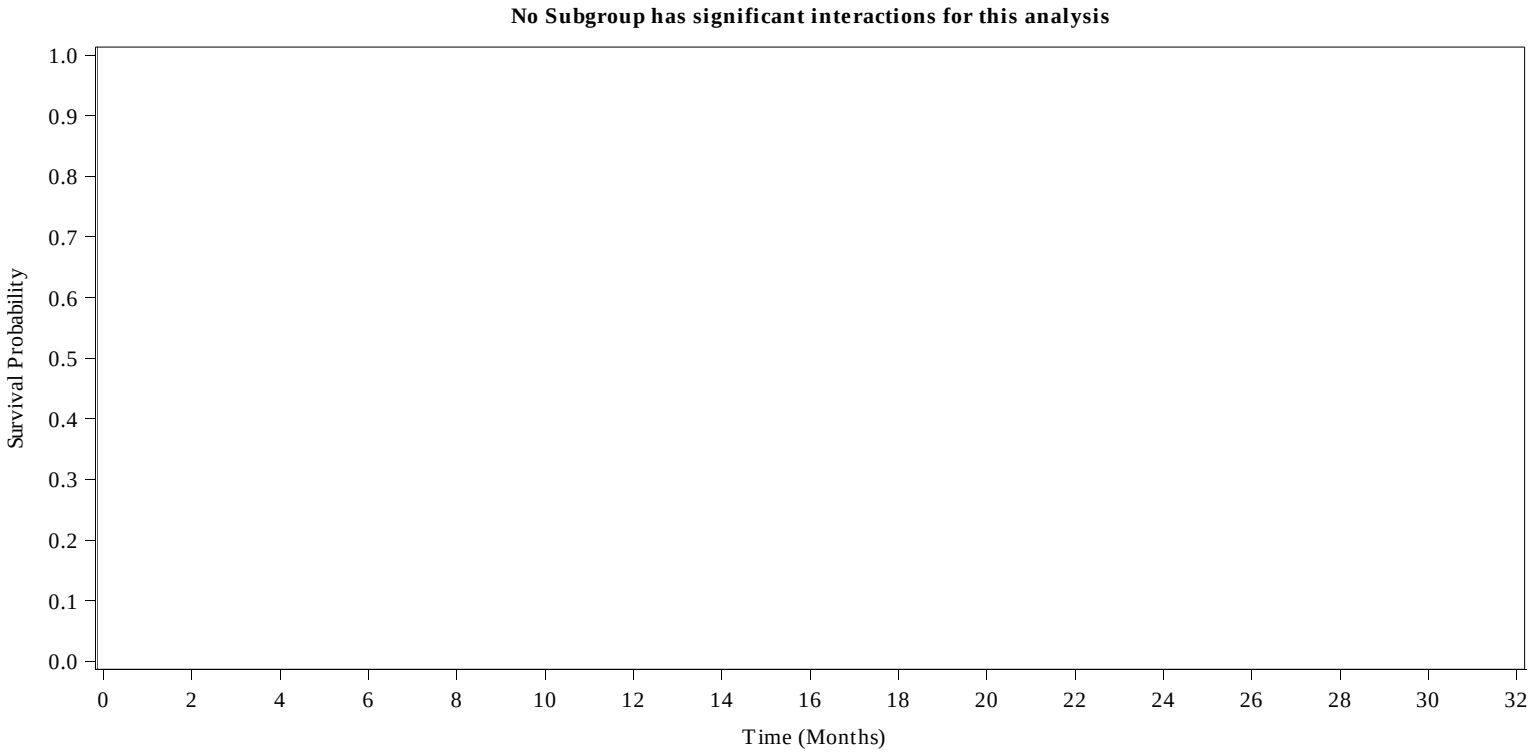
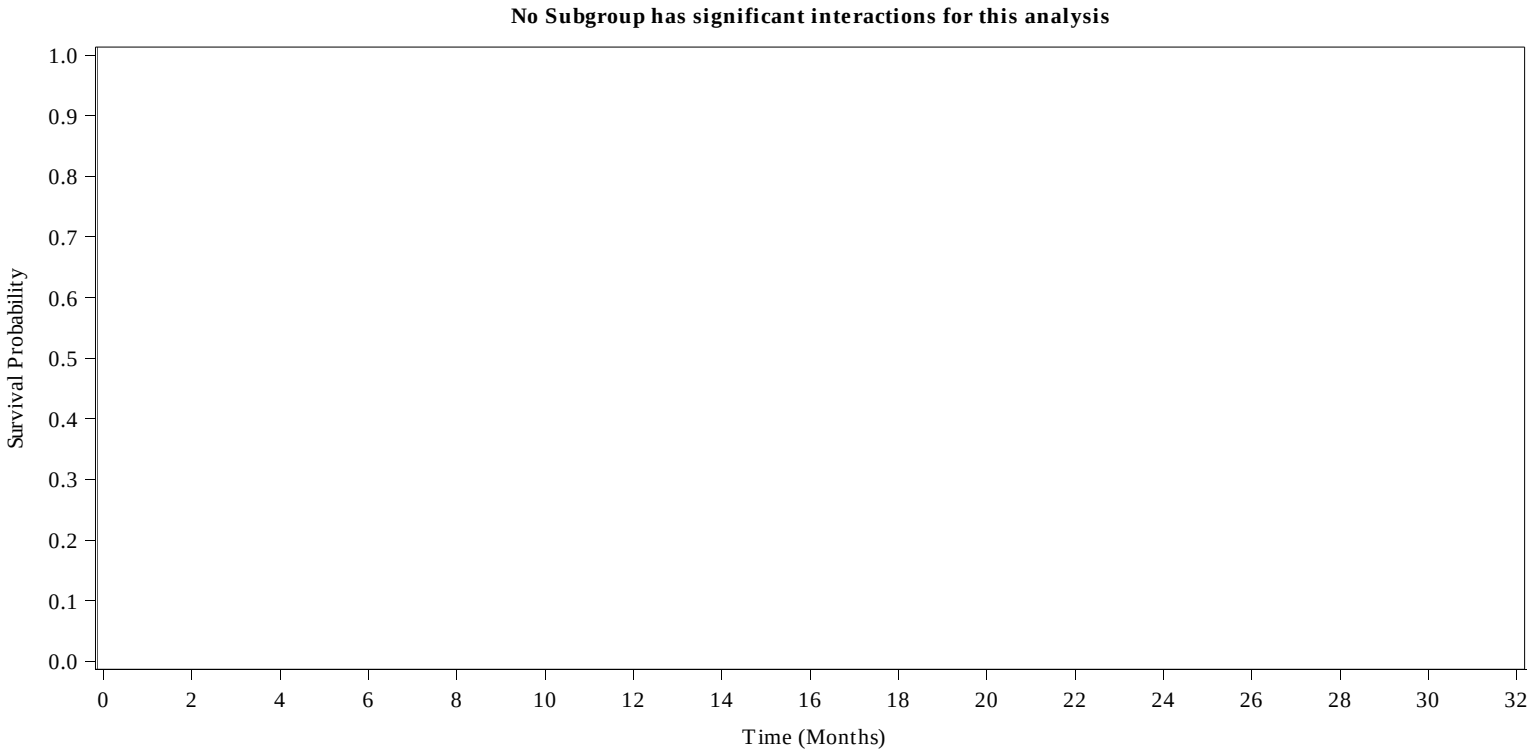
Figure 14.2.1.1.s:
Kaplan-Meier Plot of Overall Survival (OS) - Subgroup Analysis
ITT Analysis Set



Source: ADSL, ADTTE. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-subgrp.sas 16MAY2024 01:09 f-14-02-01-01-s-km-subgrp-os-itt-fa.rtf

Figure 14.2.1.1.b.s:
Kaplan-Meier Plot of Overall Survival (OS) - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTE. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
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Table 14.2.3.1:
Progression Free Survival (PFS)
ITT Analysis Set

	Tislelizumab (N = 256)	ICC (N = 256)
Progression-Free Survival		
Events, n (%)	223 (87.1)	180 (70.3)
Progressive Disease	191 (74.6)	145 (56.6)
Death	32 (12.5)	35 (13.7)
Censored, n (%)	33 (12.9)	76 (29.7)
No Post-Baseline	3 (1.2)	38 (14.8)
New Anti-Cancer Therapy	12 (4.7)	30 (11.7)
Missed >= 2 Assessments	4 (1.6)	4 (1.6)
No PD/Death [a]	14 (5.5)	4 (1.6)
Withdrew Consent	1 (0.4)	1 (0.4)
Ongoing Without Event	13 (5.1)	3 (1.2)

Source: Listing 16.2.6.3. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; PD: Progressive Disease.
Percentages were based on N.
Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley.
Progression free survival rates (cumulative probability of PFS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula.
[a] Patients at study end without PD events are counted in 'No PD/Death Study Terminated by Sponsor' category.
[b] Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
[c] Hazard ratio (Tislelizumab vs. ICC) was based on Cox regression model including treatment arm as a factor and stratified by ICC and ECOG performance status.
[d] Hazard ratio (Tislelizumab vs. ICC) was based on unstratified Cox regression model only including treatment arm as a factor.
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Table 14.2.3.1:
Progression Free Survival (PFS)
ITT Analysis Set

	Tislelizumab (N = 256)	ICC (N = 256)
Two-Sided Stratified Log-Rank Test P-value [b]	0.0585	--
Stratified Hazard Ratio (95% CI) [c]	0.825 (0.675, 1.009)	--
Unstratified Hazard Ratio (95% CI) [d]	0.829 (0.679, 1.013)	--
Progression Free Survival (months)		
Median (95% CI)	1.6 (1.4, 2.7)	2.1 (1.5, 2.7)
1st Quartile (95% CI)	1.3 (1.2, 1.4)	1.2 (1.2, 1.4)
3rd Quartile (95% CI)	5.5 (4.1, 7.4)	4.1 (3.0, 5.5)

Source: Listing 16.2.6.3. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; PD: Progressive Disease.
Percentages were based on N.
Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley.
Progression free survival rates (cumulative probability of PFS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula.
[a] Patients at study end without PD events are counted in 'No PD/Death Study Terminated by Sponsor' category.
[b] Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
[c] Hazard ratio (Tislelizumab vs. ICC) was based on Cox regression model including treatment arm as a factor and stratified by ICC and ECOG performance status.
[d] Hazard ratio (Tislelizumab vs. ICC) was based on unstratified Cox regression model only including treatment arm as a factor.
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Table 14.2.3.1:
Progression Free Survival (PFS)
ITT Analysis Set

	Tislelizumab (N = 256)	ICC (N = 256)
Progression Free Survival Rate at, % (95% CI)		
3 Months (95% CI)	36.3 (30.3, 42.2)	33.1 (26.6, 39.7)
6 Months (95% CI)	21.7 (16.7, 27.2)	14.9 (9.9, 20.9)
9 Months (95% CI)	15.8 (11.4, 20.8)	9.6 (5.5, 15.0)
12 Months (95% CI)	12.7 (8.8, 17.5)	1.9 (0.4, 5.8)

Source: Listing 16.2.6.3. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; PD: Progressive Disease.
Percentages were based on N.
Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley.
Progression free survival rates (cumulative probability of PFS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula.
[a] Patients at study end without PD events are counted in 'No PD/Death Study Terminated by Sponsor' category.
[b] Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
[c] Hazard ratio (Tislelizumab vs. ICC) was based on Cox regression model including treatment arm as a factor and stratified by ICC and ECOG performance status.
[d] Hazard ratio (Tislelizumab vs. ICC) was based on unstratified Cox regression model only including treatment arm as a factor.
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Table 14.2.3.1.b:
Progression Free Survival (PFS)
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)	ICC (N = 138)
Progression-Free Survival		
Events, n (%)	121 (87.1)	104 (75.4)
Progressive Disease	105 (75.5)	87 (63.0)
Death	16 (11.5)	17 (12.3)
Censored, n (%)	18 (12.9)	34 (24.6)
No Post-Baseline	1 (0.7)	12 (8.7)
New Anti-Cancer Therapy	4 (2.9)	16 (11.6)
Missed >= 2 Assessments	4 (2.9)	3 (2.2)
No PD/Death [a]	9 (6.5)	3 (2.2)
Withdrew Consent	1 (0.7)	0 (0.0)
Ongoing Without Event	8 (5.8)	3 (2.2)

Source: Listing 16.2.6.3. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; PD: Progressive Disease.
Percentages were based on N.
Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley.
Progression free survival rates (cumulative probability of PFS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula.
[a] Patients at study end without PD events are counted in 'No PD/Death Study Terminated by Sponsor' category.
[b] Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
[c] Hazard ratio (Tislelizumab vs. ICC) was based on Cox regression model including treatment arm as a factor and stratified by ICC and ECOG performance status.
[d] Hazard ratio (Tislelizumab vs. ICC) was based on unstratified Cox regression model only including treatment arm as a factor.
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Table 14.2.3.1.b:
Progression Free Survival (PFS)
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)	ICC (N = 138)
Two-Sided Stratified Log-Rank Test P-value [b]	0.2179	--
Stratified Hazard Ratio (95% CI) [c]	0.846 (0.647, 1.107)	--
Unstratified Hazard Ratio (95% CI) [d]	0.843 (0.645, 1.101)	--
Progression Free Survival (months)		
Median (95% CI)	2.0 (1.5, 2.8)	2.6 (1.5, 2.9)
1st Quartile (95% CI)	1.4 (1.3, 1.4)	1.4 (1.2, 1.4)
3rd Quartile (95% CI)	5.7 (4.1, 7.9)	4.3 (3.6, 6.2)

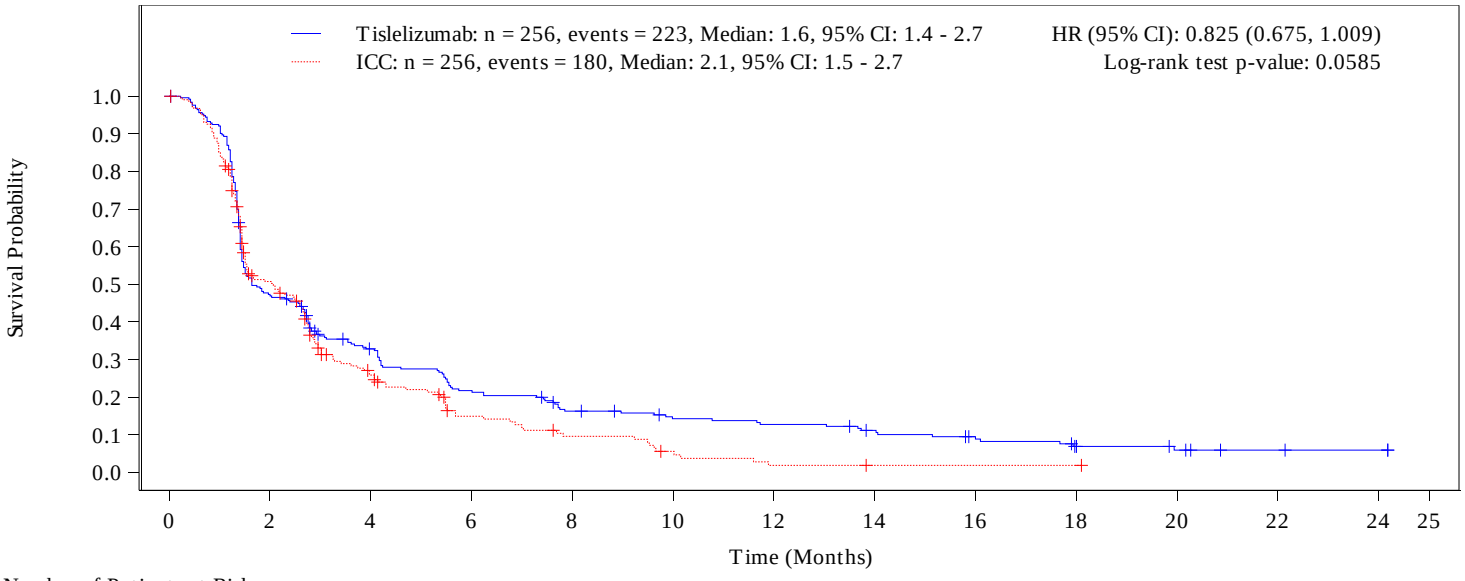
Source: Listing 16.2.6.3. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; PD: Progressive Disease.
Percentages were based on N.
Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley.
Progression free survival rates (cumulative probability of PFS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula.
[a] Patients at study end without PD events are counted in 'No PD/Death Study Terminated by Sponsor' category.
[b] Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
[c] Hazard ratio (Tislelizumab vs. ICC) was based on Cox regression model including treatment arm as a factor and stratified by ICC and ECOG performance status.
[d] Hazard ratio (Tislelizumab vs. ICC) was based on unstratified Cox regression model only including treatment arm as a factor.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-pfs.sas 09MAY2024 22:15 t-14-02-03-01-b-pfs-itts-fa.rtf

Table 14.2.3.1.b:
Progression Free Survival (PFS)
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)	ICC (N = 138)
Progression Free Survival Rate at, % (95% CI)		
3 Months (95% CI)	38.7 (30.5, 46.8)	37.4 (28.6, 46.2)
6 Months (95% CI)	24.3 (17.3, 31.9)	18.1 (11.3, 26.1)
9 Months (95% CI)	17.0 (11.0, 24.0)	10.6 (5.3, 18.0)
12 Months (95% CI)	13.4 (8.1, 20.1)	1.6 (0.1, 7.3)

Source: Listing 16.2.6.3. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; PD: Progressive Disease.
Percentages were based on N.
Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley.
Progression free survival rates (cumulative probability of PFS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula.
[a] Patients at study end without PD events are counted in 'No PD/Death Study Terminated by Sponsor' category.
[b] Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
[c] Hazard ratio (Tislelizumab vs. ICC) was based on Cox regression model including treatment arm as a factor and stratified by ICC and ECOG performance status.
[d] Hazard ratio (Tislelizumab vs. ICC) was based on unstratified Cox regression model only including treatment arm as a factor.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-pfs.sas 09MAY2024 22:15 t-14-02-03-01-b-pfs-itts-fa.rtf

Figure 14.2.4.1:
Kaplan-Meier Plot of Progression Free Survival (PFS)
ITT Analysis Set

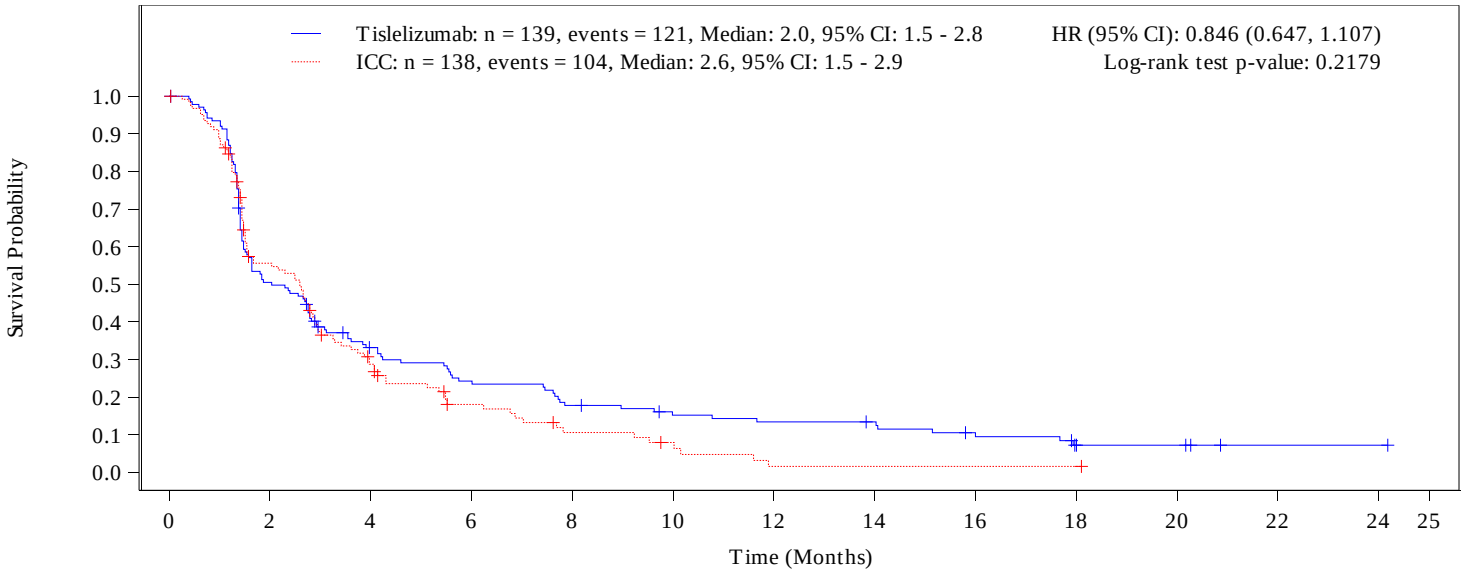


Number of Patients at Risk:

Time:	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
Tislelizumab	256	233	119	85	74	62	49	46	35	32	28	27	25	25	20	18	15	13	9	8	6	3	3	2	2	0
ICC	256	184	98	57	42	33	20	16	12	12	6	4	2	2	1	1	1	1	1	0	0	0	0	0	0	0

Source: Listing 16.2.6.3. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
Hazard ratio was based on Cox regression model including treatment as covariate stratified by ECOG status and ICC option.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km.sas 03JUN2024 19:18 f-14-02-04-01-km-pfs-itt-fa.rtf

Figure 14.2.4.1.b:
Kaplan-Meier Plot of Progression Free Survival (PFS)
ITT Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
Tislelizumab	139	129	69	50	41	36	30	29	22	20	17	16	15	15	14	12	10	9	5	4	4	1	1	1	1	0
ICC	138	110	62	40	29	22	15	12	8	8	5	3	1	1	1	1	1	1	1	0	0	0	0	0	0	0

Source: Listing 16.2.6.3. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
Hazard ratio was based on Cox regression model including treatment as covariate stratified by ECOG status and ICC option.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km.sas 03JUN2024 19:18 f-14-02-04-01-b-km-pfs-itts-fa.rtf

Table 14.2.3.1.s:
Progression Free Survival (PFS) - Subgroup Analysis
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	139 (88.5)	1.5 (1.4, 2.0)	161	118 (73.3)	1.5 (1.4, 2.1)	0.822 (0.641, 1.054)	0.1168
>= 65 Years	99	84 (84.8)	2.6 (1.5, 4.1)	95	62 (65.3)	3.0 (2.2, 4.0)	0.822 (0.585, 1.157)	0.2564
Interaction								0.7070
Gender								
Male	217	189 (87.1)	1.6 (1.4, 2.6)	215	151 (70.2)	2.0 (1.5, 2.7)	0.814 (0.654, 1.014)	0.0632
Female	39	34 (87.2)	2.3 (1.3, 2.9)	41	29 (70.7)	2.5 (1.4, 2.7)	0.859 (0.521, 1.418)	0.5493
Interaction								0.8469
Smoking Status								
Former/Current Smoker	188	165 (87.8)	1.8 (1.4, 2.7)	192	140 (72.9)	2.1 (1.5, 2.7)	0.815 (0.647, 1.026)	0.0783
Non-Smoker	68	58 (85.3)	1.5 (1.4, 2.9)	63	40 (63.5)	1.6 (1.4, 2.7)	0.885 (0.588, 1.331)	0.5523
Interaction								0.9288

Source: ADSL, ADTTE. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.3.1.s:
Progression Free Survival (PFS) - Subgroup Analysis
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	72 (86.7)	2.5 (1.6, 3.5)	85	64 (75.3)	2.6 (1.5, 3.3)	0.803 (0.568, 1.136)	0.2107
Docetaxel	56	49 (87.5)	1.5 (1.4, 2.8)	53	40 (75.5)	1.7 (1.4, 2.9)	0.902 (0.591, 1.376)	0.6266
Irinotecan	117	102 (87.2)	1.4 (1.4, 2.6)	118	76 (64.4)	1.5 (1.4, 2.2)	0.805 (0.594, 1.089)	0.1528
Interaction								0.8713
ECOG Performance Score								
0	64	55 (85.9)	2.9 (1.7, 4.2)	63	43 (68.3)	2.8 (1.7, 3.3)	0.787 (0.522, 1.186)	0.2483
1	192	168 (87.5)	1.5 (1.4, 2.0)	193	137 (71.0)	1.5 (1.4, 2.5)	0.843 (0.670, 1.061)	0.1393
Interaction								0.9846

Source: ADSL, ADTTE. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.3.1.s:
Progression Free Survival (PFS) - Subgroup Analysis
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #1								
Asia	201	173 (86.1)	1.5 (1.4, 2.6)	203	140 (69.0)	1.7 (1.5, 2.6)	0.810 (0.645, 1.017)	0.0658
Europe/North America	55	50 (90.9)	2.3 (1.5, 2.8)	53	40 (75.5)	2.7 (1.4, 3.9)	0.966 (0.636, 1.470)	0.8724
Interaction								0.3982
Region #2								
Asia (excluding Japan)	176	152 (86.4)	1.5 (1.4, 1.8)	178	119 (66.9)	1.9 (1.5, 2.6)	0.869 (0.680, 1.110)	0.2530
Japan	25	21 (84.0)	3.6 (2.0, 7.4)	25	21 (84.0)	1.7 (1.4, 2.8)	0.504 (0.266, 0.954)	0.0317
Europe/North America	55	50 (90.9)	2.3 (1.5, 2.8)	53	40 (75.5)	2.7 (1.4, 3.9)	0.966 (0.636, 1.470)	0.8724
Interaction								0.2645

Source: ADSL, ADTTE. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.3.1.s:
Progression Free Survival (PFS) - Subgroup Analysis
ITT Analysis Set

Subgroup	Tislelizumab (N = 256) Total No. of Patients	Tislelizumab (N = 256) Patients with events n (%)	Tislelizumab (N = 256) Median time to event (95% CI) [a]	ICC (N = 256) Total No. of Patients	ICC (N = 256) Patients with events n (%)	ICC (N = 256) Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	203	174 (85.7)	1.5 (1.4, 2.6)	212	146 (68.9)	1.7 (1.5, 2.6)	0.809 (0.646, 1.014)	0.0618
White	53	49 (92.5)	2.4 (1.5, 2.8)	44	34 (77.3)	2.7 (1.4, 4.3)	1.006 (0.648, 1.564)	0.9769
Interaction								0.3473
Baseline PD-L1 Status								
vCPS >= 10%	80	67 (83.8)	2.7 (1.5, 4.2)	62	41 (66.1)	2.3 (1.4, 3.0)	0.747 (0.503, 1.112)	0.1460
vCPS < 10%	100	87 (87.0)	1.5 (1.4, 2.6)	122	94 (77.0)	1.7 (1.4, 2.7)	0.883 (0.656, 1.189)	0.4067
Missing	76	69 (90.8)	1.5 (1.4, 2.8)	72	45 (62.5)	2.1 (1.4, 2.8)	0.908 (0.620, 1.331)	0.6168
Interaction								0.7888

Source: ADSL, ADTTE. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.3.1.b.s:
Progression Free Survival (PFS) - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	66 (85.7)	1.6 (1.4, 2.8)	77	58 (75.3)	1.5 (1.4, 2.7)	0.861 (0.602, 1.230)	0.4034
>= 65 Years	62	55 (88.7)	2.5 (1.5, 4.2)	61	46 (75.4)	2.9 (2.0, 3.9)	0.777 (0.516, 1.170)	0.2229
Interaction								0.9267
Gender								
Male	118	103 (87.3)	2.0 (1.5, 2.8)	111	85 (76.6)	2.6 (1.5, 3.0)	0.830 (0.618, 1.116)	0.2134
Female	21	18 (85.7)	2.3 (1.3, 4.6)	27	19 (70.4)	2.5 (1.4, 3.0)	0.859 (0.447, 1.649)	0.6457
Interaction								0.9760
Smoking Status								
Former/Current Smoker	104	93 (89.4)	2.4 (1.6, 2.8)	105	82 (78.1)	2.7 (1.5, 2.9)	0.820 (0.604, 1.113)	0.1985
Non-Smoker	35	28 (80.0)	1.5 (1.4, 3.8)	33	22 (66.7)	2.5 (1.4, 3.7)	0.879 (0.500, 1.546)	0.6500
Interaction								0.9748

Source: ADSL, ADTTE. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.3.1.b.s:
Progression Free Survival (PFS) - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	72 (86.7)	2.5 (1.6, 3.5)	85	64 (75.3)	2.6 (1.5, 3.3)	0.803 (0.568, 1.136)	0.2107
Docetaxel	56	49 (87.5)	1.5 (1.4, 2.8)	53	40 (75.5)	1.7 (1.4, 2.9)	0.902 (0.591, 1.376)	0.6266
Interaction								0.7493
ECOG Performance Score								
0	43	37 (86.0)	2.9 (1.6, 4.2)	42	31 (73.8)	2.9 (2.0, 5.1)	0.783 (0.477, 1.286)	0.3305
1	96	84 (87.5)	1.6 (1.4, 2.7)	96	73 (76.0)	2.2 (1.4, 2.8)	0.877 (0.638, 1.206)	0.4141
Interaction								0.9150
Region #1								
Asia	103	87 (84.5)	1.8 (1.4, 2.9)	105	80 (76.2)	2.5 (1.5, 2.8)	0.786 (0.576, 1.073)	0.1244
Europe/North America	36	34 (94.4)	2.7 (1.5, 2.9)	33	24 (72.7)	3.0 (1.5, 4.3)	1.128 (0.665, 1.914)	0.6523
Interaction								0.1724

Source: ADSL, ADTTE. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.3.1.b.s:
Progression Free Survival (PFS) - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	66 (84.6)	1.5 (1.4, 2.8)	80	59 (73.8)	2.6 (1.5, 3.0)	0.910 (0.636, 1.301)	0.6017
Japan	25	21 (84.0)	3.6 (2.0, 7.4)	25	21 (84.0)	1.7 (1.4, 2.8)	0.504 (0.266, 0.954)	0.0317
Europe/North America	36	34 (94.4)	2.7 (1.5, 2.9)	33	24 (72.7)	3.0 (1.5, 4.3)	1.128 (0.665, 1.914)	0.6523
Interaction								0.1321
Race								
Asian and other	105	88 (83.8)	1.6 (1.4, 2.9)	114	86 (75.4)	2.5 (1.5, 2.8)	0.783 (0.578, 1.063)	0.1124
White	34	33 (97.1)	2.7 (1.5, 3.1)	24	18 (75.0)	3.3 (1.5, 6.2)	1.272 (0.712, 2.273)	0.4132
Interaction								0.1186

Source: ADSL, ADTTE. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-os-subgrp.sas 16MAY2024 02:51 t-14-02-03-01-b-s-eff-pfs-subgrp-itts-fa.rtf

Table 14.2.3.1.b.s:
Progression Free Survival (PFS) - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	41 (91.1)	2.6 (1.5, 4.1)	34	26 (76.5)	2.6 (1.5, 3.6)	0.941 (0.573, 1.543)	0.8079
vCPS < 10%	53	43 (81.1)	2.7 (1.5, 3.9)	56	47 (83.9)	2.7 (1.4, 3.4)	0.701 (0.458, 1.074)	0.0979
Missing	41	37 (90.2)	1.4 (1.4, 2.8)	48	31 (64.6)	2.5 (1.5, 2.9)	1.018 (0.621, 1.668)	0.9440
Interaction								0.5838

Source: ADSL, ADTTE. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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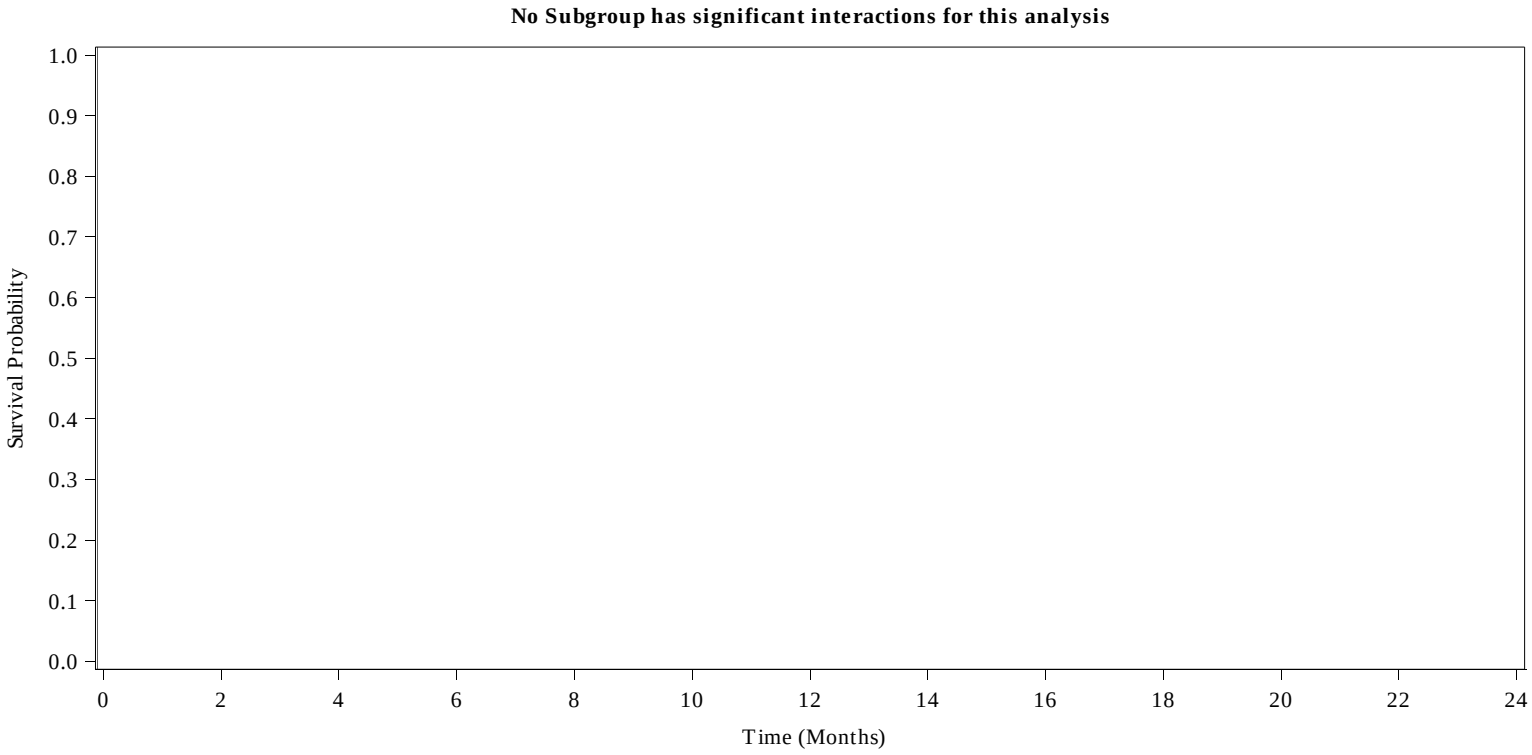
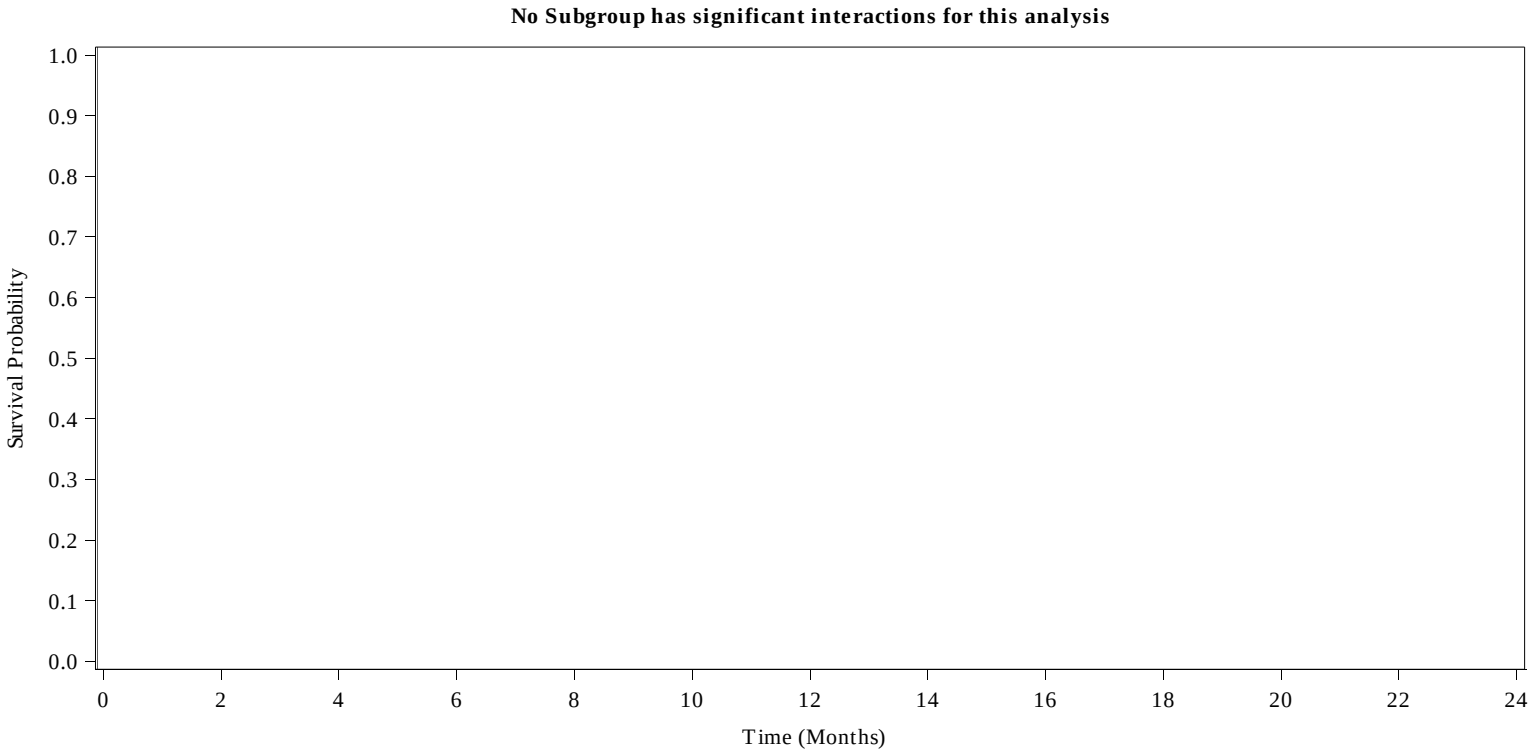
Figure 14.2.4.1.s:
Kaplan-Meier Plot of Progression Free Survival (PFS) - Subgroup Analysis
ITT Analysis Set



Source: ADSL, ADTTE. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-subgrp.sas 16MAY2024 01:09 f-14-02-04-01-s-km-subgrp-pfs-itt-fa.rtf

Figure 14.2.4.1.b.s:
Kaplan-Meier Plot of Progression Free Survival (PFS) - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTE. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-subgrp.sas 16MAY2024 01:09 f-14-02-04-01-b-s-km-subgrp-pfs-itts-fa.rtf

Table 14.2.4.1:
Objective Response
ITT Analysis Set

	Tislelizumab (N = 256)	ICC (N = 256)	Odds Ratio (95% CI) [a]	Relative Risk (95% CI) [a]	Risk Difference (95% CI) [a]	2-sided p-value [b]
Objective Response Rate (ORR), n	52	25				
%	20.3	9.8	2.389 (1.422, 4.015)	2.088 (1.341, 3.251)	10.590 (4.500, 16.680)	0.0008
Best Overall Response (BOR), n (%)						
Complete Response (CR)	5 (2.0)	1 (0.4)				
Partial Response (PR)	47 (18.4)	24 (9.4)				
Stable Disease (SD)	68 (26.6)	82 (32.0)				
Progressive Disease (PD)	116 (45.3)	86 (33.6)				
Not Evaluable (NE) [c]	1 (0.4)	3 (1.2)				
Not Assessable [d]	19 (7.4)	60 (23.4)				
Disease Control Rate (DCR), n	120	107				
%	46.9	41.8	1.236 (0.867, 1.763)	1.121 (0.926, 1.358)	5.067 (-3.397, 13.530)	0.2434

Source: ADSL, ADRS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Percentages were based on N.

ORR is unconfirmed and defined as proportion of number of patients with a PR or CR per RECIST v1.1 (i.e. ORR = CR+PR); DCR is defined as proportion of number of patients with a PR or CR or a SD per RECIST v1.1 (i.e. DCR = CR+PR+SD).

[a] Odds ratio and relative risk were assumed to be log normally distributed. Mantel-Haenszel common risk difference was estimated. 95% CI was constructed by a normal approximation and Sato's variance estimator, stratified by randomization stratification factors.

[b] P-value was calculated using the Cochran-Mantel-Haenszel Chi-square test, stratified by ECOG performance status and ICC option.

[c] Not evaluable is based on RECIST v1.1.

[d] Patients with no post-baseline tumor assessment by the data cutoff, including those who discontinued study (any reason) or died without having any post-baseline tumor assessment.

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Table 14.2.4.1.b:
Objective Response
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)	ICC (N = 138)	Odds Ratio (95% CI) [a]	Relative Risk (95% CI) [a]	Risk Difference (95% CI) [a]	2-sided p-value [b]
Objective Response Rate (ORR), n	31	19				
%	22.3	13.8	1.822 (0.968, 3.430)	1.634 (0.971, 2.748)	8.668 (-0.298, 17.635)	0.0606
Best Overall Response (BOR), n (%)						
Complete Response (CR)	3 (2.2)	1 (0.7)				
Partial Response (PR)	28 (20.1)	18 (13.0)				
Stable Disease (SD)	40 (28.8)	49 (35.5)				
Progressive Disease (PD)	62 (44.6)	45 (32.6)				
Not Evaluable (NE) [c]	0 (0.0)	2 (1.4)				
Not Assessable [d]	6 (4.3)	23 (16.7)				
Disease Control Rate (DCR), n	71	68				
%	51.1	49.3	1.080 (0.671, 1.737)	1.038 (0.823, 1.311)	1.893 (-9.783, 13.568)	0.7521

Source: ADSL, ADRS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
ORR is unconfirmed and defined as proportion of number of patients with a PR or CR per RECIST v1.1 (i.e. ORR = CR+PR); DCR is defined as proportion of number of patients with a PR or CR or a SD per RECIST v1.1 (i.e. DCR = CR+PR+SD).
[a] Odds ratio and relative risk were assumed to be log normally distributed. Mantel-Haenszel common risk difference was estimated. 95% CI was constructed by a normal approximation and Sato's variance estimator, stratified by randomization stratification factors.
[b] P-value was calculated using the Cochran-Mantel-Haenszel Chi-square test, stratified by ECOG performance status and ICC option.
[c] Not evaluable is based on RECIST v1.1.
[d] Patients with no post-baseline tumor assessment by the data cutoff, including those who discontinued study (any reason) or died without having any post-baseline tumor assessment.
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Table 14.2.4.1.s:
Analysis of Objective Response Rate - Subgroup Analysis
ITT Analysis Set

Subgroup	Tislelizumab (N = 256) Total No. of Patients	Tislelizumab (N = 256) Responders n (%)	ICC (N = 256) Total No. of Patients	ICC (N = 256) Responders n (%)	Odds Ratio (95% CI) [a]	Relative Risk (95% CI) [a]	Risk Difference (95% CI) [a]	2-sided p-value [b]
Age								
< 65 Years	157	27 (17.2)	161	16 (9.9)	1.882 (0.971, 3.649)	1.730 (0.971, 3.084)	7.260 (-0.237, 14.756)	0.0588
>= 65 Years	99	25 (25.3)	95	9 (9.5)	3.228 (1.418, 7.351)	2.666 (1.313, 5.411)	15.779 (5.390, 26.167)	0.0039
Interaction								0.3155
Gender								
Male	217	41 (18.9)	215	21 (9.8)	2.152 (1.224, 3.783)	1.934 (1.184, 3.161)	9.127 (2.579, 15.674)	0.0069
Female	39	11 (28.2)	41	4 (9.8)	3.634 (1.046, 12.623)	2.891 (1.005, 8.320)	18.449 (1.658, 35.240)	0.0357
Interaction								0.4507

Source: ADSL, ADRS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Percentages were based on N.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 responders, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of responders are displayed.

ORR is unconfirmed and defined as proportion of number of patients with a PR or CR per RECIST v1.1 (i.e. ORR = CR+PR).

[a] Odds ratio and relative risk were assumed to be log normally distributed. Mantel-Haenszel common risk difference was estimated. 95% CI was constructed by a normal approximation and Sato's variance estimator.

[b] P-value was based on unstratified chi-squared test. P-value for the interaction was based on Breslow-Day test testing for differences in treatment effect across subgroups.

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Table 14.2.4.1.s:
Analysis of Objective Response Rate - Subgroup Analysis
ITT Analysis Set

	Tislelizumab (N = 256)		ICC (N = 256)					
Subgroup	Total No. of Patients	Responders n (%)	Total No. of Patients	Responders n (%)	Odds Ratio (95% CI) [a]	Relative Risk (95% CI) [a]	Risk Difference (95% CI) [a]	2-sided p-value [b]
Smoking Status								
Former/Current Smoker	188	37 (19.7)	192	18 (9.4)	2.369 (1.295, 4.333)	2.099 (1.240, 3.553)	10.306 (3.285, 17.327)	0.0044
Non-Smoker	68	15 (22.1)	63	7 (11.1)	2.264 (0.856, 5.988)	1.985 (0.866, 4.549)	10.948 (-1.596, 23.492)	0.0952
Interaction								0.9384
ICC Options								
Paclitaxel	83	20 (24.1)	85	16 (18.8)	1.369 (0.653, 2.872)	1.280 (0.714, 2.295)	5.273 (-7.125, 17.671)	0.4064
Docetaxel	56	11 (19.6)	53	3 (5.7)	4.074 (1.068, 15.538)	3.470 (1.024, 11.755)	13.982 (1.859, 26.106)	0.0300
Irinotecan	117	21 (17.9)	118	6 (5.1)	4.083 (1.583, 10.530)	3.530 (1.478, 8.430)	12.864 (4.860, 20.868)	0.0020
Interaction								0.1301

Source: ADSL, ADRS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Percentages were based on N.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 responders, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of responders are displayed.

ORR is unconfirmed and defined as proportion of number of patients with a PR or CR per RECIST v1.1 (i.e. ORR = CR+PR).

[a] Odds ratio and relative risk were assumed to be log normally distributed. Mantel-Haenszel common risk difference was estimated. 95% CI was constructed by a normal approximation and Sato's variance estimator.

[b] P-value was based on unstratified chi-squared test. P-value for the interaction was based on Breslow-Day test testing for differences in treatment effect across subgroups.

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Table 14.2.4.1.s:
Analysis of Objective Response Rate - Subgroup Analysis
ITT Analysis Set

Subgroup	Tislelizumab (N = 256) Total No. of Patients	Tislelizumab (N = 256) Responders n (%)	ICC (N = 256) Total No. of Patients	ICC (N = 256) Responders n (%)	Odds Ratio (95% CI) [a]	Relative Risk (95% CI) [a]	Risk Difference (95% CI) [a]	2-sided p-value [b]
ECOG Performance Score								
0	64	15 (23.4)	63	10 (15.9)	1.622 (0.667, 3.949)	1.477 (0.718, 3.035)	7.564 (-6.188, 21.317)	0.2856
1	192	37 (19.3)	193	15 (7.8)	2.833 (1.498, 5.358)	2.480 (1.408, 4.366)	11.499 (4.761, 18.236)	0.0010
Interaction								0.3168
Region #1								
Asia	201	41 (20.4)	203	19 (9.4)	2.482 (1.384, 4.449)	2.179 (1.312, 3.621)	11.038 (4.176, 17.900)	0.0018
Europe/North America	55	11 (20.0)	53	6 (11.3)	1.958 (0.667, 5.746)	1.767 (0.704, 4.435)	8.679 (-4.904, 22.263)	0.2178
Interaction								0.7044

Source: ADSL, ADRS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Percentages were based on N.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 responders, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of responders are displayed.

ORR is unconfirmed and defined as proportion of number of patients with a PR or CR per RECIST v1.1 (i.e. ORR = CR+PR).

[a] Odds ratio and relative risk were assumed to be log normally distributed. Mantel-Haenszel common risk difference was estimated. 95% CI was constructed by a normal approximation and Sato's variance estimator.

[b] P-value was based on unstratified chi-squared test. P-value for the interaction was based on Breslow-Day test testing for differences in treatment effect across subgroups.

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Table 14.2.4.1.s:
Analysis of Objective Response Rate - Subgroup Analysis
ITT Analysis Set

	Tislelizumab (N = 256)		ICC (N = 256)					
Subgroup	**Total No. of Patients**	**Responders n (%)**	**Total No. of Patients**	**Responders n (%)**	**Odds Ratio (95% CI) [a]**	**Relative Risk (95% CI) [a]**	**Risk Difference (95% CI) [a]**	**2-sided p-value [b]**
Region #2								
Asia (excluding Japan)	176	33 (18.8)	178	14 (7.9)	2.703 (1.391, 5.252)	2.384 (1.322, 4.298)	10.885 (3.893, 17.877)	0.0026
Japan	25	8 (32.0)	25	5 (20.0)	1.882 (0.518, 6.845)	1.600 (0.606, 4.221)	12.000 (-12.088, 36.088)	0.3383
Europe/North America	55	11 (20.0)	53	6 (11.3)	1.958 (0.667, 5.746)	1.767 (0.704, 4.435)	8.679 (-4.904, 22.263)	0.2178
Interaction								0.8209
Race								
Asian and other	203	41 (20.2)	212	19 (9.0)	2.571 (1.436, 4.604)	2.254 (1.355, 3.748)	11.235 (4.505, 17.964)	0.0012
White	53	11 (20.8)	44	6 (13.6)	1.659 (0.559, 4.920)	1.522 (0.612, 3.784)	7.118 (-7.782, 22.019)	0.3611
Interaction								0.4852

Source: ADSL, ADRS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Percentages were based on N.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 responders, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of responders are displayed.

ORR is unconfirmed and defined as proportion of number of patients with a PR or CR per RECIST v1.1 (i.e. ORR = CR+PR).

[a] Odds ratio and relative risk were assumed to be log normally distributed. Mantel-Haenszel common risk difference was estimated. 95% CI was constructed by a normal approximation and Sato's variance estimator.

[b] P-value was based on unstratified chi-squared test. P-value for the interaction was based on Breslow-Day test testing for differences in treatment effect across subgroups.

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Table 14.2.4.1.s:
Analysis of Objective Response Rate - Subgroup Analysis
ITT Analysis Set

	Tislelizumab (N = 256)		ICC (N = 256)					
Subgroup	Total No. of Patients	Responders n (%)	Total No. of Patients	Responders n (%)	Odds Ratio (95% CI) [a]	Relative Risk (95% CI) [a]	Risk Difference (95% CI) [a]	2-sided p-value [b]
Baseline PD-L1 Status								
vCPS >= 10%	80	21 (26.3)	62	7 (11.3)	2.797 (1.102, 7.095)	2.325 (1.057, 5.115)	14.960 (2.509, 27.410)	0.0268
vCPS < 10%	100	16 (16.0)	122	11 (9.0)	1.922 (0.848, 4.357)	1.775 (0.863, 3.648)	6.984 (-1.818, 15.785)	0.1140
Missing	76	15 (19.7)	72	7 (9.7)	2.283 (0.872, 5.980)	2.030 (0.879, 4.689)	10.015 (-1.250, 21.280)	0.0880
Interaction								0.8382

Source: ADSL, ADRS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Percentages were based on N.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 responders, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of responders are displayed.

ORR is unconfirmed and defined as proportion of number of patients with a PR or CR per RECIST v1.1 (i.e. ORR = CR+PR).

[a] Odds ratio and relative risk were assumed to be log normally distributed. Mantel-Haenszel common risk difference was estimated. 95% CI was constructed by a normal approximation and Sato's variance estimator.

[b] P-value was based on unstratified chi-squared test. P-value for the interaction was based on Breslow-Day test testing for differences in treatment effect across subgroups.

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Table 14.2.4.1.b.s:
Analysis of Objective Response Rate - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)		ICC (N = 138)					
Subgroup	Total No. of Patients	Responders n (%)	Total No. of Patients	Responders n (%)	Odds Ratio (95% CI) [a]	Relative Risk (95% CI) [a]	Risk Difference (95% CI) [a]	2-sided p-value [b]
Age								
< 65 Years	77	15 (19.5)	77	12 (15.6)	1.310 (0.569, 3.021)	1.250 (0.627, 2.493)	3.896 (-8.099, 15.891)	0.5263
>= 65 Years	62	16 (25.8)	61	7 (11.5)	2.683 (1.016, 7.088)	2.249 (0.996, 5.080)	14.331 (0.818, 27.844)	0.0424
Interaction								0.2711
Gender								
Male	118	24 (20.3)	111	16 (14.4)	1.516 (0.757, 3.034)	1.411 (0.792, 2.513)	5.925 (-3.845, 15.694)	0.2390
Female	21	7 (33.3)	27	3 (11.1)	4.000 (0.888, 18.009)	3.000 (0.880, 10.227)	22.222 (-1.166, 45.611)	0.0628
Interaction								0.2456

Source: ADSL, ADRS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

Percentages were based on N.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 responders, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of responders are displayed.

ORR is unconfirmed and defined as proportion of number of patients with a PR or CR per RECIST v1.1 (i.e. ORR = CR+PR).

[a] Odds ratio and relative risk were assumed to be log normally distributed. Mantel-Haenszel common risk difference was estimated. 95% CI was constructed by a normal approximation and Sato's variance estimator.

[b] P-value was based on unstratified chi-squared test. P-value for the interaction was based on Breslow-Day test testing for differences in treatment effect across subgroups.

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Table 14.2.4.1.b.s:
Analysis of Objective Response Rate - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)		ICC (N = 138)					
Subgroup	Total No. of Patients	Responders n (%)	Total No. of Patients	Responders n (%)	Odds Ratio (95% CI) [a]	Relative Risk (95% CI) [a]	Risk Difference (95% CI) [a]	2-sided p-value [b]
Smoking Status								
Former/Current Smoker	104	23 (22.1)	105	14 (13.3)	1.846 (0.891, 3.825)	1.659 (0.904, 3.042)	8.782 (-1.509, 19.073)	0.0971
Non-Smoker	35	8 (22.9)	33	5 (15.2)	1.659 (0.482, 5.711)	1.509 (0.549, 4.146)	7.706 (-10.820, 26.231)	0.4228
Interaction								0.8844
ICC Options								
Paclitaxel	83	20 (24.1)	85	16 (18.8)	1.369 (0.653, 2.872)	1.280 (0.714, 2.295)	5.273 (-7.125, 17.671)	0.4064
Docetaxel	56	11 (19.6)	53	3 (5.7)	4.074 (1.068, 15.538)	3.470 (1.024, 11.755)	13.982 (1.859, 26.106)	0.0300
Interaction								0.1551

Source: ADSL, ADRS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

Percentages were based on N.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 responders, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of responders are displayed.

ORR is unconfirmed and defined as proportion of number of patients with a PR or CR per RECIST v1.1 (i.e. ORR = CR+PR).

[a] Odds ratio and relative risk were assumed to be log normally distributed. Mantel-Haenszel common risk difference was estimated. 95% CI was constructed by a normal approximation and Sato's variance estimator.

[b] P-value was based on unstratified chi-squared test. P-value for the interaction was based on Breslow-Day test testing for differences in treatment effect across subgroups.

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Table 14.2.4.1.b.s:
Analysis of Objective Response Rate - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)		ICC (N = 138)					
Subgroup	Total No. of Patients	Responders n (%)	Total No. of Patients	Responders n (%)	Odds Ratio (95% CI) [a]	Relative Risk (95% CI) [a]	Risk Difference (95% CI) [a]	2-sided p-value [b]
ECOG Performance Score								
0	43	9 (20.9)	42	9 (21.4)	0.971 (0.343, 2.748)	0.977 (0.430, 2.218)	-0.498 (-17.872, 16.875)	0.9554
1	96	22 (22.9)	96	10 (10.4)	2.557 (1.138, 5.745)	2.200 (1.101, 4.395)	12.500 (2.106, 22.894)	0.0205
Interaction								0.1473
Region #1								
Asia	103	25 (24.3)	105	13 (12.4)	2.268 (1.088, 4.730)	1.960 (1.062, 3.617)	11.891 (1.487, 22.295)	0.0269
Europe/North America	36	6 (16.7)	33	6 (18.2)	0.900 (0.259, 3.127)	0.917 (0.328, 2.563)	-1.515 (-19.442, 16.412)	0.8692
Interaction								0.2062

Source: ADSL, ADRS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 responders, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of responders are displayed.
ORR is unconfirmed and defined as proportion of number of patients with a PR or CR per RECIST v1.1 (i.e. ORR = CR+PR).
[a] Odds ratio and relative risk were assumed to be log normally distributed. Mantel-Haenszel common risk difference was estimated. 95% CI was constructed by a normal approximation and Sato's variance estimator.
[b] P-value was based on unstratified chi-squared test. P-value for the interaction was based on Breslow-Day test testing for differences in treatment effect across subgroups.
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Table 14.2.4.1.b.s:
Analysis of Objective Response Rate - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)		ICC (N = 138)					
Subgroup	**Total No. of Patients**	**Responders n (%)**	**Total No. of Patients**	**Responders n (%)**	**Odds Ratio (95% CI) [a]**	**Relative Risk (95% CI) [a]**	**Risk Difference (95% CI) [a]**	**2-sided p-value [b]**
Region #2								
Asia (excluding Japan)	78	17 (21.8)	80	8 (10.0)	2.508 (1.013, 6.212)	2.179 (0.999, 4.756)	11.795 (0.518, 23.071)	0.0429
Japan	25	8 (32.0)	25	5 (20.0)	1.882 (0.518, 6.845)	1.600 (0.606, 4.221)	12.000 (-12.088, 36.088)	0.3383
Europe/North America	36	6 (16.7)	33	6 (18.2)	0.900 (0.259, 3.127)	0.917 (0.328, 2.563)	-1.515 (-19.442, 16.412)	0.8692
Interaction								0.4190
Race								
Asian and other	105	25 (23.8)	114	13 (11.4)	2.428 (1.168, 5.046)	2.088 (1.128, 3.864)	12.406 (2.385, 22.427)	0.0157
White	34	6 (17.6)	24	6 (25.0)	0.643 (0.179, 2.306)	0.706 (0.259, 1.926)	-7.353 (-28.901, 14.195)	0.4997
Interaction								0.0717

Source: ADSL, ADRS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

Percentages were based on N.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 responders, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of responders are displayed.

ORR is unconfirmed and defined as proportion of number of patients with a PR or CR per RECIST v1.1 (i.e. ORR = CR+PR).

[a] Odds ratio and relative risk were assumed to be log normally distributed. Mantel-Haenszel common risk difference was estimated. 95% CI was constructed by a normal approximation and Sato's variance estimator.

[b] P-value was based on unstratified chi-squared test. P-value for the interaction was based on Breslow-Day test testing for differences in treatment effect across subgroups.

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Table 14.2.4.1.b.s:
Analysis of Objective Response Rate - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)		ICC (N = 138)					
Subgroup	**Total No. of Patients**	**Responders n (%)**	**Total No. of Patients**	**Responders n (%)**	**Odds Ratio (95% CI) [a]**	**Relative Risk (95% CI) [a]**	**Risk Difference (95% CI) [a]**	**2-sided p-value [b]**
Baseline PD-L1 Status								
vCPS >= 10%	45	12 (26.7)	34	4 (11.8)	2.727 (0.793, 9.376)	2.267 (0.801, 6.415)	14.902 (-1.957, 31.761)	0.1049
vCPS < 10%	53	12 (22.6)	56	10 (17.9)	1.346 (0.527, 3.443)	1.268 (0.599, 2.685)	4.784 (-10.301, 19.870)	0.5358
Missing	41	7 (17.1)	48	5 (10.4)	1.771 (0.516, 6.074)	1.639 (0.563, 4.775)	6.657 (-7.743, 21.056)	0.3621
Interaction								0.6694

Source: ADSL, ADRS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

Percentages were based on N.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 responders, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of responders are displayed.

ORR is unconfirmed and defined as proportion of number of patients with a PR or CR per RECIST v1.1 (i.e. ORR = CR+PR).

[a] Odds ratio and relative risk were assumed to be log normally distributed. Mantel-Haenszel common risk difference was estimated. 95% CI was constructed by a normal approximation and Sato's variance estimator.

[b] P-value was based on unstratified chi-squared test. P-value for the interaction was based on Breslow-Day test testing for differences in treatment effect across subgroups.

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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set

Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab (N = 256)	ICC (N = 256)
Baseline		
Patients in study at visit, n	256	256
Patients complete questionnaire, n	242	247
Completion rate (%) [a]	94.5	96.5
Adjusted completion rate (%) [b]	94.5	96.5
Cycle 1		
Patients in study at visit, n	256	256
Patients complete questionnaire, n	140	134
Completion rate (%) [a]	54.7	52.3
Adjusted completion rate (%) [b]	54.7	52.3
Cycle 2		
Patients in study at visit, n	237	184
Patients complete questionnaire, n	222	174
Completion rate (%) [a]	86.7	68.0
Adjusted completion rate (%) [b]	93.7	94.6

Source: Listing 16.2.6.6.1, 16.2.6.6.2, 16.2.6.6.3. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients in study at relevant visits in relevant treatment arm.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set

Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab (N = 256)	ICC (N = 256)
Cycle 3		
Patients in study at visit, n	188	99
Patients complete questionnaire, n	181	92
Completion rate (%) [a]	70.7	35.9
Adjusted completion rate (%) [b]	96.3	92.9
Cycle 4		
Patients in study at visit, n	157	83
Patients complete questionnaire, n	147	77
Completion rate (%) [a]	57.4	30.1
Adjusted completion rate (%) [b]	93.6	92.8
Cycle 5		
Patients in study at visit, n	116	48
Patients complete questionnaire, n	108	45
Completion rate (%) [a]	42.2	17.6
Adjusted completion rate (%) [b]	93.1	93.8

Source: Listing 16.2.6.6.1, 16.2.6.6.2, 16.2.6.6.3. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients in study at relevant visits in relevant treatment arm.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-comp.sas 22APR2024 22:42 t-14-02-06-01-01-qs-comp-itt-fa.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set

Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab (N = 256)	ICC (N = 256)
Cycle 6		
Patients in study at visit, n	100	39
Patients complete questionnaire, n	99	38
Completion rate (%) [a]	38.7	14.8
Adjusted completion rate (%) [b]	99.0	97.4
End of Treatment		
Patients in study at visit, n	240	255
Patients complete questionnaire, n	74	83
Completion rate (%) [a]	28.9	32.4
Adjusted completion rate (%) [b]	30.8	32.5
Safety Follow-up		
Patients in study at visit, n	137	118
Patients complete questionnaire, n	106	96
Completion rate (%) [a]	41.4	37.5
Adjusted completion rate (%) [b]	77.4	81.4

Source: Listing 16.2.6.6.1, 16.2.6.6.2, 16.2.6.6.3. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients in study at relevant visits in relevant treatment arm.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set

Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab (N = 256)	ICC (N = 256)
Baseline		
Patients in study at visit, n	256	256
Patients complete questionnaire, n	240	248
Completion rate (%) [a]	93.8	96.9
Adjusted completion rate (%) [b]	93.8	96.9
Cycle 1		
Patients in study at visit, n	256	256
Patients complete questionnaire, n	138	132
Completion rate (%) [a]	53.9	51.6
Adjusted completion rate (%) [b]	53.9	51.6
Cycle 2		
Patients in study at visit, n	237	184
Patients complete questionnaire, n	224	174
Completion rate (%) [a]	87.5	68.0
Adjusted completion rate (%) [b]	94.5	94.6

Source: Listing 16.2.6.6.1, 16.2.6.6.2, 16.2.6.6.3. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients in study at relevant visits in relevant treatment arm.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set

Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab (N = 256)	ICC (N = 256)
Cycle 3		
Patients in study at visit, n	188	99
Patients complete questionnaire, n	181	91
Completion rate (%) [a]	70.7	35.5
Adjusted completion rate (%) [b]	96.3	91.9
Cycle 4		
Patients in study at visit, n	157	83
Patients complete questionnaire, n	146	76
Completion rate (%) [a]	57.0	29.7
Adjusted completion rate (%) [b]	93.0	91.6
Cycle 5		
Patients in study at visit, n	116	48
Patients complete questionnaire, n	110	45
Completion rate (%) [a]	43.0	17.6
Adjusted completion rate (%) [b]	94.8	93.8

Source: Listing 16.2.6.6.1, 16.2.6.6.2, 16.2.6.6.3. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients in study at relevant visits in relevant treatment arm.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set

Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab (N = 256)	ICC (N = 256)
Cycle 6		
Patients in study at visit, n	100	39
Patients complete questionnaire, n	99	37
Completion rate (%) [a]	38.7	14.5
Adjusted completion rate (%) [b]	99.0	94.9
End of Treatment		
Patients in study at visit, n	240	255
Patients complete questionnaire, n	71	83
Completion rate (%) [a]	27.7	32.4
Adjusted completion rate (%) [b]	29.6	32.5
Safety Follow-up		
Patients in study at visit, n	137	118
Patients complete questionnaire, n	106	96
Completion rate (%) [a]	41.4	37.5
Adjusted completion rate (%) [b]	77.4	81.4

Source: Listing 16.2.6.6.1, 16.2.6.6.2, 16.2.6.6.3. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients in study at relevant visits in relevant treatment arm.
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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set

Questionnaire: EQ-5D VAS

Visit	Tislelizumab (N = 256)	ICC (N = 256)
Baseline		
Patients in study at visit, n	256	256
Patients complete questionnaire, n	242	247
Completion rate (%) [a]	94.5	96.5
Adjusted completion rate (%) [b]	94.5	96.5
Cycle 1		
Patients in study at visit, n	256	256
Patients complete questionnaire, n	140	134
Completion rate (%) [a]	54.7	52.3
Adjusted completion rate (%) [b]	54.7	52.3
Cycle 2		
Patients in study at visit, n	237	184
Patients complete questionnaire, n	223	173
Completion rate (%) [a]	87.1	67.6
Adjusted completion rate (%) [b]	94.1	94.0

Source: Listing 16.2.6.6.1, 16.2.6.6.2, 16.2.6.6.3. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.

[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients in study at relevant visits in relevant treatment arm.

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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set

Questionnaire: EQ-5D VAS

Visit	Tislelizumab (N = 256)	ICC (N = 256)
Cycle 3		
Patients in study at visit, n	188	99
Patients complete questionnaire, n	180	90
Completion rate (%) [a]	70.3	35.2
Adjusted completion rate (%) [b]	95.7	90.9
Cycle 4		
Patients in study at visit, n	157	83
Patients complete questionnaire, n	147	77
Completion rate (%) [a]	57.4	30.1
Adjusted completion rate (%) [b]	93.6	92.8
Cycle 5		
Patients in study at visit, n	116	48
Patients complete questionnaire, n	109	45
Completion rate (%) [a]	42.6	17.6
Adjusted completion rate (%) [b]	94.0	93.8

Source: Listing 16.2.6.6.1, 16.2.6.6.2, 16.2.6.6.3. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients in study at relevant visits in relevant treatment arm.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-comp.sas 22APR2024 22:42 t-14-02-06-01-01-qs-comp-itt-fa.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set

Questionnaire: EQ-5D VAS

Visit	Tislelizumab (N = 256)	ICC (N = 256)
Cycle 6		
Patients in study at visit, n	100	39
Patients complete questionnaire, n	99	36
Completion rate (%) [a]	38.7	14.1
Adjusted completion rate (%) [b]	99.0	92.3
End of Treatment		
Patients in study at visit, n	240	255
Patients complete questionnaire, n	73	83
Completion rate (%) [a]	28.5	32.4
Adjusted completion rate (%) [b]	30.4	32.5
Safety Follow-up		
Patients in study at visit, n	137	118
Patients complete questionnaire, n	106	96
Completion rate (%) [a]	41.4	37.5
Adjusted completion rate (%) [b]	77.4	81.4

Source: Listing 16.2.6.6.1, 16.2.6.6.2, 16.2.6.6.3. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients in study at relevant visits in relevant treatment arm.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-comp.sas 22APR2024 22:42 t-14-02-06-01-01-qs-comp-itt-fa.rtf

Table 14.2.6.1.1.b:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation without Irinotecan

Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab (N = 139)	ICC (N = 138)
Baseline		
Patients in study at visit, n	139	138
Patients complete questionnaire, n	128	133
Completion rate (%) [a]	92.1	96.4
Adjusted completion rate (%) [b]	92.1	96.4
Cycle 1		
Patients in study at visit, n	139	138
Patients complete questionnaire, n	83	83
Completion rate (%) [a]	59.7	60.1
Adjusted completion rate (%) [b]	59.7	60.1
Cycle 2		
Patients in study at visit, n	132	105
Patients complete questionnaire, n	123	97
Completion rate (%) [a]	88.5	70.3
Adjusted completion rate (%) [b]	93.2	92.4

Source: Listing 16.2.6.6.1, 16.2.6.6.2, 16.2.6.6.3. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients in study at relevant visits in relevant treatment arm.
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Table 14.2.6.1.1.b:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation without Irinotecan

Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab (N = 139)	ICC (N = 138)
Cycle 3		
Patients in study at visit, n	103	65
Patients complete questionnaire, n	98	58
Completion rate (%) [a]	70.5	42.0
Adjusted completion rate (%) [b]	95.1	89.2
Cycle 4		
Patients in study at visit, n	82	56
Patients complete questionnaire, n	77	52
Completion rate (%) [a]	55.4	37.7
Adjusted completion rate (%) [b]	93.9	92.9
Cycle 5		
Patients in study at visit, n	62	33
Patients complete questionnaire, n	56	32
Completion rate (%) [a]	40.3	23.2
Adjusted completion rate (%) [b]	90.3	97.0

Source: Listing 16.2.6.6.1, 16.2.6.6.2, 16.2.6.6.3. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients in study at relevant visits in relevant treatment arm.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-comp.sas 22APR2024 22:42 t-14-02-06-01-01-b-qs-comp-itts-fa.rtf

Table 14.2.6.1.1.b:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation without Irinotecan

Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab (N = 139)	ICC (N = 138)
Cycle 6		
Patients in study at visit, n	55	27
Patients complete questionnaire, n	55	26
Completion rate (%) [a]	39.6	18.8
Adjusted completion rate (%) [b]	100.0	96.3
End of Treatment		
Patients in study at visit, n	128	137
Patients complete questionnaire, n	39	46
Completion rate (%) [a]	28.1	33.3
Adjusted completion rate (%) [b]	30.5	33.6
Safety Follow-up		
Patients in study at visit, n	82	77
Patients complete questionnaire, n	62	61
Completion rate (%) [a]	44.6	44.2
Adjusted completion rate (%) [b]	75.6	79.2

Source: Listing 16.2.6.6.1, 16.2.6.6.2, 16.2.6.6.3. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients in study at relevant visits in relevant treatment arm.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-comp.sas 22APR2024 22:42 t-14-02-06-01-01-b-qs-comp-itts-fa.rtf

Table 14.2.6.1.1.b:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation without Irinotecan

Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab (N = 139)	ICC (N = 138)
Baseline		
Patients in study at visit, n	139	138
Patients complete questionnaire, n	128	134
Completion rate (%) [a]	92.1	97.1
Adjusted completion rate (%) [b]	92.1	97.1
Cycle 1		
Patients in study at visit, n	139	138
Patients complete questionnaire, n	82	82
Completion rate (%) [a]	59.0	59.4
Adjusted completion rate (%) [b]	59.0	59.4
Cycle 2		
Patients in study at visit, n	132	105
Patients complete questionnaire, n	124	97
Completion rate (%) [a]	89.2	70.3
Adjusted completion rate (%) [b]	93.9	92.4

Source: Listing 16.2.6.6.1, 16.2.6.6.2, 16.2.6.6.3. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients in study at relevant visits in relevant treatment arm.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-comp.sas 22APR2024 22:42 t-14-02-06-01-01-b-qs-comp-itts-fa.rtf

Table 14.2.6.1.1.b:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation without Irinotecan

Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab (N = 139)	ICC (N = 138)
Cycle 3		
Patients in study at visit, n	103	65
Patients complete questionnaire, n	98	57
Completion rate (%) [a]	70.5	41.3
Adjusted completion rate (%) [b]	95.1	87.7
Cycle 4		
Patients in study at visit, n	82	56
Patients complete questionnaire, n	76	52
Completion rate (%) [a]	54.7	37.7
Adjusted completion rate (%) [b]	92.7	92.9
Cycle 5		
Patients in study at visit, n	62	33
Patients complete questionnaire, n	57	32
Completion rate (%) [a]	41.0	23.2
Adjusted completion rate (%) [b]	91.9	97.0

Source: Listing 16.2.6.6.1, 16.2.6.6.2, 16.2.6.6.3. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients in study at relevant visits in relevant treatment arm.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-comp.sas 22APR2024 22:42 t-14-02-06-01-01-b-qs-comp-itts-fa.rtf

Table 14.2.6.1.1.b:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation without Irinotecan

Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab (N = 139)	ICC (N = 138)
Cycle 6		
Patients in study at visit, n	55	27
Patients complete questionnaire, n	54	26
Completion rate (%) [a]	38.8	18.8
Adjusted completion rate (%) [b]	98.2	96.3
End of Treatment		
Patients in study at visit, n	128	137
Patients complete questionnaire, n	37	46
Completion rate (%) [a]	26.6	33.3
Adjusted completion rate (%) [b]	28.9	33.6
Safety Follow-up		
Patients in study at visit, n	82	77
Patients complete questionnaire, n	62	61
Completion rate (%) [a]	44.6	44.2
Adjusted completion rate (%) [b]	75.6	79.2

Source: Listing 16.2.6.6.1, 16.2.6.6.2, 16.2.6.6.3. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients in study at relevant visits in relevant treatment arm.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-comp.sas 22APR2024 22:42 t-14-02-06-01-01-b-qs-comp-itts-fa.rtf

Table 14.2.6.1.1.b:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation without Irinotecan

Questionnaire: EQ-5D VAS

Visit	Tislelizumab (N = 139)	ICC (N = 138)
Baseline		
Patients in study at visit, n	139	138
Patients complete questionnaire, n	128	134
Completion rate (%) [a]	92.1	97.1
Adjusted completion rate (%) [b]	92.1	97.1
Cycle 1		
Patients in study at visit, n	139	138
Patients complete questionnaire, n	83	83
Completion rate (%) [a]	59.7	60.1
Adjusted completion rate (%) [b]	59.7	60.1
Cycle 2		
Patients in study at visit, n	132	105
Patients complete questionnaire, n	124	96
Completion rate (%) [a]	89.2	69.6
Adjusted completion rate (%) [b]	93.9	91.4

Source: Listing 16.2.6.6.1, 16.2.6.6.2, 16.2.6.6.3. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients in study at relevant visits in relevant treatment arm.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-comp.sas 22APR2024 22:42 t-14-02-06-01-01-b-qs-comp-itts-fa.rtf

Table 14.2.6.1.1.b:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation without Irinotecan

Questionnaire: EQ-5D VAS

Visit	Tislelizumab (N = 139)	ICC (N = 138)
Cycle 3		
Patients in study at visit, n	103	65
Patients complete questionnaire, n	98	57
Completion rate (%) [a]	70.5	41.3
Adjusted completion rate (%) [b]	95.1	87.7
Cycle 4		
Patients in study at visit, n	82	56
Patients complete questionnaire, n	77	52
Completion rate (%) [a]	55.4	37.7
Adjusted completion rate (%) [b]	93.9	92.9
Cycle 5		
Patients in study at visit, n	62	33
Patients complete questionnaire, n	57	32
Completion rate (%) [a]	41.0	23.2
Adjusted completion rate (%) [b]	91.9	97.0

Source: Listing 16.2.6.6.1, 16.2.6.6.2, 16.2.6.6.3. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients in study at relevant visits in relevant treatment arm.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-comp.sas 22APR2024 22:42 t-14-02-06-01-01-b-qs-comp-itts-fa.rtf

Table 14.2.6.1.1.b:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation without Irinotecan

Questionnaire: EQ-5D VAS

Visit	Tislelizumab (N = 139)	ICC (N = 138)
Cycle 6		
Patients in study at visit, n	55	27
Patients complete questionnaire, n	55	25
Completion rate (%) [a]	39.6	18.1
Adjusted completion rate (%) [b]	100.0	92.6
End of Treatment		
Patients in study at visit, n	128	137
Patients complete questionnaire, n	38	46
Completion rate (%) [a]	27.3	33.3
Adjusted completion rate (%) [b]	29.7	33.6
Safety Follow-up		
Patients in study at visit, n	82	77
Patients complete questionnaire, n	62	61
Completion rate (%) [a]	44.6	44.2
Adjusted completion rate (%) [b]	75.6	79.2

Source: Listing 16.2.6.6.1, 16.2.6.6.2, 16.2.6.6.3. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients in study at relevant visits in relevant treatment arm.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-comp.sas 22APR2024 22:42 t-14-02-06-01-01-b-qs-comp-itts-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: QLQ-C30 index-score

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	239		246	
	Mean (SD)	16.2 (12.28)		18.3 (13.86)	
	Median	13.8		14.8	
	Min, Max	0, 88		0, 74	
Cycle 1	n	139	131	133	129
	Mean (SD)	17.1 (13.34)	0.6 (6.07)	19.7 (13.94)	1.5 (7.71)
	Median	13.7	0.4	15.9	1.6
	Min, Max	0, 89	-23, 23	0, 65	-25, 20
Cycle 2	n	220	208	174	171
	Mean (SD)	17.5 (14.80)	2.1 (9.66)	21.0 (15.06)	4.0 (10.32)
	Median	13.1	0.7	17.0	2.7
	Min, Max	0, 93	-28, 50	0, 70	-28, 46
Cycle 3	n	180	170	92	89
	Mean (SD)	16.7 (13.40)	2.2 (9.33)	18.0 (14.12)	1.8 (9.33)
	Median	13.1	0.5	15.1	1.1
	Min, Max	0, 67	-19, 45	0, 65	-34, 24

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: QLQ-C30 index-score

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	147	138	77	74
	Mean (SD)	14.9 (12.81)	1.0 (10.06)	19.7 (14.22)	4.1 (11.17)
	Median	11.4	0.0	16.3	2.5
	Min, Max	0, 63	-26, 41	0, 60	-21, 44
Cycle 5	n	107	102	45	43
	Mean (SD)	12.5 (9.55)	-0.6 (7.96)	15.6 (11.62)	2.5 (11.25)
	Median	10.5	-0.4	13.7	1.2
	Min, Max	0, 39	-26, 30	2, 41	-38, 28
Cycle 6	n	98	93	38	36
	Mean (SD)	13.2 (10.54)	0.2 (8.28)	16.9 (12.18)	4.8 (9.38)
	Median	10.8	-0.8	14.3	3.1
	Min, Max	0, 49	-20, 28	1, 51	-15, 28
End of Treatment	n	71	69	83	81
	Mean (SD)	26.8 (19.60)	11.4 (15.14)	26.2 (17.28)	10.9 (11.56)
	Median	20.9	8.1	25.6	8.9
	Min, Max	1, 71	-10, 59	0, 75	-8, 37

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: QLQ-C30 index-score

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	104	100	96	95
	Mean (SD)	24.9 (18.72)	9.0 (14.87)	26.4 (17.73)	9.8 (12.82)
	Median	19.1	5.6	22.3	8.1
	Min, Max	1, 89	-21, 62	0, 79	-23, 50
Worst Post-Baseline Value	n	245	229	227	220
	Mean (SD)	26.1 (17.92)	10.3 (13.40)	29.3 (17.34)	11.3 (12.38)
	Median	20.9	7.0	26.7	9.6
	Min, Max	1, 93	-23, 62	0, 79	-28, 50

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Global health status / QoL

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	241		247	
	Mean (SD)	66.7 (19.34)		67.3 (19.12)	
	Median	66.7		66.7	
	Min, Max	8, 100		0, 100	
Cycle 1	n	140	133	133	130
	Mean (SD)	66.4 (18.95)	-1.1 (13.66)	65.1 (18.18)	-2.4 (15.30)
	Median	66.7	0.0	66.7	0.0
	Min, Max	17, 100	-58, 33	17, 100	-58, 33
Cycle 2	n	222	211	174	171
	Mean (SD)	66.0 (19.78)	-1.9 (16.03)	62.2 (20.29)	-5.6 (17.78)
	Median	66.7	0.0	66.7	0.0
	Min, Max	0, 100	-67, 50	0, 100	-67, 42
Cycle 3	n	181	172	92	90
	Mean (SD)	67.0 (18.89)	-1.7 (14.45)	69.2 (16.28)	1.3 (17.88)
	Median	66.7	0.0	66.7	0.0
	Min, Max	0, 100	-42, 33	17, 100	-33, 83

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Global health status / QoL

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	147	139	77	75
	Mean (SD)	70.2 (17.03)	0.5 (16.14)	64.3 (18.33)	-3.8 (17.13)
	Median	66.7	0.0	66.7	0.0
	Min, Max	25, 100	-42, 33	0, 100	-67, 33
Cycle 5	n	108	103	45	43
	Mean (SD)	73.1 (15.35)	2.1 (15.86)	69.6 (16.01)	-1.4 (17.15)
	Median	66.7	0.0	66.7	0.0
	Min, Max	33, 100	-50, 50	33, 100	-33, 50
Cycle 6	n	99	94	38	36
	Mean (SD)	72.6 (17.17)	1.9 (16.45)	66.0 (14.55)	-6.3 (14.82)
	Median	75.0	0.0	66.7	-8.3
	Min, Max	25, 100	-33, 42	42, 100	-42, 25
End of Treatment	n	74	72	83	81
	Mean (SD)	52.4 (23.02)	-13.7 (20.09)	54.9 (21.86)	-14.2 (18.18)
	Median	50.0	-16.7	50.0	-16.7
	Min, Max	0, 100	-83, 33	0, 100	-67, 25

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Global health status / QoL

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	105	101	96	95
	Mean (SD)	57.0 (22.29)	-9.7 (19.40)	56.2 (22.30)	-11.7 (21.79)
	Median	58.3	-8.3	58.3	-8.3
	Min, Max	0, 100	-75, 33	0, 100	-75, 33
Worst Post-Baseline Value	n	245	231	227	221
	Mean (SD)	53.4 (21.91)	-14.0 (18.06)	51.5 (20.63)	-16.1 (19.60)
	Median	50.0	-16.7	50.0	-16.7
	Min, Max	0, 100	-83, 33	0, 100	-75, 42

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Physical functioning

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	242		247	
	Mean (SD)	87.4 (13.88)		84.4 (16.59)	
	Median	93.3		86.7	
	Min, Max	33, 100		0, 100	
Cycle 1	n	140	133	134	131
	Mean (SD)	87.4 (15.46)	-0.5 (9.22)	83.1 (16.40)	-2.3 (10.18)
	Median	93.3	0.0	86.7	0.0
	Min, Max	20, 100	-53, 27	20, 100	-33, 27
Cycle 2	n	222	211	174	171
	Mean (SD)	84.5 (18.07)	-4.0 (13.24)	79.8 (20.31)	-6.5 (15.62)
	Median	86.7	0.0	86.7	0.0
	Min, Max	0, 100	-60, 27	0, 100	-80, 33
Cycle 3	n	181	172	92	90
	Mean (SD)	85.4 (17.11)	-4.5 (13.67)	81.4 (19.34)	-5.4 (15.77)
	Median	86.7	0.0	86.7	0.0
	Min, Max	0, 100	-67, 20	27, 100	-60, 47

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Physical functioning

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	147	139	77	75
	Mean (SD)	87.6 (14.63)	-3.4 (11.75)	81.5 (19.24)	-5.9 (14.70)
	Median	93.3	0.0	86.7	0.0
	Min, Max	33, 100	-60, 20	20, 100	-60, 27
Cycle 5	n	108	103	45	43
	Mean (SD)	89.9 (13.84)	-1.6 (10.93)	86.4 (13.48)	-2.9 (13.36)
	Median	93.3	0.0	86.7	0.0
	Min, Max	33, 100	-47, 20	47, 100	-33, 40
Cycle 6	n	99	94	38	36
	Mean (SD)	89.8 (13.45)	-1.9 (10.33)	84.0 (14.08)	-5.7 (12.05)
	Median	93.3	0.0	86.7	0.0
	Min, Max	40, 100	-40, 20	47, 100	-33, 20
End of Treatment	n	74	72	83	81
	Mean (SD)	72.7 (27.01)	-15.5 (22.98)	71.0 (26.59)	-17.2 (21.91)
	Median	80.0	-13.3	80.0	-13.3
	Min, Max	7, 100	-80, 13	0, 100	-80, 13

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Physical functioning

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	106	102	96	95
	Mean (SD)	76.7 (23.70)	-11.6 (20.38)	72.7 (24.53)	-14.0 (19.88)
	Median	86.7	-6.7	80.0	-6.7
	Min, Max	0, 100	-93, 20	0, 100	-67, 20
Worst Post-Baseline Value	n	246	232	228	222
	Mean (SD)	74.0 (23.84)	-14.4 (19.82)	68.2 (24.76)	-16.8 (20.07)
	Median	80.0	-6.7	80.0	-13.3
	Min, Max	0, 100	-93, 20	0, 100	-80, 27

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Role functioning

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	242		247	
	Mean (SD)	88.8 (18.13)		84.7 (23.39)	
	Median	100.0		100.0	
	Min, Max	0, 100		0, 100	
Cycle 1	n	140	133	134	131
	Mean (SD)	85.4 (21.01)	-5.4 (15.96)	83.1 (23.66)	-2.2 (18.07)
	Median	100.0	0.0	100.0	0.0
	Min, Max	0, 100	-100, 33	0, 100	-67, 67
Cycle 2	n	222	211	174	171
	Mean (SD)	83.9 (24.35)	-6.2 (19.08)	81.0 (26.78)	-6.4 (20.95)
	Median	100.0	0.0	100.0	0.0
	Min, Max	0, 100	-100, 33	0, 100	-100, 67
Cycle 3	n	181	172	92	90
	Mean (SD)	86.3 (21.88)	-4.7 (19.93)	79.9 (27.13)	-7.6 (23.46)
	Median	100.0	0.0	100.0	0.0
	Min, Max	0, 100	-100, 50	0, 100	-83, 83

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Role functioning

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	147	139	77	75
	Mean (SD)	86.8 (20.57)	-5.6 (19.51)	77.7 (27.92)	-10.2 (25.54)
	Median	100.0	0.0	83.3	0.0
	Min, Max	0, 100	-100, 33	0, 100	-100, 33
Cycle 5	n	108	103	45	43
	Mean (SD)	89.0 (15.81)	-2.6 (14.15)	86.3 (18.22)	-4.3 (23.60)
	Median	100.0	0.0	100.0	0.0
	Min, Max	33, 100	-33, 33	33, 100	-67, 83
Cycle 6	n	99	94	38	36
	Mean (SD)	88.0 (16.84)	-3.9 (14.75)	84.2 (16.87)	-6.0 (16.97)
	Median	100.0	0.0	83.3	0.0
	Min, Max	33, 100	-33, 50	50, 100	-33, 33
End of Treatment	n	74	72	83	81
	Mean (SD)	67.1 (32.87)	-22.5 (29.09)	68.9 (31.10)	-20.2 (26.97)
	Median	66.7	-16.7	66.7	-16.7
	Min, Max	0, 100	-100, 33	0, 100	-100, 33

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Role functioning

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	106	102	96	95
	Mean (SD)	73.7 (29.72)	-17.0 (26.11)	69.8 (29.05)	-18.4 (24.61)
	Median	83.3	0.0	66.7	-16.7
	Min, Max	0, 100	-100, 33	0, 100	-100, 33
Worst Post-Baseline Value	n	246	232	228	222
	Mean (SD)	69.2 (30.19)	-20.5 (26.12)	65.4 (31.34)	-20.3 (27.37)
	Median	66.7	-16.7	66.7	-16.7
	Min, Max	0, 100	-100, 33	0, 100	-100, 67

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Emotional functioning

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	242		247	
	Mean (SD)	85.8 (15.70)		85.0 (17.62)	
	Median	91.7		91.7	
	Min, Max	0, 100		17, 100	
Cycle 1	n	140	133	133	130
	Mean (SD)	86.0 (15.17)	-0.8 (10.50)	83.1 (17.71)	-0.8 (13.98)
	Median	91.7	0.0	83.3	0.0
	Min, Max	0, 100	-42, 33	17, 100	-42, 50
Cycle 2	n	222	211	174	171
	Mean (SD)	86.6 (17.38)	-0.6 (12.09)	84.8 (17.11)	-1.2 (15.02)
	Median	91.7	0.0	91.7	0.0
	Min, Max	0, 100	-42, 42	8, 100	-75, 58
Cycle 3	n	181	172	92	90
	Mean (SD)	86.1 (16.53)	-2.0 (14.30)	85.5 (19.53)	-0.8 (14.84)
	Median	91.7	0.0	91.7	0.0
	Min, Max	17, 100	-58, 58	17, 100	-58, 58

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Emotional functioning

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	147	139	77	75
	Mean (SD)	88.5 (14.99)	0.0 (13.42)	85.7 (19.54)	-0.8 (14.45)
	Median	91.7	0.0	91.7	0.0
	Min, Max	33, 100	-42, 50	17, 100	-67, 25
Cycle 5	n	108	103	45	43
	Mean (SD)	90.1 (13.39)	0.3 (12.88)	90.2 (14.13)	1.2 (18.60)
	Median	100.0	0.0	100.0	0.0
	Min, Max	50, 100	-42, 42	58, 100	-42, 75
Cycle 6	n	99	94	38	36
	Mean (SD)	89.1 (14.27)	-0.7 (13.31)	88.4 (17.17)	-2.5 (17.46)
	Median	91.7	0.0	100.0	0.0
	Min, Max	33, 100	-42, 42	33, 100	-67, 33
End of Treatment	n	74	72	83	81
	Mean (SD)	76.8 (22.08)	-7.3 (17.47)	76.4 (24.69)	-8.2 (18.56)
	Median	75.0	0.0	83.3	0.0
	Min, Max	17, 100	-58, 25	0, 100	-83, 25

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Emotional functioning

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	105	101	96	95
	Mean (SD)	78.3 (22.78)	-8.1 (21.16)	78.4 (23.34)	-8.2 (20.48)
	Median	83.3	0.0	83.3	0.0
	Min, Max	8, 100	-92, 58	0, 100	-92, 25
Worst Post-Baseline Value	n	245	231	227	221
	Mean (SD)	75.4 (21.99)	-11.5 (17.79)	74.4 (22.58)	-10.6 (19.18)
	Median	75.0	-8.3	75.0	-8.3
	Min, Max	0, 100	-92, 33	0, 100	-92, 50

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Cognitive functioning

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	242		247	
	Mean (SD)	90.3 (14.20)		88.5 (17.04)	
	Median	100.0		100.0	
	Min, Max	0, 100		0, 100	
Cycle 1	n	140	133	133	130
	Mean (SD)	88.3 (14.24)	-1.1 (11.27)	87.1 (16.99)	-2.4 (14.84)
	Median	83.3	0.0	83.3	0.0
	Min, Max	17, 100	-33, 33	17, 100	-50, 50
Cycle 2	n	222	211	174	171
	Mean (SD)	88.4 (16.73)	-2.1 (12.95)	87.5 (16.15)	-1.6 (14.15)
	Median	100.0	0.0	100.0	0.0
	Min, Max	0, 100	-50, 50	33, 100	-33, 33
Cycle 3	n	181	172	92	90
	Mean (SD)	89.0 (16.04)	-2.9 (14.57)	88.0 (19.19)	-0.9 (16.45)
	Median	100.0	0.0	100.0	0.0
	Min, Max	0, 100	-67, 50	0, 100	-67, 50

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Cognitive functioning

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	147	139	77	75
	Mean (SD)	89.5 (13.80)	-1.8 (12.80)	85.5 (20.48)	-4.2 (18.40)
	Median	100.0	0.0	100.0	0.0
	Min, Max	50, 100	-50, 33	0, 100	-67, 33
Cycle 5	n	108	103	45	43
	Mean (SD)	89.7 (15.07)	-2.9 (14.84)	91.1 (12.10)	-0.4 (11.78)
	Median	100.0	0.0	100.0	0.0
	Min, Max	17, 100	-67, 33	50, 100	-33, 33
Cycle 6	n	99	94	38	36
	Mean (SD)	88.7 (15.21)	-4.3 (15.05)	89.9 (14.26)	-2.3 (13.31)
	Median	100.0	0.0	100.0	0.0
	Min, Max	17, 100	-67, 33	50, 100	-33, 33
End of Treatment	n	74	72	83	81
	Mean (SD)	78.4 (21.50)	-10.9 (18.38)	81.3 (21.21)	-8.2 (16.06)
	Median	83.3	0.0	83.3	0.0
	Min, Max	33, 100	-67, 33	0, 100	-50, 33

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Cognitive functioning

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	105	101	96	95
	Mean (SD)	80.8 (21.65)	-7.1 (20.46)	83.0 (17.93)	-6.0 (17.68)
	Median	83.3	0.0	83.3	0.0
	Min, Max	17, 100	-67, 50	33, 100	-50, 50
Worst Post-Baseline Value	n	245	231	227	221
	Mean (SD)	78.0 (21.48)	-12.8 (17.97)	78.3 (20.79)	-10.3 (17.71)
	Median	83.3	0.0	83.3	0.0
	Min, Max	0, 100	-67, 33	0, 100	-67, 33

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Social functioning

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	242		247	
	Mean (SD)	81.7 (20.11)		79.4 (24.10)	
	Median	83.3		83.3	
	Min, Max	0, 100		0, 100	
Cycle 1	n	139	132	133	130
	Mean (SD)	81.1 (21.44)	-0.9 (17.87)	74.4 (28.10)	-3.1 (22.33)
	Median	83.3	0.0	83.3	0.0
	Min, Max	0, 100	-50, 67	0, 100	-83, 67
Cycle 2	n	222	211	174	171
	Mean (SD)	79.1 (25.46)	-3.6 (20.36)	76.2 (27.66)	-3.1 (24.25)
	Median	83.3	0.0	83.3	0.0
	Min, Max	0, 100	-67, 50	0, 100	-100, 67
Cycle 3	n	181	172	92	90
	Mean (SD)	83.4 (19.36)	-0.9 (18.84)	80.4 (24.78)	-0.4 (23.43)
	Median	83.3	0.0	83.3	0.0
	Min, Max	0, 100	-67, 67	0, 100	-83, 50

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Social functioning

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	147	139	77	75
	Mean (SD)	83.2 (20.41)	-1.7 (20.19)	76.6 (25.97)	-5.6 (24.71)
	Median	83.3	0.0	83.3	0.0
	Min, Max	0, 100	-83, 67	0, 100	-100, 33
Cycle 5	n	108	103	45	43
	Mean (SD)	86.1 (16.51)	0.5 (17.06)	81.5 (23.36)	-1.9 (26.03)
	Median	100.0	0.0	83.3	0.0
	Min, Max	17, 100	-50, 50	0, 100	-67, 83
Cycle 6	n	99	94	38	36
	Mean (SD)	86.7 (16.32)	-0.0 (15.84)	79.4 (22.07)	-5.1 (22.82)
	Median	100.0	0.0	83.3	0.0
	Min, Max	50, 100	-50, 33	33, 100	-50, 50
End of Treatment	n	74	72	83	81
	Mean (SD)	68.9 (29.88)	-11.6 (27.36)	73.1 (28.73)	-11.3 (27.11)
	Median	66.7	0.0	66.7	0.0
	Min, Max	0, 100	-100, 33	0, 100	-100, 33

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Social functioning

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	105	101	96	95
	Mean (SD)	72.9 (29.35)	-9.9 (30.38)	65.8 (31.19)	-17.0 (26.74)
	Median	83.3	0.0	66.7	-16.7
	Min, Max	0, 100	-100, 67	0, 100	-100, 33
Worst Post-Baseline Value	n	245	231	227	221
	Mean (SD)	66.3 (28.05)	-15.8 (25.00)	60.8 (29.99)	-18.9 (24.95)
	Median	66.7	-16.7	66.7	-16.7
	Min, Max	0, 100	-100, 50	0, 100	-100, 50

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Fatigue

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	242		247	
	Mean (SD)	23.3 (20.18)		27.0 (22.39)	
	Median	22.2		22.2	
	Min, Max	0, 100		0, 100	
Cycle 1	n	140	133	134	131
	Mean (SD)	26.0 (20.64)	3.7 (14.16)	29.1 (22.50)	1.5 (14.44)
	Median	22.2	0.0	33.3	0.0
	Min, Max	0, 100	-33, 61	0, 100	-44, 33
Cycle 2	n	222	211	174	171
	Mean (SD)	26.2 (23.26)	4.5 (17.34)	31.7 (22.78)	7.1 (17.61)
	Median	22.2	0.0	33.3	0.0
	Min, Max	0, 100	-33, 89	0, 100	-56, 56
Cycle 3	n	181	172	92	90
	Mean (SD)	24.7 (22.02)	4.1 (17.45)	29.5 (24.23)	6.9 (21.17)
	Median	22.2	0.0	33.3	0.0
	Min, Max	0, 100	-33, 78	0, 100	-100, 89

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Fatigue

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	147	139	77	75
	Mean (SD)	21.9 (22.03)	3.0 (17.89)	33.8 (25.90)	12.3 (21.11)
	Median	22.2	0.0	33.3	11.1
	Min, Max	0, 100	-33, 67	0, 100	-33, 67
Cycle 5	n	108	103	45	43
	Mean (SD)	17.5 (18.49)	0.3 (15.59)	22.7 (19.95)	3.9 (23.24)
	Median	11.1	0.0	22.2	0.0
	Min, Max	0, 100	-33, 44	0, 78	-89, 44
Cycle 6	n	99	94	38	36
	Mean (SD)	18.5 (16.95)	1.4 (14.78)	25.0 (18.16)	9.4 (16.31)
	Median	22.2	0.0	33.3	11.1
	Min, Max	0, 67	-33, 33	0, 67	-33, 33
End of Treatment	n	74	72	83	81
	Mean (SD)	40.4 (30.97)	16.4 (23.66)	41.8 (27.03)	19.5 (22.81)
	Median	33.3	11.1	33.3	22.2
	Min, Max	0, 100	-22, 89	0, 100	-33, 89

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Fatigue

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	106	102	96	95
	Mean (SD)	36.1 (28.43)	13.7 (23.98)	40.6 (26.63)	17.5 (22.67)
	Median	33.3	11.1	33.3	22.2
	Min, Max	0, 100	-44, 100	0, 100	-44, 78
Worst Post-Baseline Value	n	246	232	228	222
	Mean (SD)	40.2 (26.77)	18.4 (21.26)	45.9 (26.71)	19.4 (22.81)
	Median	33.3	11.1	33.3	22.2
	Min, Max	0, 100	-33, 100	0, 100	-33, 89

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Nausea and vomiting

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	242		247	
	Mean (SD)	7.2 (13.97)		8.4 (17.13)	
	Median	0.0		0.0	
	Min, Max	0, 100		0, 100	
Cycle 1	n	140	133	134	131
	Mean (SD)	8.9 (19.01)	1.6 (13.74)	7.7 (16.05)	-1.4 (13.56)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-50, 83	0, 100	-33, 67
Cycle 2	n	221	210	174	171
	Mean (SD)	10.1 (20.56)	3.3 (18.84)	11.4 (17.26)	4.4 (16.63)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-50, 100	0, 83	-67, 67
Cycle 3	n	180	171	92	90
	Mean (SD)	9.7 (19.53)	4.1 (18.86)	8.0 (15.91)	2.2 (14.18)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 83	-33, 67

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Nausea and vomiting

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	147	139	77	75
	Mean (SD)	7.0 (15.96)	1.6 (14.73)	7.8 (13.68)	2.7 (14.25)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-50, 67	0, 50	-33, 33
Cycle 5	n	108	103	45	43
	Mean (SD)	3.5 (8.84)	-1.0 (10.90)	10.7 (15.14)	6.2 (16.68)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 33	-67, 33	0, 67	-33, 33
Cycle 6	n	99	94	38	36
	Mean (SD)	4.2 (10.47)	0.5 (11.84)	9.2 (17.20)	5.6 (18.69)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 50	-67, 33	0, 67	-33, 67
End of Treatment	n	73	71	83	81
	Mean (SD)	16.4 (27.29)	8.5 (23.38)	12.9 (21.98)	6.2 (19.27)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-50, 83	0, 100	-50, 67

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Nausea and vomiting

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	106	102	96	95
	Mean (SD)	15.3 (25.10)	7.4 (23.75)	10.6 (18.75)	3.5 (22.00)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 83	-100, 83
Worst Post-Baseline Value	n	246	232	228	222
	Mean (SD)	18.4 (26.69)	12.0 (23.74)	18.2 (22.70)	9.5 (21.40)
	Median	0.0	0.0	16.7	0.0
	Min, Max	0, 100	-50, 100	0, 100	-100, 83

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Pain

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	242		247	
	Mean (SD)	21.1 (22.51)		23.3 (26.74)	
	Median	16.7		16.7	
	Min, Max	0, 100		0, 100	
Cycle 1	n	140	133	134	131
	Mean (SD)	23.9 (23.16)	2.5 (15.28)	24.1 (25.08)	1.4 (15.75)
	Median	16.7	0.0	16.7	0.0
	Min, Max	0, 100	-33, 67	0, 100	-50, 50
Cycle 2	n	222	211	174	171
	Mean (SD)	21.5 (23.18)	2.0 (16.90)	24.0 (25.69)	4.0 (22.48)
	Median	16.7	0.0	16.7	0.0
	Min, Max	0, 100	-33, 83	0, 100	-67, 83
Cycle 3	n	181	172	92	90
	Mean (SD)	20.8 (20.85)	2.3 (18.41)	19.0 (24.53)	2.4 (20.07)
	Median	16.7	0.0	16.7	0.0
	Min, Max	0, 100	-67, 67	0, 100	-67, 67

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Pain

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	147	139	77	75
	Mean (SD)	17.3 (19.69)	-0.4 (19.08)	22.1 (25.71)	6.9 (23.74)
	Median	16.7	0.0	16.7	0.0
	Min, Max	0, 67	-67, 67	0, 100	-33, 83
Cycle 5	n	108	103	45	43
	Mean (SD)	14.7 (17.90)	-2.1 (18.03)	14.1 (17.39)	2.3 (18.40)
	Median	8.3	0.0	0.0	0.0
	Min, Max	0, 67	-67, 50	0, 67	-33, 50
Cycle 6	n	99	94	38	36
	Mean (SD)	15.2 (19.65)	-2.0 (20.43)	16.7 (19.76)	6.0 (18.32)
	Median	0.0	0.0	16.7	0.0
	Min, Max	0, 83	-67, 83	0, 67	-33, 50
End of Treatment	n	74	72	83	81
	Mean (SD)	36.0 (31.58)	16.2 (28.66)	27.3 (26.75)	10.1 (22.31)
	Median	33.3	16.7	16.7	0.0
	Min, Max	0, 100	-33, 100	0, 100	-83, 67

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Pain

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	106	102	96	95
	Mean (SD)	31.1 (26.44)	12.7 (23.59)	30.2 (28.85)	10.7 (24.42)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-50, 100
Worst Post-Baseline Value	n	246	232	228	222
	Mean (SD)	36.3 (26.81)	16.2 (23.89)	37.9 (29.55)	15.5 (24.05)
	Median	33.3	16.7	33.3	16.7
	Min, Max	0, 100	-33, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Dyspnoea

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	241		247	
	Mean (SD)	13.6 (19.97)		14.8 (21.57)	
	Median	0.0		0.0	
	Min, Max	0, 100		0, 100	
Cycle 1	n	140	132	134	131
	Mean (SD)	14.8 (20.10)	1.8 (16.12)	15.9 (21.52)	0.0 (18.95)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 67	0, 100	-67, 67
Cycle 2	n	222	210	174	171
	Mean (SD)	17.1 (23.24)	4.6 (18.30)	17.8 (21.70)	4.7 (21.18)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 67	0, 100	-33, 67
Cycle 3	n	181	172	92	90
	Mean (SD)	15.5 (22.36)	3.7 (20.85)	13.8 (18.59)	4.1 (18.58)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 67	-33, 67

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Dyspnoea

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	147	139	77	75
	Mean (SD)	14.3 (20.27)	2.9 (20.65)	14.7 (20.59)	4.4 (19.25)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-33, 67	0, 67	-33, 33
Cycle 5	n	108	103	45	43
	Mean (SD)	11.1 (18.23)	-0.3 (16.50)	15.6 (24.20)	4.7 (23.66)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-33, 33	0, 100	-33, 67
Cycle 6	n	99	94	38	36
	Mean (SD)	11.4 (19.73)	-0.4 (18.61)	18.4 (22.86)	8.3 (20.12)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 33	0, 67	-33, 33
End of Treatment	n	74	72	83	81
	Mean (SD)	25.2 (28.57)	13.9 (27.83)	25.3 (28.79)	15.2 (27.41)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-33, 100

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Dyspnoea

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	106	102	96	95
	Mean (SD)	23.0 (24.50)	8.8 (24.79)	27.1 (29.14)	13.7 (28.97)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-67, 100	0, 100	-33, 100
Worst Post-Baseline Value	n	246	231	228	222
	Mean (SD)	28.5 (27.33)	15.9 (24.24)	31.1 (27.99)	16.1 (27.77)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-33, 100

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Insomnia

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	241		247	
	Mean (SD)	17.6 (25.10)		22.9 (26.29)	
	Median	0.0		33.3	
	Min, Max	0, 100		0, 100	
Cycle 1	n	140	132	134	131
	Mean (SD)	15.2 (22.04)	-1.0 (18.85)	23.1 (25.93)	2.0 (20.15)
	Median	0.0	0.0	33.3	0.0
	Min, Max	0, 100	-67, 33	0, 100	-67, 67
Cycle 2	n	222	210	174	171
	Mean (SD)	16.2 (23.67)	1.4 (23.13)	21.1 (27.11)	-0.0 (23.43)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 67
Cycle 3	n	181	172	92	90
	Mean (SD)	17.1 (24.75)	2.7 (23.48)	16.7 (24.46)	-2.6 (21.91)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 33

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Insomnia

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	147	139	77	75
	Mean (SD)	14.1 (21.34)	-0.0 (24.08)	18.6 (24.48)	-0.9 (23.87)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 67	0, 100	-67, 67
Cycle 5	n	108	103	45	43
	Mean (SD)	12.0 (19.04)	-1.6 (24.87)	12.6 (19.19)	-1.6 (20.51)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-67, 67	0, 67	-67, 33
Cycle 6	n	99	94	38	36
	Mean (SD)	14.5 (22.42)	0.4 (25.63)	14.0 (22.77)	1.9 (19.43)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 67	0, 67	-33, 67
End of Treatment	n	74	72	83	81
	Mean (SD)	25.7 (31.96)	11.6 (28.06)	27.3 (30.42)	7.8 (31.74)
	Median	0.0	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Insomnia

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	106	102	96	95
	Mean (SD)	26.1 (32.20)	11.8 (29.16)	28.1 (31.09)	5.3 (30.49)
	Median	0.0	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100
Worst Post-Baseline Value	n	246	231	228	222
	Mean (SD)	31.4 (29.75)	15.9 (27.59)	34.1 (30.57)	11.9 (29.14)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Appetite loss

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	241		246	
	Mean (SD)	19.2 (24.80)		19.4 (26.24)	
	Median	0.0		0.0	
	Min, Max	0, 100		0, 100	
Cycle 1	n	140	133	134	130
	Mean (SD)	18.6 (24.74)	-1.5 (21.66)	21.6 (27.50)	4.9 (22.39)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 100	0, 100	-67, 100
Cycle 2	n	220	209	174	171
	Mean (SD)	18.8 (27.60)	1.3 (25.50)	26.2 (29.02)	8.4 (24.28)
	Median	0.0	0.0	33.3	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 100
Cycle 3	n	181	171	92	89
	Mean (SD)	20.6 (26.84)	3.5 (25.32)	17.4 (25.90)	0.4 (28.20)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-100, 100

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Appetite loss

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	147	138	77	74
	Mean (SD)	13.8 (20.95)	-0.5 (25.15)	21.2 (27.52)	6.3 (26.27)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 67	0, 100	-67, 100
Cycle 5	n	107	102	45	43
	Mean (SD)	9.7 (17.74)	-4.2 (23.77)	15.6 (24.20)	4.7 (31.36)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 100	0, 100	-100, 100
Cycle 6	n	98	93	38	36
	Mean (SD)	10.2 (16.86)	-5.0 (25.03)	14.9 (24.13)	7.4 (27.73)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-100, 67	0, 100	-67, 100
End of Treatment	n	72	70	83	81
	Mean (SD)	33.3 (34.03)	16.2 (33.45)	30.5 (29.08)	16.5 (29.40)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Appetite loss

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	105	101	96	95
	Mean (SD)	31.7 (31.14)	15.2 (31.10)	28.8 (33.38)	13.3 (28.10)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-33, 100
Worst Post-Baseline Value	n	246	231	228	221
	Mean (SD)	36.7 (32.19)	18.6 (31.16)	38.6 (30.52)	20.8 (26.19)
	Median	33.3	0.0	33.3	33.3
	Min, Max	0, 100	-100, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Constipation

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	242		247	
	Mean (SD)	13.1 (22.90)		13.8 (22.48)	
	Median	0.0		0.0	
	Min, Max	0, 100		0, 100	
Cycle 1	n	140	133	134	131
	Mean (SD)	14.3 (24.04)	0.3 (18.58)	12.4 (20.71)	0.3 (17.29)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 67	0, 100	-67, 67
Cycle 2	n	222	211	174	171
	Mean (SD)	14.0 (23.73)	1.6 (22.48)	12.1 (20.93)	1.4 (20.88)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 67	0, 100	-67, 100
Cycle 3	n	181	172	92	90
	Mean (SD)	13.6 (23.27)	1.9 (24.90)	13.0 (21.52)	2.6 (18.17)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-33, 67

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Constipation

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	147	139	77	75
	Mean (SD)	12.0 (22.05)	0.7 (23.90)	12.1 (22.24)	0.9 (22.58)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 100
Cycle 5	n	108	103	45	43
	Mean (SD)	9.0 (17.42)	0.6 (17.45)	11.1 (21.32)	1.6 (16.19)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 33	0, 67	-33, 67
Cycle 6	n	99	94	38	36
	Mean (SD)	10.1 (18.72)	1.4 (20.69)	11.4 (26.02)	2.8 (20.12)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-33, 67
End of Treatment	n	73	71	83	81
	Mean (SD)	16.4 (23.65)	2.3 (25.40)	16.1 (22.91)	5.3 (26.59)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-100, 67

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Constipation

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	106	102	96	95
	Mean (SD)	20.1 (28.98)	5.9 (29.07)	14.9 (21.56)	1.8 (23.50)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 67
Worst Post-Baseline Value	n	246	232	228	222
	Mean (SD)	27.2 (30.77)	14.9 (27.34)	23.4 (26.52)	10.1 (25.05)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-67, 100	0, 100	-100, 100

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Diarrhea

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	242		247	
	Mean (SD)	6.5 (15.16)		5.9 (14.44)	
	Median	0.0		0.0	
	Min, Max	0, 100		0, 67	
Cycle 1	n	140	133	133	130
	Mean (SD)	4.5 (12.13)	-2.0 (12.14)	6.3 (14.30)	0.8 (12.77)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-33, 33	0, 67	-67, 33
Cycle 2	n	222	211	174	171
	Mean (SD)	5.7 (15.45)	-0.8 (17.35)	13.0 (21.72)	6.6 (23.04)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 100
Cycle 3	n	181	172	92	90
	Mean (SD)	5.3 (13.23)	-1.2 (16.08)	10.9 (17.89)	4.4 (18.83)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-67, 67	0, 67	-33, 67

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Diarrhea

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	147	139	77	75
	Mean (SD)	5.2 (13.35)	-1.2 (16.74)	10.4 (18.93)	3.1 (18.32)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-67, 67	0, 100	-33, 100
Cycle 5	n	108	103	45	43
	Mean (SD)	4.9 (13.53)	-1.3 (15.43)	10.4 (17.15)	6.2 (16.68)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-33, 67	0, 67	-33, 33
Cycle 6	n	99	94	38	36
	Mean (SD)	8.1 (17.23)	2.1 (19.44)	12.3 (18.04)	8.3 (16.67)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-33, 67	0, 67	-33, 33
End of Treatment	n	73	71	83	81
	Mean (SD)	7.8 (16.22)	-0.0 (19.52)	10.0 (19.29)	2.9 (23.69)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-67, 67	0, 100	-67, 100

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Diarrhea

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	105	101	96	95
	Mean (SD)	6.3 (17.35)	-1.3 (17.59)	10.4 (20.70)	4.9 (22.26)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 67	0, 100	-67, 67
Worst Post-Baseline Value	n	245	231	227	221
	Mean (SD)	12.5 (21.70)	6.1 (20.89)	18.4 (24.71)	12.1 (24.72)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Financial difficulties

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	242		247	
	Mean (SD)	26.9 (30.36)		30.2 (31.87)	
	Median	33.3		33.3	
	Min, Max	0, 100		0, 100	
Cycle 1	n	139	132	133	130
	Mean (SD)	27.1 (28.82)	-1.8 (21.92)	30.3 (30.56)	0.5 (23.10)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-67, 67	0, 100	-67, 67
Cycle 2	n	222	211	174	171
	Mean (SD)	24.8 (28.92)	-1.6 (22.95)	29.7 (30.30)	-0.6 (26.68)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-100, 67	0, 100	-67, 67
Cycle 3	n	181	172	92	90
	Mean (SD)	23.8 (26.88)	-1.9 (23.83)	26.1 (28.31)	-3.7 (20.87)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-100, 100	0, 100	-67, 33

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Financial difficulties

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	147	139	77	75
	Mean (SD)	23.1 (28.30)	-3.1 (26.89)	26.0 (28.42)	-4.4 (27.58)
	Median	0.0	0.0	33.3	0.0
	Min, Max	0, 100	-67, 100	0, 100	-100, 67
Cycle 5	n	108	103	45	43
	Mean (SD)	21.0 (27.57)	-4.2 (26.68)	26.7 (26.21)	-0.8 (27.69)
	Median	0.0	0.0	33.3	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 33
Cycle 6	n	99	94	38	36
	Mean (SD)	19.2 (26.12)	-4.3 (26.88)	22.8 (26.96)	-5.6 (29.28)
	Median	0.0	0.0	33.3	0.0
	Min, Max	0, 100	-100, 100	0, 100	-100, 33
End of Treatment	n	74	72	83	81
	Mean (SD)	29.7 (28.97)	7.4 (25.16)	28.1 (33.12)	0.8 (28.86)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-100, 67

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Financial difficulties

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	105	101	96	95
	Mean (SD)	28.9 (31.71)	0.0 (30.55)	30.9 (30.68)	1.4 (31.48)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-100, 100	0, 100	-100, 100
Worst Post-Baseline Value	n	245	231	227	221
	Mean (SD)	37.4 (31.82)	10.0 (25.67)	39.1 (32.61)	9.2 (25.24)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-qs-chg-c30-itt-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: QLQ-C30 index-score

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	127		132	
	Mean (SD)	16.1 (11.38)		17.8 (14.06)	
	Median	13.8		13.9	
	Min, Max	0, 50		0, 74	
Cycle 1	n	82	76	82	80
	Mean (SD)	16.8 (12.53)	1.1 (5.38)	19.9 (14.72)	2.0 (7.19)
	Median	14.2	0.4	15.4	1.6
	Min, Max	0, 52	-17, 23	0, 62	-14, 20
Cycle 2	n	123	112	97	96
	Mean (SD)	17.7 (15.15)	2.4 (10.16)	20.0 (15.21)	3.3 (9.15)
	Median	13.3	0.6	15.0	3.5
	Min, Max	0, 93	-19, 50	0, 69	-28, 33
Cycle 3	n	97	88	58	56
	Mean (SD)	17.5 (14.90)	2.6 (10.45)	17.1 (13.85)	1.2 (9.66)
	Median	13.1	0.0	11.4	0.9
	Min, Max	0, 67	-19, 45	0, 65	-34, 24

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: QLQ-C30 index-score

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	77	69	52	50
	Mean (SD)	15.5 (14.36)	1.4 (11.08)	20.9 (14.63)	5.3 (10.15)
	Median	10.5	0.0	17.2	3.3
	Min, Max	0, 63	-19, 41	0, 56	-12, 36
Cycle 5	n	55	50	32	31
	Mean (SD)	12.8 (10.35)	-0.6 (7.60)	15.9 (12.46)	2.1 (12.43)
	Median	10.6	-1.3	13.0	1.2
	Min, Max	0, 39	-22, 30	2, 41	-38, 28
Cycle 6	n	54	49	26	25
	Mean (SD)	13.5 (10.89)	0.3 (8.25)	16.5 (11.14)	4.3 (8.30)
	Median	12.1	-1.5	13.2	2.5
	Min, Max	0, 49	-16, 28	2, 38	-14, 18
End of Treatment	n	39	37	46	45
	Mean (SD)	31.4 (19.74)	15.1 (14.95)	26.1 (18.79)	12.1 (11.88)
	Median	30.3	9.7	23.7	11.8
	Min, Max	1, 71	-4, 59	0, 75	-8, 37

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: QLQ-C30 index-score

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	62	58	61	60
	Mean (SD)	29.0 (19.81)	11.5 (15.91)	24.7 (17.96)	9.6 (11.87)
	Median	27.8	8.0	20.7	8.3
	Min, Max	1, 89	-18, 62	0, 79	-19, 43
Worst Post-Baseline Value	n	136	124	128	124
	Mean (SD)	27.8 (18.67)	12.2 (14.07)	29.2 (17.67)	11.3 (12.07)
	Median	22.6	7.4	24.6	10.3
	Min, Max	1, 93	-13, 62	0, 79	-28, 43

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Global health status / QoL

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		133	
	Mean (SD)	67.1 (17.87)		66.9 (19.37)	
	Median	66.7		66.7	
	Min, Max	25, 100		0, 100	
Cycle 1	n	83	78	82	81
	Mean (SD)	66.6 (19.89)	-2.5 (13.50)	63.9 (18.93)	-3.0 (16.68)
	Median	66.7	0.0	66.7	0.0
	Min, Max	17, 100	-58, 25	17, 100	-58, 33
Cycle 2	n	123	113	97	96
	Mean (SD)	65.0 (20.05)	-3.1 (14.95)	62.8 (20.38)	-4.7 (17.18)
	Median	66.7	0.0	66.7	0.0
	Min, Max	0, 100	-33, 33	0, 100	-67, 42
Cycle 3	n	98	89	58	57
	Mean (SD)	65.7 (19.36)	-2.4 (14.55)	69.5 (17.14)	2.9 (20.01)
	Median	66.7	0.0	66.7	0.0
	Min, Max	0, 100	-42, 25	17, 100	-33, 83

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Global health status / QoL

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	77	69	52	51
	Mean (SD)	69.4 (17.75)	1.3 (15.03)	62.5 (17.19)	-3.6 (15.57)
	Median	66.7	0.0	66.7	0.0
	Min, Max	25, 100	-42, 33	25, 100	-42, 25
Cycle 5	n	56	51	32	31
	Mean (SD)	72.3 (16.06)	1.8 (15.57)	68.0 (16.27)	0.0 (18.63)
	Median	66.7	0.0	66.7	0.0
	Min, Max	33, 100	-50, 33	33, 100	-33, 50
Cycle 6	n	55	50	26	25
	Mean (SD)	72.9 (17.58)	2.3 (15.34)	66.3 (14.43)	-4.3 (15.24)
	Median	75.0	0.0	66.7	0.0
	Min, Max	25, 100	-33, 42	50, 100	-42, 25
End of Treatment	n	39	37	46	45
	Mean (SD)	45.5 (21.10)	-19.8 (21.19)	54.9 (23.28)	-13.7 (16.59)
	Median	50.0	-16.7	50.0	-16.7
	Min, Max	0, 83	-83, 17	0, 100	-42, 25

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Global health status / QoL

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	62	58	61	60
	Mean (SD)	52.3 (23.14)	-12.1 (20.84)	55.7 (23.40)	-12.9 (20.89)
	Median	50.0	-8.3	66.7	-8.3
	Min, Max	0, 100	-75, 25	0, 100	-67, 25
Worst Post-Baseline Value	n	136	125	128	125
	Mean (SD)	51.3 (22.36)	-16.5 (18.22)	51.6 (21.15)	-15.9 (19.11)
	Median	50.0	-16.7	50.0	-16.7
	Min, Max	0, 100	-83, 17	0, 100	-67, 42

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Physical functioning

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		133	
	Mean (SD)	87.8 (13.75)		83.7 (17.01)	
	Median	93.3		86.7	
	Min, Max	33, 100		0, 100	
Cycle 1	n	83	78	83	82
	Mean (SD)	87.5 (15.80)	-0.8 (10.42)	81.6 (16.93)	-2.7 (10.46)
	Median	93.3	0.0	86.7	0.0
	Min, Max	40, 100	-53, 20	20, 100	-33, 27
Cycle 2	n	123	113	97	96
	Mean (SD)	84.0 (18.48)	-4.7 (13.82)	79.2 (20.78)	-6.3 (13.54)
	Median	86.7	0.0	86.7	0.0
	Min, Max	0, 100	-60, 27	0, 100	-60, 13
Cycle 3	n	98	89	58	57
	Mean (SD)	83.2 (20.36)	-6.4 (16.01)	80.0 (19.94)	-6.4 (16.47)
	Median	86.7	0.0	86.7	0.0
	Min, Max	0, 100	-67, 13	27, 100	-60, 47

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Physical functioning

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	77	69	52	51
	Mean (SD)	87.0 (16.11)	-3.8 (13.31)	78.7 (20.33)	-8.0 (15.95)
	Median	93.3	0.0	86.7	-6.7
	Min, Max	33, 100	-60, 20	20, 100	-60, 27
Cycle 5	n	56	51	32	31
	Mean (SD)	89.4 (14.70)	-2.1 (10.11)	84.6 (14.80)	-3.4 (14.49)
	Median	93.3	0.0	86.7	0.0
	Min, Max	33, 100	-47, 13	47, 100	-33, 40
Cycle 6	n	55	50	26	25
	Mean (SD)	89.1 (13.66)	-2.0 (9.64)	83.8 (14.87)	-5.3 (12.62)
	Median	93.3	0.0	86.7	0.0
	Min, Max	47, 100	-33, 13	47, 100	-33, 20
End of Treatment	n	39	37	46	45
	Mean (SD)	68.2 (27.55)	-21.6 (23.49)	68.7 (28.90)	-19.7 (23.57)
	Median	73.3	-13.3	80.0	-13.3
	Min, Max	7, 100	-80, 13	0, 100	-80, 13

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Physical functioning

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	62	58	61	60
	Mean (SD)	72.7 (24.55)	-14.7 (21.22)	73.1 (24.46)	-13.8 (18.77)
	Median	73.3	-6.7	80.0	-6.7
	Min, Max	0, 100	-87, 20	0, 100	-67, 13
Worst Post-Baseline Value	n	136	125	129	126
	Mean (SD)	72.1 (24.96)	-16.5 (21.14)	66.3 (25.09)	-17.5 (19.85)
	Median	80.0	-13.3	73.3	-13.3
	Min, Max	0, 100	-87, 20	0, 100	-80, 27

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Role functioning

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		133	
	Mean (SD)	89.3 (16.30)		83.6 (25.12)	
	Median	100.0		100.0	
	Min, Max	33, 100		0, 100	
Cycle 1	n	83	78	83	82
	Mean (SD)	83.9 (22.00)	-6.0 (17.61)	80.9 (24.71)	-3.0 (17.20)
	Median	100.0	0.0	83.3	0.0
	Min, Max	0, 100	-100, 33	0, 100	-50, 67
Cycle 2	n	123	113	97	96
	Mean (SD)	83.3 (24.24)	-6.9 (20.62)	80.4 (26.68)	-6.1 (19.21)
	Median	100.0	0.0	100.0	0.0
	Min, Max	0, 100	-100, 33	0, 100	-67, 67
Cycle 3	n	98	89	58	57
	Mean (SD)	83.2 (25.94)	-7.7 (22.90)	80.7 (24.94)	-7.6 (24.61)
	Median	100.0	0.0	100.0	0.0
	Min, Max	0, 100	-100, 33	0, 100	-83, 83

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Role functioning

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	77	69	52	51
	Mean (SD)	85.3 (21.63)	-7.5 (22.42)	74.7 (28.29)	-13.1 (23.41)
	Median	100.0	0.0	83.3	-16.7
	Min, Max	0, 100	-100, 33	0, 100	-100, 33
Cycle 5	n	56	51	32	31
	Mean (SD)	89.0 (15.33)	-2.3 (12.92)	85.4 (19.74)	-2.7 (26.21)
	Median	100.0	0.0	100.0	0.0
	Min, Max	50, 100	-33, 33	33, 100	-67, 83
Cycle 6	n	55	50	26	25
	Mean (SD)	87.9 (15.86)	-4.0 (11.93)	84.0 (17.31)	-5.3 (16.47)
	Median	100.0	0.0	83.3	0.0
	Min, Max	67, 100	-33, 17	50, 100	-33, 33
End of Treatment	n	39	37	46	45
	Mean (SD)	65.4 (33.20)	-27.5 (30.74)	66.7 (32.01)	-22.2 (28.65)
	Median	66.7	-33.3	66.7	-16.7
	Min, Max	0, 100	-100, 17	0, 100	-100, 33

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Role functioning

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	62	58	61	60
	Mean (SD)	70.2 (30.94)	-20.1 (29.25)	69.4 (27.92)	-20.8 (23.09)
	Median	66.7	0.0	66.7	-16.7
	Min, Max	0, 100	-100, 33	0, 100	-100, 33
Worst Post-Baseline Value	n	136	125	129	126
	Mean (SD)	66.4 (30.96)	-23.3 (28.32)	62.8 (30.30)	-21.3 (27.94)
	Median	66.7	-16.7	66.7	-16.7
	Min, Max	0, 100	-100, 33	0, 100	-100, 67

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Emotional functioning

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		133	
	Mean (SD)	85.7 (13.92)		85.0 (18.71)	
	Median	91.7		91.7	
	Min, Max	33, 100		17, 100	
Cycle 1	n	83	78	82	81
	Mean (SD)	85.8 (13.63)	-1.6 (10.32)	82.6 (18.30)	-1.3 (15.28)
	Median	91.7	0.0	83.3	0.0
	Min, Max	50, 100	-33, 33	17, 100	-42, 50
Cycle 2	n	123	113	97	96
	Mean (SD)	86.5 (16.51)	-0.4 (13.22)	85.2 (17.70)	-1.0 (16.85)
	Median	91.7	0.0	91.7	0.0
	Min, Max	0, 100	-42, 42	8, 100	-75, 58
Cycle 3	n	98	89	58	57
	Mean (SD)	85.0 (17.67)	-2.4 (16.68)	86.6 (17.45)	-0.1 (14.39)
	Median	91.7	0.0	91.7	0.0
	Min, Max	17, 100	-58, 58	25, 100	-33, 58

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Emotional functioning

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	77	69	52	51
	Mean (SD)	86.3 (16.54)	-2.2 (13.83)	85.1 (19.96)	-2.1 (12.89)
	Median	91.7	0.0	91.7	0.0
	Min, Max	42, 100	-42, 25	17, 100	-42, 25
Cycle 5	n	56	51	32	31
	Mean (SD)	88.5 (14.95)	-1.1 (12.47)	89.8 (14.93)	1.3 (21.31)
	Median	100.0	0.0	100.0	0.0
	Min, Max	50, 100	-42, 25	58, 100	-42, 75
Cycle 6	n	55	50	26	25
	Mean (SD)	87.4 (14.86)	-2.2 (11.76)	90.1 (16.50)	-1.3 (18.43)
	Median	91.7	0.0	100.0	0.0
	Min, Max	33, 100	-42, 25	33, 100	-67, 33
End of Treatment	n	39	37	46	45
	Mean (SD)	72.0 (21.84)	-10.6 (16.63)	75.9 (25.89)	-9.4 (20.92)
	Median	66.7	-8.3	83.3	-8.3
	Min, Max	25, 100	-58, 25	0, 100	-83, 25

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Emotional functioning

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	62	58	61	60
	Mean (SD)	74.9 (23.06)	-10.6 (22.34)	81.7 (21.13)	-6.3 (20.62)
	Median	75.0	-8.3	83.3	0.0
	Min, Max	8, 100	-92, 58	0, 100	-92, 25
Worst Post-Baseline Value	n	136	125	128	125
	Mean (SD)	72.7 (22.10)	-14.1 (18.43)	74.1 (23.18)	-11.1 (19.68)
	Median	75.0	-8.3	75.0	-8.3
	Min, Max	0, 100	-92, 33	0, 100	-92, 50

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Cognitive functioning

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		133	
	Mean (SD)	90.1 (13.46)		88.8 (17.85)	
	Median	100.0		100.0	
	Min, Max	50, 100		0, 100	
Cycle 1	n	83	78	82	81
	Mean (SD)	88.4 (13.46)	-1.1 (10.86)	86.0 (19.33)	-2.9 (15.32)
	Median	83.3	0.0	91.7	0.0
	Min, Max	33, 100	-33, 33	17, 100	-50, 33
Cycle 2	n	123	113	97	96
	Mean (SD)	87.5 (17.02)	-2.5 (13.22)	87.3 (15.73)	-1.4 (13.39)
	Median	100.0	0.0	83.3	0.0
	Min, Max	0, 100	-50, 50	33, 100	-33, 33
Cycle 3	n	98	89	58	57
	Mean (SD)	87.8 (17.35)	-3.6 (15.98)	86.5 (20.82)	-1.8 (16.57)
	Median	100.0	0.0	100.0	0.0
	Min, Max	0, 100	-67, 50	0, 100	-67, 33

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Cognitive functioning

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	77	69	52	51
	Mean (SD)	88.1 (14.52)	-2.4 (12.87)	83.7 (22.01)	-5.2 (18.41)
	Median	100.0	0.0	83.3	0.0
	Min, Max	50, 100	-50, 17	0, 100	-67, 33
Cycle 5	n	56	51	32	31
	Mean (SD)	88.7 (15.93)	-3.6 (15.39)	91.7 (12.70)	-0.0 (12.91)
	Median	100.0	0.0	100.0	0.0
	Min, Max	17, 100	-67, 33	50, 100	-33, 33
Cycle 6	n	55	50	26	25
	Mean (SD)	88.8 (16.68)	-4.3 (16.77)	89.1 (14.10)	-3.3 (13.61)
	Median	100.0	0.0	100.0	0.0
	Min, Max	17, 100	-67, 17	50, 100	-33, 33
End of Treatment	n	39	37	46	45
	Mean (SD)	74.8 (21.24)	-12.6 (19.41)	79.0 (23.68)	-11.1 (17.77)
	Median	83.3	0.0	83.3	-16.7
	Min, Max	33, 100	-67, 33	0, 100	-50, 33

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Cognitive functioning

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	62	58	61	60
	Mean (SD)	77.2 (22.83)	-8.6 (21.91)	83.6 (17.35)	-7.8 (15.79)
	Median	83.3	0.0	83.3	0.0
	Min, Max	17, 100	-67, 50	33, 100	-50, 17
Worst Post-Baseline Value	n	136	125	128	125
	Mean (SD)	76.1 (22.47)	-14.3 (17.92)	76.3 (22.29)	-12.1 (17.50)
	Median	83.3	-16.7	83.3	-16.7
	Min, Max	0, 100	-67, 17	0, 100	-67, 33

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Social functioning

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		133	
	Mean (SD)	81.5 (20.62)		82.5 (23.06)	
	Median	83.3		100.0	
	Min, Max	17, 100		0, 100	
Cycle 1	n	82	77	82	81
	Mean (SD)	81.3 (21.82)	-0.4 (16.88)	74.4 (28.59)	-6.2 (21.96)
	Median	83.3	0.0	83.3	0.0
	Min, Max	17, 100	-50, 50	0, 100	-83, 50
Cycle 2	n	123	113	97	96
	Mean (SD)	81.8 (23.95)	-0.9 (20.02)	77.1 (27.88)	-4.3 (23.97)
	Median	100.0	0.0	83.3	0.0
	Min, Max	0, 100	-67, 50	0, 100	-67, 50
Cycle 3	n	98	89	58	57
	Mean (SD)	85.5 (19.97)	1.9 (20.17)	81.3 (25.95)	-2.6 (25.35)
	Median	100.0	0.0	100.0	0.0
	Min, Max	0, 100	-67, 67	0, 100	-83, 50

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Social functioning

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	77	69	52	51
	Mean (SD)	85.7 (18.68)	0.5 (21.76)	75.6 (27.31)	-7.8 (23.89)
	Median	100.0	0.0	83.3	0.0
	Min, Max	17, 100	-83, 67	0, 100	-67, 33
Cycle 5	n	56	51	32	31
	Mean (SD)	88.1 (14.46)	3.3 (16.34)	81.8 (24.81)	-2.7 (27.59)
	Median	100.0	0.0	100.0	0.0
	Min, Max	67, 100	-17, 50	0, 100	-67, 83
Cycle 6	n	55	50	26	25
	Mean (SD)	87.9 (16.18)	1.0 (15.58)	80.8 (20.92)	-4.7 (21.26)
	Median	100.0	0.0	83.3	0.0
	Min, Max	50, 100	-33, 33	33, 100	-50, 33
End of Treatment	n	39	37	46	45
	Mean (SD)	66.2 (29.49)	-14.4 (25.81)	73.6 (29.31)	-16.3 (27.64)
	Median	66.7	0.0	83.3	0.0
	Min, Max	0, 100	-100, 33	0, 100	-100, 33

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Social functioning

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	62	58	61	60
	Mean (SD)	71.0 (30.32)	-10.9 (33.99)	70.8 (30.22)	-15.3 (26.63)
	Median	75.0	0.0	66.7	0.0
	Min, Max	0, 100	-100, 67	0, 100	-100, 33
Worst Post-Baseline Value	n	136	125	128	125
	Mean (SD)	66.7 (28.18)	-14.7 (26.99)	61.1 (30.47)	-21.2 (25.96)
	Median	66.7	0.0	66.7	-16.7
	Min, Max	0, 100	-100, 50	0, 100	-100, 50

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Fatigue

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		133	
	Mean (SD)	21.8 (18.55)		27.7 (23.36)	
	Median	22.2		22.2	
	Min, Max	0, 67		0, 100	
Cycle 1	n	83	78	83	82
	Mean (SD)	26.0 (21.62)	5.5 (14.67)	29.5 (23.57)	0.8 (14.89)
	Median	22.2	0.0	33.3	0.0
	Min, Max	0, 78	-33, 61	0, 100	-44, 33
Cycle 2	n	123	113	97	96
	Mean (SD)	25.8 (22.92)	5.1 (17.53)	31.0 (24.42)	5.2 (16.90)
	Median	22.2	0.0	33.3	0.0
	Min, Max	0, 100	-33, 78	0, 100	-56, 44
Cycle 3	n	98	89	58	57
	Mean (SD)	26.9 (24.30)	6.4 (19.09)	29.1 (24.87)	6.2 (24.22)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-22, 78	0, 100	-100, 89

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Fatigue

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	77	69	52	51
	Mean (SD)	21.6 (21.62)	2.4 (17.96)	35.7 (27.60)	13.5 (21.92)
	Median	11.1	0.0	33.3	11.1
	Min, Max	0, 67	-33, 44	0, 100	-33, 67
Cycle 5	n	56	51	32	31
	Mean (SD)	16.7 (17.34)	-0.7 (15.14)	23.3 (21.37)	3.6 (25.56)
	Median	11.1	0.0	22.2	0.0
	Min, Max	0, 78	-33, 44	0, 78	-89, 44
Cycle 6	n	55	50	26	25
	Mean (SD)	18.2 (16.75)	-0.4 (15.71)	25.9 (18.79)	9.1 (16.73)
	Median	22.2	0.0	33.3	11.1
	Min, Max	0, 67	-33, 33	0, 67	-33, 33
End of Treatment	n	39	37	46	45
	Mean (SD)	46.2 (30.54)	23.1 (23.04)	42.8 (28.78)	21.0 (24.53)
	Median	44.4	22.2	33.3	22.2
	Min, Max	0, 100	-11, 89	0, 100	-33, 89

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Fatigue

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	62	58	61	60
	Mean (SD)	41.0 (28.42)	17.2 (24.90)	37.5 (26.77)	14.6 (21.89)
	Median	33.3	11.1	33.3	11.1
	Min, Max	0, 100	-33, 89	0, 100	-44, 78
Worst Post-Baseline Value	n	136	125	129	126
	Mean (SD)	42.6 (27.13)	21.8 (21.07)	46.6 (27.21)	19.2 (24.07)
	Median	33.3	22.2	33.3	19.4
	Min, Max	0, 100	-11, 89	0, 100	-33, 89

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Nausea and vomiting

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		133	
	Mean (SD)	6.9 (13.48)		9.1 (19.30)	
	Median	0.0		0.0	
	Min, Max	0, 67		0, 100	
Cycle 1	n	83	78	83	82
	Mean (SD)	7.8 (16.94)	0.6 (12.14)	7.4 (17.89)	-1.0 (13.19)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-50, 67	0, 100	-33, 67
Cycle 2	n	123	113	97	96
	Mean (SD)	11.1 (23.15)	4.4 (21.94)	8.9 (17.52)	2.1 (16.97)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-50, 100	0, 83	-67, 67
Cycle 3	n	97	88	58	57
	Mean (SD)	10.8 (20.13)	4.9 (19.44)	5.5 (12.25)	0.3 (10.20)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 50	-33, 33

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Nausea and vomiting

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	77	69	52	51
	Mean (SD)	7.4 (16.56)	1.4 (14.50)	5.1 (11.21)	0.7 (11.04)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-50, 50	0, 50	-33, 33
Cycle 5	n	56	51	32	31
	Mean (SD)	4.5 (9.26)	0.3 (13.54)	9.4 (15.23)	5.4 (14.52)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 33	-67, 33	0, 67	-33, 33
Cycle 6	n	55	50	26	25
	Mean (SD)	4.2 (9.74)	0.7 (13.02)	7.7 (16.49)	4.7 (17.02)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 33	-67, 33	0, 67	-33, 67
End of Treatment	n	39	37	46	45
	Mean (SD)	18.8 (29.91)	9.9 (24.68)	8.0 (19.16)	1.5 (17.34)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-50, 83	0, 100	-50, 67

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Nausea and vomiting

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	62	58	61	60
	Mean (SD)	18.5 (27.84)	9.2 (26.15)	9.0 (18.90)	1.9 (22.98)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 83	-100, 83
Worst Post-Baseline Value	n	136	125	129	126
	Mean (SD)	19.4 (27.68)	13.2 (25.34)	16.4 (23.20)	7.1 (21.85)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-50, 100	0, 100	-100, 83

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Pain

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		133	
	Mean (SD)	20.3 (20.91)		22.4 (26.75)	
	Median	16.7		16.7	
	Min, Max	0, 83		0, 100	
Cycle 1	n	83	78	83	82
	Mean (SD)	23.1 (23.55)	4.5 (14.88)	23.7 (25.39)	1.2 (13.55)
	Median	16.7	0.0	16.7	0.0
	Min, Max	0, 83	-33, 67	0, 100	-50, 33
Cycle 2	n	123	113	97	96
	Mean (SD)	20.2 (21.26)	1.3 (14.80)	22.9 (25.50)	2.8 (21.99)
	Median	16.7	0.0	16.7	0.0
	Min, Max	0, 100	-33, 50	0, 100	-67, 67
Cycle 3	n	98	89	58	57
	Mean (SD)	21.3 (22.55)	2.2 (19.49)	18.1 (21.92)	1.2 (22.02)
	Median	16.7	0.0	16.7	0.0
	Min, Max	0, 100	-67, 67	0, 67	-67, 67

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Pain

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	77	69	52	51
	Mean (SD)	19.3 (19.70)	1.4 (20.36)	24.0 (26.28)	7.5 (23.41)
	Median	16.7	0.0	16.7	0.0
	Min, Max	0, 67	-50, 67	0, 100	-33, 83
Cycle 5	n	56	51	32	31
	Mean (SD)	15.8 (18.10)	-1.0 (16.47)	15.1 (19.10)	0.5 (18.50)
	Median	16.7	0.0	0.0	0.0
	Min, Max	0, 67	-33, 50	0, 67	-33, 50
Cycle 6	n	55	50	26	25
	Mean (SD)	15.5 (19.99)	-1.3 (20.44)	16.0 (20.81)	3.3 (19.25)
	Median	0.0	0.0	8.3	0.0
	Min, Max	0, 83	-50, 83	0, 67	-33, 50
End of Treatment	n	39	37	46	45
	Mean (SD)	41.0 (31.73)	23.9 (32.52)	27.5 (28.16)	11.1 (18.80)
	Median	33.3	16.7	16.7	0.0
	Min, Max	0, 100	-33, 100	0, 100	-50, 67

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Pain

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	62	58	61	60
	Mean (SD)	34.9 (26.26)	15.5 (24.95)	28.7 (28.73)	9.2 (20.22)
	Median	33.3	8.3	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-33, 67
Worst Post-Baseline Value	n	136	125	129	126
	Mean (SD)	37.7 (25.92)	17.9 (25.24)	37.5 (29.02)	14.9 (24.66)
	Median	33.3	16.7	33.3	16.7
	Min, Max	0, 100	-33, 100	0, 100	-67, 83

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Dyspnoea

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	127		133	
	Mean (SD)	13.9 (18.99)		15.0 (21.50)	
	Median	0.0		0.0	
	Min, Max	0, 100		0, 100	
Cycle 1	n	83	77	83	82
	Mean (SD)	15.3 (20.36)	1.3 (15.71)	15.3 (21.02)	0.4 (19.24)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 67	0, 67	-67, 67
Cycle 2	n	123	112	97	96
	Mean (SD)	17.9 (24.99)	4.5 (20.74)	18.2 (20.98)	6.3 (20.12)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 67	0, 100	-33, 67
Cycle 3	n	98	89	58	57
	Mean (SD)	17.7 (25.42)	4.5 (23.67)	16.7 (18.99)	5.3 (18.68)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 67	-33, 33

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Dyspnoea

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	77	69	52	51
	Mean (SD)	14.3 (21.24)	1.0 (22.12)	17.3 (22.38)	5.9 (21.81)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-33, 67	0, 67	-33, 33
Cycle 5	n	56	51	32	31
	Mean (SD)	13.1 (19.78)	-0.7 (15.62)	17.7 (26.75)	5.4 (27.35)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-33, 33	0, 100	-33, 67
Cycle 6	n	55	50	26	25
	Mean (SD)	14.5 (21.05)	-0.0 (20.20)	19.2 (23.42)	8.0 (22.11)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 33	0, 67	-33, 33
End of Treatment	n	39	37	46	45
	Mean (SD)	31.6 (30.54)	21.6 (31.64)	27.5 (30.88)	18.5 (27.11)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-33, 100

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Dyspnoea

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	62	58	61	60
	Mean (SD)	28.0 (27.79)	12.1 (28.41)	28.4 (29.71)	15.6 (29.73)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-67, 100	0, 100	-33, 100
Worst Post-Baseline Value	n	136	124	129	126
	Mean (SD)	31.6 (29.63)	18.8 (26.96)	33.6 (28.72)	19.0 (28.10)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-33, 100

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Insomnia

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	127		133	
	Mean (SD)	16.3 (22.56)		21.3 (24.73)	
	Median	0.0		33.3	
	Min, Max	0, 100		0, 100	
Cycle 1	n	83	77	83	82
	Mean (SD)	12.9 (19.36)	0.4 (16.66)	23.3 (28.39)	2.0 (22.44)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-33, 33	0, 100	-67, 67
Cycle 2	n	123	112	97	96
	Mean (SD)	15.4 (23.49)	1.5 (22.98)	20.6 (27.40)	1.7 (21.29)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-33, 67
Cycle 3	n	98	89	58	57
	Mean (SD)	18.4 (25.83)	3.7 (24.33)	19.0 (25.83)	1.2 (20.86)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-33, 33

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Insomnia

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	77	69	52	51
	Mean (SD)	14.3 (21.92)	0.5 (21.76)	23.1 (26.02)	3.3 (22.37)
	Median	0.0	0.0	33.3	0.0
	Min, Max	0, 100	-67, 67	0, 100	-33, 67
Cycle 5	n	56	51	32	31
	Mean (SD)	13.7 (19.88)	-0.0 (23.09)	14.6 (20.63)	1.1 (16.06)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-33, 67	0, 67	-33, 33
Cycle 6	n	55	50	26	25
	Mean (SD)	12.7 (20.78)	-1.3 (22.29)	11.5 (20.96)	-1.3 (15.15)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 67	0, 67	-33, 33
End of Treatment	n	39	37	46	45
	Mean (SD)	29.1 (34.35)	16.2 (27.91)	27.5 (32.44)	11.9 (31.10)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-33, 100

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Insomnia

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	62	58	61	60
	Mean (SD)	30.6 (34.30)	14.9 (30.70)	27.9 (31.14)	7.2 (26.82)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-33, 67
Worst Post-Baseline Value	n	136	124	129	126
	Mean (SD)	32.8 (30.89)	18.5 (27.32)	35.7 (30.67)	14.6 (26.83)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Appetite loss

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		132	
	Mean (SD)	19.8 (24.90)		17.9 (26.18)	
	Median	0.0		0.0	
	Min, Max	0, 100		0, 100	
Cycle 1	n	83	78	83	81
	Mean (SD)	19.3 (25.57)	-1.7 (19.29)	20.5 (27.46)	4.9 (22.43)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 67	0, 100	-67, 100
Cycle 2	n	123	113	97	96
	Mean (SD)	19.2 (28.31)	2.1 (24.10)	22.3 (29.55)	4.5 (24.48)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 100
Cycle 3	n	98	89	58	56
	Mean (SD)	24.1 (29.81)	6.0 (27.32)	12.6 (23.22)	-3.0 (30.67)
	Median	16.7	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-100, 100

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Appetite loss

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	77	69	52	50
	Mean (SD)	16.5 (23.34)	2.4 (25.77)	23.1 (27.64)	9.3 (25.23)
	Median	0.0	0.0	33.3	0.0
	Min, Max	0, 100	-67, 67	0, 100	-33, 100
Cycle 5	n	55	50	32	31
	Mean (SD)	9.1 (14.98)	-4.7 (23.34)	13.5 (25.20)	3.2 (30.25)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 33	-100, 33	0, 100	-100, 100
Cycle 6	n	54	49	26	25
	Mean (SD)	11.7 (17.32)	-4.1 (27.75)	15.4 (25.35)	9.3 (24.57)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-100, 33	0, 100	-33, 100
End of Treatment	n	39	37	46	45
	Mean (SD)	36.8 (33.15)	18.9 (31.95)	29.7 (33.13)	16.3 (33.05)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Appetite loss

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	62	58	61	60
	Mean (SD)	37.1 (30.84)	19.5 (29.31)	27.9 (35.06)	13.9 (28.32)
	Median	33.3	33.3	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-33, 100
Worst Post-Baseline Value	n	136	125	129	125
	Mean (SD)	39.5 (32.00)	21.3 (30.94)	37.5 (32.01)	20.0 (27.44)
	Median	33.3	33.3	33.3	33.3
	Min, Max	0, 100	-100, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Constipation

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		133	
	Mean (SD)	14.1 (23.14)		14.8 (22.63)	
	Median	0.0		0.0	
	Min, Max	0, 100		0, 100	
Cycle 1	n	83	78	83	82
	Mean (SD)	17.3 (25.69)	4.3 (16.43)	12.0 (19.88)	-1.2 (16.93)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 67	0, 67	-67, 33
Cycle 2	n	123	113	97	96
	Mean (SD)	16.0 (25.01)	3.5 (22.43)	13.1 (21.28)	1.4 (19.89)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 67	0, 100	-67, 67
Cycle 3	n	98	89	58	57
	Mean (SD)	14.6 (23.96)	1.9 (23.76)	10.9 (20.12)	-0.6 (16.05)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-33, 33

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Constipation

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	77	69	52	51
	Mean (SD)	17.3 (25.71)	5.3 (27.19)	12.2 (21.92)	-1.3 (18.81)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 33
Cycle 5	n	56	51	32	31
	Mean (SD)	9.5 (18.76)	-0.0 (20.00)	11.5 (21.77)	-1.1 (13.56)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 33	0, 67	-33, 33
Cycle 6	n	55	50	26	25
	Mean (SD)	12.1 (21.62)	2.0 (23.72)	14.1 (28.55)	1.3 (20.37)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-33, 33
End of Treatment	n	39	37	46	45
	Mean (SD)	19.7 (23.84)	4.5 (19.50)	15.9 (19.55)	7.4 (22.35)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 33	0, 67	-67, 67

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Constipation

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	62	58	61	60
	Mean (SD)	28.0 (30.89)	10.9 (31.46)	15.3 (19.79)	1.7 (24.10)
	Median	33.3	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 67	-67, 67
Worst Post-Baseline Value	n	136	125	129	126
	Mean (SD)	30.4 (32.58)	17.3 (29.21)	23.3 (25.21)	8.5 (23.07)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 67

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Diarrhea

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		133	
	Mean (SD)	7.8 (16.98)		6.3 (15.43)	
	Median	0.0		0.0	
	Min, Max	0, 100		0, 67	
Cycle 1	n	83	78	82	81
	Mean (SD)	4.4 (11.37)	-2.1 (12.41)	7.7 (15.97)	1.6 (11.67)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 33	-33, 33	0, 67	-33, 33
Cycle 2	n	123	113	97	96
	Mean (SD)	7.6 (16.43)	-0.3 (16.96)	7.6 (17.01)	0.7 (15.28)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 67	-33, 67
Cycle 3	n	98	89	58	57
	Mean (SD)	5.8 (13.56)	-3.7 (17.00)	8.0 (14.39)	0.6 (13.35)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-67, 33	0, 33	-33, 33

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Diarrhea

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	77	69	52	51
	Mean (SD)	6.5 (14.35)	-3.9 (18.56)	7.7 (14.18)	0.7 (14.13)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-67, 33	0, 33	-33, 33
Cycle 5	n	56	51	32	31
	Mean (SD)	7.1 (15.19)	-2.0 (15.51)	10.4 (17.84)	5.4 (15.15)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-33, 33	0, 67	-33, 33
Cycle 6	n	55	50	26	25
	Mean (SD)	11.5 (20.51)	3.3 (22.59)	12.8 (19.04)	8.0 (14.53)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-33, 67	0, 67	0, 33
End of Treatment	n	39	37	46	45
	Mean (SD)	9.4 (17.01)	-2.7 (19.84)	5.8 (12.77)	-3.0 (15.61)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-67, 67	0, 33	-33, 33

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Diarrhea

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	62	58	61	60
	Mean (SD)	8.6 (19.96)	-2.9 (19.03)	6.0 (14.28)	1.7 (16.72)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 67	0, 67	-33, 67
Worst Post-Baseline Value	n	136	125	128	125
	Mean (SD)	14.7 (22.87)	7.2 (20.56)	12.8 (20.11)	6.1 (17.65)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 67	-33, 67

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Financial difficulties

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		133	
	Mean (SD)	23.7 (30.21)		26.3 (29.03)	
	Median	0.0		33.3	
	Min, Max	0, 100		0, 100	
Cycle 1	n	82	77	82	81
	Mean (SD)	22.4 (27.24)	-2.6 (21.47)	27.6 (30.90)	1.2 (18.59)
	Median	0.0	0.0	33.3	0.0
	Min, Max	0, 100	-67, 33	0, 100	-33, 33
Cycle 2	n	123	113	97	96
	Mean (SD)	20.1 (26.56)	-2.1 (24.91)	26.8 (29.91)	0.7 (26.92)
	Median	0.0	0.0	33.3	0.0
	Min, Max	0, 100	-100, 67	0, 100	-67, 67
Cycle 3	n	98	89	58	57
	Mean (SD)	18.4 (22.00)	-3.4 (26.61)	21.3 (26.27)	-3.5 (19.60)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-100, 67	0, 100	-67, 33

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Financial difficulties

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	77	69	52	51
	Mean (SD)	17.7 (25.70)	-3.9 (29.45)	25.0 (27.91)	-0.0 (25.82)
	Median	0.0	0.0	33.3	0.0
	Min, Max	0, 100	-67, 100	0, 100	-100, 67
Cycle 5	n	56	51	32	31
	Mean (SD)	15.5 (22.89)	-4.6 (29.07)	25.0 (28.08)	1.1 (25.07)
	Median	0.0	0.0	33.3	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 33
Cycle 6	n	55	50	26	25
	Mean (SD)	12.7 (22.67)	-4.7 (33.00)	19.2 (23.42)	-2.7 (23.41)
	Median	0.0	0.0	16.7	0.0
	Min, Max	0, 100	-100, 100	0, 100	-67, 33
End of Treatment	n	39	37	46	45
	Mean (SD)	30.8 (26.91)	4.5 (21.03)	26.1 (34.36)	4.4 (29.81)
	Median	33.3	0.0	0.0	0.0
	Min, Max	0, 100	-33, 33	0, 100	-100, 67

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Financial difficulties

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	62	58	61	60
	Mean (SD)	25.8 (29.21)	-1.7 (33.29)	23.5 (27.45)	1.1 (28.10)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-100, 100	0, 100	-100, 67
Worst Post-Baseline Value	n	136	125	128	125
	Mean (SD)	32.4 (29.80)	7.7 (25.45)	36.2 (31.31)	10.4 (24.47)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 67

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-02-01-b-qs-chg-c30-itts-fa.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Global health status / QoL									
Cycle 4	139		0.46 (1.23)	75		-4.35 (1.57)	4.81 (0.98, 8.64)	0.32 (0.06, 0.58)	0.0140
Cycle 6	94		-0.58 (1.35)	36		-8.02 (1.98)	7.44 (2.81, 12.06)	0.51 (0.19, 0.83)	0.0018
Overall Treatment Effect	229	66.67 (19.34)	-0.48 (0.87)	208	67.31 (19.12)	-3.27 (1.03)	2.78 (0.29, 5.28)	0.25 (0.03, 0.48)	0.0289

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Only patients with baseline and postbaseline value are included in analysis.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-02-01-01-eff-mmrmqs-c30-itt-fa.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Physical functioning									
Cycle 4	139		-3.61 (1.11)	75		-6.55 (1.38)	2.94 (-0.45, 6.32)	0.21 (-0.03, 0.45)	0.0886
Cycle 6	94		-4.02 (1.20)	36		-8.60 (1.68)	4.59 (0.59, 8.58)	0.33 (0.04, 0.62)	0.0248
Overall Treatment Effect	229	87.38 (13.88)	-2.98 (0.86)	209	84.40 (16.59)	-5.89 (1.02)	2.91 (0.41, 5.41)	0.26 (0.04, 0.49)	0.0225

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-02-01-01-eff-mmrmqs-c30-itt-fa.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Role functioning									
Cycle 4	139		-6.31 (1.85)	75		-9.96 (2.37)	3.65 (-2.13, 9.44)	0.16 (-0.09, 0.41)	0.2147
Cycle 6	94		-6.37 (1.67)	36		-7.90 (2.41)	1.53 (-4.14, 7.20)	0.08 (-0.22, 0.39)	0.5951
Overall Treatment Effect	229	88.77 (18.13)	-5.22 (1.25)	209	84.68 (23.39)	-6.58 (1.49)	1.37 (-2.26, 4.99)	0.09 (-0.14, 0.31)	0.4588

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-02-01-01-eff-mmrmqs-c30-itt-fa.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Emotional functioning									
Cycle 4	139		0.58 (1.15)	75		-1.46 (1.52)	2.04 (-1.63, 5.72)	0.15 (-0.12, 0.42)	0.2748
Cycle 6	94		-0.58 (1.38)	36		-2.79 (2.06)	2.21 (-2.62, 7.04)	0.15 (-0.18, 0.48)	0.3677
Overall Treatment Effect	229	85.85 (15.70)	-0.30 (0.80)	208	85.02 (17.62)	-1.26 (0.99)	0.96 (-1.41, 3.33)	0.10 (-0.14, 0.34)	0.4251

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-02-01-01-eff-mmrmqs-c30-itt-fa.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Cognitive functioning									
Cycle 4	139		-1.65 (1.16)	75		-4.99 (1.49)	3.34 (-0.28, 6.96)	0.23 (-0.02, 0.49)	0.0705
Cycle 6	94		-4.40 (1.34)	36		-2.03 (2.00)	-2.36 (-7.05, 2.32)	-0.16 (-0.48, 0.16)	0.3206
Overall Treatment Effect	229	90.29 (14.20)	-2.51 (0.84)	208	88.53 (17.04)	-1.99 (1.01)	-0.51 (-2.96, 1.93)	-0.05 (-0.28, 0.18)	0.6795

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-02-01-01-eff-mmrmqs-c30-itt-fa.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Social functioning									
Cycle 4	139		-0.08 (1.73)	75		-5.45 (2.20)	5.38 (0.01, 10.74)	0.26 (-0.00, 0.51)	0.0496
Cycle 6	94		-1.53 (1.88)	36		-7.19 (2.63)	5.66 (-0.60, 11.92)	0.26 (-0.03, 0.56)	0.0759
Overall Treatment Effect	229	81.75 (20.11)	-0.13 (1.27)	208	79.42 (24.10)	-3.75 (1.52)	3.62 (-0.06, 7.30)	0.23 (-0.00, 0.46)	0.0537

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-02-01-01-eff-mmrmqs-c30-itt-fa.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Fatigue									
Cycle 4	139		3.04 (1.58)	75		11.59 (2.02)	-8.55 (-13.48, -3.61)	-0.44 (-0.70, -0.18)	0.0008
Cycle 6	94		2.16 (1.52)	36		7.66 (2.22)	-5.50 (-10.70, -0.30)	-0.33 (-0.65, -0.02)	0.0384
Overall Treatment Effect	229	23.35 (20.18)	2.71 (1.08)	209	27.04 (22.39)	6.45 (1.29)	-3.74 (-6.88, -0.60)	-0.27 (-0.50, -0.04)	0.0199

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-02-01-01-eff-mmrmqs-c30-itt-fa.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Nausea and vomiting									
Cycle 4	139		2.20 (1.19)	75		1.80 (1.52)	0.40 (-3.29, 4.09)	0.03 (-0.22, 0.28)	0.8309
Cycle 6	94		2.62 (1.41)	36		3.98 (2.02)	-1.36 (-6.13, 3.41)	-0.08 (-0.38, 0.21)	0.5738
Overall Treatment Effect	229	7.23 (13.97)	2.27 (0.96)	209	8.43 (17.13)	2.47 (1.13)	-0.20 (-2.94, 2.54)	-0.02 (-0.24, 0.21)	0.8866

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-02-01-01-eff-mmrmqs-c30-itt-fa.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Pain									
Cycle 4	139		-0.45 (1.72)	75		7.26 (2.23)	-7.71 (-13.13, -2.28)	-0.37 (-0.62, -0.11)	0.0056
Cycle 6	94		-0.19 (1.85)	36		7.01 (2.77)	-7.19 (-13.66, -0.72)	-0.37 (-0.70, -0.04)	0.0295
Overall Treatment Effect	229	21.14 (22.51)	0.52 (1.17)	209	23.35 (26.74)	4.68 (1.42)	-4.17 (-7.59, -0.74)	-0.28 (-0.52, -0.05)	0.0172

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-02-01-01-eff-mmrmqs-c30-itt-fa.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Dyspnoea									
Cycle 4	139		3.00 (1.62)	75		2.80 (2.11)	0.19 (-4.94, 5.33)	0.01 (-0.25, 0.27)	0.9408
Cycle 6	94		0.83 (1.87)	36		6.84 (2.89)	-6.01 (-12.73, 0.71)	-0.32 (-0.67, 0.04)	0.0794
Overall Treatment Effect	228	13.55 (19.97)	2.04 (1.07)	209	14.84 (21.57)	3.48 (1.31)	-1.44 (-4.58, 1.70)	-0.11 (-0.35, 0.13)	0.3666

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-02-01-01-eff-mmrmqs-c30-itt-fa.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Insomnia									
Cycle 4	139		-0.53 (1.75)	75		-1.22 (2.24)	0.69 (-4.77, 6.16)	0.03 (-0.23, 0.29)	0.8029
Cycle 6	94		1.37 (2.23)	36		-1.14 (3.40)	2.51 (-5.42, 10.45)	0.11 (-0.24, 0.46)	0.5329
Overall Treatment Effect	228	17.57 (25.10)	-0.14 (1.27)	209	22.94 (26.29)	-0.98 (1.54)	0.84 (-2.86, 4.54)	0.05 (-0.19, 0.29)	0.6554

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-02-01-01-eff-mmrmqs-c30-itt-fa.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Appetite loss									
Cycle 4	138		-1.86 (1.87)	74		6.52 (2.39)	-8.38 (-14.16, -2.60)	-0.37 (-0.63, -0.11)	0.0046
Cycle 6	93		-1.23 (2.26)	36		6.84 (3.29)	-8.08 (-15.79, -0.36)	-0.33 (-0.64, -0.01)	0.0403
Overall Treatment Effect	228	19.23 (24.80)	-1.05 (1.45)	208	19.38 (26.24)	4.74 (1.74)	-5.79 (-9.98, -1.61)	-0.32 (-0.55, -0.09)	0.0068

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-02-01-01-eff-mmrmqs-c30-itt-fa.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Constipation									
Cycle 4	139		-0.49 (1.72)	75		0.83 (2.30)	-1.32 (-6.90, 4.25)	-0.06 (-0.34, 0.21)	0.6410
Cycle 6	94		-0.19 (1.83)	36		1.38 (2.78)	-1.58 (-8.08, 4.92)	-0.08 (-0.42, 0.25)	0.6322
Overall Treatment Effect	229	13.09 (22.90)	0.14 (1.05)	209	13.77 (22.48)	0.53 (1.34)	-0.39 (-3.58, 2.81)	-0.03 (-0.29, 0.22)	0.8114

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-02-01-01-eff-mmrmqs-c30-itt-fa.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Diarrhea									
Cycle 4	139		-1.39 (1.20)	75		3.96 (1.53)	-5.35 (-9.10, -1.60)	-0.36 (-0.62, -0.11)	0.0053
Cycle 6	94		1.44 (1.73)	36		6.13 (2.70)	-4.68 (-10.96, 1.59)	-0.27 (-0.63, 0.09)	0.1425
Overall Treatment Effect	229	6.47 (15.16)	-0.81 (0.86)	208	5.94 (14.44)	4.38 (1.08)	-5.18 (-7.78, -2.58)	-0.49 (-0.74, -0.24)	0.0001

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Only patients with baseline and postbaseline value are included in analysis.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

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Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Financial difficulties									
Cycle 4	139		-4.26 (1.86)	75		-3.05 (2.38)	-1.22 (-7.02, 4.59)	-0.05 (-0.31, 0.20)	0.6804
Cycle 6	94		-4.05 (2.18)	36		-4.31 (3.18)	0.26 (-7.23, 7.74)	0.01 (-0.30, 0.32)	0.9462
Overall Treatment Effect	229	26.86 (30.36)	-3.98 (1.36)	208	30.23 (31.87)	-2.05 (1.62)	-1.94 (-5.87, 1.99)	-0.11 (-0.34, 0.12)	0.3329

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Only patients with baseline and postbaseline value are included in analysis.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

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Table 14.2.6.2.1.1.b:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Global health status / QoL									
Cycle 4	69		0.36 (1.57)	51		-4.25 (1.78)	4.61 (0.04, 9.18)	0.33 (0.00, 0.66)	0.0482
Cycle 6	50		-0.19 (1.77)	25		-5.77 (2.34)	5.58 (-0.17, 11.33)	0.39 (-0.01, 0.79)	0.0570
Overall Treatment Effect	123	67.06 (17.87)	-1.00 (1.19)	119	66.85 (19.37)	-2.63 (1.33)	1.63 (-1.73, 4.99)	0.14 (-0.15, 0.44)	0.3394

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

Only patients with baseline and postbaseline value are included in analysis.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-02-01-01-b-eff-mmrmqs-c30-itts-fa.rtf

Table 14.2.6.2.1.1.b:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Physical functioning									
Cycle 4	69		-4.37 (1.69)	51		-8.28 (1.90)	3.91 (-1.04, 8.86)	0.25 (-0.07, 0.56)	0.1204
Cycle 6	50		-3.83 (1.54)	25		-7.46 (1.90)	3.63 (-1.14, 8.40)	0.26 (-0.08, 0.61)	0.1337
Overall Treatment Effect	123	87.81 (13.75)	-3.48 (1.21)	120	83.66 (17.01)	-6.16 (1.34)	2.69 (-0.77, 6.14)	0.23 (-0.07, 0.52)	0.1268

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-02-01-01-b-eff-mmrmqs-c30-itts-fa.rtf

Table 14.2.6.2.1.1.b:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Role functioning									
Cycle 4	69		-8.73 (2.71)	51		-10.49 (3.07)	1.76 (-6.24, 9.76)	0.07 (-0.25, 0.40)	0.6639
Cycle 6	50		-5.59 (2.06)	25		-6.60 (2.72)	1.00 (-5.71, 7.71)	0.06 (-0.34, 0.47)	0.7659
Overall Treatment Effect	123	89.32 (16.30)	-5.98 (1.71)	120	83.58 (25.12)	-6.22 (1.91)	0.24 (-4.67, 5.16)	0.01 (-0.28, 0.31)	0.9225

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-02-01-01-b-eff-mmrmqs-c30-itts-fa.rtf

Table 14.2.6.2.1.1.b:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Emotional functioning									
Cycle 4	69		-1.77 (1.67)	51		-2.52 (1.94)	0.75 (-4.25, 5.75)	0.05 (-0.30, 0.41)	0.7670
Cycle 6	50		-2.47 (1.91)	25		0.02 (2.57)	-2.49 (-8.80, 3.82)	-0.17 (-0.61, 0.26)	0.4346
Overall Treatment Effect	123	85.74 (13.92)	-1.42 (1.11)	119	85.03 (18.71)	-0.87 (1.29)	-0.55 (-3.80, 2.69)	-0.05 (-0.37, 0.26)	0.7372

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-02-01-01-b-eff-mmrmqs-c30-itts-fa.rtf

Table 14.2.6.2.1.1.b:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Cognitive functioning									
Cycle 4	69		-2.98 (1.68)	51		-5.82 (1.91)	2.85 (-2.11, 7.81)	0.19 (-0.14, 0.52)	0.2586
Cycle 6	50		-4.75 (1.95)	25		-2.58 (2.57)	-2.18 (-8.51, 4.16)	-0.14 (-0.54, 0.26)	0.4974
Overall Treatment Effect	123	90.10 (13.46)	-3.22 (1.14)	119	88.85 (17.85)	-2.55 (1.30)	-0.67 (-3.99, 2.65)	-0.06 (-0.37, 0.24)	0.6901

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-02-01-01-b-eff-mmrmqs-c30-itts-fa.rtf

Table 14.2.6.2.1.1.b:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Social functioning									
Cycle 4	69		1.51 (2.47)	51		-7.22 (2.86)	8.73 (1.36, 16.09)	0.40 (0.06, 0.73)	0.0206
Cycle 6	50		-1.16 (2.43)	25		-8.22 (2.98)	7.07 (-0.46, 14.59)	0.33 (-0.02, 0.69)	0.0653
Overall Treatment Effect	123	81.51 (20.62)	1.39 (1.72)	119	82.46 (23.06)	-5.20 (1.95)	6.59 (1.63, 11.55)	0.40 (0.10, 0.71)	0.0096

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-02-01-01-b-eff-mmrmqs-c30-itts-fa.rtf

Table 14.2.6.2.1.1.b:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Fatigue									
Cycle 4	69		3.44 (2.22)	51		11.69 (2.55)	-8.24 (-14.84, -1.65)	-0.42 (-0.76, -0.08)	0.0146
Cycle 6	50		0.84 (2.12)	25		6.70 (2.83)	-5.86 (-12.81, 1.09)	-0.35 (-0.77, 0.07)	0.0972
Overall Treatment Effect	123	21.83 (18.55)	3.13 (1.47)	120	27.65 (23.36)	5.38 (1.66)	-2.25 (-6.49, 1.98)	-0.16 (-0.47, 0.14)	0.2941

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-02-01-01-b-eff-mmrmqs-c30-itts-fa.rtf

Table 14.2.6.2.1.1.b:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Nausea and vomiting									
Cycle 4	69		3.07 (1.56)	51		-0.71 (1.82)	3.78 (-0.87, 8.43)	0.26 (-0.06, 0.59)	0.1105
Cycle 6	50		2.89 (1.92)	25		2.76 (2.51)	0.14 (-6.08, 6.35)	0.01 (-0.38, 0.40)	0.9656
Overall Treatment Effect	123	6.90 (13.48)	3.12 (1.29)	120	9.15 (19.30)	0.84 (1.47)	2.28 (-1.47, 6.02)	0.18 (-0.12, 0.48)	0.2310

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-02-01-01-b-eff-mmrmqs-c30-itts-fa.rtf

Table 14.2.6.2.1.1.b:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Pain									
Cycle 4	69		1.47 (2.54)	51		9.39 (2.94)	-7.92 (-15.54, -0.30)	-0.35 (-0.69, -0.01)	0.0419
Cycle 6	50		-1.10 (2.60)	25		7.40 (3.35)	-8.50 (-16.89, -0.12)	-0.39 (-0.77, -0.00)	0.0470
Overall Treatment Effect	123	20.31 (20.91)	0.67 (1.59)	120	22.43 (26.75)	4.67 (1.83)	-4.00 (-8.68, 0.68)	-0.26 (-0.57, 0.05)	0.0930

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-02-01-01-b-eff-mmrmqs-c30-itts-fa.rtf

Table 14.2.6.2.1.1.b:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Dyspnoea									
Cycle 4	69		1.92 (2.48)	51		4.30 (2.88)	-2.38 (-9.82, 5.06)	-0.11 (-0.46, 0.24)	0.5275
Cycle 6	50		3.45 (2.83)	25		7.11 (3.81)	-3.66 (-13.05, 5.72)	-0.17 (-0.60, 0.26)	0.4392
Overall Treatment Effect	122	13.91 (18.99)	2.57 (1.56)	120	15.04 (21.50)	4.33 (1.80)	-1.76 (-6.31, 2.79)	-0.12 (-0.44, 0.19)	0.4464

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-02-01-01-b-eff-mmrmqs-c30-itts-fa.rtf

Table 14.2.6.2.1.1.b:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Insomnia									
Cycle 4	69		-0.15 (2.36)	51		3.43 (2.74)	-3.58 (-10.63, 3.47)	-0.18 (-0.53, 0.17)	0.3172
Cycle 6	50		-0.23 (2.70)	25		-1.56 (3.63)	1.32 (-7.59, 10.24)	0.06 (-0.37, 0.49)	0.7682
Overall Treatment Effect	122	16.27 (22.56)	0.18 (1.57)	120	21.30 (24.73)	0.71 (1.76)	-0.53 (-4.99, 3.94)	-0.04 (-0.34, 0.27)	0.8154

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
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[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-02-01-01-b-eff-mmrmqs-c30-itts-fa.rtf

Table 14.2.6.2.1.1.b:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Appetite loss									
Cycle 4	69		0.86 (2.59)	50		8.23 (2.99)	-7.37 (-15.01, 0.28)	-0.32 (-0.65, 0.01)	0.0589
Cycle 6	49		-1.07 (3.15)	25		7.63 (4.17)	-8.71 (-18.96, 1.55)	-0.36 (-0.78, 0.06)	0.0951
Overall Treatment Effect	123	19.79 (24.90)	-0.15 (1.91)	119	17.93 (26.18)	3.45 (2.18)	-3.60 (-9.10, 1.90)	-0.20 (-0.50, 0.10)	0.1975

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
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[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
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unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-02-01-01-b-eff-mmrmqs-c30-itts-fa.rtf

Table 14.2.6.2.1.1.b:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Constipation									
Cycle 4	69		3.93 (2.53)	51		0.17 (2.93)	3.76 (-3.83, 11.35)	0.17 (-0.17, 0.51)	0.3290
Cycle 6	50		0.19 (2.65)	25		3.16 (3.52)	-2.97 (-11.64, 5.71)	-0.14 (-0.54, 0.26)	0.4989
Overall Treatment Effect	123	14.06 (23.14)	1.52 (1.44)	120	14.79 (22.63)	-0.39 (1.68)	1.91 (-2.32, 6.15)	0.14 (-0.17, 0.46)	0.3742

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
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[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
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Table 14.2.6.2.1.1.b:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Diarrhea									
Cycle 4	69		-2.15 (1.53)	51		0.33 (1.77)	-2.48 (-7.06, 2.11)	-0.19 (-0.54, 0.16)	0.2870
Cycle 6	50		2.92 (2.61)	25		5.72 (3.62)	-2.80 (-11.65, 6.05)	-0.15 (-0.61, 0.32)	0.5304
Overall Treatment Effect	123	7.81 (16.98)	-0.85 (1.05)	119	6.27 (15.43)	1.79 (1.26)	-2.64 (-5.81, 0.54)	-0.28 (-0.63, 0.06)	0.1027

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
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[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
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Table 14.2.6.2.1.1.b:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Financial difficulties									
Cycle 4	69		-4.46 (2.60)	51		-1.18 (2.98)	-3.28 (-10.98, 4.41)	-0.14 (-0.47, 0.19)	0.4003
Cycle 6	50		-5.43 (3.00)	25		-2.29 (3.89)	-3.14 (-12.79, 6.50)	-0.13 (-0.52, 0.26)	0.5198
Overall Treatment Effect	123	23.70 (30.21)	-4.79 (1.84)	119	26.32 (29.03)	-0.71 (2.06)	-4.07 (-9.35, 1.21)	-0.23 (-0.53, 0.07)	0.1297

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
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Table 14.2.6.2.1.2:
Analyses of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Global Health Status/QOL	256	59 (23.0)	NR (NE, NE)	256	47 (18.4)	NR (NE, NE)	0.990 (0.671, 1.460)	0.9585
Physical Functioning	256	47 (18.4)	NR (NE, NE)	256	52 (20.3)	10.0 (4.5, NE)	0.702 (0.470, 1.050)	0.0816
Role Functioning	256	63 (24.6)	NR (NE, NE)	256	62 (24.2)	4.9 (3.3, NE)	0.802 (0.560, 1.150)	0.2232
Emotional Functioning	256	31 (12.1)	NR (NE, NE)	256	35 (13.7)	NR (NE, NE)	0.705 (0.432, 1.151)	0.1575
Cognitive Functioning	256	50 (19.5)	NR (NE, NE)	256	41 (16.0)	10.2 (10.0, NE)	0.997 (0.655, 1.517)	0.9870
Social Functioning	256	55 (21.5)	NR (NE, NE)	256	48 (18.8)	NR (4.7, NE)	0.931 (0.630, 1.376)	0.7171
Fatigue	256	87 (34.0)	7.0 (3.5, NE)	256	83 (32.4)	3.1 (2.1, 3.8)	0.787 (0.578, 1.072)	0.1212
Nausea and Vomiting	256	42 (16.4)	NR (NE, NE)	256	35 (13.7)	NR (NE, NE)	0.926 (0.587, 1.459)	0.7385

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.
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Table 14.2.6.2.1.2:
Analyses of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Pain	256	61 (23.8)	NR (11.8, NE)	256	53 (20.7)	10.0 (3.8, NE)	0.946 (0.650, 1.376)	0.7685
Dyspnoea	256	41 (16.0)	NR (NE, NE)	256	38 (14.8)	NR (10.2, NE)	0.863 (0.552, 1.350)	0.5157
Insomnia	256	46 (18.0)	NR (NE, NE)	256	26 (10.2)	NR (NE, NE)	1.416 (0.869, 2.306)	0.1561
Appetite Loss	256	46 (18.0)	NR (11.8, NE)	256	40 (15.6)	NR (NE, NE)	0.917 (0.596, 1.410)	0.6906
Constipation	256	36 (14.1)	NR (NE, NE)	256	23 (9.0)	NR (NE, NE)	1.304 (0.766, 2.221)	0.3244
Diarrhea	256	14 (5.5)	NR (NE, NE)	256	23 (9.0)	NR (NE, NE)	0.416 (0.211, 0.821)	0.0089
Financial Difficulties	256	25 (9.8)	28.4 (NE, NE)	256	28 (10.9)	NR (NE, NE)	0.722 (0.417, 1.249)	0.2377

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-tte-qlq.sas 16MAY2024 03:12 t-14-02-06-02-01-02-eff-tte-qlq-c30-itt-fa.rtf

Table 14.2.6.2.1.2.b:
Analyses of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Global Health Status/QOL	139	32 (23.0)	NR (9.1, NE)	138	30 (21.7)	NR (NE, NE)	0.969 (0.587, 1.598)	0.8990
Physical Functioning	139	26 (18.7)	NR (NE, NE)	138	34 (24.6)	10.0 (3.5, NE)	0.689 (0.411, 1.156)	0.1537
Role Functioning	139	35 (25.2)	NR (9.1, NE)	138	42 (30.4)	4.9 (2.7, NE)	0.778 (0.493, 1.229)	0.2738
Emotional Functioning	139	20 (14.4)	NR (9.1, NE)	138	23 (16.7)	NR (NE, NE)	0.786 (0.431, 1.434)	0.4279
Cognitive Functioning	139	30 (21.6)	NR (9.1, NE)	138	27 (19.6)	10.0 (10.0, NE)	1.001 (0.590, 1.698)	0.9981
Social Functioning	139	25 (18.0)	NR (NE, NE)	138	31 (22.5)	NR (4.7, NE)	0.729 (0.429, 1.238)	0.2353
Fatigue	139	53 (38.1)	3.7 (2.8, 11.8)	138	50 (36.2)	2.3 (1.7, 3.8)	0.933 (0.630, 1.382)	0.7245
Nausea and Vomiting	139	26 (18.7)	NR (NE, NE)	138	15 (10.9)	NR (NE, NE)	1.555 (0.819, 2.949)	0.1719

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.
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Table 14.2.6.2.1.2.b:
Analyses of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Pain	139	33 (23.7)	NR (11.8, NE)	138	30 (21.7)	10.0 (3.8, NE)	1.048 (0.635, 1.731)	0.8530
Dyspnoea	139	25 (18.0)	NR (NE, NE)	138	26 (18.8)	NR (3.8, NE)	0.847 (0.487, 1.473)	0.5527
Insomnia	139	25 (18.0)	NR (NE, NE)	138	18 (13.0)	NR (NE, NE)	1.276 (0.692, 2.353)	0.4271
Appetite Loss	139	27 (19.4)	NR (9.1, NE)	138	20 (14.5)	NR (NE, NE)	1.225 (0.683, 2.197)	0.4935
Constipation	139	20 (14.4)	NR (NE, NE)	138	11 (8.0)	NR (NE, NE)	1.928 (0.919, 4.042)	0.0754
Diarrhea	139	6 (4.3)	NR (NE, NE)	138	8 (5.8)	NR (NE, NE)	0.690 (0.237, 2.008)	0.4937
Financial Difficulties	139	16 (11.5)	NR (NE, NE)	138	14 (10.1)	NR (NE, NE)	1.080 (0.526, 2.215)	0.8329

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.
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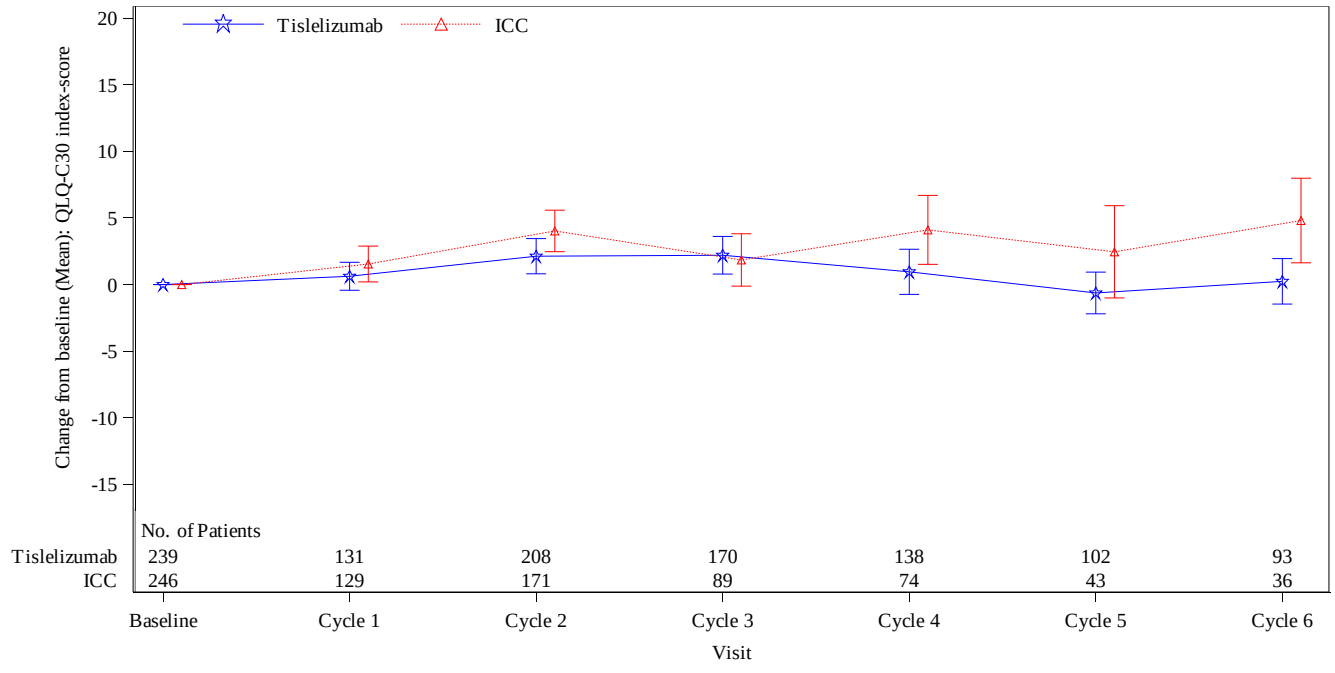
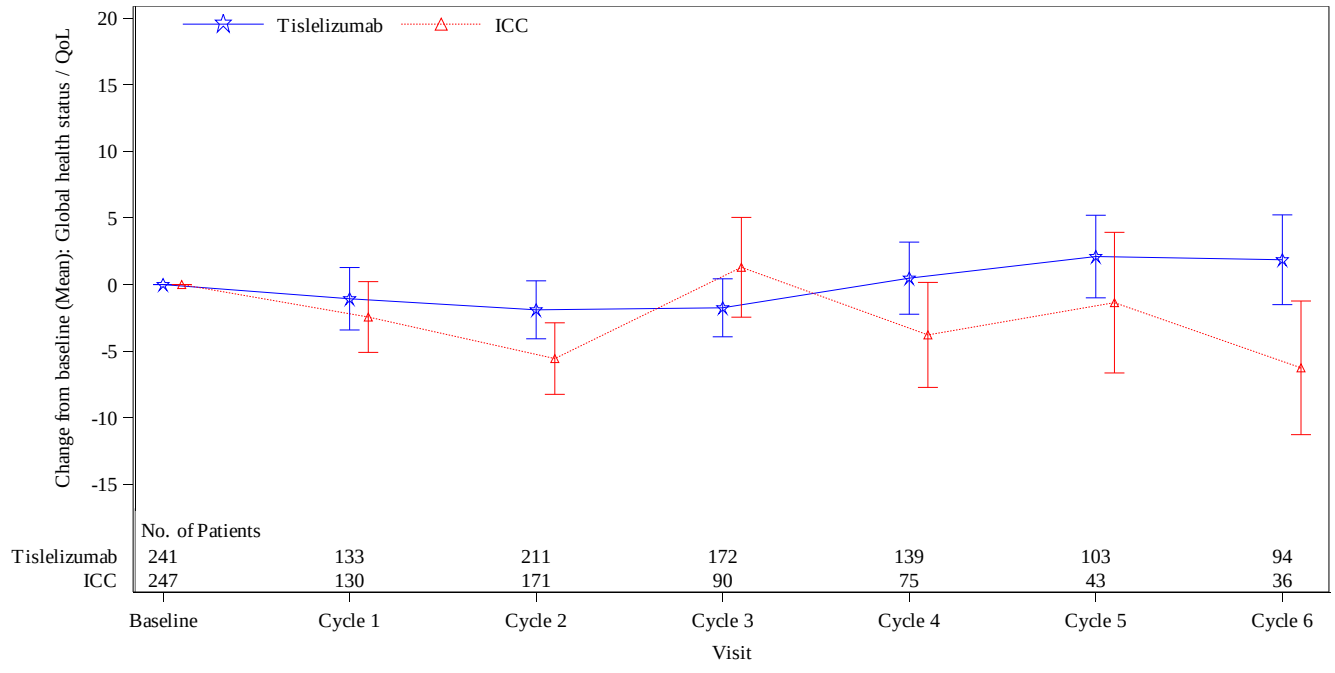
Figure 14.2.7.1:
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set



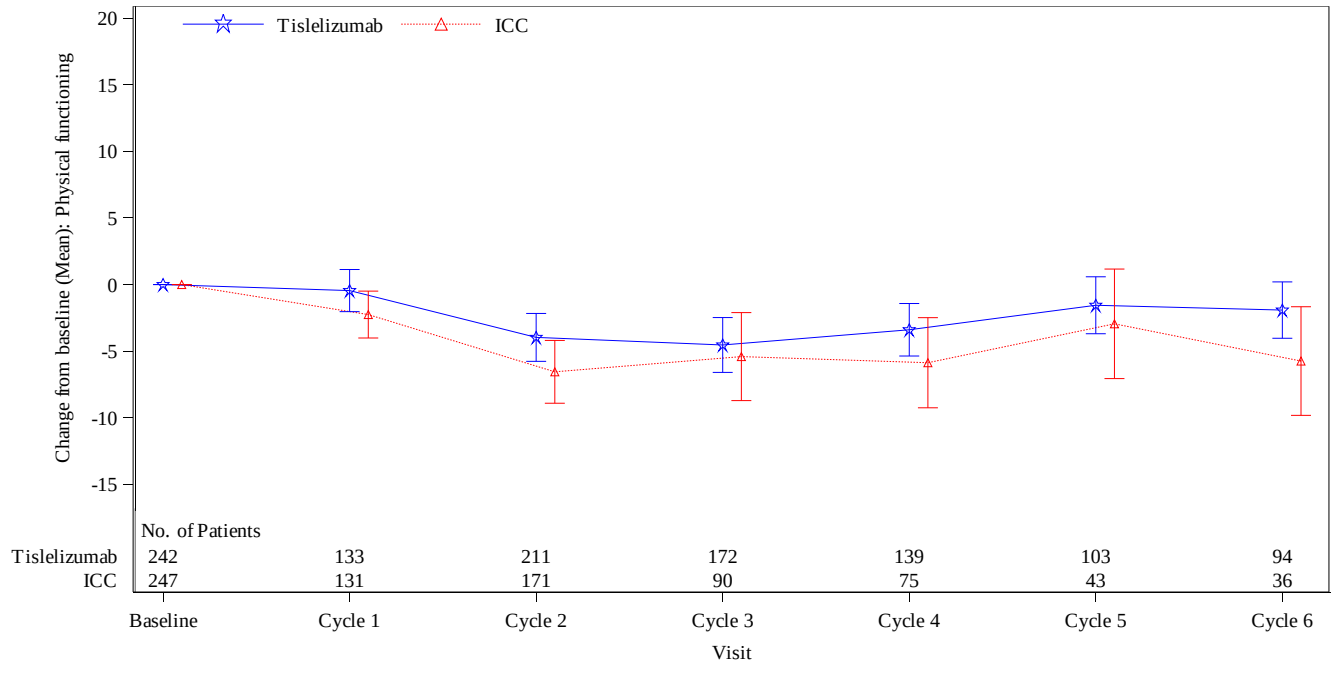
Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Datapoints represent means and 95% CI.
Increases in scores for global health status/QoL, physical functioning, role functioning, emotional functioning, cognitive functioning and social functioning are improvements, while increases in scores for index score, fatigue, nausea and vomiting, pain, dyspnoea, insomnia, appetite loss, constipation, diarrhea and financial difficulty are deteriorations for C30.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-series.sas 15MAY2024 20:01 f-14-02-07-01-series-c30-itt-fa.rtf

Figure 14.2.7.1:
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set



Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Datapoints represent means and 95% CI.
Increases in scores for global health status/QoL, physical functioning, role functioning, emotional functioning, cognitive functioning and social functioning are improvements, while increases in scores for index score, fatigue, nausea and vomiting, pain, dyspnoea, insomnia, appetite loss, constipation, diarrhea and financial difficulty are deteriorations for C30.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-series.sas 15MAY2024 20:01 f-14-02-07-01-series-c30-itt-fa.rtf

Figure 14.2.7.1:
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set



Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Datapoints represent means and 95% CI.
Increases in scores for global health status/QoL, physical functioning, role functioning, emotional functioning, cognitive functioning and social functioning are improvements, while increases in scores for index score, fatigue, nausea and vomiting, pain, dyspnoea, insomnia, appetite loss, constipation, diarrhea and financial difficulty are deteriorations for C30.
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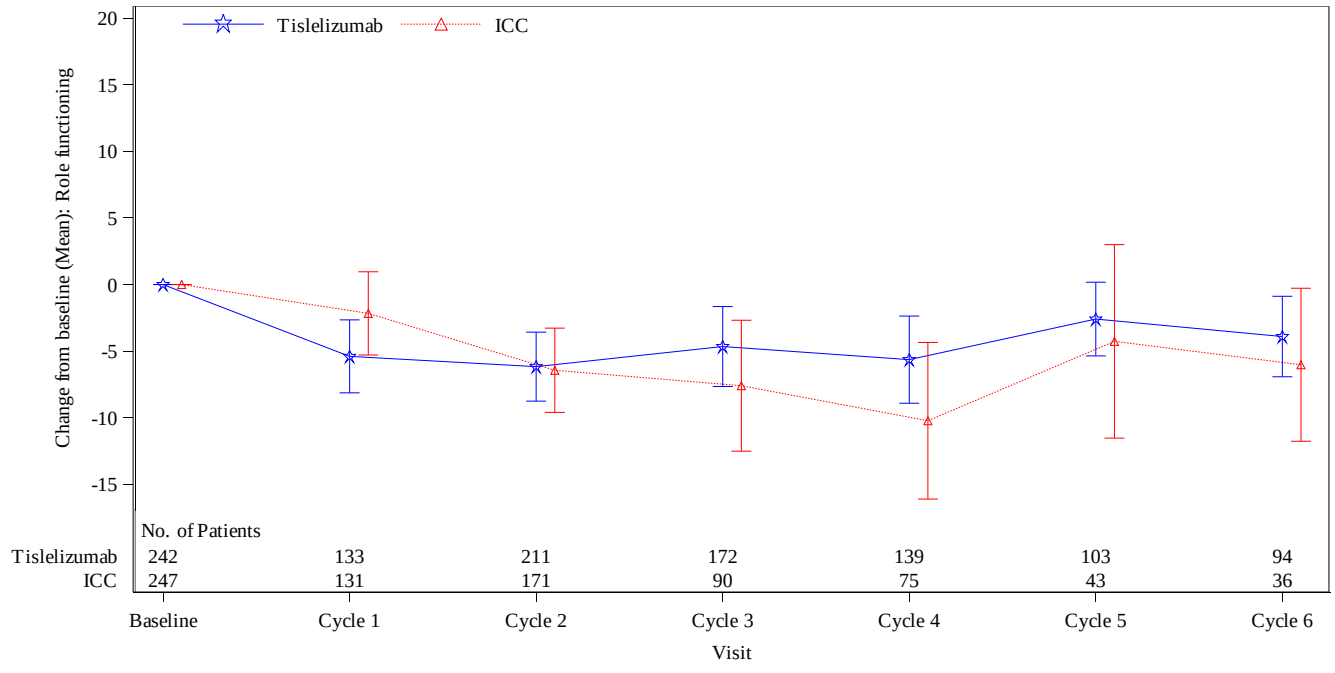
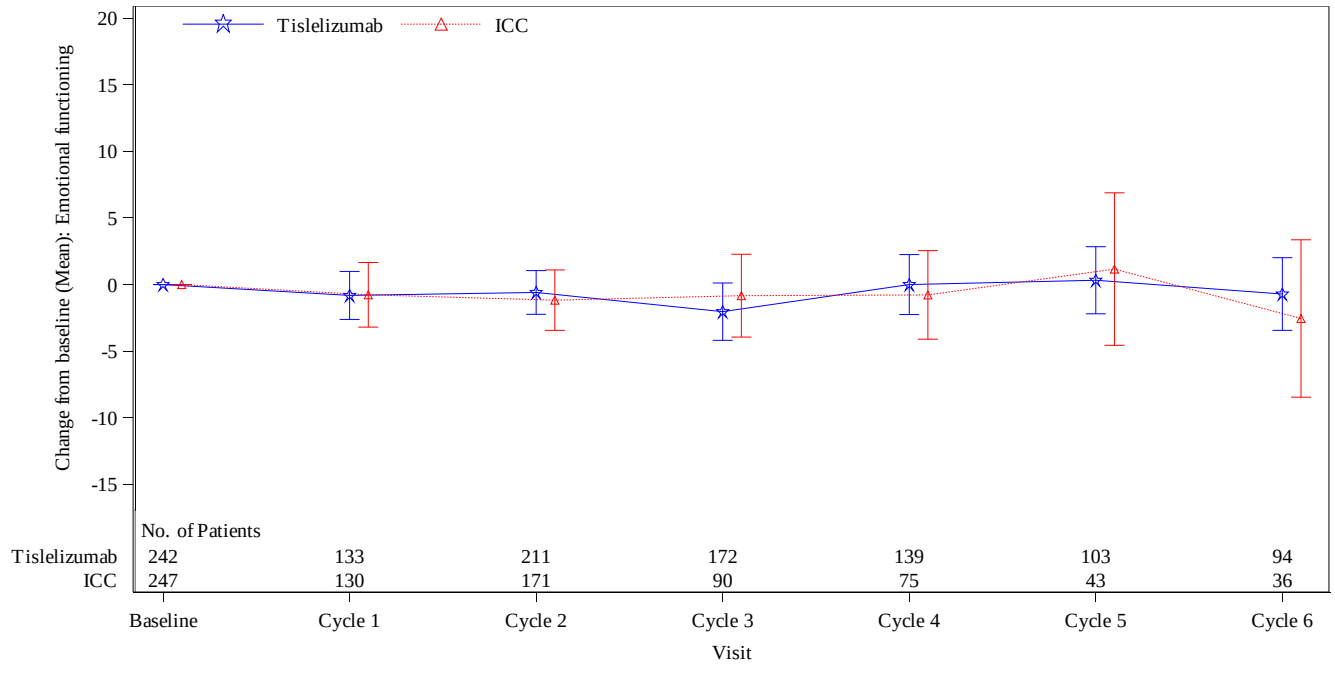
Figure 14.2.7.1:
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set



Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Datapoints represent means and 95% CI.
Increases in scores for global health status/QoL, physical functioning, role functioning, emotional functioning, cognitive functioning and social functioning are improvements, while increases in scores for index score, fatigue, nausea and vomiting, pain, dyspnoea, insomnia, appetite loss, constipation, diarrhea and financial difficulty are deteriorations for C30.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-series.sas 15MAY2024 20:01 f-14-02-07-01-series-c30-itt-fa.rtf

Figure 14.2.7.1:
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set



Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Datapoints represent means and 95% CI.
Increases in scores for global health status/QoL, physical functioning, role functioning, emotional functioning, cognitive functioning and social functioning are improvements, while increases in scores for index score, fatigue, nausea and vomiting, pain, dyspnoea, insomnia, appetite loss, constipation, diarrhea and financial difficulty are deteriorations for C30.
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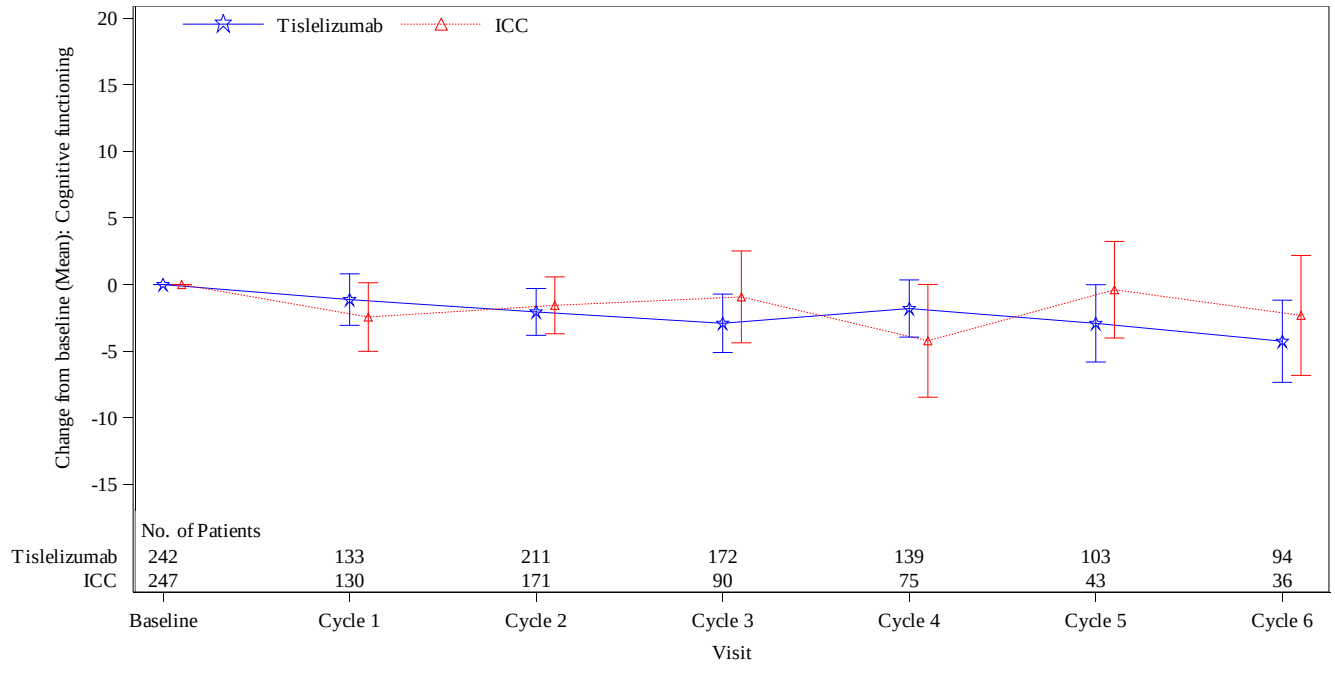
Figure 14.2.7.1:
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set



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Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Datapoints represent means and 95% CI.
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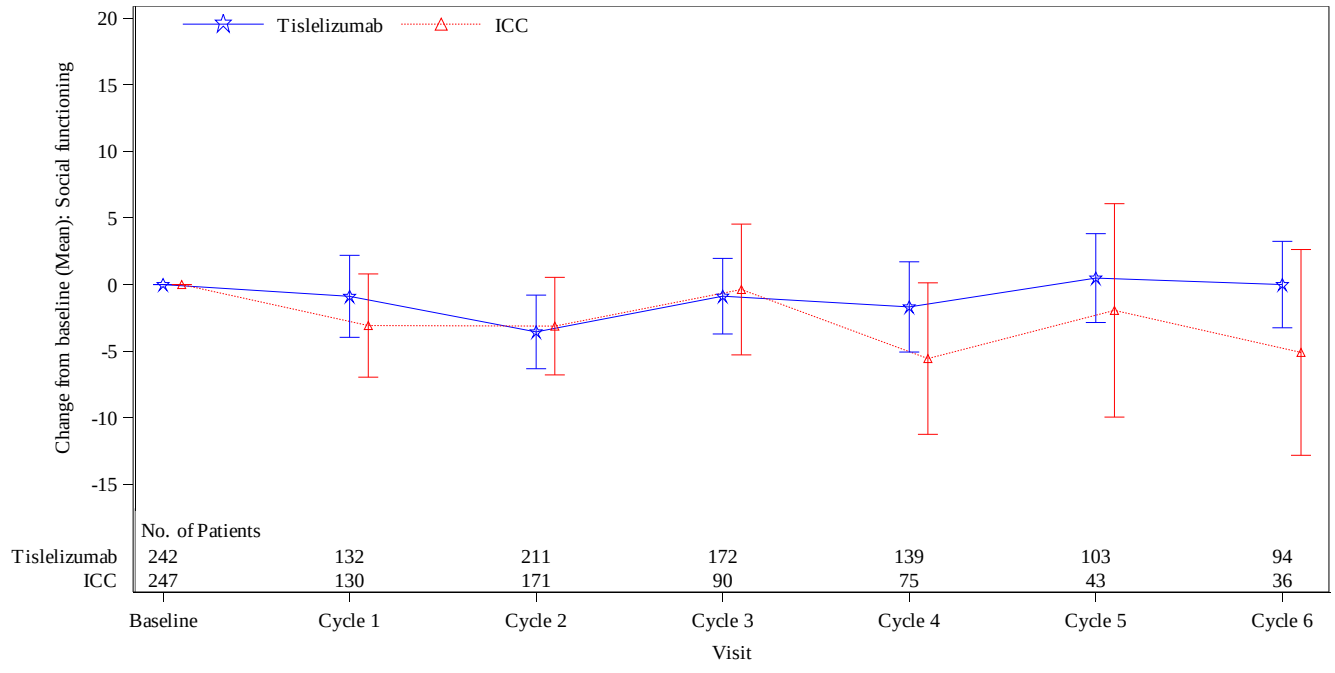
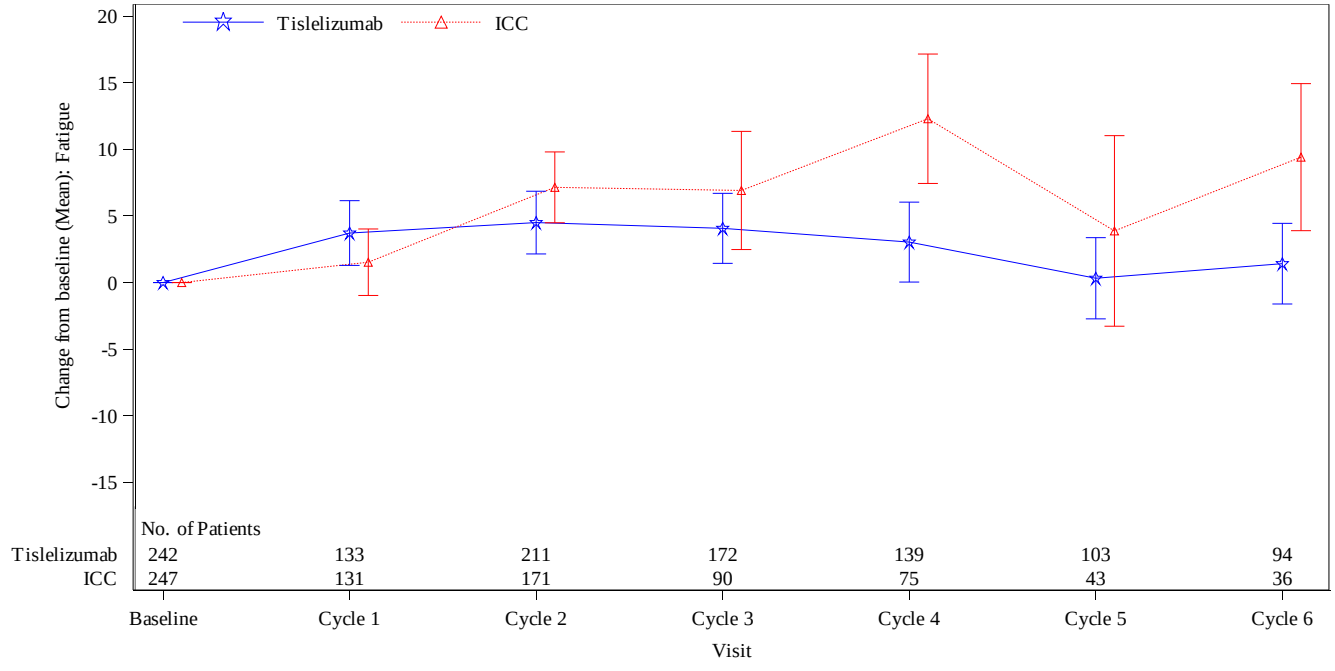
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-series.sas 15MAY2024 20:01 f-14-02-07-01-series-c30-itt-fa.rtf

Figure 14.2.7.1:
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set



Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Datapoints represent means and 95% CI.
Increases in scores for global health status/QoL, physical functioning, role functioning, emotional functioning, cognitive functioning and social functioning are improvements, while increases in scores for index score, fatigue, nausea and vomiting, pain, dyspnoea, insomnia, appetite loss, constipation, diarrhea and financial difficulty are deteriorations for C30.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-series.sas 15MAY2024 20:01 f-14-02-07-01-series-c30-itt-fa.rtf

Figure 14.2.7.1:
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set



Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Datapoints represent means and 95% CI.
Increases in scores for global health status/QoL, physical functioning, role functioning, emotional functioning, cognitive functioning and social functioning are improvements, while increases in scores for index score, fatigue, nausea and vomiting, pain, dyspnoea, insomnia, appetite loss, constipation, diarrhea and financial difficulty are deteriorations for C30.
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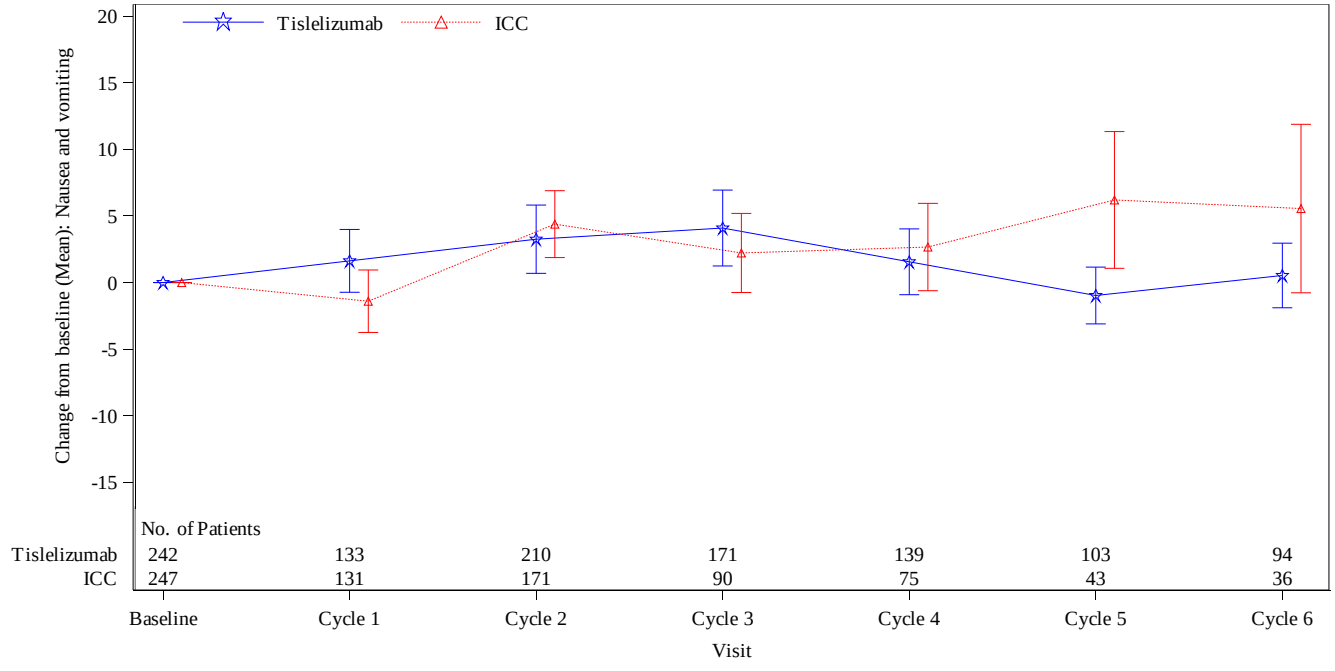
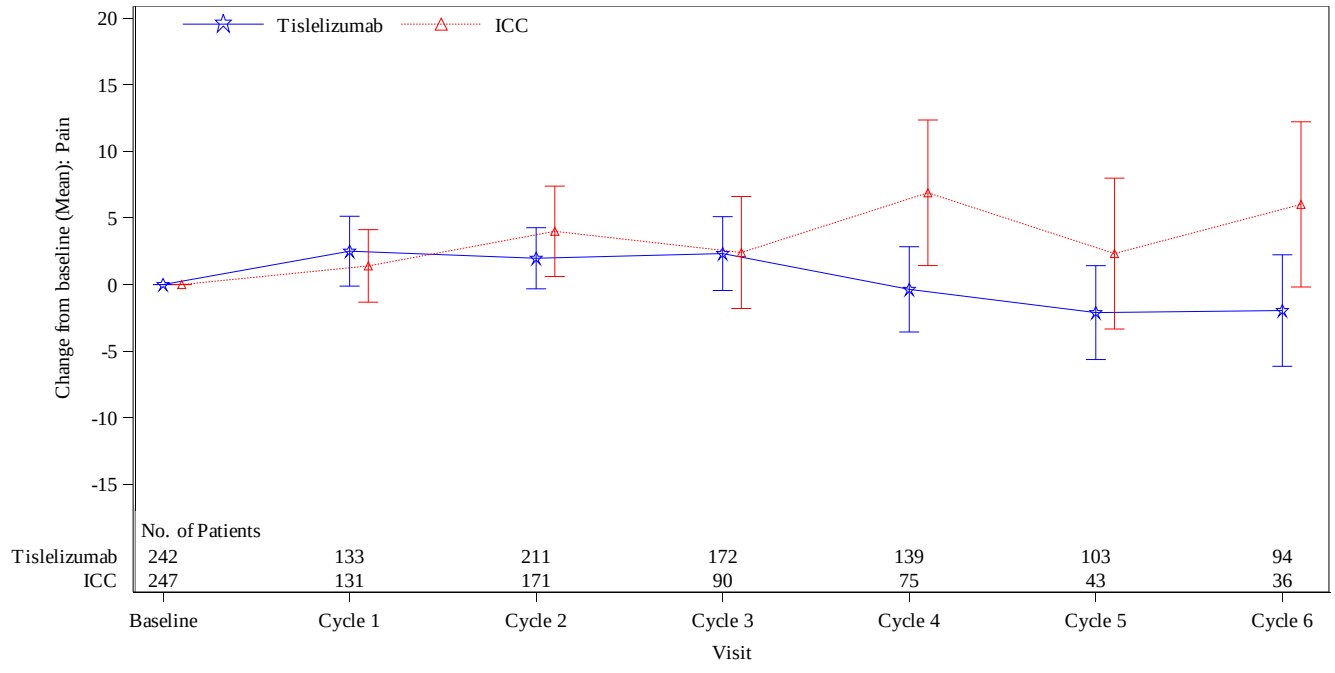
Figure 14.2.7.1:
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set



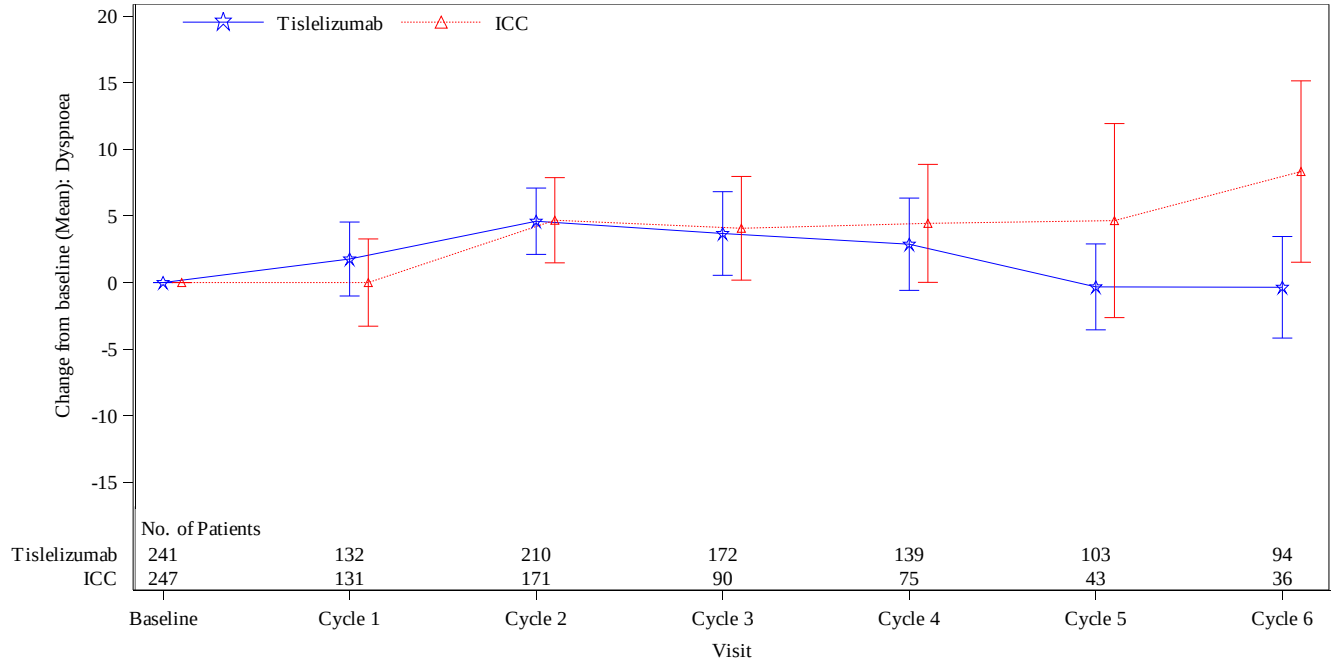
Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Datapoints represent means and 95% CI.
Increases in scores for global health status/QoL, physical functioning, role functioning, emotional functioning, cognitive functioning and social functioning are improvements, while increases in scores for index score, fatigue, nausea and vomiting, pain, dyspnoea, insomnia, appetite loss, constipation, diarrhea and financial difficulty are deteriorations for C30.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-series.sas 15MAY2024 20:01 f-14-02-07-01-series-c30-itt-fa.rtf

Figure 14.2.7.1:
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set



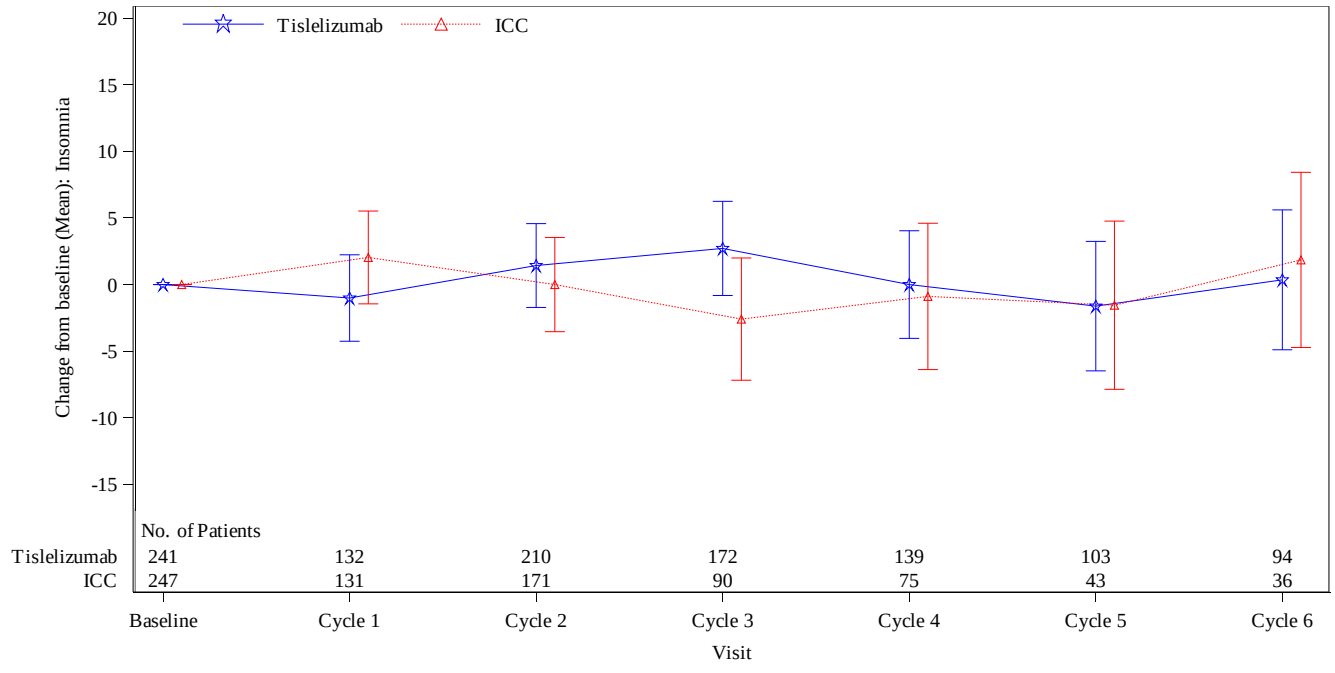
Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Datapoints represent means and 95% CI.
Increases in scores for global health status/QoL, physical functioning, role functioning, emotional functioning, cognitive functioning and social functioning are improvements, while increases in scores for index score, fatigue, nausea and vomiting, pain, dyspnoea, insomnia, appetite loss, constipation, diarrhea and financial difficulty are deteriorations for C30.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-series.sas 15MAY2024 20:01 f-14-02-07-01-series-c30-itt-fa.rtf

Figure 14.2.7.1:
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set



Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Datapoints represent means and 95% CI.
Increases in scores for global health status/QoL, physical functioning, role functioning, emotional functioning, cognitive functioning and social functioning are improvements, while increases in scores for index score, fatigue, nausea and vomiting, pain, dyspnoea, insomnia, appetite loss, constipation, diarrhea and financial difficulty are deteriorations for C30.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-series.sas 15MAY2024 20:01 f-14-02-07-01-series-c30-itt-fa.rtf

Figure 14.2.7.1:
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set



Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
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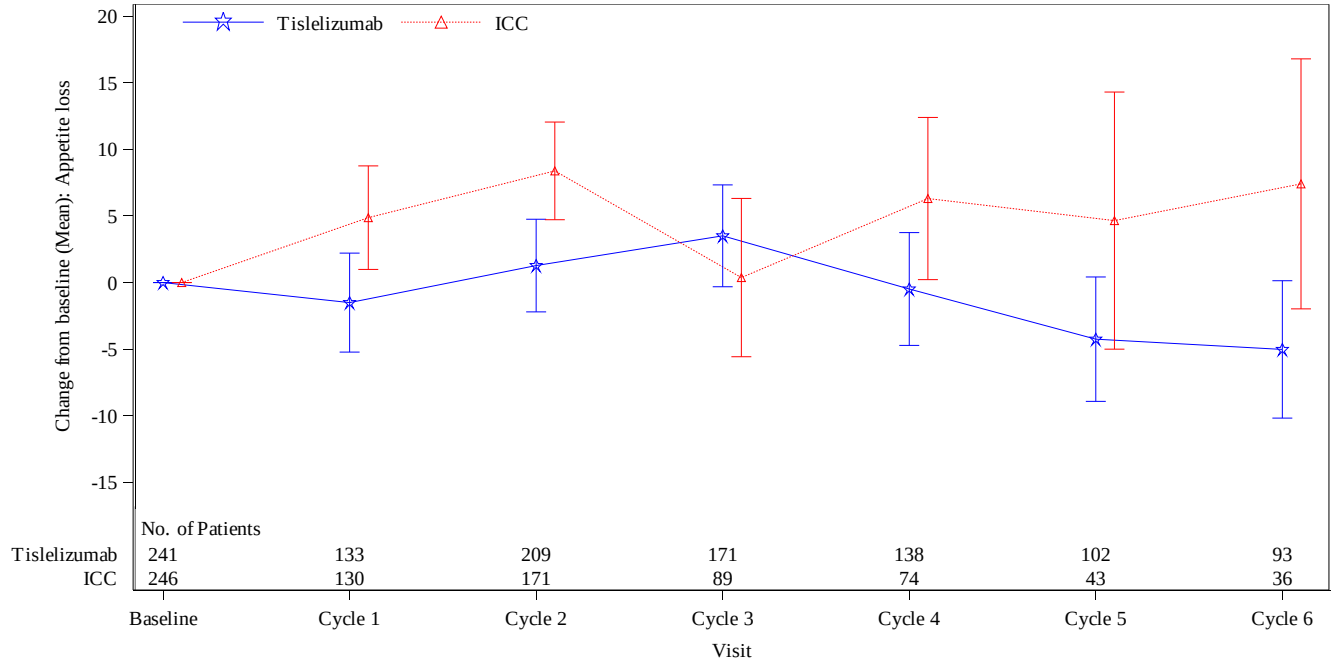

Source: Listing 16.2.6.6.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
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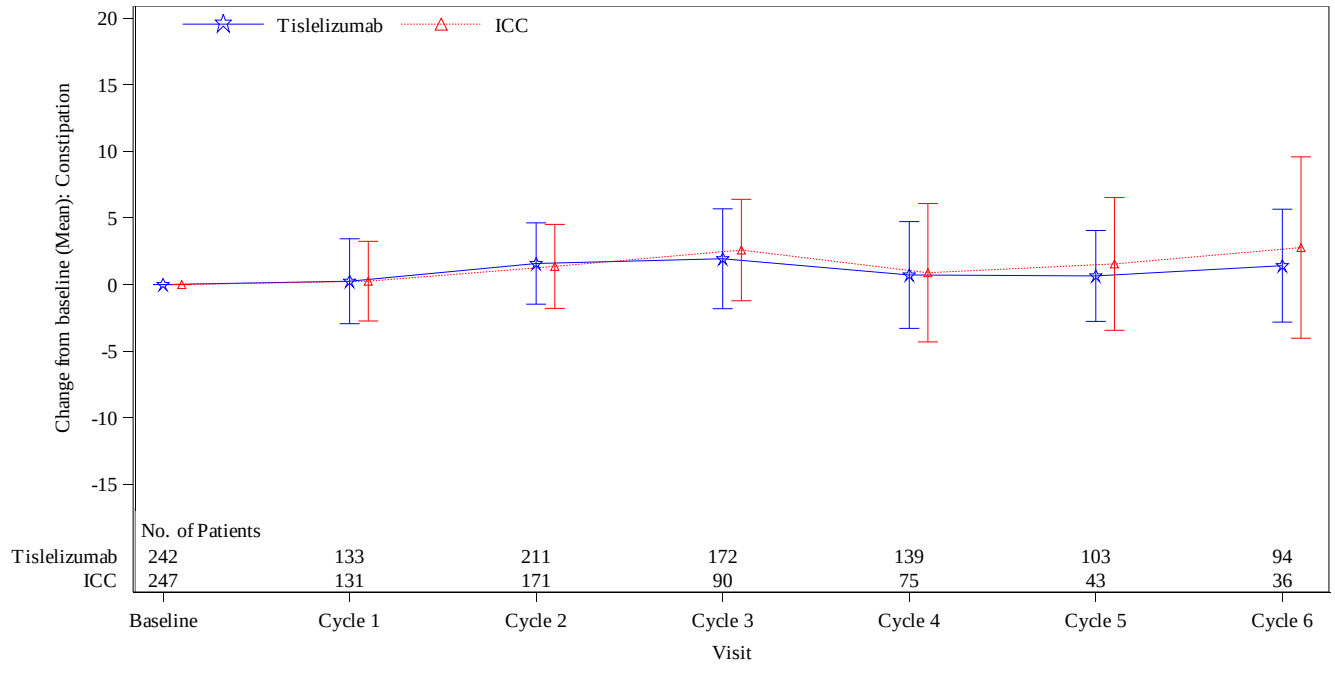

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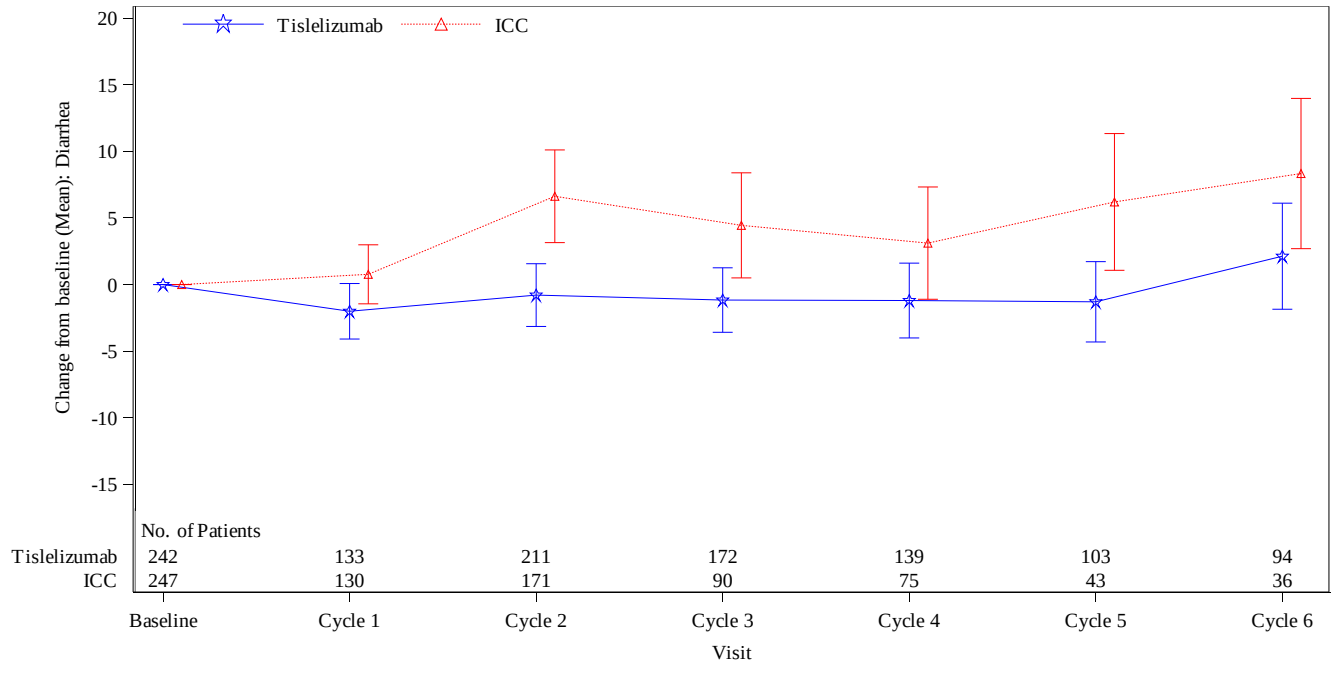

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ITT Analysis Set

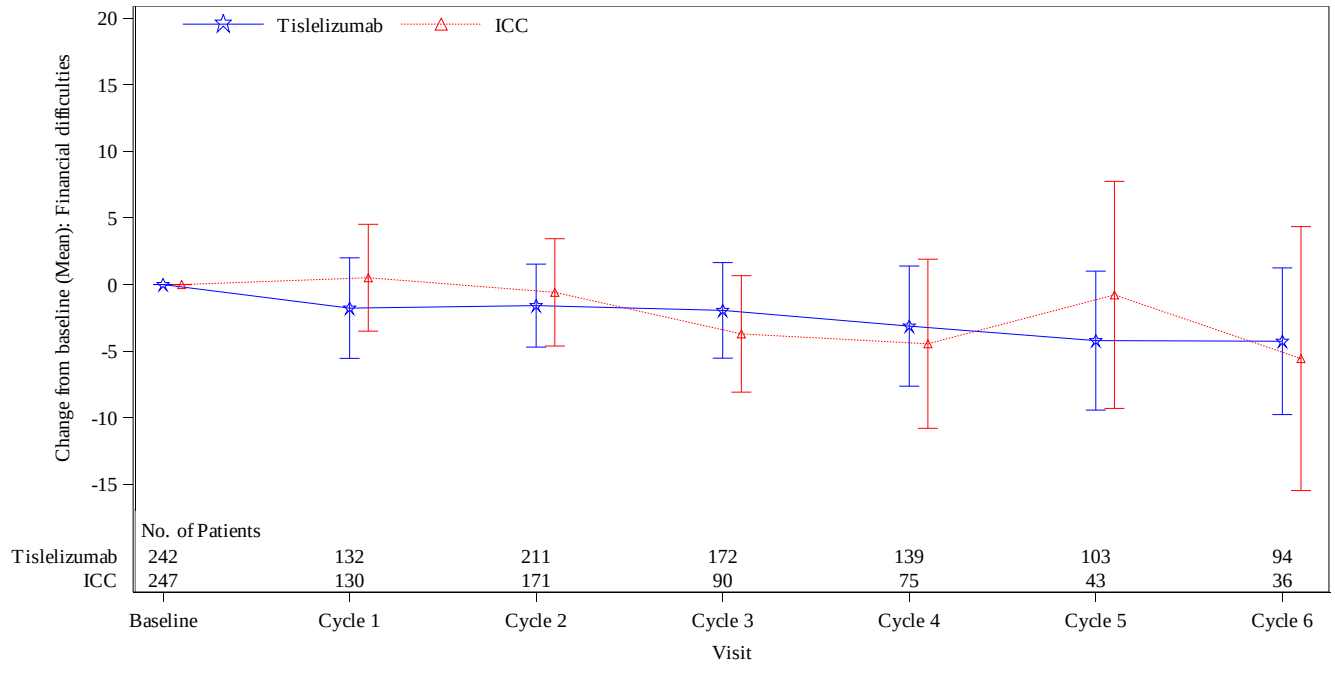

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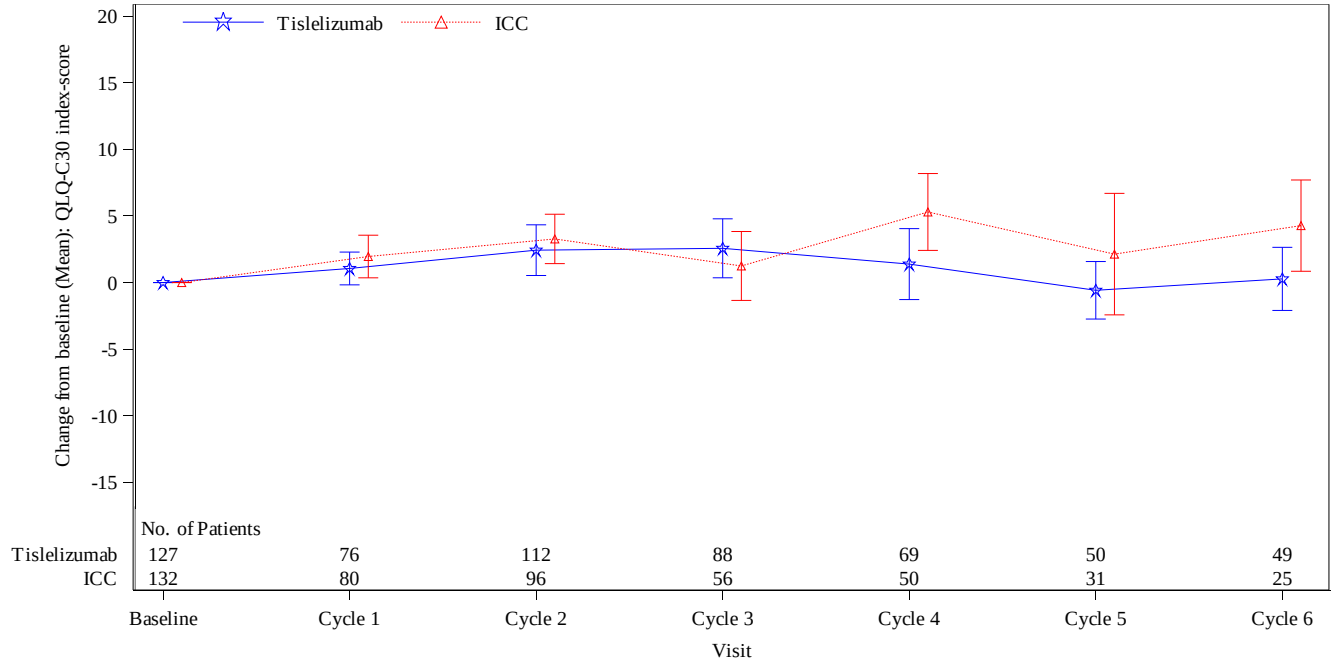
Figure 14.2.7.1.b:
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set - Subpopulation without Irinotecan



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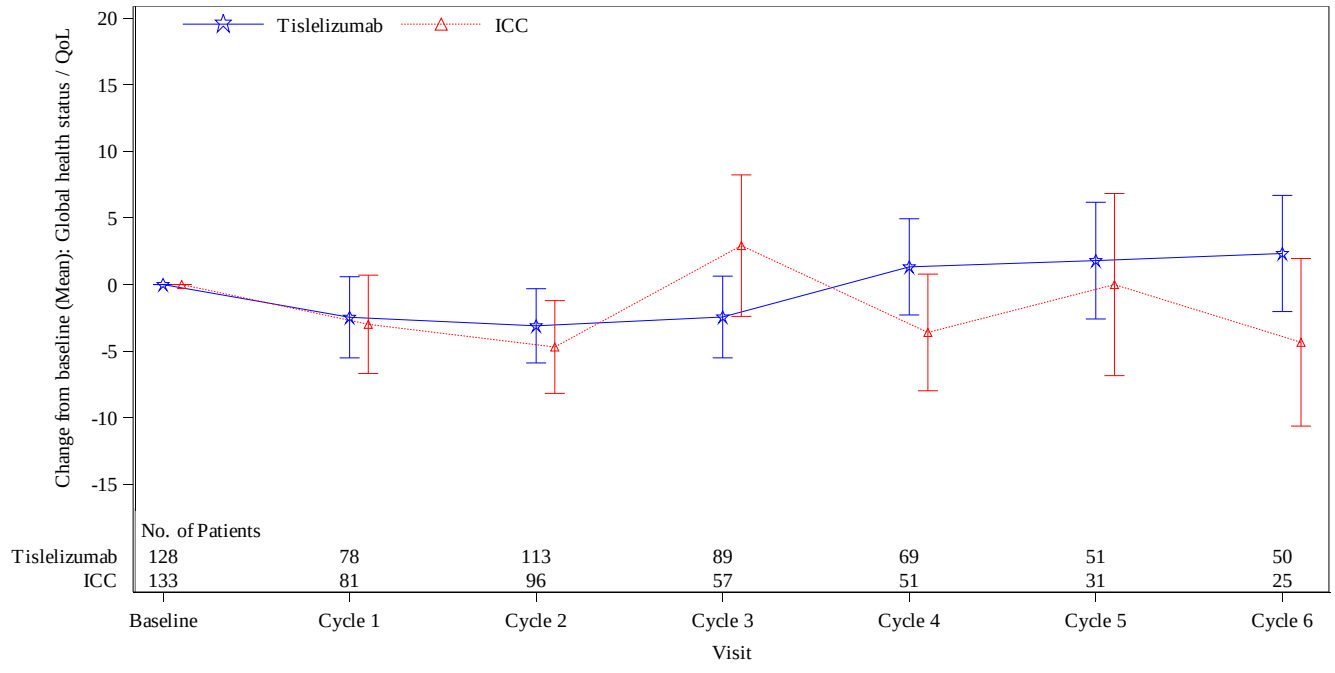
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set - Subpopulation without Irinotecan



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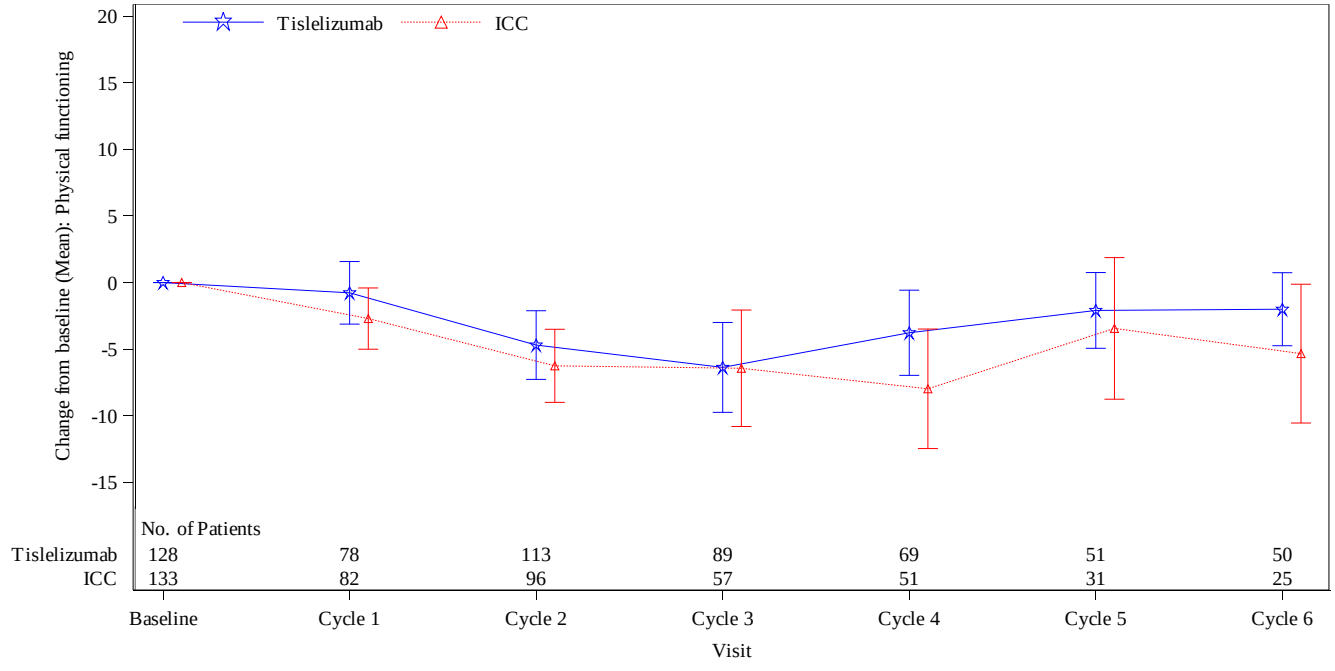
ITT Analysis Set - Subpopulation without Irinotecan



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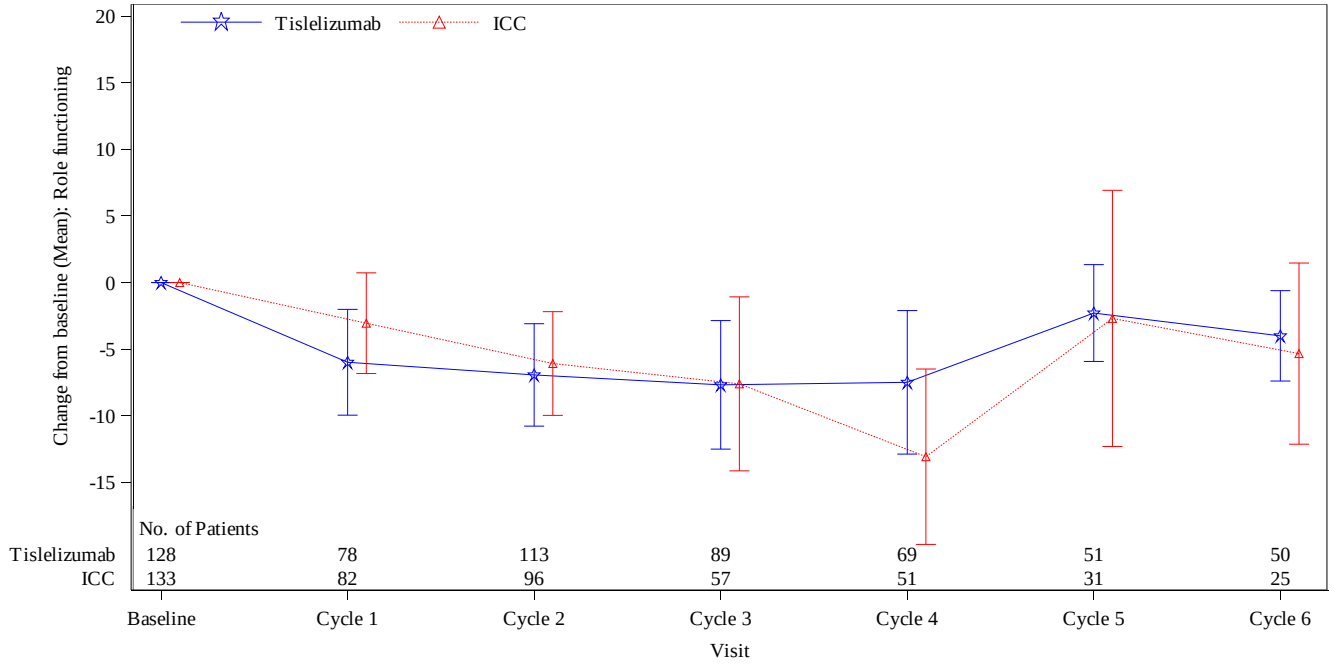
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set - Subpopulation without Irinotecan



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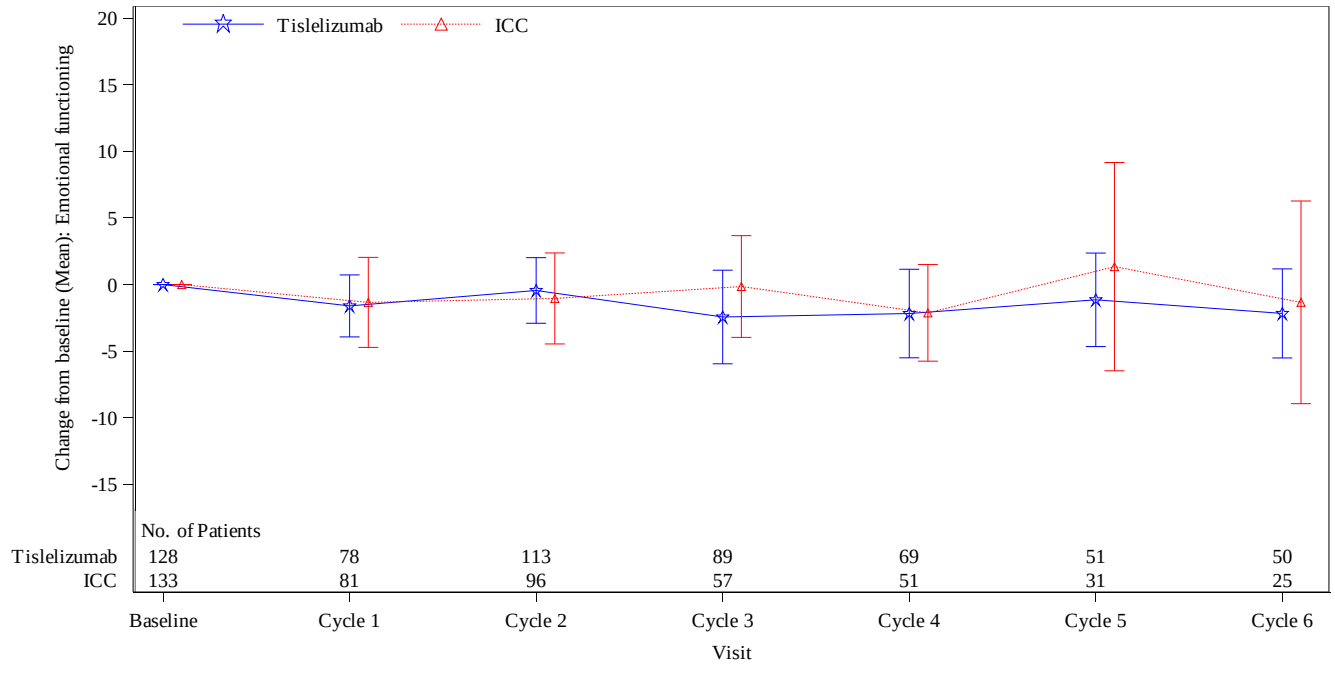
ITT Analysis Set - Subpopulation without Irinotecan



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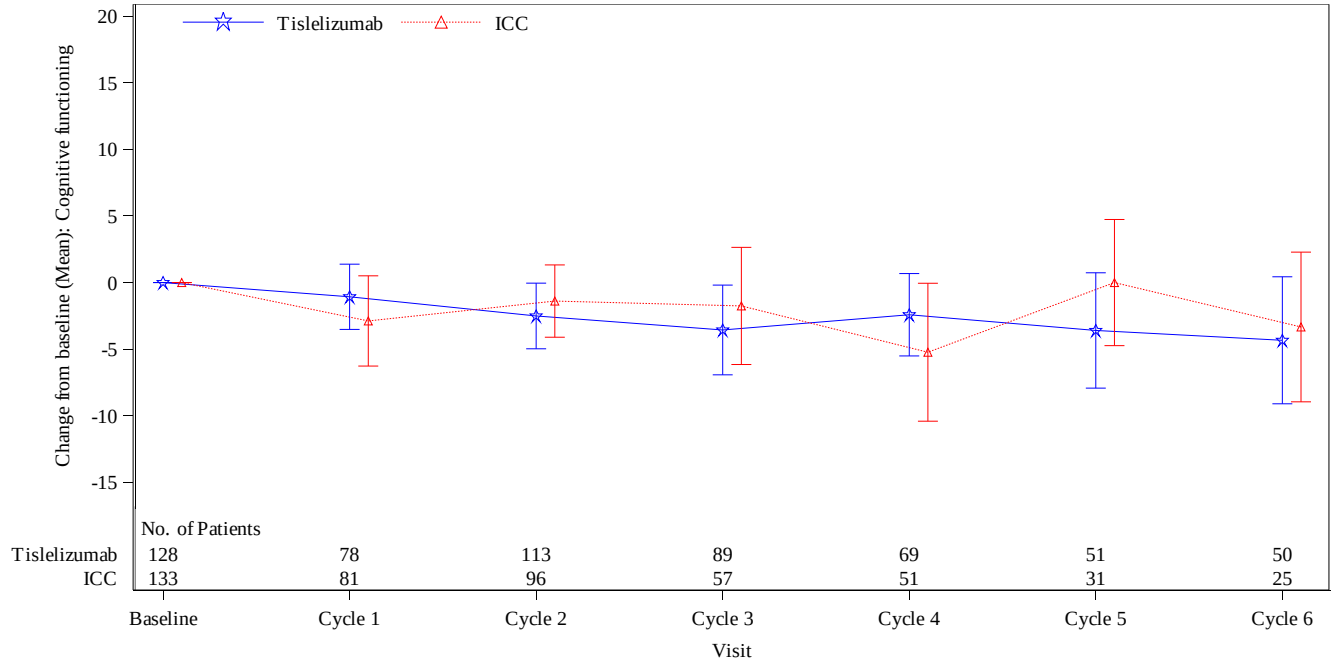
ITT Analysis Set - Subpopulation without Irinotecan



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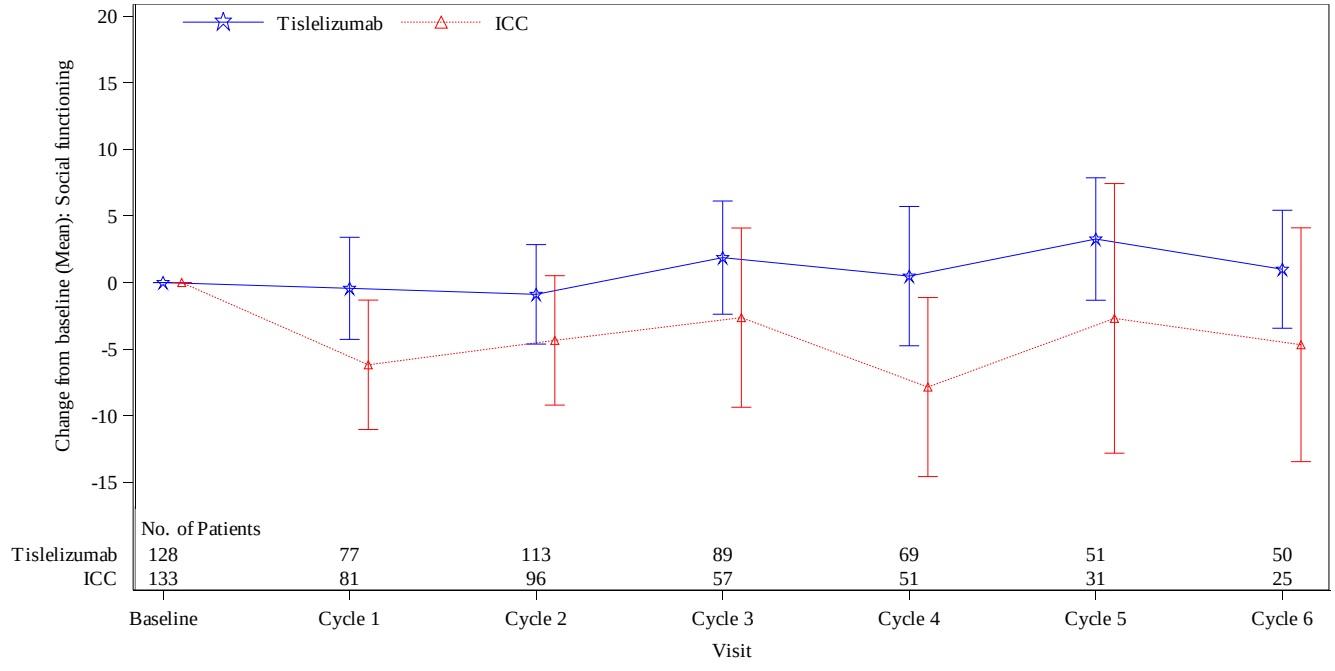
ITT Analysis Set - Subpopulation without Irinotecan



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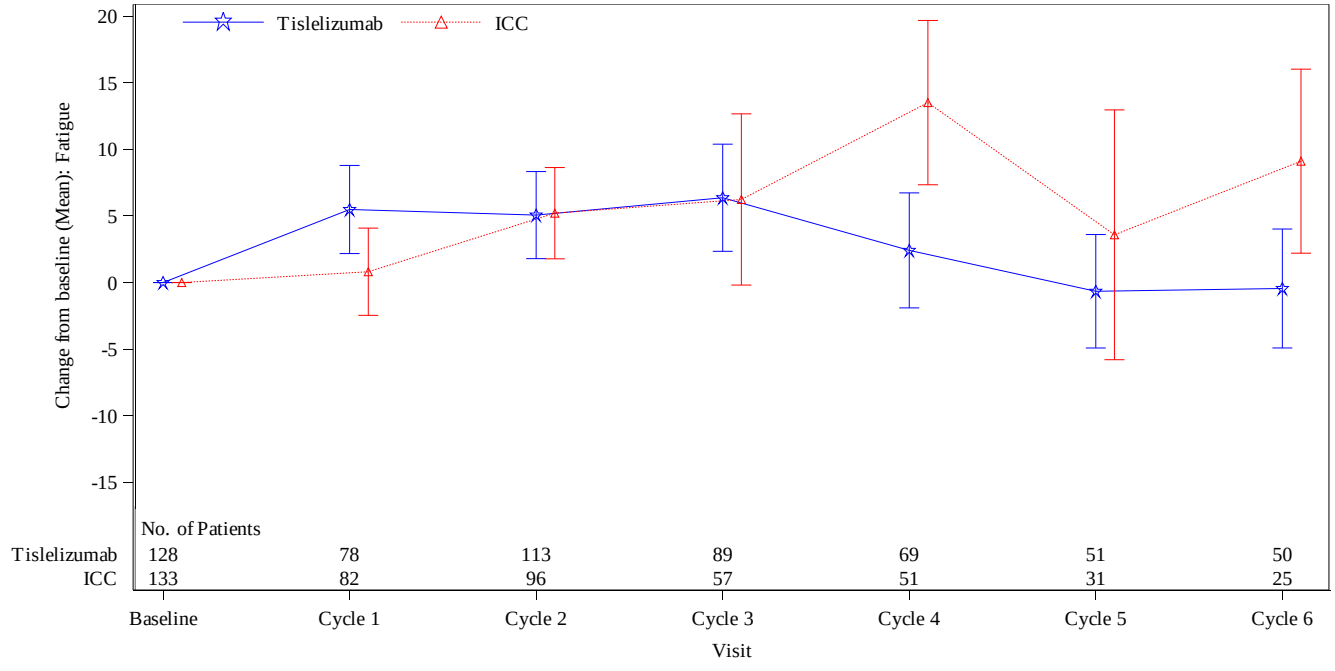

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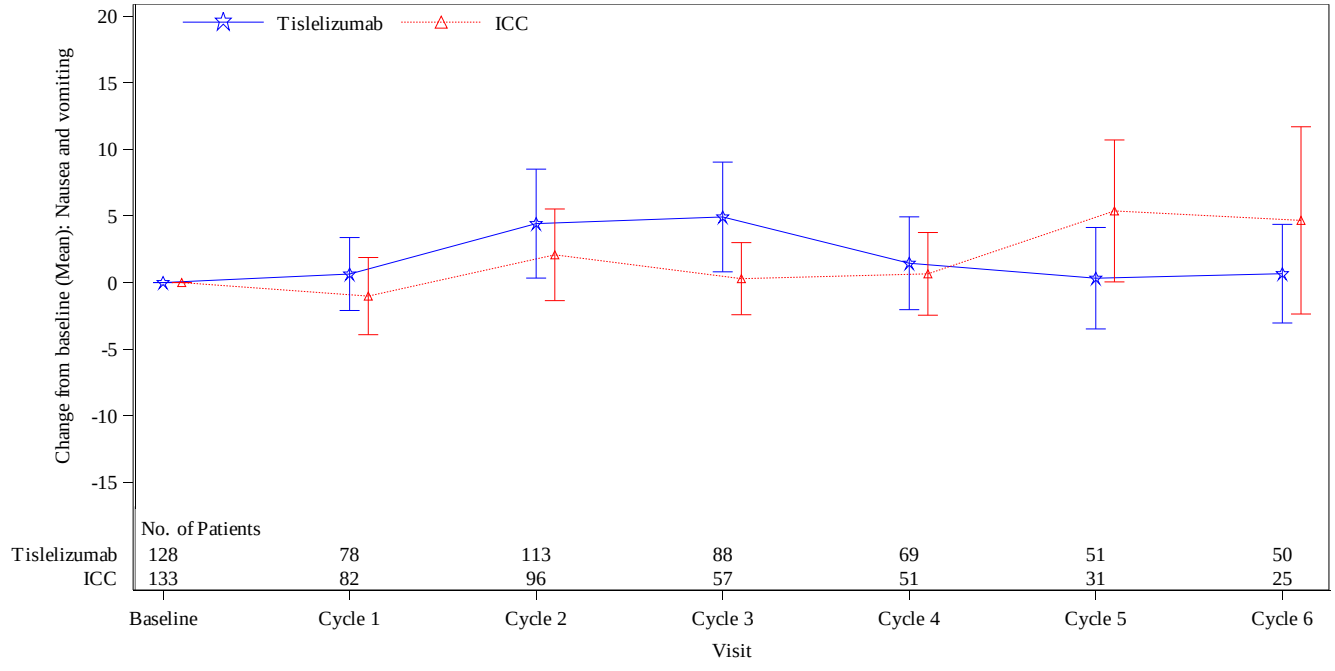

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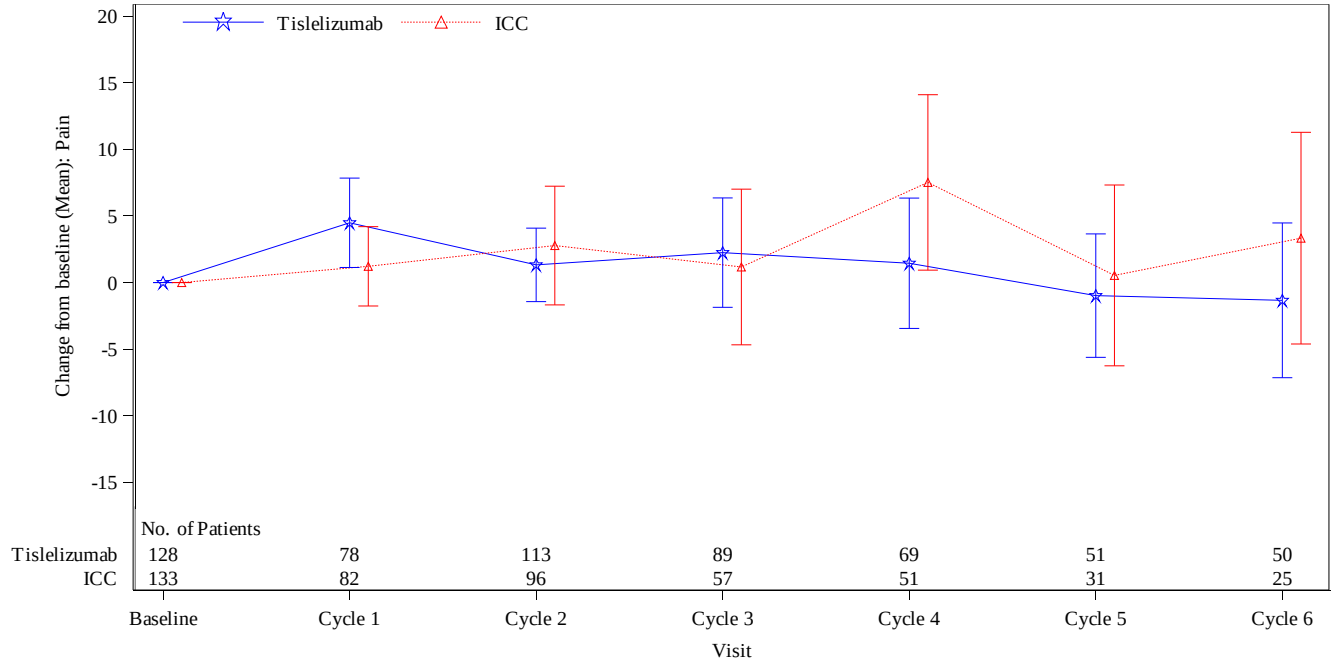

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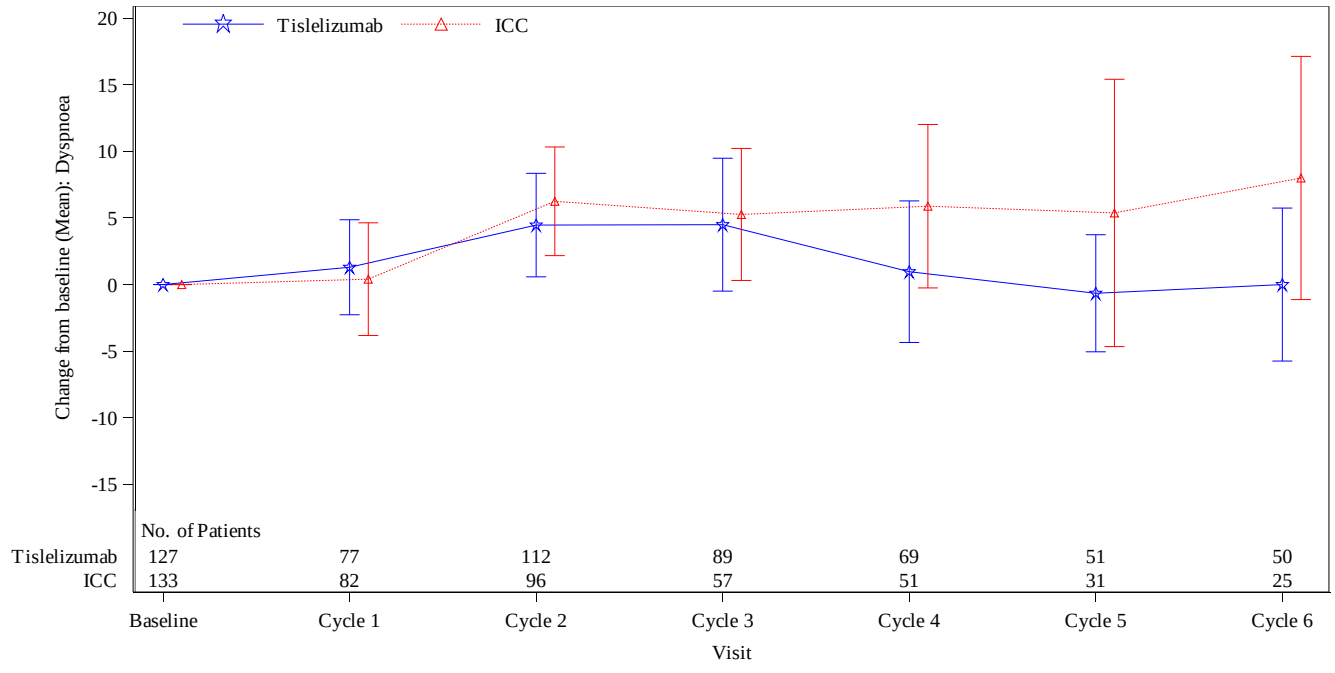

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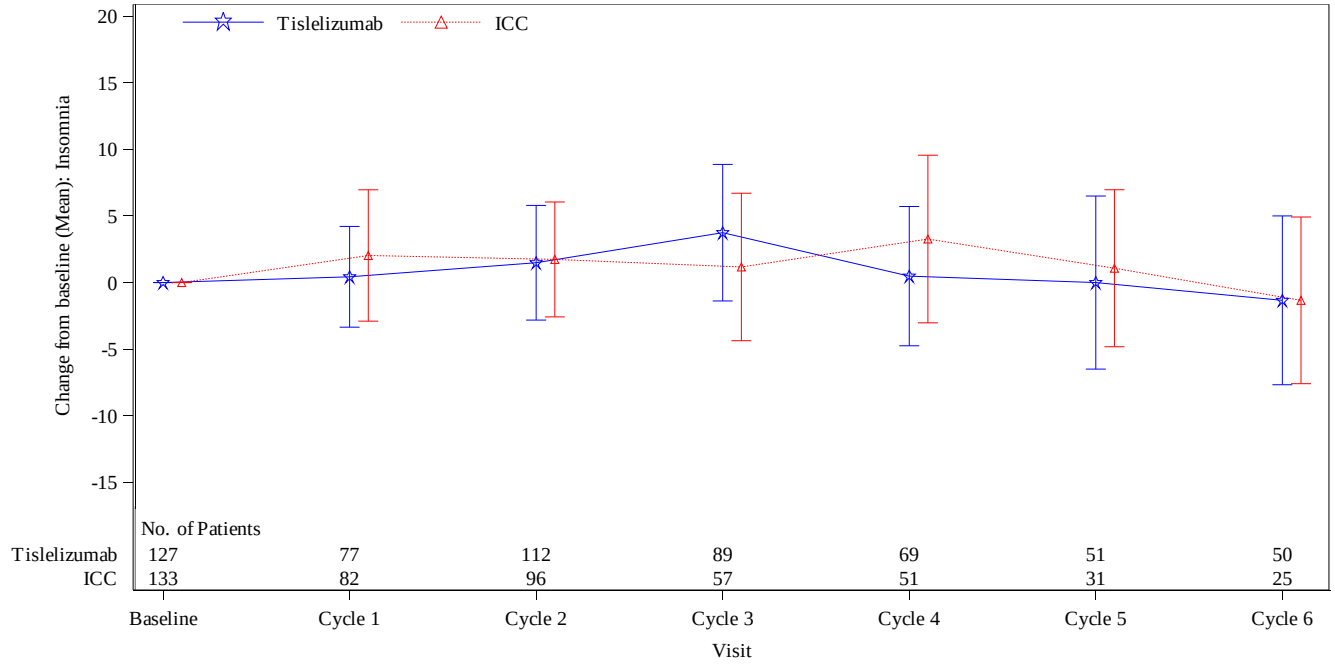

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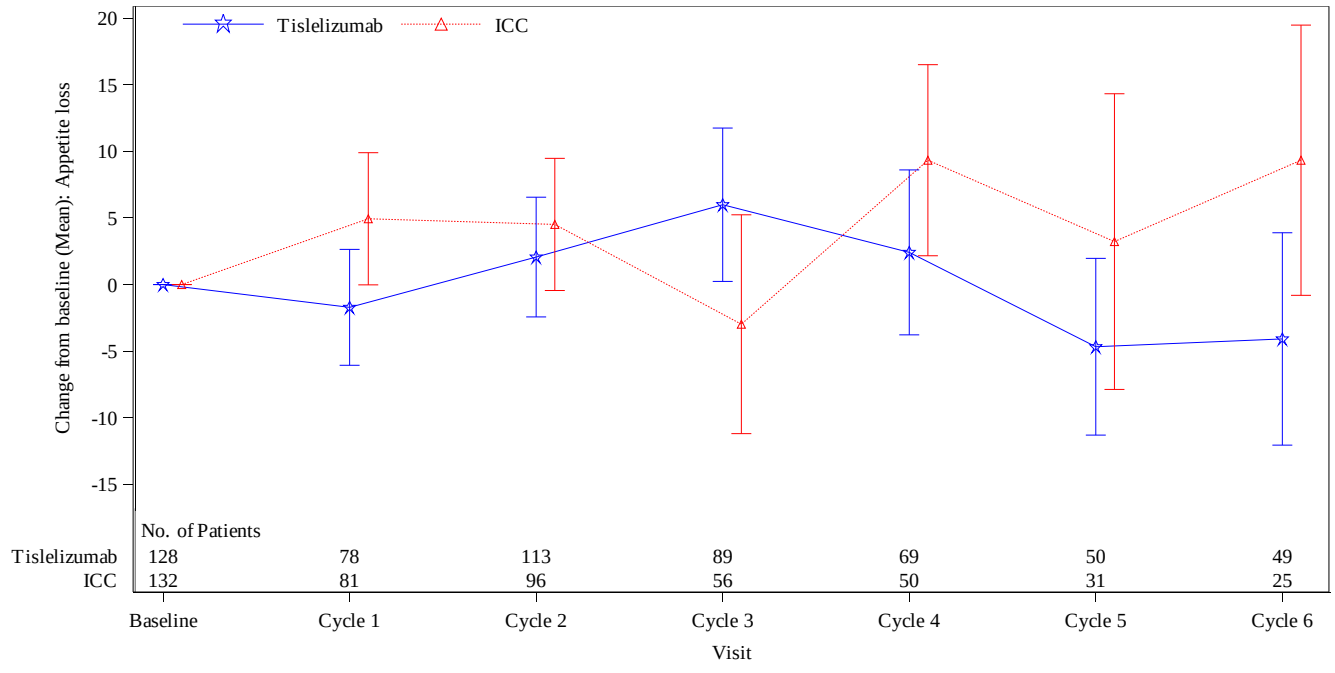

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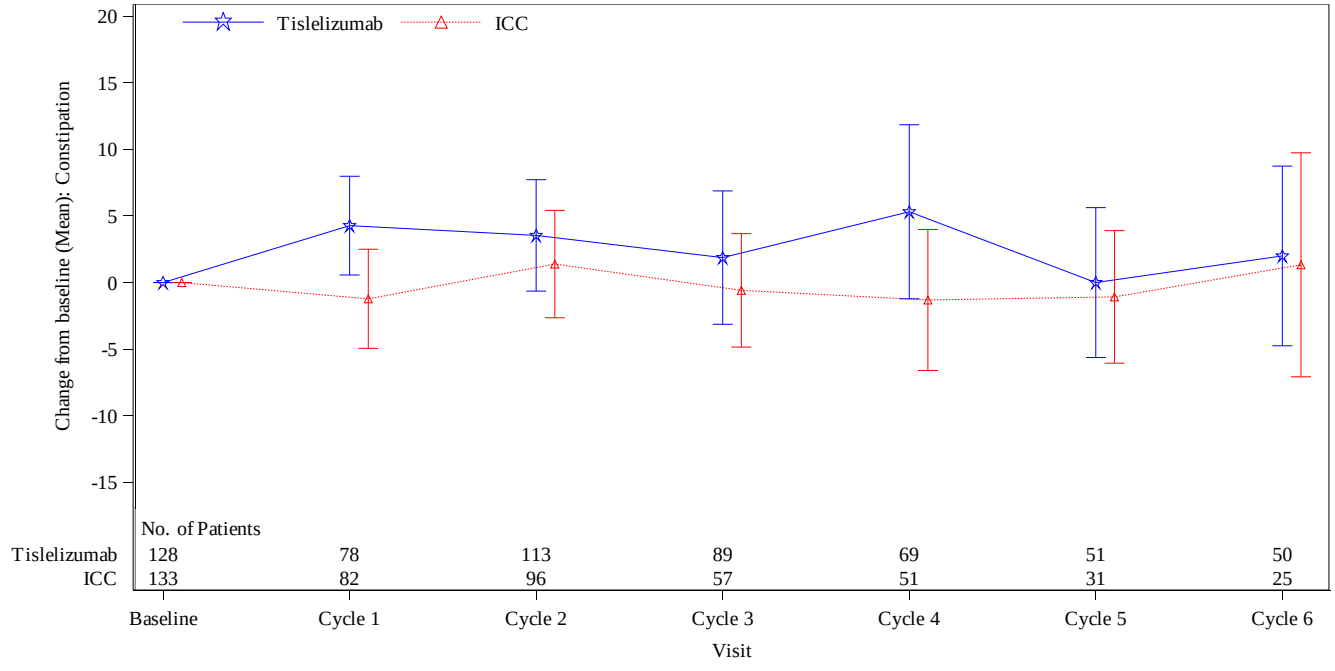

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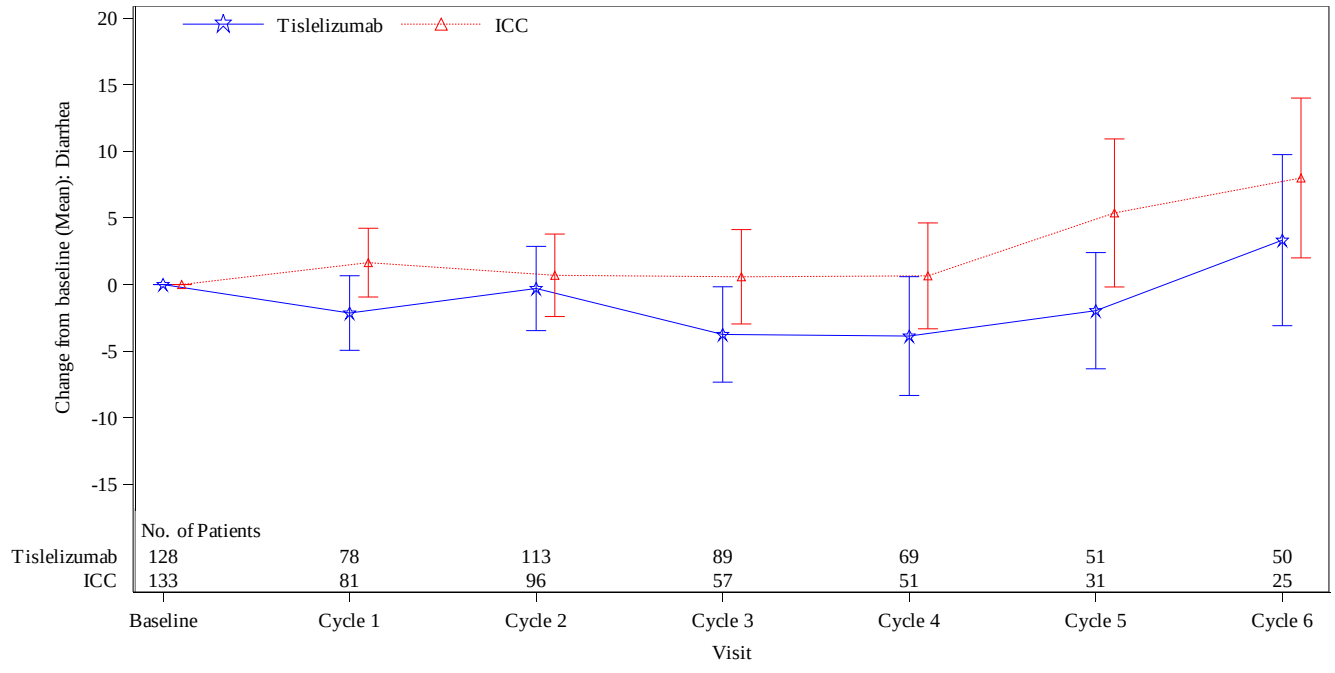

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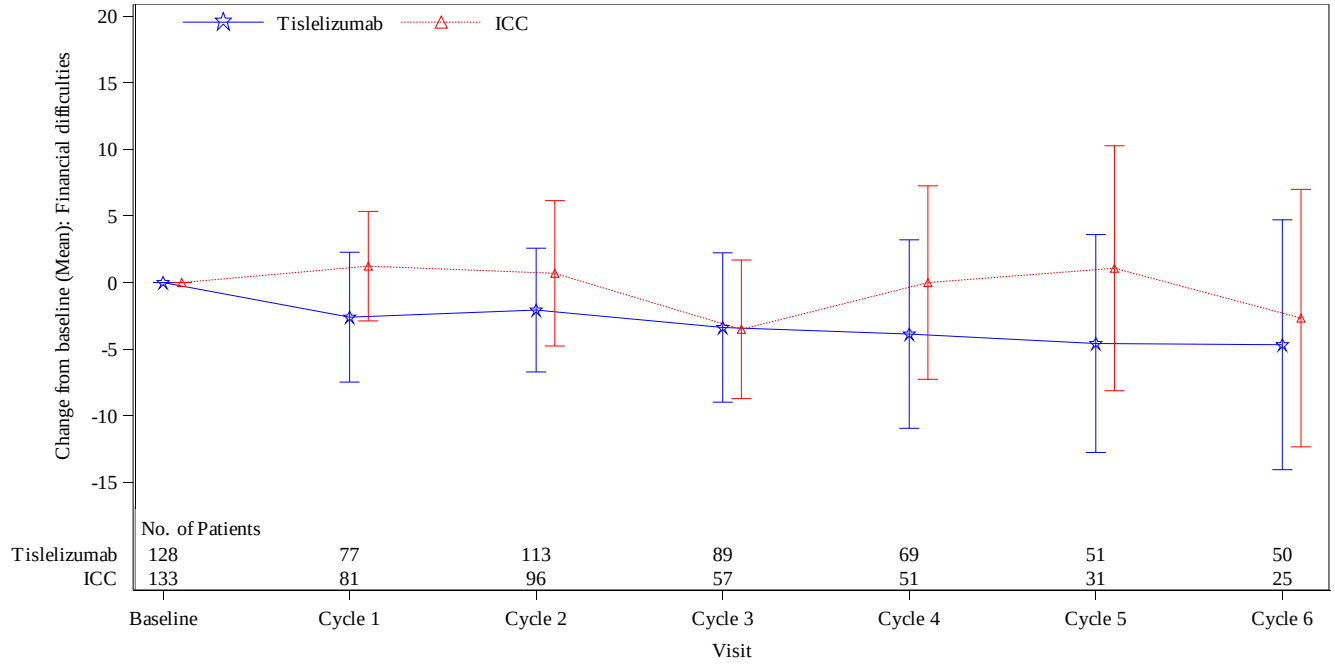

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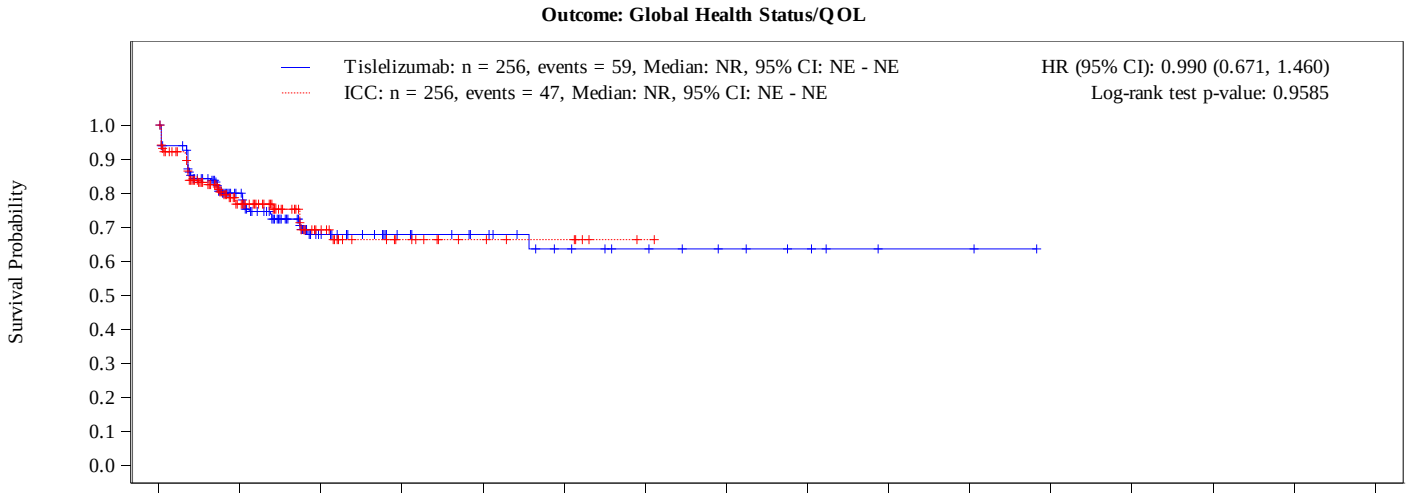
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Datapoints represent means and 95% CI.
Increases in scores for global health status/QoL, physical functioning, role functioning, emotional functioning, cognitive functioning and social functioning are improvements, while increases in scores for index score, fatigue, nausea and vomiting, pain, dyspnoea, insomnia, appetite loss, constipation, diarrhea and financial difficulty are deteriorations for C30.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-series.sas 15MAY2024 20:01 f-14-02-07-01-b-series-c30-itts-fa.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set

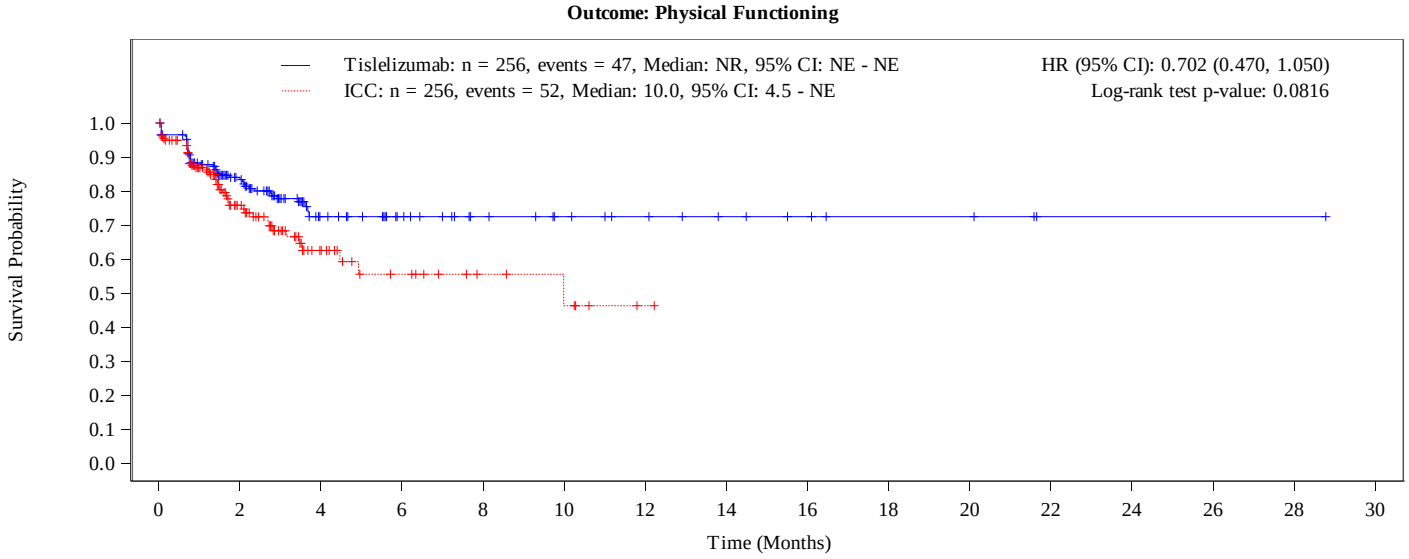


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	256	122	41	26	19	13	10	7	5	2	2	0	0	0	0	0
ICC	256	74	27	14	8	6	1	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-01-02-km-qs-c30-itt-fa.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set

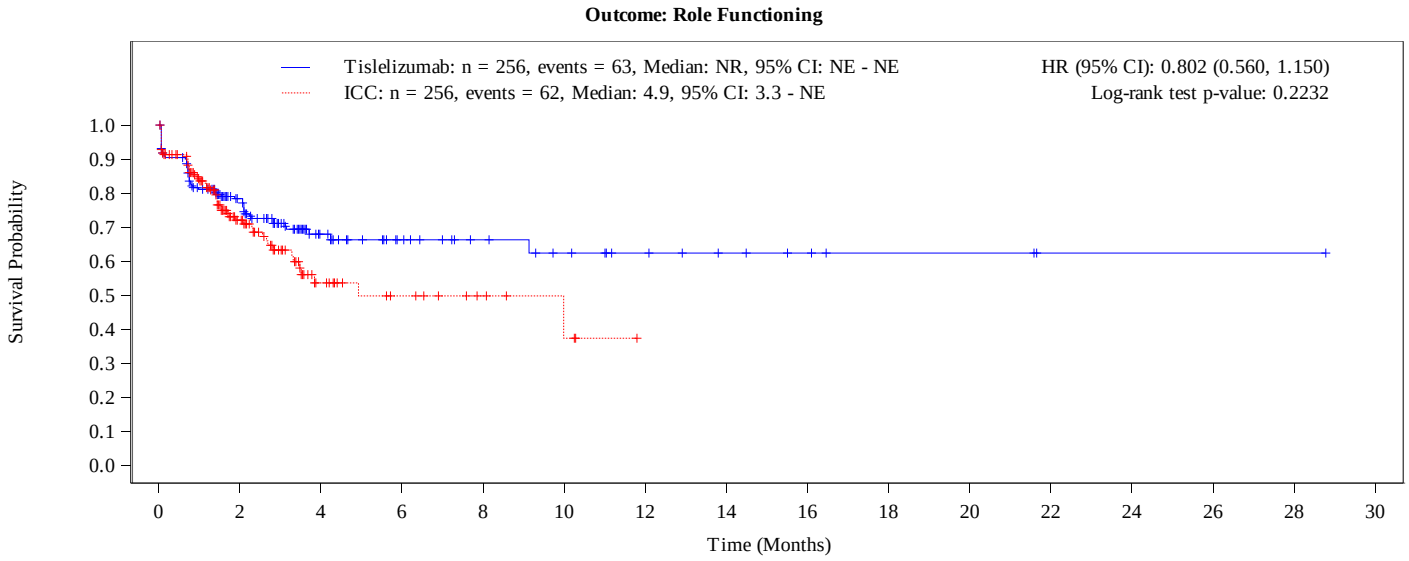


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	256	130	43	29	19	15	12	8	6	4	4	1	1	1	1	0
ICC	256	72	24	13	7	5	1	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-01-02-km-qs-c30-itt-fa.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set

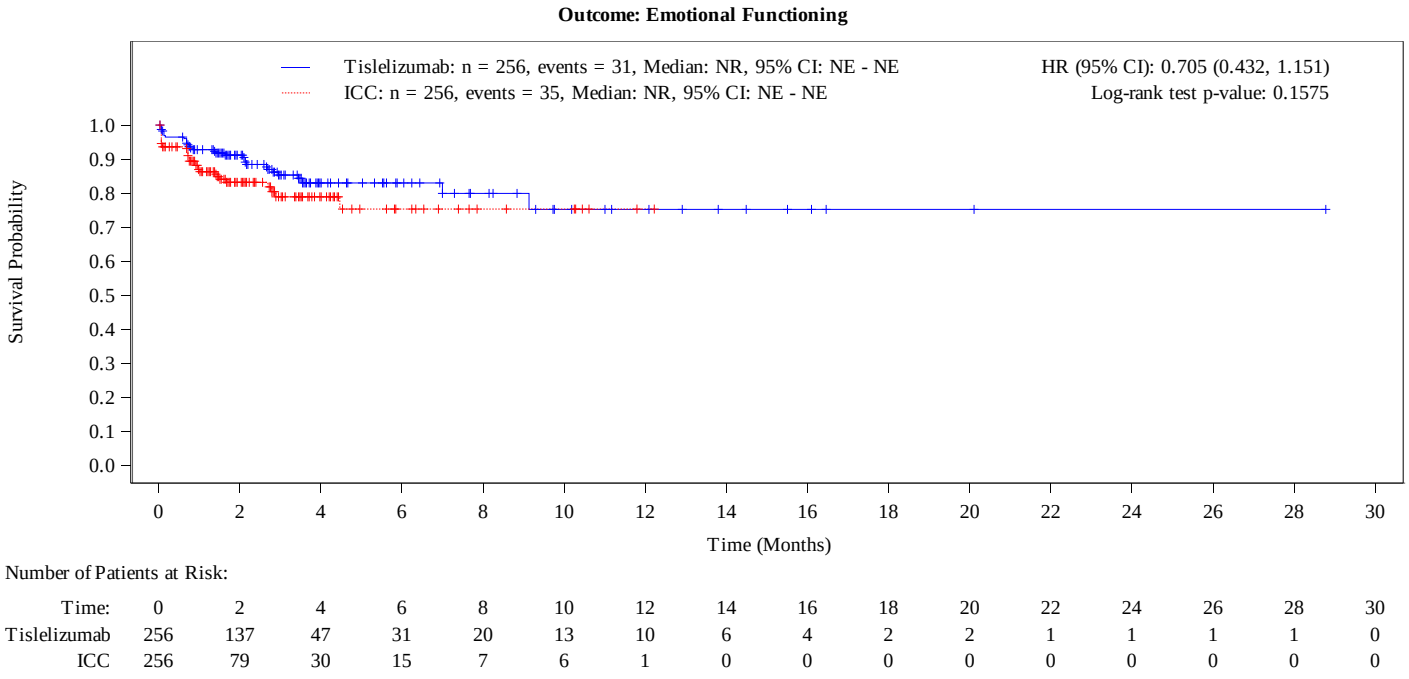


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	256	123	42	26	18	14	10	7	5	3	3	1	1	1	1	0
ICC	256	67	20	11	6	3	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-01-02-km-qs-c30-itt-fa.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set

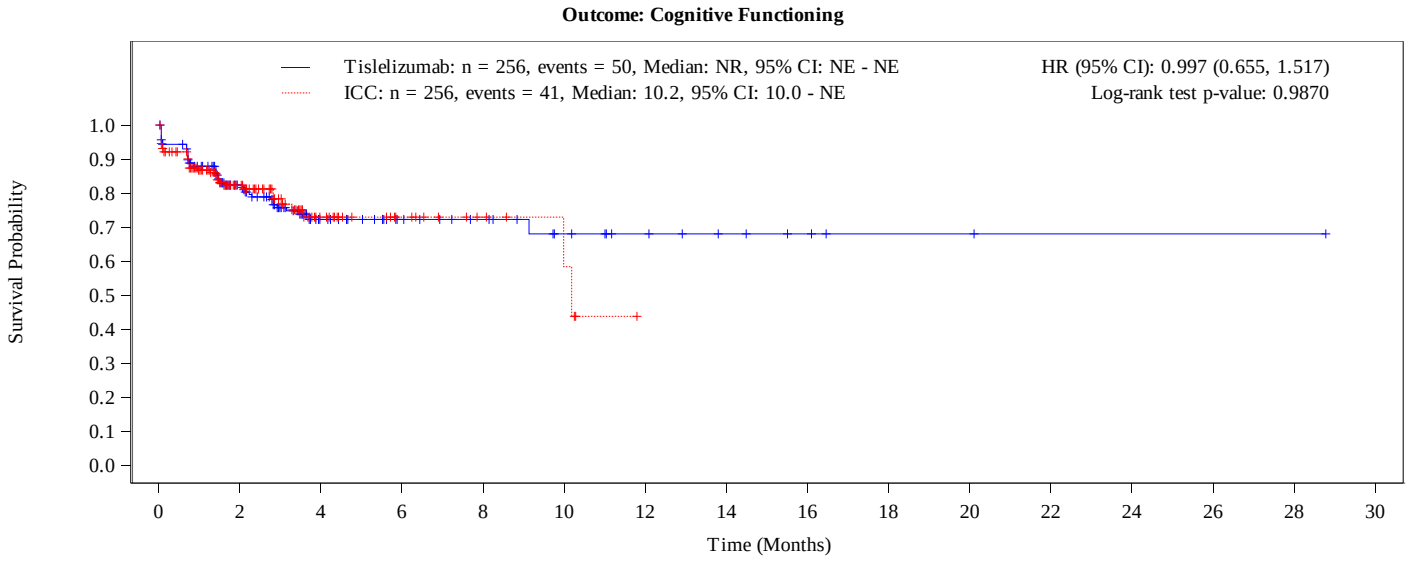


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	256	137	47	31	20	13	10	6	4	2	2	1	1	1	1	0
ICC	256	79	30	15	7	6	1	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-01-02-km-qs-c30-itt-fa.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set

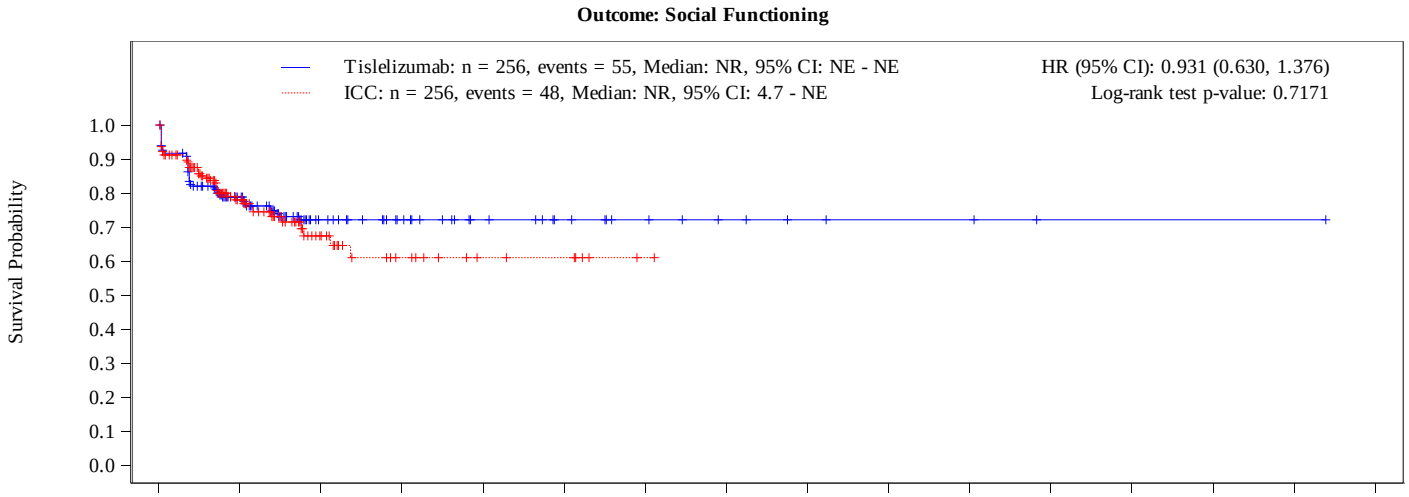


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	256	121	40	26	20	14	10	6	4	2	2	1	1	1	1	0
ICC	256	79	26	14	7	4	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-01-02-km-qs-c30-itt-fa.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set

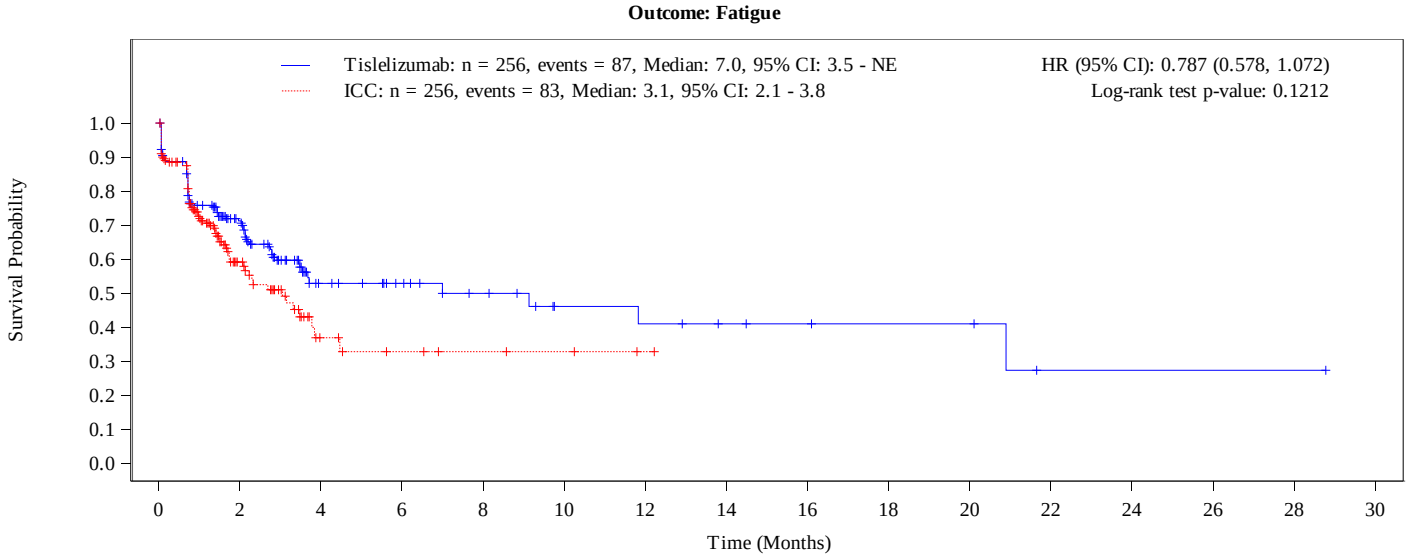


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	256	123	43	30	19	14	10	6	4	3	3	1	1	1	1	0
ICC	256	74	27	13	7	6	1	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-01-02-km-qs-c30-itt-fa.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set

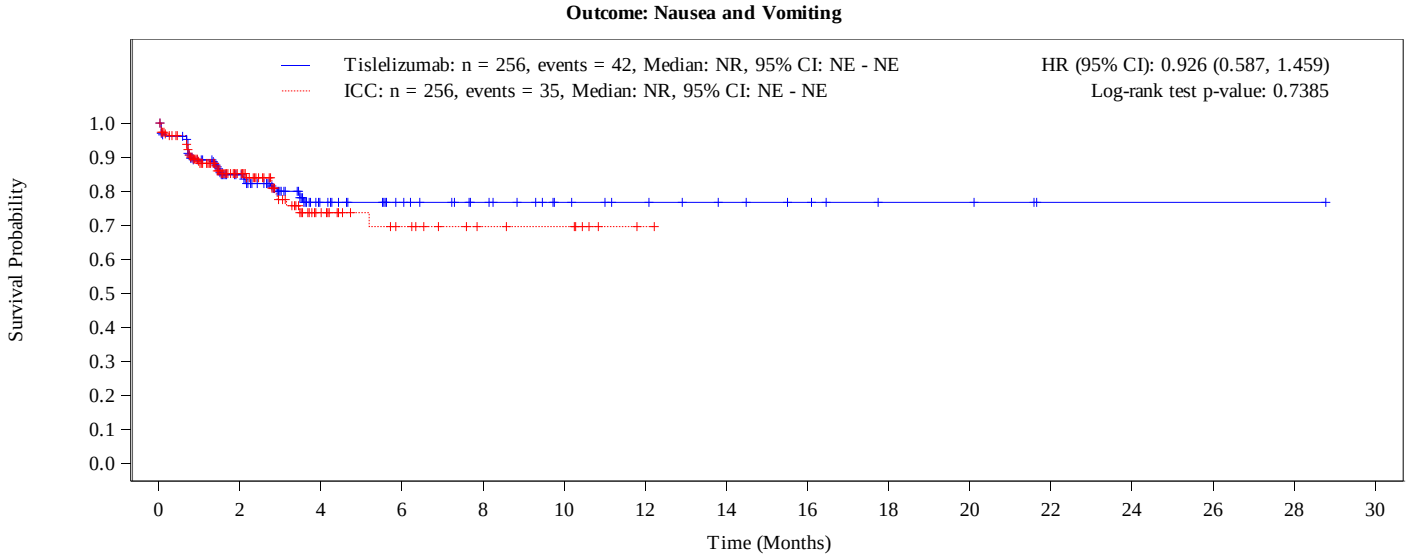


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	256	107	29	21	15	9	8	6	5	4	4	1	1	1	1	0
ICC	256	49	10	6	4	3	1	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-01-02-km-qs-c30-itt-fa.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set

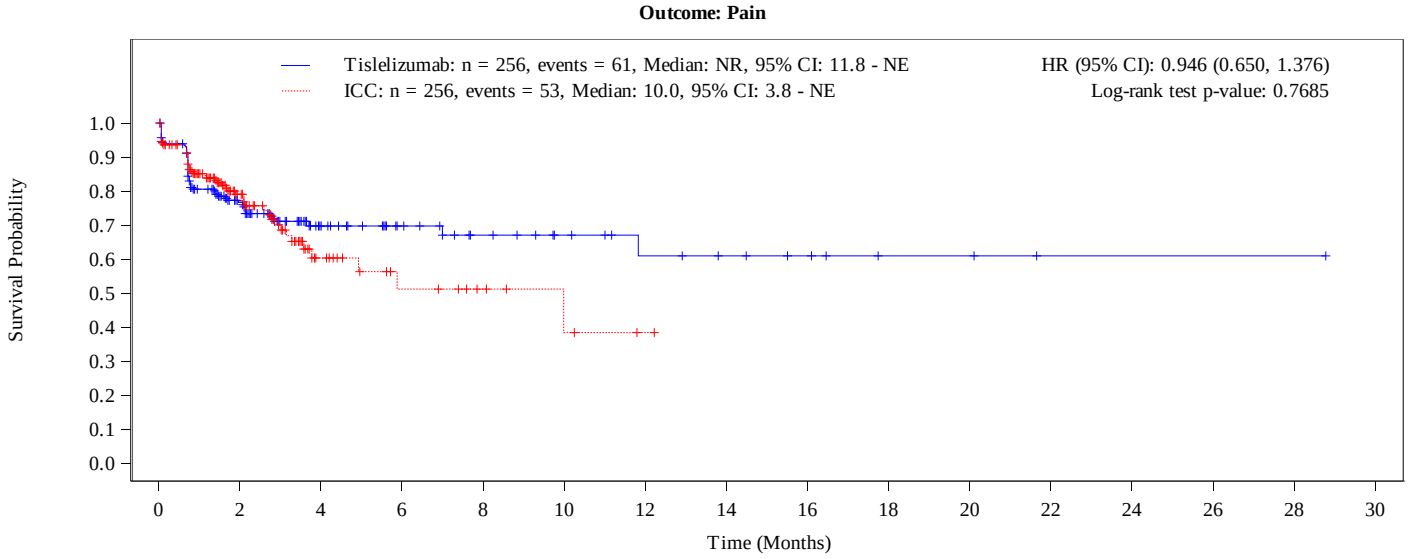


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	256	132	45	31	23	16	13	9	7	4	4	1	1	1	1	0
ICC	256	76	26	15	8	7	1	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-01-02-km-qs-c30-itt-fa.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set

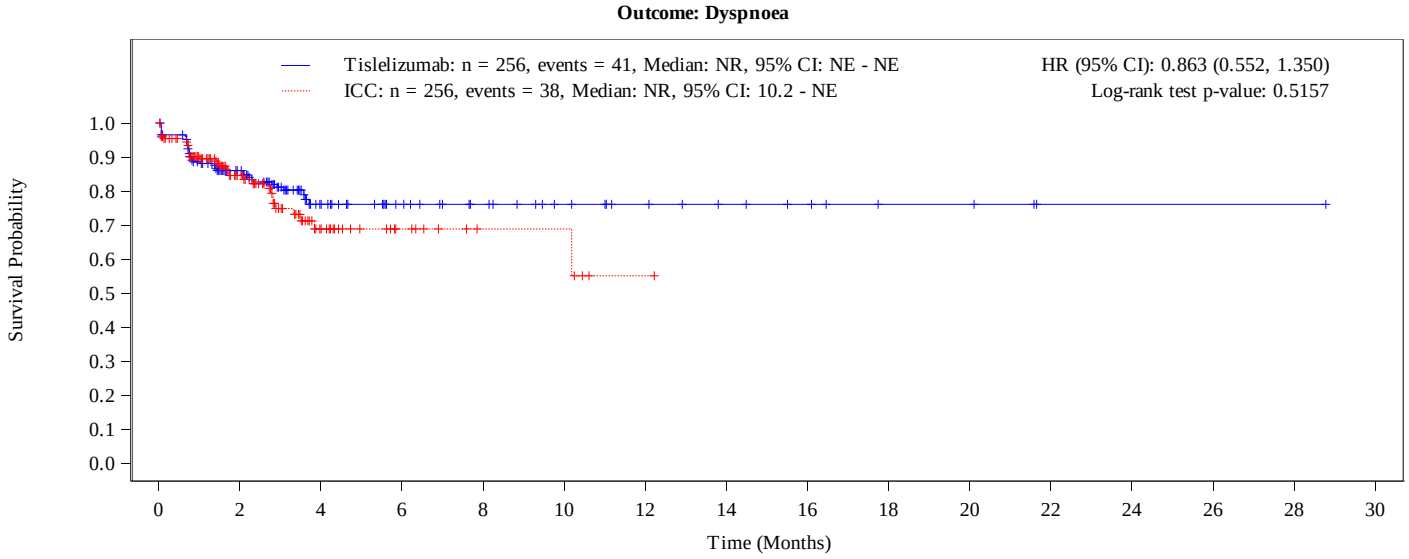


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	256	120	44	29	19	14	10	8	6	3	3	1	1	1	1	0
ICC	256	76	20	10	6	3	1	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-01-02-km-qs-c30-itt-fa.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set

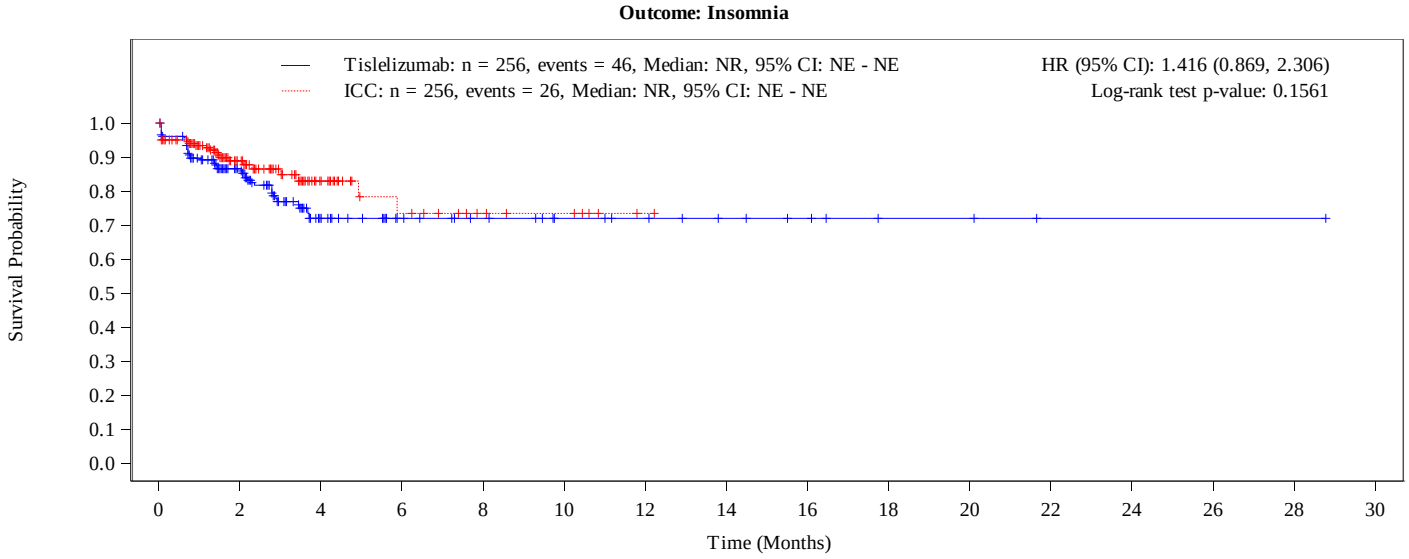


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	256	132	47	31	23	17	13	9	7	4	4	1	1	1	1	0
ICC	256	78	26	12	5	5	1	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-01-02-km-qs-c30-itt-fa.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set

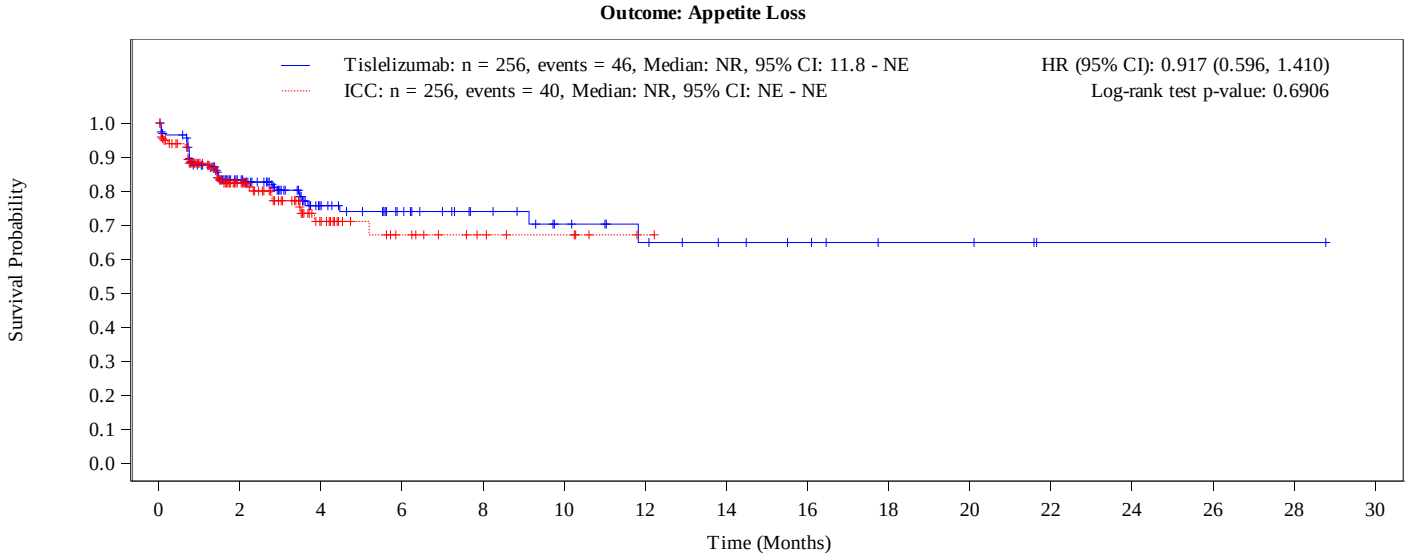


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	256	131	41	25	19	14	12	8	6	3	3	1	1	1	1	0
ICC	256	83	29	15	8	6	1	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-01-02-km-qs-c30-itt-fa.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set

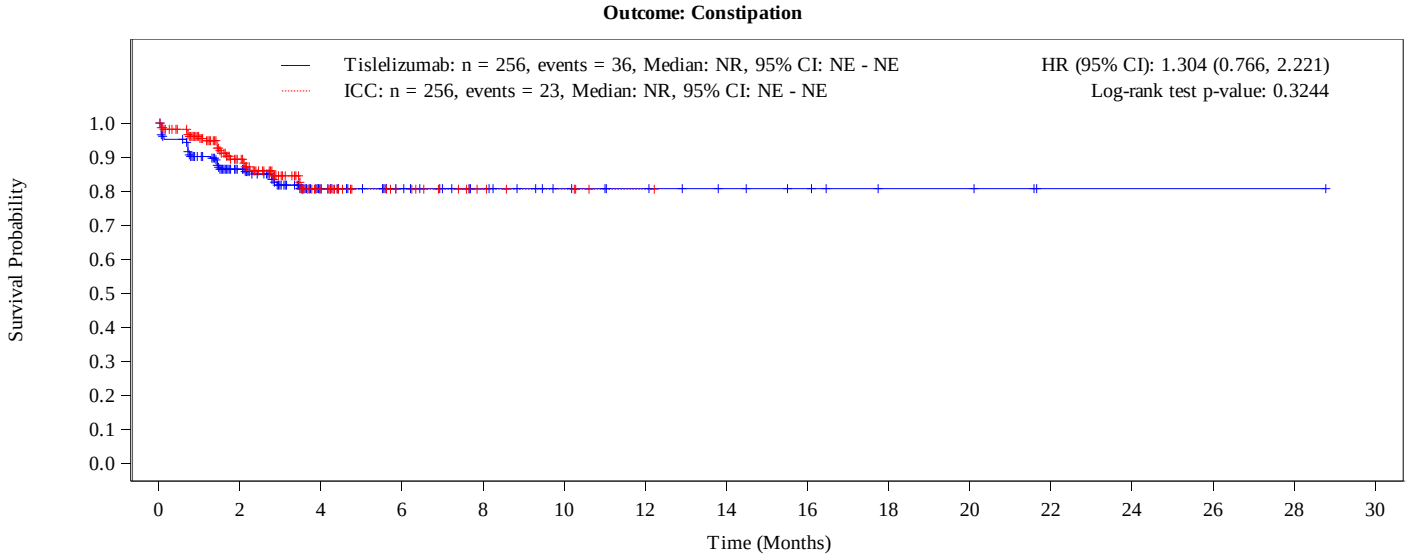


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	256	126	48	33	22	16	12	9	7	4	4	1	1	1	1	0
ICC	256	77	28	14	7	5	1	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-01-02-km-qs-c30-itt-fa.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set

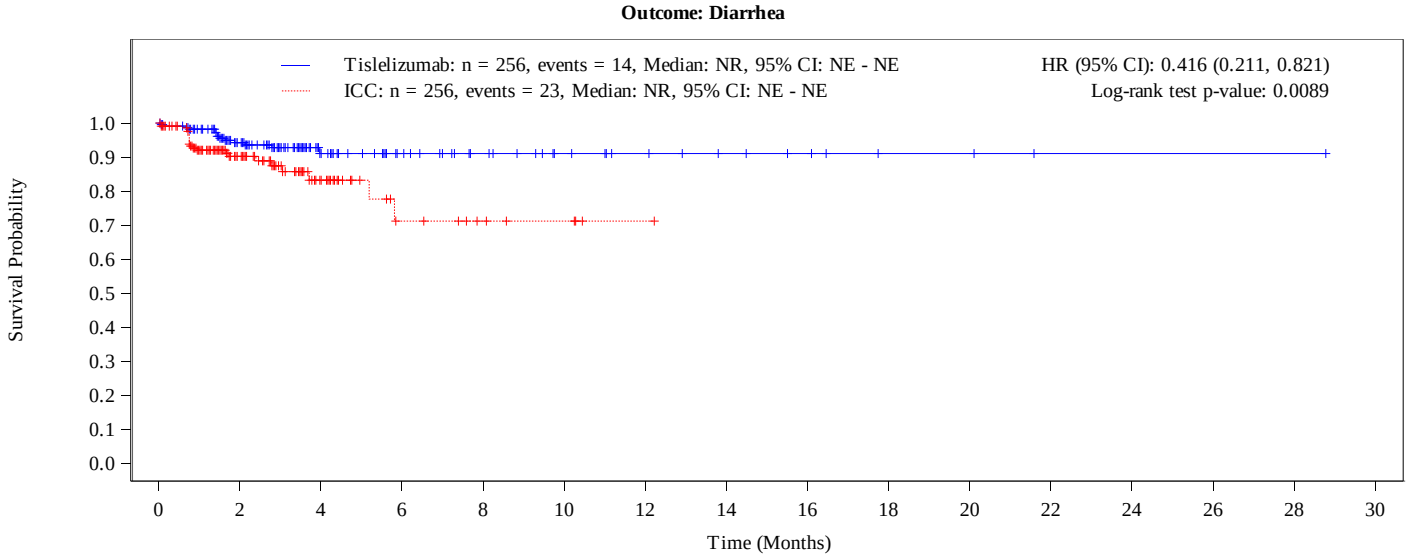


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	256	128	44	29	21	15	12	9	7	4	4	1	1	1	1	0
ICC	256	87	29	15	6	4	1	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-01-02-km-qs-c30-itt-fa.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set

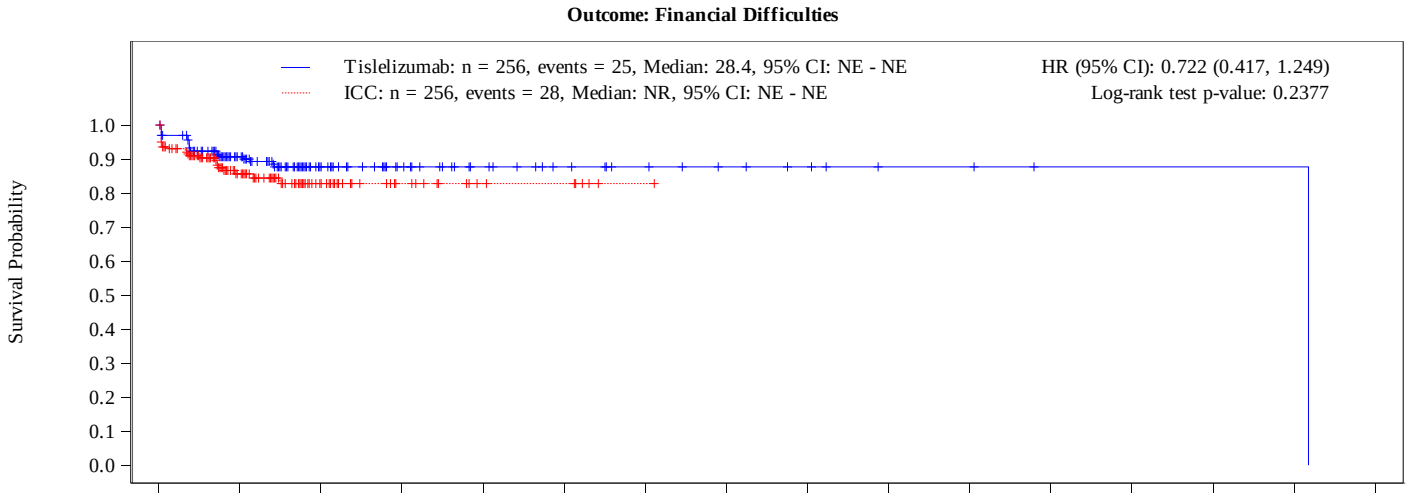


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	256	141	51	33	23	16	12	8	6	3	3	1	1	1	1	0
ICC	256	83	28	10	6	4	1	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-01-02-km-qs-c30-itt-fa.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set

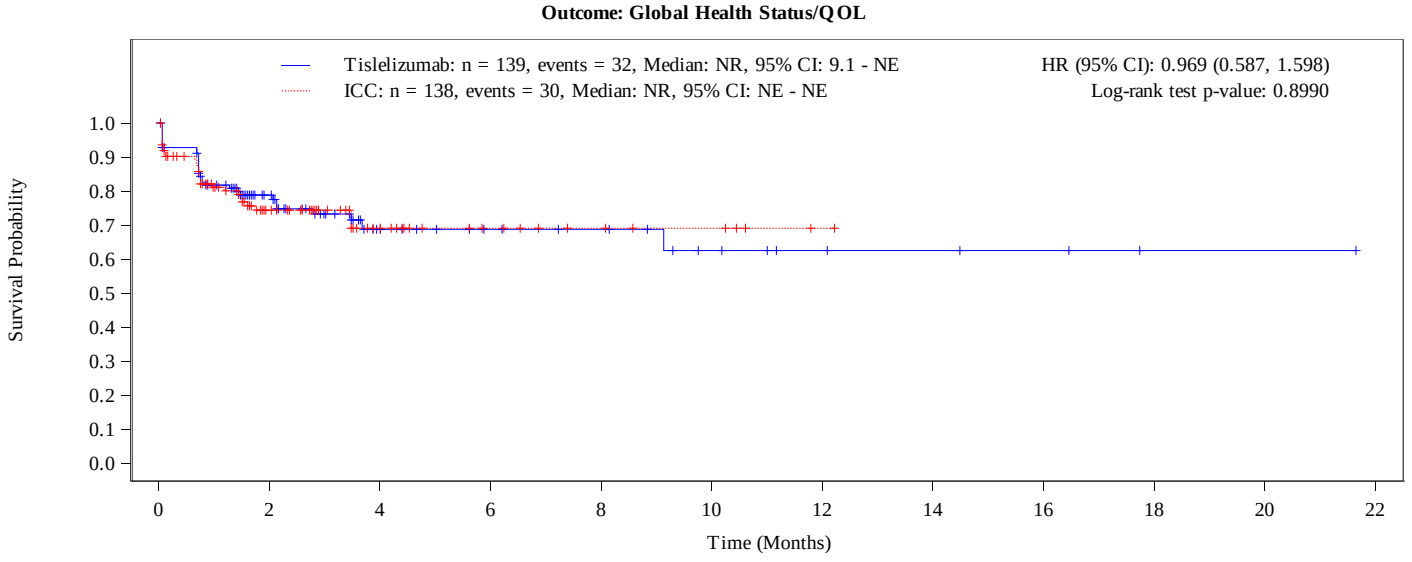


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	256	136	53	34	22	16	12	8	6	3	3	1	1	1	1	0
ICC	256	80	31	15	7	6	1	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-01-02-km-qs-c30-itt-fa.rtf

Figure 14.2.7.1.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation without Irinotecan

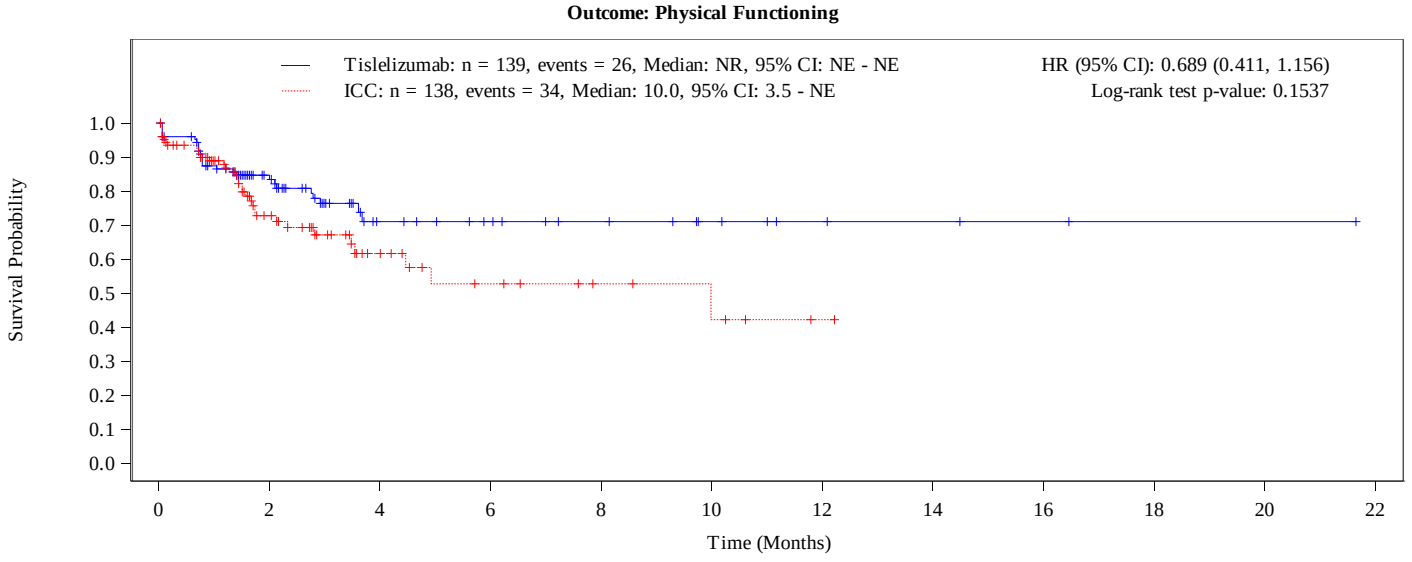


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	139	61	21	15	13	8	5	4	3	1	1	0
ICC	138	47	20	11	7	5	1	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-01-02-b-km-qs-c30-itts-fa.rtf

Figure 14.2.7.1.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation without Irinotecan

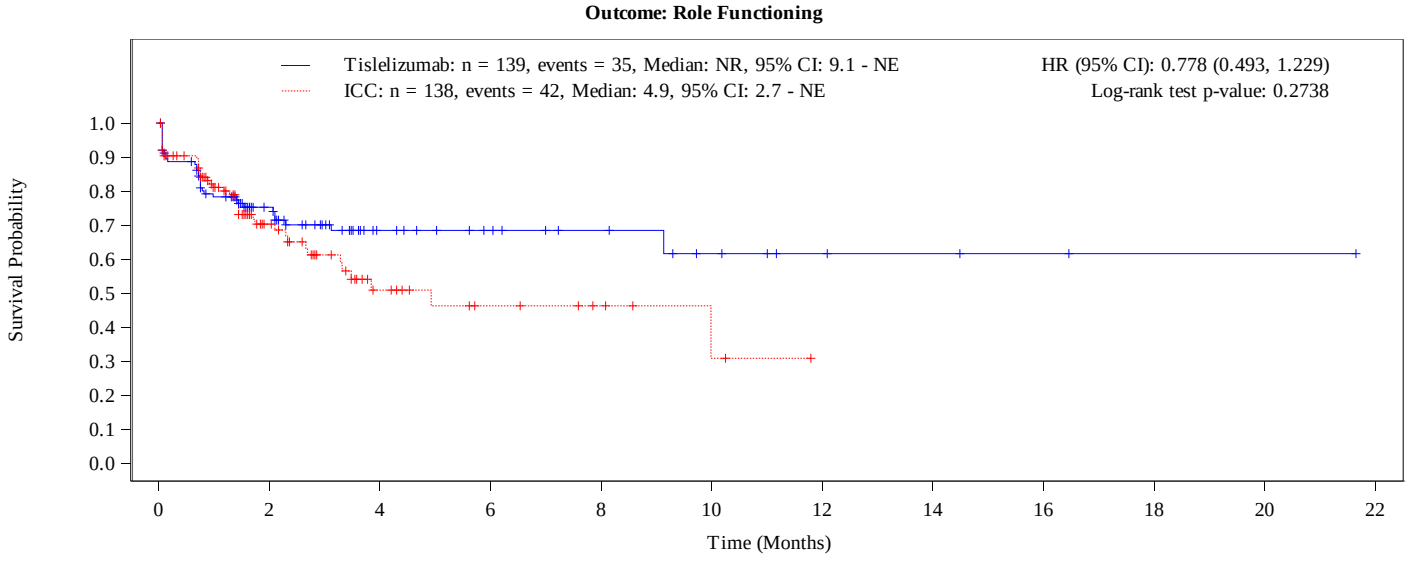


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	139	67	21	16	12	8	5	3	2	1	1	0
ICC	138	45	18	10	6	4	1	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-01-02-b-km-qs-c30-itts-fa.rtf

Figure 14.2.7.1.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation without Irinotecan

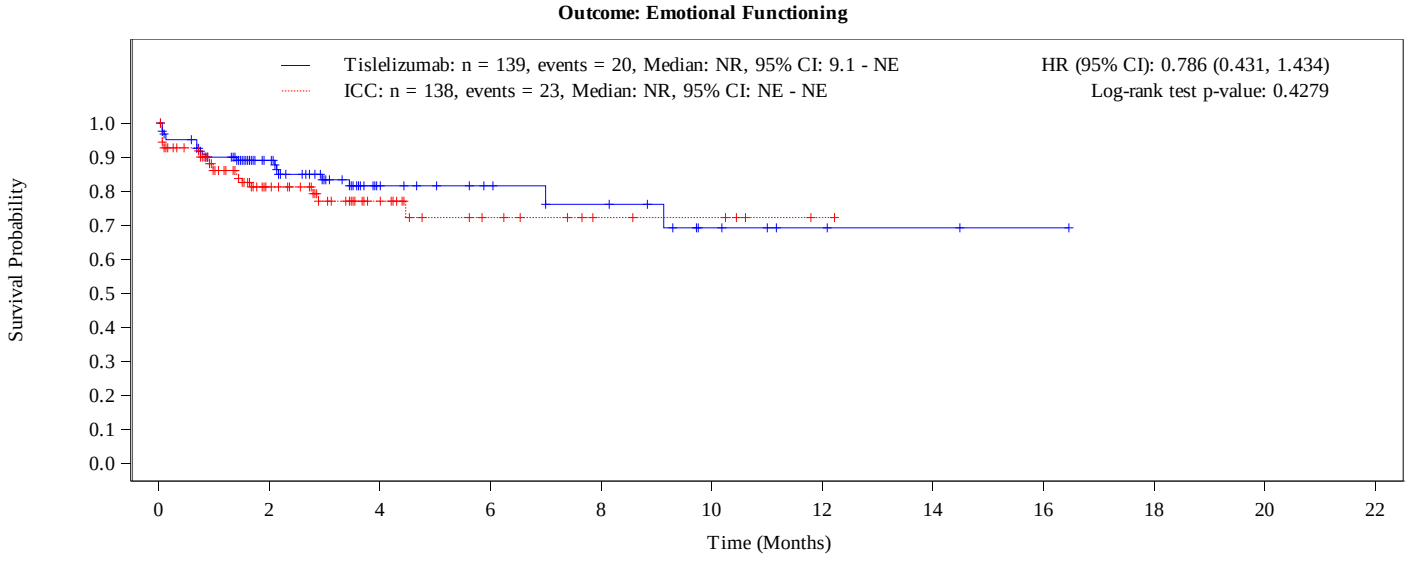


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	139	60	21	15	11	7	4	3	2	1	1	0
ICC	138	43	15	8	5	2	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-01-02-b-km-qs-c30-itts-fa.rtf

Figure 14.2.7.1.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation without Irinotecan

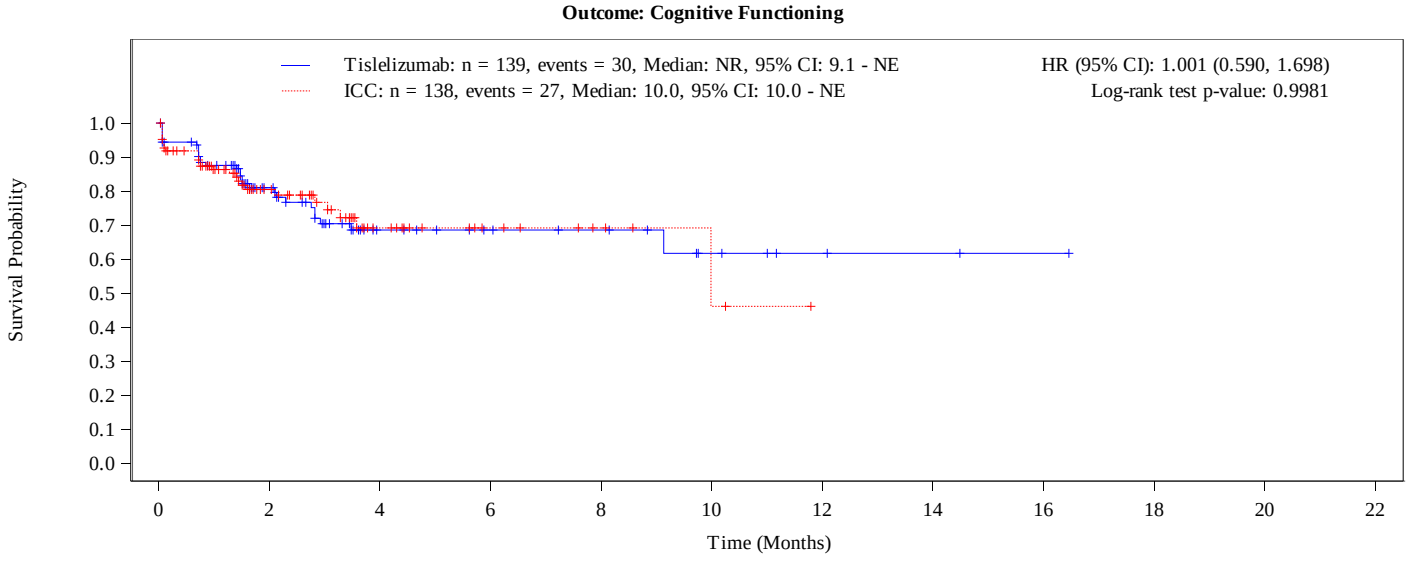


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	139	68	22	16	13	7	4	2	1	0	0	0
ICC	138	51	22	11	6	5	1	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-01-02-b-km-qs-c30-itts-fa.rtf

Figure 14.2.7.1.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation without Irinotecan

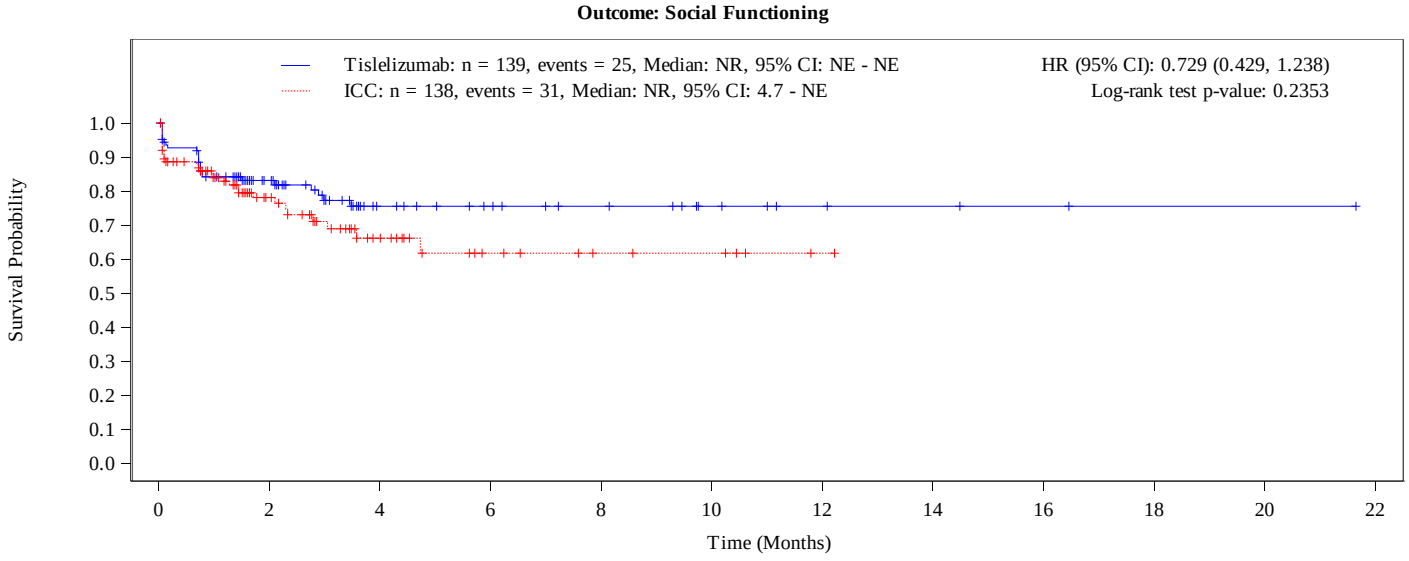


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	139	59	19	14	12	7	4	2	1	0	0	0
ICC	138	51	18	9	5	2	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-01-02-b-km-qs-c30-itts-fa.rtf

Figure 14.2.7.1.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation without Irinotecan

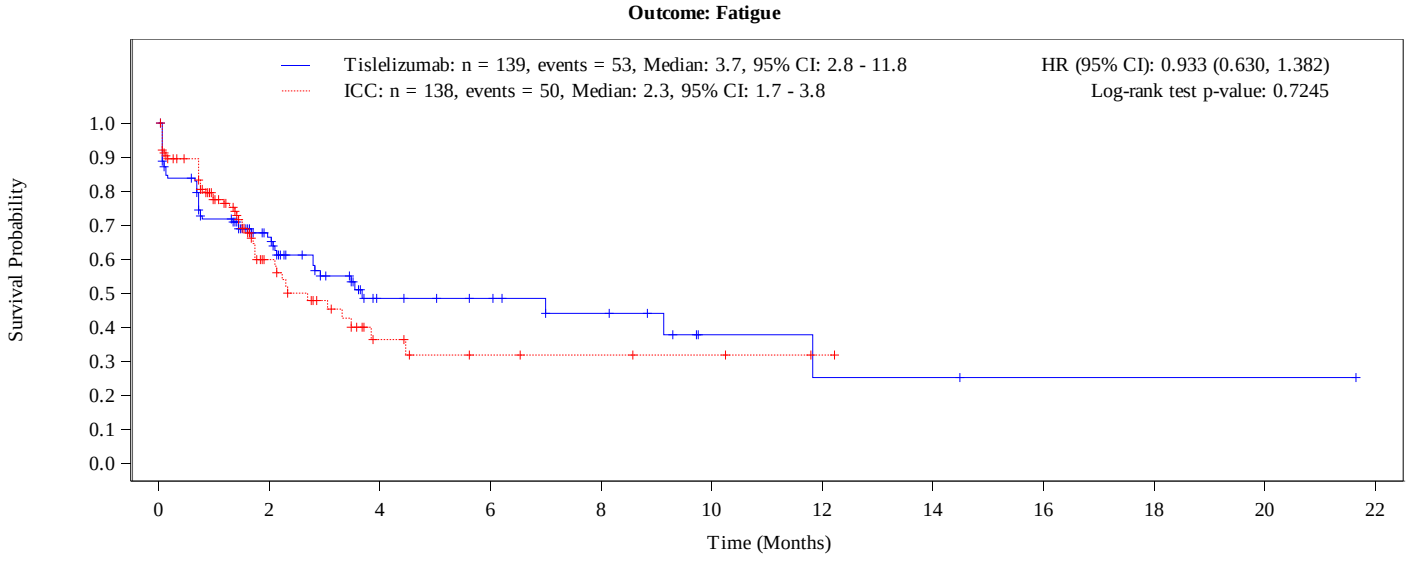


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	139	65	23	17	13	8	5	3	2	1	1	0
ICC	138	50	21	10	6	5	1	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-01-02-b-km-qs-c30-itts-fa.rtf

Figure 14.2.7.1.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation without Irinotecan

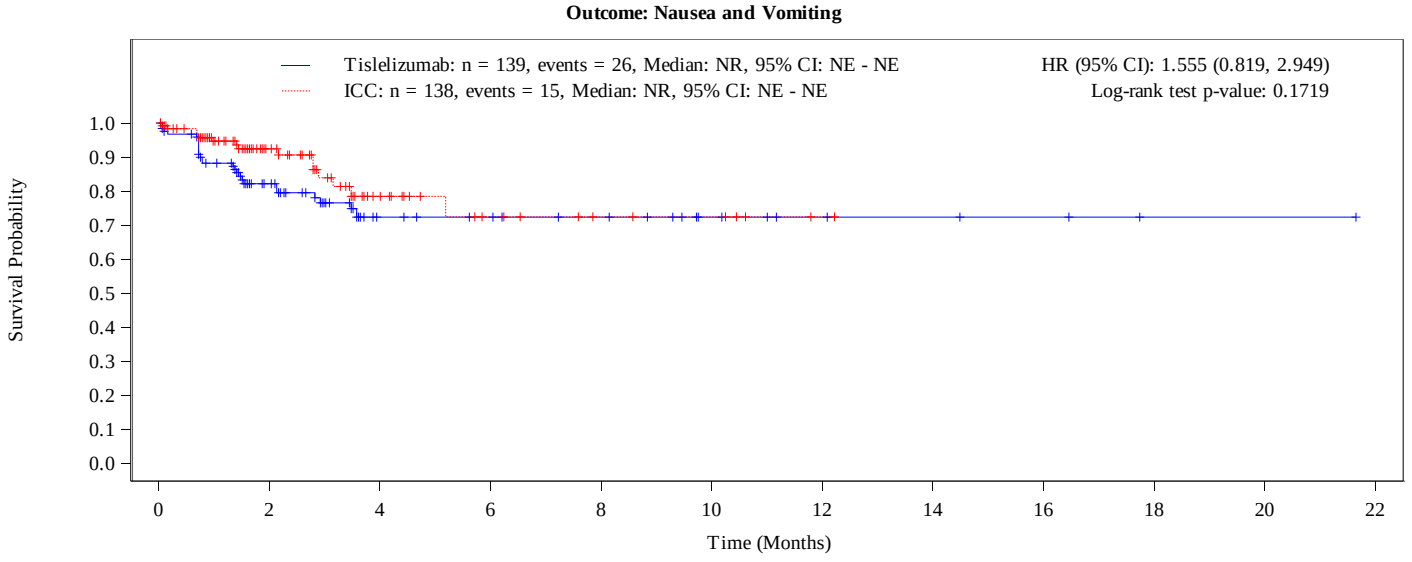


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	139	52	16	13	9	3	2	2	1	1	1	0
ICC	138	31	9	5	4	3	1	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-01-02-b-km-qs-c30-itts-fa.rtf

Figure 14.2.7.1.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation without Irinotecan

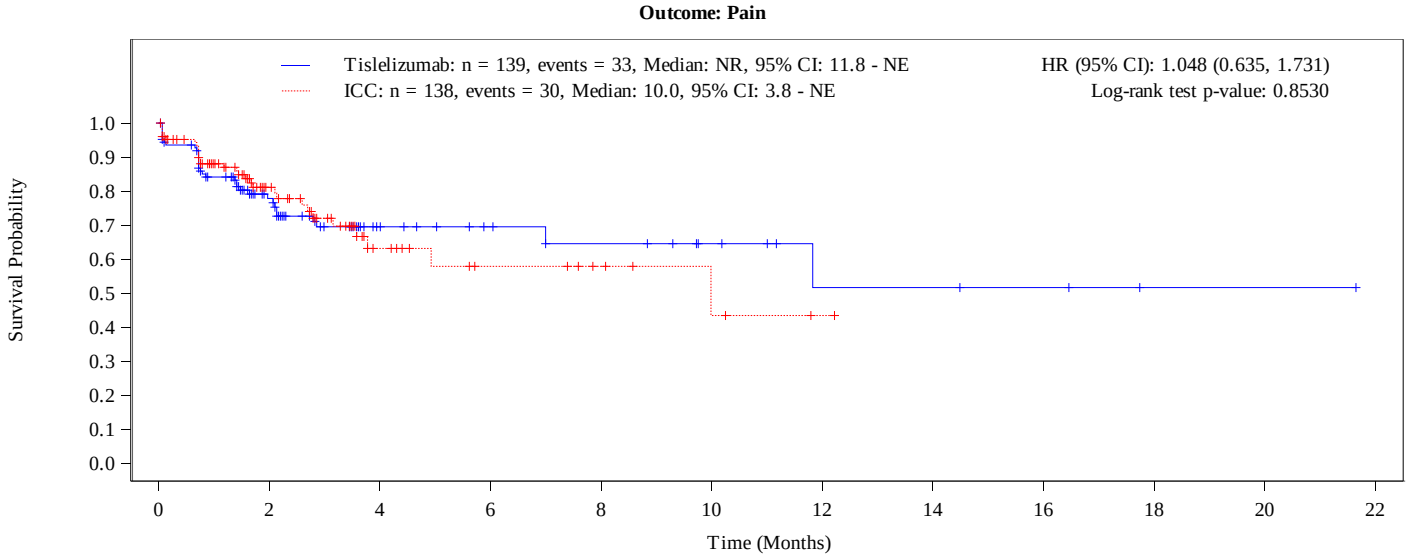


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	139	64	21	18	15	9	6	4	3	1	1	0
ICC	138	55	20	10	6	5	1	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-01-02-b-km-qs-c30-itts-fa.rtf

Figure 14.2.7.1.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation without Irinotecan

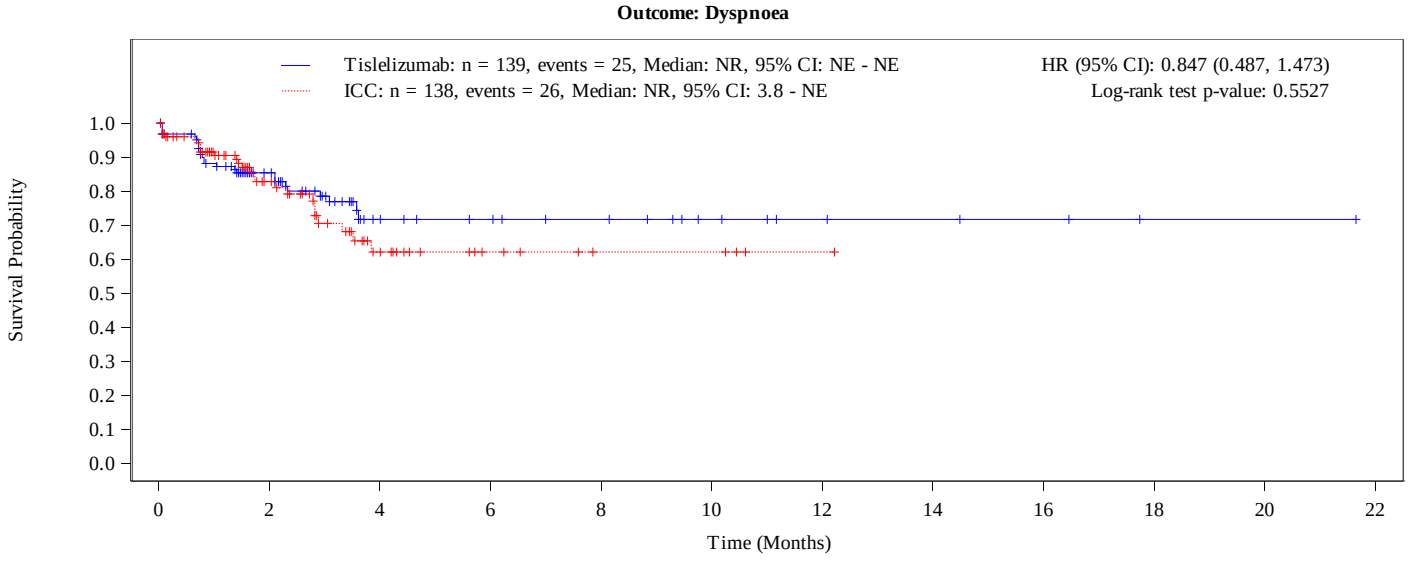


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	139	61	21	15	12	8	4	4	3	1	1	0
ICC	138	51	16	9	6	3	1	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-01-02-b-km-qs-c30-itts-fa.rtf

Figure 14.2.7.1.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation without Irinotecan

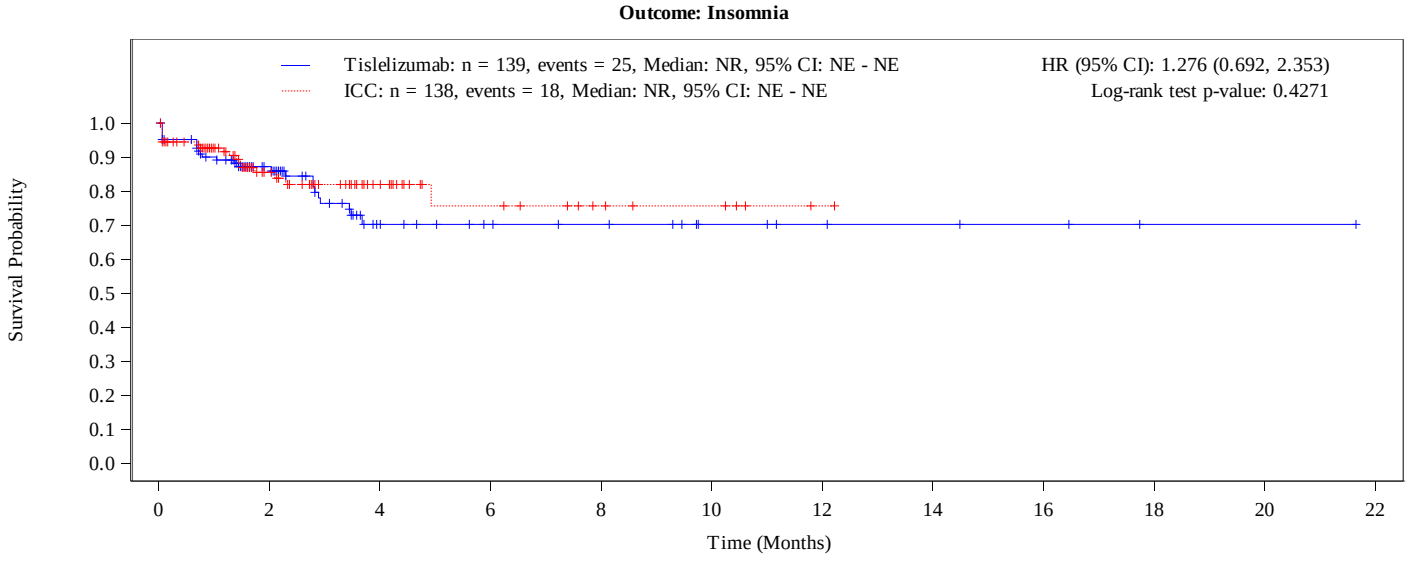


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	139	67	21	17	14	9	6	4	3	1	1	0
ICC	138	49	18	8	4	4	1	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-01-02-b-km-qs-c30-itts-fa.rtf

Figure 14.2.7.1.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	139	67	21	15	13	8	6	4	3	1	1	0
ICC	138	52	23	12	7	5	1	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
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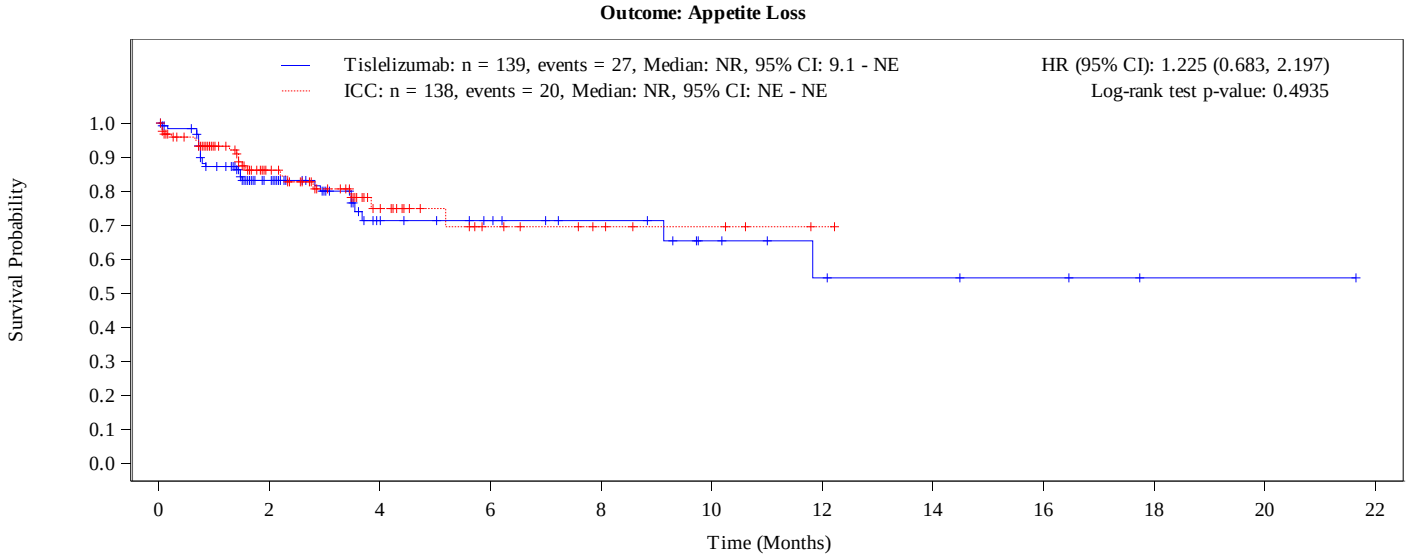
Figure 14.2.7.1.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation without Irinotecan

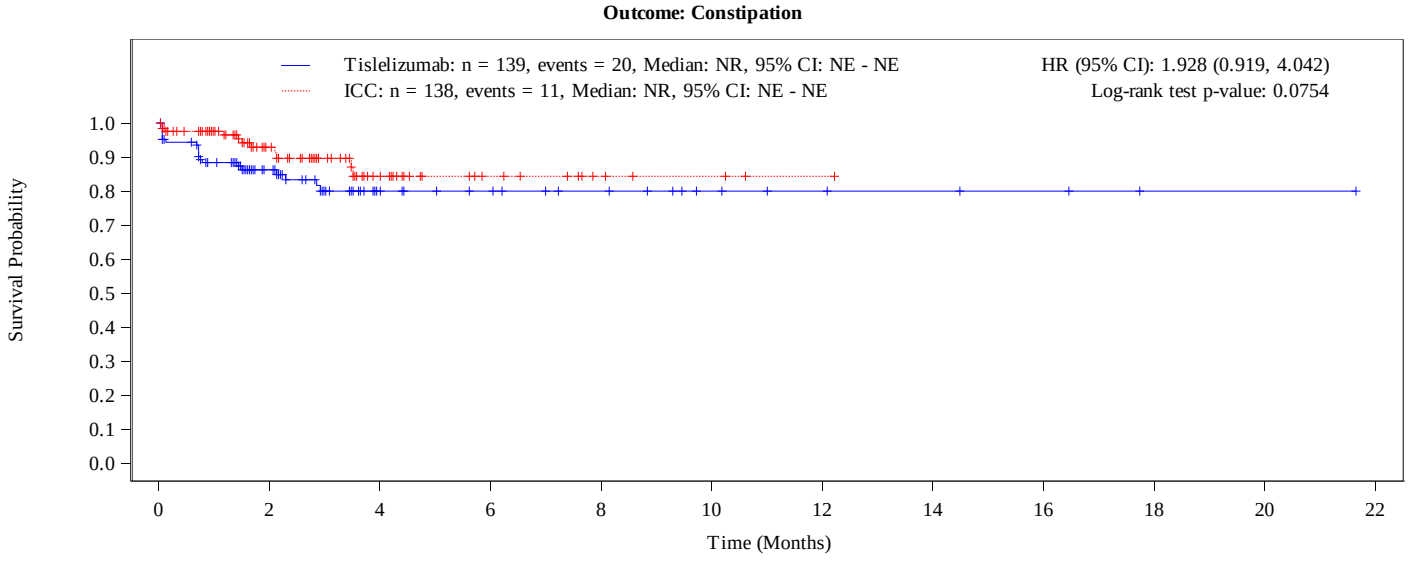


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	139	64	22	17	13	8	5	4	3	1	1	0
ICC	138	53	22	10	6	4	1	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-01-02-b-km-qs-c30-itts-fa.rtf

Figure 14.2.7.1.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation without Irinotecan

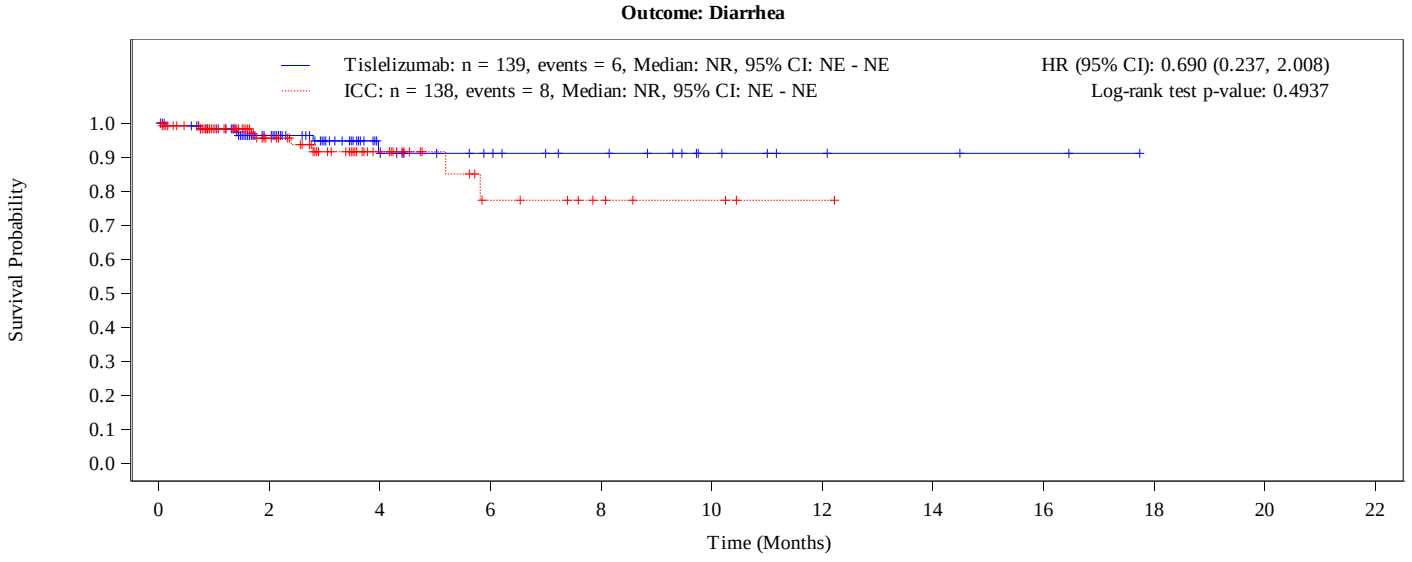


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	139	63	21	16	12	7	5	4	3	1	1	0
ICC	138	60	24	11	5	3	1	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-01-02-b-km-qs-c30-itts-fa.rtf

Figure 14.2.7.1.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation without Irinotecan

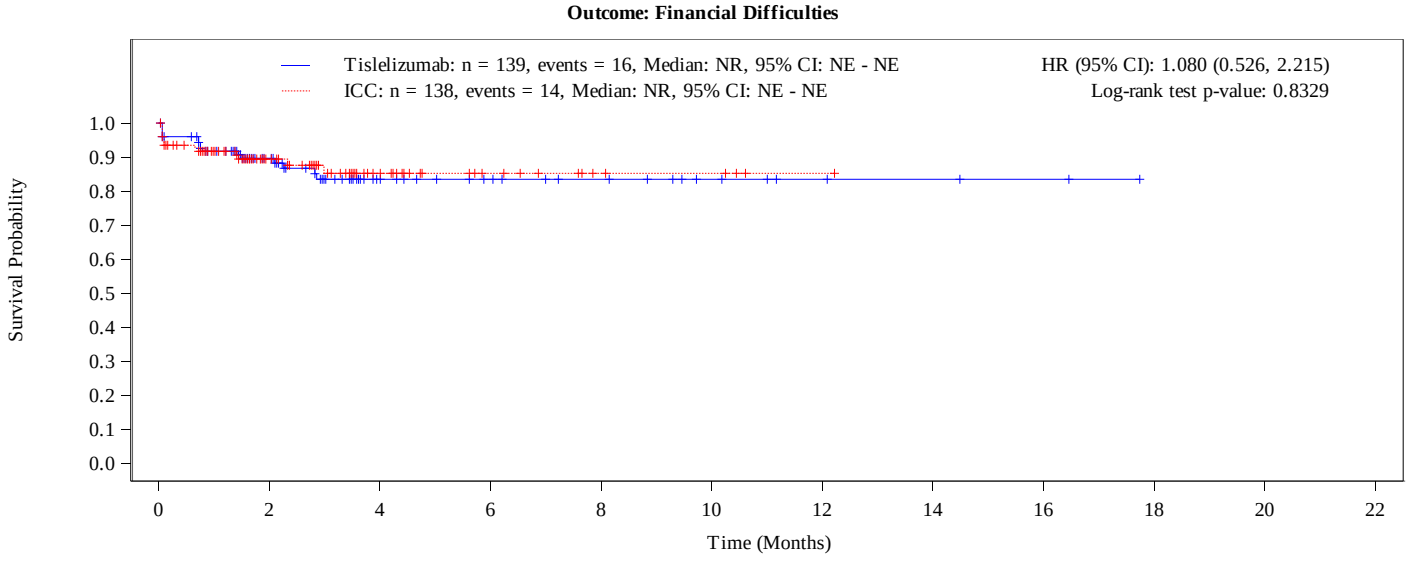


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	139	72	25	18	14	8	5	3	2	0	0	0
ICC	138	59	24	9	5	3	1	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-01-02-b-km-qs-c30-itts-fa.rtf

Figure 14.2.7.1.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	139	66	24	17	13	8	5	3	2	0	0	0
ICC	138	54	23	11	5	4	1	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
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unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-01-02-b-km-qs-c30-itts-fa.rtf

Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Global Health Status/QOL

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	36 (22.9)	NR (9.1, NE)	161	30 (18.6)	NR (4.2, NE)	0.921 (0.566, 1.499)	0.7383
>= 65 Years	99	23 (23.2)	NR (NE, NE)	95	17 (17.9)	NR (NE, NE)	1.139 (0.608, 2.137)	0.6800
Interaction								0.6568
Gender								
Male	217	54 (24.9)	NR (9.1, NE)	215	41 (19.1)	NR (NE, NE)	1.035 (0.689, 1.557)	0.8647
Female	39	5 (12.8)	NR (NE, NE)	41	6 (14.6)	NR (1.9, NE)	0.660 (0.198, 2.206)	0.4937
Interaction								0.5356

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Global Health Status/QOL

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	49 (26.1)	NR (9.1, NE)	192	38 (19.8)	NR (NE, NE)	1.070 (0.700, 1.637)	0.7505
Non-Smoker	68	10 (14.7)	NR (NE, NE)	63	9 (14.3)	NR (3.5, NE)	0.760 (0.303, 1.905)	0.5523
Interaction								0.4794
ICC Options								
Paclitaxel	83	21 (25.3)	9.1 (3.7, NE)	85	15 (17.6)	NR (NE, NE)	1.432 (0.738, 2.780)	0.2812
Docetaxel	56	11 (19.6)	NR (NE, NE)	53	15 (28.3)	NR (3.5, NE)	0.582 (0.266, 1.273)	0.1627
Irinotecan	117	27 (23.1)	NR (NE, NE)	118	17 (14.4)	NR (3.5, NE)	0.999 (0.540, 1.849)	0.9972
Interaction								0.1659

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Global Health Status/QOL

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	19 (29.7)	NR (3.7, NE)	63	12 (19.0)	NR (NE, NE)	1.252 (0.605, 2.591)	0.5361
1	192	40 (20.8)	NR (NE, NE)	193	35 (18.1)	NR (4.2, NE)	0.897 (0.569, 1.415)	0.6358
Interaction								0.4348
Region #1								
Asia	201	50 (24.9)	NR (NE, NE)	203	41 (20.2)	NR (4.2, NE)	0.951 (0.628, 1.441)	0.8110
Europe/North America	55	9 (16.4)	NR (9.1, NE)	53	6 (11.3)	NR (NE, NE)	1.277 (0.454, 3.590)	0.6406
Interaction								0.5671

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Global Health Status/QOL

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	41 (23.3)	NR (NE, NE)	178	34 (19.1)	NR (4.2, NE)	0.928 (0.587, 1.465)	0.7445
Japan	25	9 (36.0)	NR (2.1, NE)	25	7 (28.0)	NR (1.6, NE)	1.131 (0.416, 3.076)	0.8074
Europe/North America	55	9 (16.4)	NR (9.1, NE)	53	6 (11.3)	NR (NE, NE)	1.277 (0.454, 3.590)	0.6406
Interaction								0.8026
Race								
Asian and other	203	50 (24.6)	NR (NE, NE)	212	42 (19.8)	NR (4.2, NE)	0.954 (0.632, 1.442)	0.8217
White	53	9 (17.0)	NR (9.1, NE)	44	5 (11.4)	NR (NE, NE)	1.400 (0.469, 4.181)	0.5423
Interaction								0.4894

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Global Health Status/QOL

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	18 (22.5)	NR (9.1, NE)	62	9 (14.5)	NR (NE, NE)	1.140 (0.509, 2.555)	0.7483
vCPS < 10%	100	24 (24.0)	NR (NE, NE)	122	24 (19.7)	NR (4.2, NE)	1.048 (0.594, 1.847)	0.8692
Missing	76	17 (22.4)	NR (3.5, NE)	72	14 (19.4)	NR (3.5, NE)	0.866 (0.425, 1.767)	0.6880
Interaction								0.9029

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Physical Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	29 (18.5)	NR (NE, NE)	161	31 (19.3)	10.0 (3.5, NE)	0.680 (0.408, 1.132)	0.1332
>= 65 Years	99	18 (18.2)	NR (NE, NE)	95	21 (22.1)	4.9 (3.2, NE)	0.606 (0.320, 1.146)	0.1163
Interaction								0.7881
Gender								
Male	217	39 (18.0)	NR (NE, NE)	215	45 (20.9)	NR (4.5, NE)	0.611 (0.397, 0.942)	0.0232
Female	39	8 (20.5)	NR (3.4, NE)	41	7 (17.1)	10.0 (2.7, NE)	1.148 (0.393, 3.352)	0.7995
Interaction								0.3815

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Physical Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	36 (19.1)	NR (NE, NE)	192	44 (22.9)	10.0 (3.5, NE)	0.596 (0.383, 0.930)	0.0202
Non-Smoker	68	11 (16.2)	NR (NE, NE)	63	8 (12.7)	NR (NE, NE)	0.985 (0.395, 2.459)	0.9747
Interaction								0.4086
ICC Options								
Paclitaxel	83	14 (16.9)	NR (3.7, NE)	85	22 (25.9)	4.9 (2.8, NE)	0.589 (0.301, 1.155)	0.1177
Docetaxel	56	12 (21.4)	NR (2.9, NE)	53	12 (22.6)	NR (3.5, NE)	0.808 (0.362, 1.804)	0.6009
Irinotecan	117	21 (17.9)	NR (NE, NE)	118	18 (15.3)	NR (3.2, NE)	0.718 (0.379, 1.362)	0.3037
Interaction								0.8502

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Physical Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	12 (18.8)	NR (NE, NE)	63	17 (27.0)	4.5 (2.3, NE)	0.492 (0.233, 1.040)	0.0565
1	192	35 (18.2)	NR (NE, NE)	193	35 (18.1)	10.0 (4.9, NE)	0.724 (0.452, 1.161)	0.1756
Interaction								0.3906
Region #1								
Asia	201	34 (16.9)	NR (NE, NE)	203	39 (19.2)	10.0 (4.5, NE)	0.615 (0.387, 0.979)	0.0372
Europe/North America	55	13 (23.6)	NR (3.6, NE)	53	13 (24.5)	3.5 (2.7, NE)	0.781 (0.361, 1.693)	0.5285
Interaction								0.5395

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Physical Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	30 (17.0)	NR (NE, NE)	178	30 (16.9)	10.0 (4.5, NE)	0.705 (0.423, 1.175)	0.1749
Japan	25	4 (16.0)	NR (NE, NE)	25	9 (36.0)	4.9 (1.7, NE)	0.337 (0.103, 1.107)	0.0581
Europe/North America	55	13 (23.6)	NR (3.6, NE)	53	13 (24.5)	3.5 (2.7, NE)	0.781 (0.361, 1.693)	0.5285
Interaction								0.4188
Race								
Asian and other	203	35 (17.2)	NR (NE, NE)	212	40 (18.9)	10.0 (4.5, NE)	0.634 (0.401, 1.002)	0.0477
White	53	12 (22.6)	NR (3.6, NE)	44	12 (27.3)	3.5 (2.7, NE)	0.716 (0.320, 1.598)	0.4093
Interaction								0.7349

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Physical Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	17 (21.3)	NR (NE, NE)	62	12 (19.4)	10.0 (10.0, NE)	0.731 (0.347, 1.539)	0.4060
vCPS < 10%	100	18 (18.0)	NR (NE, NE)	122	23 (18.9)	NR (3.5, NE)	0.762 (0.410, 1.417)	0.3866
Missing	76	12 (15.8)	NR (NE, NE)	72	17 (23.6)	3.5 (1.7, NE)	0.450 (0.213, 0.949)	0.0305
Interaction								0.5683

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Role Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	36 (22.9)	NR (9.1, NE)	161	33 (20.5)	10.0 (3.3, NE)	0.794 (0.492, 1.280)	0.3368
>= 65 Years	99	27 (27.3)	NR (NE, NE)	95	29 (30.5)	3.8 (2.1, NE)	0.747 (0.441, 1.267)	0.2698
Interaction								0.7569
Gender								
Male	217	54 (24.9)	NR (NE, NE)	215	48 (22.3)	NR (3.5, NE)	0.857 (0.579, 1.269)	0.4350
Female	39	9 (23.1)	NR (3.1, NE)	41	14 (34.1)	2.7 (1.4, NE)	0.473 (0.203, 1.106)	0.0732
Interaction								0.2651

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Role Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	51 (27.1)	NR (9.1, NE)	192	48 (25.0)	10.0 (3.3, NE)	0.834 (0.561, 1.242)	0.3651
Non-Smoker	68	12 (17.6)	NR (NE, NE)	63	14 (22.2)	3.8 (2.6, NE)	0.576 (0.265, 1.255)	0.1566
Interaction								0.3726
ICC Options								
Paclitaxel	83	24 (28.9)	NR (9.1, NE)	85	32 (37.6)	3.3 (1.7, 10.0)	0.658 (0.387, 1.120)	0.1156
Docetaxel	56	11 (19.6)	NR (NE, NE)	53	10 (18.9)	NR (3.5, NE)	0.995 (0.422, 2.345)	0.9899
Irinotecan	117	28 (23.9)	NR (NE, NE)	118	20 (16.9)	NR (2.8, NE)	0.851 (0.474, 1.529)	0.5849
Interaction								0.6767

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Role Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	12 (18.8)	NR (9.1, NE)	63	19 (30.2)	3.5 (2.7, NE)	0.398 (0.189, 0.835)	0.0108
1	192	51 (26.6)	NR (NE, NE)	193	43 (22.3)	10.0 (3.3, NE)	0.935 (0.621, 1.406)	0.7434
Interaction								0.0653
Region #1								
Asia	201	46 (22.9)	NR (NE, NE)	203	50 (24.6)	4.9 (3.3, NE)	0.689 (0.459, 1.033)	0.0663
Europe/North America	55	17 (30.9)	4.2 (3.1, NE)	53	12 (22.6)	NR (2.7, NE)	1.139 (0.542, 2.394)	0.7287
Interaction								0.1975

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Role Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	38 (21.6)	NR (NE, NE)	178	39 (21.9)	10.0 (3.5, NE)	0.716 (0.456, 1.124)	0.1401
Japan	25	8 (32.0)	NR (0.8, NE)	25	11 (44.0)	3.3 (1.3, NE)	0.634 (0.252, 1.590)	0.3072
Europe/North America	55	17 (30.9)	4.2 (3.1, NE)	53	12 (22.6)	NR (2.7, NE)	1.139 (0.542, 2.394)	0.7287
Interaction								0.4049
Race								
Asian and other	203	48 (23.6)	NR (NE, NE)	212	52 (24.5)	4.9 (3.3, NE)	0.714 (0.480, 1.062)	0.0906
White	53	15 (28.3)	4.2 (3.1, NE)	44	10 (22.7)	NR (2.7, NE)	1.088 (0.487, 2.431)	0.8350
Interaction								0.2992

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Role Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	24 (30.0)	NR (4.2, NE)	62	15 (24.2)	10.0 (1.4, NE)	0.879 (0.458, 1.688)	0.6951
vCPS < 10%	100	26 (26.0)	NR (3.7, NE)	122	28 (23.0)	NR (3.3, NE)	0.957 (0.560, 1.636)	0.8704
Missing	76	13 (17.1)	NR (NE, NE)	72	19 (26.4)	3.5 (1.5, NE)	0.441 (0.216, 0.900)	0.0195
Interaction								0.2290

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Emotional Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	19 (12.1)	NR (9.1, NE)	161	20 (12.4)	NR (NE, NE)	0.714 (0.379, 1.344)	0.2911
>= 65 Years	99	12 (12.1)	NR (NE, NE)	95	15 (15.8)	NR (NE, NE)	0.627 (0.292, 1.343)	0.2237
Interaction								0.7532
Gender								
Male	217	26 (12.0)	NR (NE, NE)	215	29 (13.5)	NR (NE, NE)	0.647 (0.379, 1.105)	0.1060
Female	39	5 (12.8)	NR (NE, NE)	41	6 (14.6)	NR (2.7, NE)	0.777 (0.236, 2.554)	0.6757
Interaction								0.8427

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Emotional Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	23 (12.2)	NR (NE, NE)	192	26 (13.5)	NR (NE, NE)	0.684 (0.389, 1.204)	0.1830
Non-Smoker	68	8 (11.8)	NR (NE, NE)	63	9 (14.3)	NR (2.7, NE)	0.604 (0.232, 1.578)	0.2980
Interaction								0.8172
ICC Options								
Paclitaxel	83	12 (14.5)	NR (9.1, NE)	85	12 (14.1)	NR (NE, NE)	0.958 (0.430, 2.135)	0.9170
Docetaxel	56	8 (14.3)	NR (NE, NE)	53	11 (20.8)	NR (2.9, NE)	0.561 (0.224, 1.406)	0.2052
Irinotecan	117	11 (9.4)	NR (NE, NE)	118	12 (10.2)	NR (NE, NE)	0.552 (0.239, 1.273)	0.1563
Interaction								0.5730

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Emotional Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	9 (14.1)	NR (9.1, NE)	63	10 (15.9)	NR (4.5, NE)	0.654 (0.263, 1.625)	0.3537
1	192	22 (11.5)	NR (NE, NE)	193	25 (13.0)	NR (NE, NE)	0.658 (0.370, 1.171)	0.1503
Interaction								0.9787
Region #1								
Asia	201	22 (10.9)	NR (NE, NE)	203	24 (11.8)	NR (NE, NE)	0.688 (0.384, 1.234)	0.2040
Europe/North America	55	9 (16.4)	NR (9.1, NE)	53	11 (20.8)	NR (2.7, NE)	0.625 (0.258, 1.514)	0.2930
Interaction								0.9802

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Emotional Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	17 (9.7)	NR (NE, NE)	178	20 (11.2)	NR (NE, NE)	0.625 (0.326, 1.199)	0.1517
Japan	25	5 (20.0)	NR (7.0, NE)	25	4 (16.0)	NR (NE, NE)	1.049 (0.276, 3.980)	0.9432
Europe/North America	55	9 (16.4)	NR (9.1, NE)	53	11 (20.8)	NR (2.7, NE)	0.625 (0.258, 1.514)	0.2930
Interaction								0.8487
Race								
Asian and other	203	22 (10.8)	NR (NE, NE)	212	26 (12.3)	NR (NE, NE)	0.645 (0.363, 1.144)	0.1282
White	53	9 (17.0)	NR (9.1, NE)	44	9 (20.5)	NR (2.7, NE)	0.720 (0.285, 1.820)	0.4855
Interaction								0.7342

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Emotional Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	7 (8.8)	NR (NE, NE)	62	5 (8.1)	NR (NE, NE)	0.796 (0.250, 2.533)	0.6975
vCPS < 10%	100	11 (11.0)	NR (NE, NE)	122	19 (15.6)	NR (4.5, NE)	0.576 (0.273, 1.214)	0.1400
Missing	76	13 (17.1)	NR (7.0, NE)	72	11 (15.3)	NR (NE, NE)	0.801 (0.356, 1.802)	0.5895
Interaction								0.8243

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Cognitive Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	30 (19.1)	NR (9.1, NE)	161	28 (17.4)	NR (10.0, NE)	0.800 (0.476, 1.344)	0.3937
>= 65 Years	99	20 (20.2)	NR (NE, NE)	95	13 (13.7)	10.2 (NE, NE)	1.273 (0.629, 2.574)	0.4979
Interaction								0.3424
Gender								
Male	217	40 (18.4)	NR (NE, NE)	215	36 (16.7)	NR (10.2, NE)	0.846 (0.538, 1.332)	0.4655
Female	39	10 (25.6)	NR (2.8, NE)	41	5 (12.2)	10.0 (NE, NE)	1.834 (0.624, 5.385)	0.2596
Interaction								0.1884

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Cognitive Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	31 (16.5)	NR (NE, NE)	192	33 (17.2)	10.2 (10.0, NE)	0.751 (0.458, 1.231)	0.2500
Non-Smoker	68	19 (27.9)	NR (2.3, NE)	63	8 (12.7)	NR (NE, NE)	1.724 (0.753, 3.945)	0.1879
Interaction								0.0904
ICC Options								
Paclitaxel	83	17 (20.5)	NR (9.1, NE)	85	17 (20.0)	10.0 (3.6, NE)	0.927 (0.473, 1.818)	0.8248
Docetaxel	56	13 (23.2)	NR (3.5, NE)	53	10 (18.9)	NR (NE, NE)	1.123 (0.491, 2.565)	0.7814
Irinotecan	117	20 (17.1)	NR (NE, NE)	118	14 (11.9)	10.2 (10.2, NE)	0.993 (0.498, 1.982)	0.9849
Interaction								0.9753

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Cognitive Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	15 (23.4)	NR (9.1, NE)	63	16 (25.4)	10.2 (3.3, NE)	0.685 (0.336, 1.399)	0.2889
1	192	35 (18.2)	NR (NE, NE)	193	25 (13.0)	NR (10.0, NE)	1.125 (0.672, 1.883)	0.6515
Interaction								0.2907
Region #1								
Asia	201	39 (19.4)	NR (NE, NE)	203	33 (16.3)	10.0 (10.0, NE)	0.915 (0.573, 1.460)	0.7077
Europe/North America	55	11 (20.0)	9.1 (3.7, NE)	53	8 (15.1)	NR (10.2, NE)	1.233 (0.493, 3.082)	0.6526
Interaction								0.5763

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Cognitive Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	32 (18.2)	NR (NE, NE)	178	27 (15.2)	10.0 (10.0, NE)	0.906 (0.541, 1.518)	0.7046
Japan	25	7 (28.0)	NR (2.1, NE)	25	6 (24.0)	3.6 (3.3, NE)	0.981 (0.326, 2.952)	0.9720
Europe/North America	55	11 (20.0)	9.1 (3.7, NE)	53	8 (15.1)	NR (10.2, NE)	1.233 (0.493, 3.082)	0.6526
Interaction								0.8573
Race								
Asian and other	203	39 (19.2)	NR (NE, NE)	212	34 (16.0)	10.0 (10.0, NE)	0.913 (0.574, 1.451)	0.6981
White	53	11 (20.8)	9.1 (3.7, NE)	44	7 (15.9)	NR (10.2, NE)	1.289 (0.496, 3.350)	0.5997
Interaction								0.5390

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Cognitive Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	17 (21.3)	NR (9.1, NE)	62	8 (12.9)	NR (10.0, NE)	1.187 (0.509, 2.767)	0.6899
vCPS < 10%	100	20 (20.0)	NR (3.7, NE)	122	21 (17.2)	10.2 (10.2, NE)	0.969 (0.524, 1.791)	0.9199
Missing	76	13 (17.1)	NR (NE, NE)	72	12 (16.7)	NR (3.6, NE)	0.819 (0.372, 1.801)	0.6119
Interaction								0.7813

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Social Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	33 (21.0)	NR (NE, NE)	161	25 (15.5)	NR (NE, NE)	1.072 (0.636, 1.806)	0.7916
>= 65 Years	99	22 (22.2)	NR (NE, NE)	95	23 (24.2)	4.7 (3.5, NE)	0.749 (0.416, 1.349)	0.3279
Interaction								0.4339
Gender								
Male	217	46 (21.2)	NR (NE, NE)	215	40 (18.6)	NR (4.7, NE)	0.924 (0.604, 1.414)	0.7122
Female	39	9 (23.1)	NR (2.9, NE)	41	8 (19.5)	NR (1.9, NE)	0.908 (0.347, 2.380)	0.8439
Interaction								0.9454

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Social Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	42 (22.3)	NR (NE, NE)	192	40 (20.8)	NR (4.2, NE)	0.869 (0.562, 1.342)	0.5200
Non-Smoker	68	13 (19.1)	NR (NE, NE)	63	8 (12.7)	NR (NE, NE)	1.193 (0.492, 2.889)	0.6937
Interaction								0.5361
ICC Options								
Paclitaxel	83	15 (18.1)	NR (NE, NE)	85	18 (21.2)	NR (4.7, NE)	0.784 (0.395, 1.559)	0.4829
Docetaxel	56	10 (17.9)	NR (NE, NE)	53	13 (24.5)	NR (2.8, NE)	0.640 (0.280, 1.463)	0.2802
Irinotecan	117	30 (25.6)	NR (NE, NE)	118	17 (14.4)	NR (3.5, NE)	1.256 (0.688, 2.292)	0.4510
Interaction								0.3452

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Social Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	10 (15.6)	NR (NE, NE)	63	11 (17.5)	NR (3.5, NE)	0.680 (0.287, 1.609)	0.3747
1	192	45 (23.4)	NR (NE, NE)	193	37 (19.2)	NR (4.7, NE)	0.989 (0.639, 1.531)	0.9610
Interaction								0.5556
Region #1								
Asia	201	47 (23.4)	NR (NE, NE)	203	36 (17.7)	NR (4.2, NE)	1.046 (0.676, 1.618)	0.8382
Europe/North America	55	8 (14.5)	NR (NE, NE)	53	12 (22.6)	NR (3.5, NE)	0.556 (0.227, 1.362)	0.1875
Interaction								0.1855

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Social Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	42 (23.9)	NR (NE, NE)	178	29 (16.3)	NR (4.2, NE)	1.157 (0.719, 1.863)	0.5418
Japan	25	5 (20.0)	NR (NE, NE)	25	7 (28.0)	NR (1.3, NE)	0.581 (0.183, 1.846)	0.3491
Europe/North America	55	8 (14.5)	NR (NE, NE)	53	12 (22.6)	NR (3.5, NE)	0.556 (0.227, 1.362)	0.1875
Interaction								0.2236
Race								
Asian and other	203	48 (23.6)	NR (NE, NE)	212	37 (17.5)	NR (NE, NE)	1.071 (0.696, 1.648)	0.7523
White	53	7 (13.2)	NR (NE, NE)	44	11 (25.0)	NR (3.5, NE)	0.470 (0.182, 1.215)	0.1070
Interaction								0.1072

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Social Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	14 (17.5)	NR (NE, NE)	62	8 (12.9)	NR (NE, NE)	1.028 (0.429, 2.464)	0.9511
vCPS < 10%	100	22 (22.0)	NR (NE, NE)	122	26 (21.3)	NR (4.2, NE)	0.886 (0.501, 1.566)	0.6716
Missing	76	19 (25.0)	NR (2.9, NE)	72	14 (19.4)	NR (3.6, NE)	1.021 (0.510, 2.043)	0.9519
Interaction								0.9313

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Fatigue

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	47 (29.9)	9.1 (3.7, NE)	161	48 (29.8)	3.1 (2.1, NE)	0.667 (0.443, 1.006)	0.0477
>= 65 Years	99	40 (40.4)	3.5 (2.1, NE)	95	35 (36.8)	2.2 (1.5, NE)	0.866 (0.546, 1.373)	0.5311
Interaction								0.3969
Gender								
Male	217	71 (32.7)	9.1 (3.5, NE)	215	73 (34.0)	2.7 (1.7, 3.8)	0.654 (0.468, 0.913)	0.0104
Female	39	16 (41.0)	2.8 (0.7, NE)	41	10 (24.4)	3.3 (1.7, NE)	1.490 (0.672, 3.301)	0.3128
Interaction								0.0606

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Fatigue

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	68 (36.2)	3.7 (2.8, NE)	192	65 (33.9)	2.7 (1.7, 4.5)	0.814 (0.577, 1.148)	0.2295
Non-Smoker	68	19 (27.9)	11.8 (2.8, NE)	63	18 (28.6)	3.5 (1.5, NE)	0.570 (0.290, 1.119)	0.0938
Interaction								0.4191
ICC Options								
Paclitaxel	83	34 (41.0)	3.7 (2.1, 11.8)	85	31 (36.5)	2.7 (1.7, 4.5)	0.981 (0.602, 1.601)	0.9393
Docetaxel	56	19 (33.9)	3.5 (2.1, NE)	53	19 (35.8)	2.3 (1.4, NE)	0.790 (0.415, 1.505)	0.4619
Irinotecan	117	34 (29.1)	20.9 (3.7, NE)	118	33 (28.0)	3.8 (1.1, NE)	0.594 (0.362, 0.973)	0.0326
Interaction								0.2456

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Fatigue

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	27 (42.2)	7.0 (2.8, 11.8)	63	27 (42.9)	1.7 (1.1, NE)	0.605 (0.350, 1.044)	0.0645
1	192	60 (31.3)	20.9 (3.5, NE)	193	56 (29.0)	3.3 (2.1, 3.8)	0.820 (0.567, 1.185)	0.2790
Interaction								0.4813
Region #1								
Asia	201	66 (32.8)	11.8 (3.5, NE)	203	68 (33.5)	2.7 (1.7, 3.8)	0.667 (0.472, 0.942)	0.0180
Europe/North America	55	21 (38.2)	3.7 (2.0, NE)	53	15 (28.3)	NR (1.1, NE)	1.180 (0.604, 2.306)	0.6236
Interaction								0.1645

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Fatigue

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	54 (30.7)	20.9 (3.5, NE)	178	56 (31.5)	3.2 (2.1, 4.5)	0.665 (0.454, 0.972)	0.0299
Japan	25	12 (48.0)	7.0 (0.8, NE)	25	12 (48.0)	1.7 (1.6, NE)	0.774 (0.340, 1.763)	0.5332
Europe/North America	55	21 (38.2)	3.7 (2.0, NE)	53	15 (28.3)	NR (1.1, NE)	1.180 (0.604, 2.306)	0.6236
Interaction								0.3405
Race								
Asian and other	203	68 (33.5)	11.8 (3.5, NE)	212	68 (32.1)	3.1 (2.1, 3.8)	0.717 (0.509, 1.011)	0.0513
White	53	19 (35.8)	3.7 (2.1, NE)	44	15 (34.1)	3.3 (0.9, NE)	0.900 (0.453, 1.787)	0.7598
Interaction								0.6166

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Fatigue

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	31 (38.8)	3.7 (2.2, NE)	62	15 (24.2)	NR (3.8, NE)	1.194 (0.643, 2.218)	0.5681
vCPS < 10%	100	33 (33.0)	3.7 (2.8, NE)	122	47 (38.5)	2.3 (1.5, 3.3)	0.634 (0.404, 0.994)	0.0417
Missing	76	23 (30.3)	11.8 (7.0, NE)	72	21 (29.2)	2.1 (1.7, NE)	0.668 (0.358, 1.248)	0.1888
Interaction								0.2942

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Nausea and Vomiting

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	30 (19.1)	NR (NE, NE)	161	20 (12.4)	NR (NE, NE)	1.136 (0.642, 2.010)	0.6591
>= 65 Years	99	12 (12.1)	NR (NE, NE)	95	15 (15.8)	NR (5.2, NE)	0.588 (0.274, 1.265)	0.1684
Interaction								0.2024
Gender								
Male	217	34 (15.7)	NR (NE, NE)	215	30 (14.0)	NR (NE, NE)	0.835 (0.509, 1.369)	0.4714
Female	39	8 (20.5)	NR (3.5, NE)	41	5 (12.2)	NR (NE, NE)	1.411 (0.454, 4.382)	0.5479
Interaction								0.4464

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Nausea and Vomiting

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	30 (16.0)	NR (NE, NE)	192	26 (13.5)	NR (NE, NE)	0.903 (0.532, 1.532)	0.7029
Non-Smoker	68	12 (17.6)	NR (NE, NE)	63	9 (14.3)	NR (3.2, NE)	0.922 (0.386, 2.202)	0.8545
Interaction								0.8861
ICC Options								
Paclitaxel	83	16 (19.3)	NR (NE, NE)	85	11 (12.9)	NR (5.2, NE)	1.418 (0.658, 3.057)	0.3691
Docetaxel	56	10 (17.9)	NR (3.6, NE)	53	4 (7.5)	NR (2.9, NE)	1.844 (0.571, 5.950)	0.2975
Irinotecan	117	16 (13.7)	NR (NE, NE)	118	20 (16.9)	NR (NE, NE)	0.505 (0.258, 0.988)	0.0401
Interaction								0.0244

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Nausea and Vomiting

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	7 (10.9)	NR (NE, NE)	63	10 (15.9)	NR (5.2, NE)	0.508 (0.192, 1.343)	0.1635
1	192	35 (18.2)	NR (NE, NE)	193	25 (13.0)	NR (NE, NE)	1.074 (0.641, 1.800)	0.7837
Interaction								0.2177
Region #1								
Asia	201	31 (15.4)	NR (NE, NE)	203	26 (12.8)	NR (NE, NE)	0.909 (0.537, 1.536)	0.7185
Europe/North America	55	11 (20.0)	NR (3.5, NE)	53	9 (17.0)	NR (2.9, NE)	0.932 (0.384, 2.262)	0.8757
Interaction								0.7778

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Nausea and Vomiting

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	28 (15.9)	NR (NE, NE)	178	25 (14.0)	NR (NE, NE)	0.831 (0.483, 1.432)	0.5009
Japan	25	3 (12.0)	NR (NE, NE)	25	1 (4.0)	NR (5.2, NE)	2.671 (0.276, 25.818)	0.3773
Europe/North America	55	11 (20.0)	NR (3.5, NE)	53	9 (17.0)	NR (2.9, NE)	0.932 (0.384, 2.262)	0.8757
Interaction								0.5836
Race								
Asian and other	203	32 (15.8)	NR (NE, NE)	212	27 (12.7)	NR (NE, NE)	0.929 (0.554, 1.556)	0.7776
White	53	10 (18.9)	NR (3.5, NE)	44	8 (18.2)	NR (2.9, NE)	0.847 (0.332, 2.160)	0.7272
Interaction								0.9549

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Nausea and Vomiting

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	10 (12.5)	NR (NE, NE)	62	4 (6.5)	NR (NE, NE)	1.417 (0.441, 4.549)	0.5552
vCPS < 10%	100	19 (19.0)	NR (NE, NE)	122	21 (17.2)	NR (NE, NE)	0.877 (0.470, 1.636)	0.6777
Missing	76	13 (17.1)	NR (NE, NE)	72	10 (13.9)	NR (3.5, NE)	0.944 (0.410, 2.170)	0.8906
Interaction								0.8051

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Pain

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	41 (26.1)	NR (7.0, NE)	161	31 (19.3)	10.0 (3.8, NE)	1.076 (0.673, 1.720)	0.7557
>= 65 Years	99	20 (20.2)	NR (11.8, NE)	95	22 (23.2)	4.9 (3.2, NE)	0.663 (0.357, 1.229)	0.1835
Interaction								0.2786
Gender								
Male	217	53 (24.4)	NR (11.8, NE)	215	45 (20.9)	5.9 (3.8, NE)	0.895 (0.599, 1.337)	0.5831
Female	39	8 (20.5)	NR (NE, NE)	41	8 (19.5)	10.0 (3.3, NE)	1.013 (0.366, 2.800)	0.9801
Interaction								0.9653

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Pain

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	50 (26.6)	NR (NE, NE)	192	43 (22.4)	5.9 (3.8, NE)	0.942 (0.625, 1.420)	0.7725
Non-Smoker	68	11 (16.2)	NR (11.8, NE)	63	10 (15.9)	NR (3.2, NE)	0.741 (0.307, 1.787)	0.4991
Interaction								0.6475
ICC Options								
Paclitaxel	83	20 (24.1)	11.8 (7.0, NE)	85	21 (24.7)	10.0 (3.6, NE)	0.905 (0.489, 1.674)	0.7496
Docetaxel	56	13 (23.2)	NR (2.1, NE)	53	9 (17.0)	NR (NE, NE)	1.312 (0.561, 3.071)	0.5247
Irinotecan	117	28 (23.9)	NR (NE, NE)	118	23 (19.5)	5.9 (3.0, NE)	0.819 (0.467, 1.437)	0.4794
Interaction								0.6460

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Pain

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	20 (31.3)	11.8 (7.0, NE)	63	14 (22.2)	NR (3.6, NE)	1.146 (0.575, 2.283)	0.6964
1	192	41 (21.4)	NR (NE, NE)	193	39 (20.2)	5.9 (3.3, NE)	0.801 (0.515, 1.246)	0.3177
Interaction								0.3744
Region #1								
Asia	201	47 (23.4)	NR (11.8, NE)	203	41 (20.2)	5.9 (3.6, NE)	0.846 (0.553, 1.294)	0.4338
Europe/North America	55	14 (25.5)	NR (2.9, NE)	53	12 (22.6)	NR (2.7, NE)	1.041 (0.481, 2.255)	0.9179
Interaction								0.6291

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Pain

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	41 (23.3)	NR (NE, NE)	178	36 (20.2)	5.9 (3.3, NE)	0.876 (0.558, 1.377)	0.5609
Japan	25	6 (24.0)	11.8 (7.0, NE)	25	5 (20.0)	4.9 (3.6, NE)	0.679 (0.199, 2.323)	0.5345
Europe/North America	55	14 (25.5)	NR (2.9, NE)	53	12 (22.6)	NR (2.7, NE)	1.041 (0.481, 2.255)	0.9179
Interaction								0.8830
Race								
Asian and other	203	48 (23.6)	NR (11.8, NE)	212	42 (19.8)	5.9 (3.8, NE)	0.869 (0.571, 1.323)	0.5075
White	53	13 (24.5)	NR (2.9, NE)	44	11 (25.0)	NR (2.7, NE)	0.947 (0.424, 2.118)	0.8944
Interaction								0.8298

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Pain

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	15 (18.8)	NR (NE, NE)	62	13 (21.0)	10.0 (3.3, NE)	0.620 (0.293, 1.314)	0.2042
vCPS < 10%	100	25 (25.0)	NR (3.7, NE)	122	28 (23.0)	NR (3.2, NE)	0.905 (0.527, 1.554)	0.7143
Missing	76	21 (27.6)	11.8 (7.0, NE)	72	12 (16.7)	4.9 (2.8, NE)	1.380 (0.672, 2.834)	0.3696
Interaction								0.3063

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Dyspnoea

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	29 (18.5)	NR (NE, NE)	161	26 (16.1)	NR (NE, NE)	0.836 (0.490, 1.425)	0.5060
>= 65 Years	99	12 (12.1)	NR (NE, NE)	95	12 (12.6)	10.2 (NE, NE)	0.713 (0.316, 1.611)	0.4124
Interaction								0.9527
Gender								
Male	217	35 (16.1)	NR (NE, NE)	215	33 (15.3)	NR (10.2, NE)	0.785 (0.486, 1.268)	0.3175
Female	39	6 (15.4)	NR (NE, NE)	41	5 (12.2)	NR (3.3, NE)	1.040 (0.314, 3.442)	0.9484
Interaction								0.7031

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Dyspnoea

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	33 (17.6)	NR (NE, NE)	192	35 (18.2)	NR (10.2, NE)	0.736 (0.456, 1.188)	0.2036
Non-Smoker	68	8 (11.8)	NR (NE, NE)	63	3 (4.8)	NR (3.8, NE)	1.768 (0.464, 6.727)	0.3962
Interaction								0.1946
ICC Options								
Paclitaxel	83	17 (20.5)	NR (NE, NE)	85	15 (17.6)	NR (3.5, NE)	1.082 (0.539, 2.170)	0.8232
Docetaxel	56	8 (14.3)	NR (NE, NE)	53	11 (20.8)	NR (2.9, NE)	0.531 (0.212, 1.331)	0.1690
Irinotecan	117	16 (13.7)	NR (NE, NE)	118	12 (10.2)	10.2 (NE, NE)	0.899 (0.419, 1.928)	0.7830
Interaction								0.4703

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Dyspnoea

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	10 (15.6)	NR (NE, NE)	63	10 (15.9)	NR (10.2, NE)	0.768 (0.318, 1.855)	0.5532
1	192	31 (16.1)	NR (NE, NE)	193	28 (14.5)	NR (3.8, NE)	0.828 (0.494, 1.385)	0.4672
Interaction								0.9112
Region #1								
Asia	201	36 (17.9)	NR (NE, NE)	203	30 (14.8)	NR (NE, NE)	0.905 (0.555, 1.474)	0.6843
Europe/North America	55	5 (9.1)	NR (NE, NE)	53	8 (15.1)	10.2 (3.3, NE)	0.493 (0.161, 1.516)	0.2077
Interaction								0.3884

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Dyspnoea

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	30 (17.0)	NR (NE, NE)	178	23 (12.9)	NR (NE, NE)	0.984 (0.569, 1.700)	0.9525
Japan	25	6 (24.0)	NR (3.1, NE)	25	7 (28.0)	NR (1.7, NE)	0.757 (0.252, 2.271)	0.6147
Europe/North America	55	5 (9.1)	NR (NE, NE)	53	8 (15.1)	10.2 (3.3, NE)	0.493 (0.161, 1.516)	0.2077
Interaction								0.5372
Race								
Asian and other	203	37 (18.2)	NR (NE, NE)	212	31 (14.6)	NR (NE, NE)	0.929 (0.574, 1.502)	0.7621
White	53	4 (7.5)	NR (NE, NE)	44	7 (15.9)	10.2 (2.9, NE)	0.403 (0.117, 1.385)	0.1354
Interaction								0.2522

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Dyspnoea

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	11 (13.8)	NR (NE, NE)	62	11 (17.7)	NR (NE, NE)	0.577 (0.249, 1.337)	0.1913
vCPS < 10%	100	22 (22.0)	NR (3.6, NE)	122	17 (13.9)	10.2 (10.2, NE)	1.430 (0.757, 2.701)	0.2641
Missing	76	8 (10.5)	NR (NE, NE)	72	10 (13.9)	NR (2.8, NE)	0.480 (0.186, 1.241)	0.1199
Interaction								0.0785

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Insomnia

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	26 (16.6)	NR (NE, NE)	161	17 (10.6)	NR (5.9, NE)	1.129 (0.609, 2.090)	0.6980
>= 65 Years	99	20 (20.2)	NR (NE, NE)	95	9 (9.5)	NR (4.9, NE)	1.870 (0.849, 4.116)	0.1124
Interaction								0.3097
Gender								
Male	217	37 (17.1)	NR (NE, NE)	215	24 (11.2)	NR (NE, NE)	1.163 (0.693, 1.949)	0.5645
Female	39	9 (23.1)	NR (2.8, NE)	41	2 (4.9)	NR (NE, NE)	4.209 (0.906, 19.543)	0.0455
Interaction								0.1099

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Insomnia

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	34 (18.1)	NR (NE, NE)	192	24 (12.5)	NR (NE, NE)	1.122 (0.664, 1.898)	0.6641
Non-Smoker	68	12 (17.6)	NR (NE, NE)	63	2 (3.2)	NR (NE, NE)	4.611 (1.030, 20.650)	0.0276
Interaction								0.0894
ICC Options								
Paclitaxel	83	16 (19.3)	NR (3.7, NE)	85	8 (9.4)	NR (NE, NE)	2.022 (0.864, 4.733)	0.0964
Docetaxel	56	9 (16.1)	NR (NE, NE)	53	10 (18.9)	NR (2.3, NE)	0.674 (0.271, 1.676)	0.3847
Irinotecan	117	21 (17.9)	NR (NE, NE)	118	8 (6.8)	NR (5.9, NE)	1.694 (0.744, 3.857)	0.2021
Interaction								0.1674

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Insomnia

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	13 (20.3)	NR (NE, NE)	63	9 (14.3)	NR (NE, NE)	1.166 (0.496, 2.739)	0.7203
1	192	33 (17.2)	NR (NE, NE)	193	17 (8.8)	NR (5.9, NE)	1.492 (0.829, 2.686)	0.1768
Interaction								0.5048
Region #1								
Asia	201	36 (17.9)	NR (NE, NE)	203	21 (10.3)	NR (5.9, NE)	1.274 (0.740, 2.192)	0.3767
Europe/North America	55	10 (18.2)	NR (3.7, NE)	53	5 (9.4)	NR (NE, NE)	1.876 (0.638, 5.513)	0.2437
Interaction								0.5111

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Insomnia

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	29 (16.5)	NR (NE, NE)	178	15 (8.4)	NR (5.9, NE)	1.433 (0.765, 2.685)	0.2555
Japan	25	7 (28.0)	NR (2.8, NE)	25	6 (24.0)	NR (1.7, NE)	0.990 (0.331, 2.962)	0.9849
Europe/North America	55	10 (18.2)	NR (3.7, NE)	53	5 (9.4)	NR (NE, NE)	1.876 (0.638, 5.513)	0.2437
Interaction								0.6537
Race								
Asian and other	203	36 (17.7)	NR (NE, NE)	212	22 (10.4)	NR (5.9, NE)	1.248 (0.731, 2.131)	0.4124
White	53	10 (18.9)	NR (3.7, NE)	44	4 (9.1)	NR (NE, NE)	2.147 (0.670, 6.876)	0.1863
Interaction								0.4057

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Insomnia

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	15 (18.8)	NR (NE, NE)	62	7 (11.3)	NR (5.9, NE)	1.175 (0.476, 2.898)	0.7242
vCPS < 10%	100	15 (15.0)	NR (NE, NE)	122	10 (8.2)	NR (NE, NE)	1.511 (0.677, 3.372)	0.3082
Missing	76	16 (21.1)	NR (NE, NE)	72	9 (12.5)	NR (4.9, NE)	1.341 (0.590, 3.048)	0.4774
Interaction								0.9152

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Appetite Loss

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	28 (17.8)	NR (9.1, NE)	161	24 (14.9)	NR (NE, NE)	0.887 (0.512, 1.537)	0.6659
>= 65 Years	99	18 (18.2)	NR (11.8, NE)	95	16 (16.8)	NR (5.2, NE)	0.805 (0.405, 1.599)	0.5323
Interaction								0.9150
Gender								
Male	217	39 (18.0)	NR (11.8, NE)	215	33 (15.3)	NR (NE, NE)	0.886 (0.555, 1.414)	0.6077
Female	39	7 (17.9)	NR (4.5, NE)	41	7 (17.1)	NR (3.5, NE)	0.714 (0.243, 2.101)	0.5380
Interaction								0.7650

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Appetite Loss

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	30 (16.0)	NR (NE, NE)	192	31 (16.1)	NR (NE, NE)	0.754 (0.455, 1.250)	0.2689
Non-Smoker	68	16 (23.5)	NR (11.8, NE)	63	9 (14.3)	NR (3.8, NE)	1.205 (0.526, 2.760)	0.6563
Interaction								0.3792
ICC Options								
Paclitaxel	83	19 (22.9)	11.8 (9.1, NE)	85	13 (15.3)	NR (5.2, NE)	1.422 (0.700, 2.888)	0.3267
Docetaxel	56	8 (14.3)	NR (NE, NE)	53	7 (13.2)	NR (NE, NE)	0.879 (0.316, 2.444)	0.8037
Irinotecan	117	19 (16.2)	NR (NE, NE)	118	20 (16.9)	NR (3.5, NE)	0.633 (0.334, 1.199)	0.1521
Interaction								0.1497

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Appetite Loss

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	11 (17.2)	NR (9.1, NE)	63	10 (15.9)	NR (5.2, NE)	0.773 (0.324, 1.844)	0.5602
1	192	35 (18.2)	NR (NE, NE)	193	30 (15.5)	NR (NE, NE)	0.897 (0.549, 1.464)	0.6598
Interaction								0.9954
Region #1								
Asia	201	33 (16.4)	NR (NE, NE)	203	35 (17.2)	NR (5.2, NE)	0.670 (0.414, 1.084)	0.0979
Europe/North America	55	13 (23.6)	9.1 (4.5, NE)	53	5 (9.4)	NR (NE, NE)	2.414 (0.858, 6.790)	0.0827
Interaction								0.0266

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Appetite Loss

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	30 (17.0)	NR (NE, NE)	178	29 (16.3)	NR (NE, NE)	0.757 (0.453, 1.265)	0.2820
Japan	25	3 (12.0)	NR (3.5, NE)	25	6 (24.0)	NR (2.2, NE)	0.335 (0.082, 1.368)	0.1100
Europe/North America	55	13 (23.6)	9.1 (4.5, NE)	53	5 (9.4)	NR (NE, NE)	2.414 (0.858, 6.790)	0.0827
Interaction								0.0588
Race								
Asian and other	203	34 (16.7)	NR (NE, NE)	212	35 (16.5)	NR (5.2, NE)	0.713 (0.442, 1.150)	0.1606
White	53	12 (22.6)	9.1 (4.5, NE)	44	5 (11.4)	NR (NE, NE)	1.993 (0.701, 5.669)	0.1838
Interaction								0.0784

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Appetite Loss

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	14 (17.5)	NR (9.1, NE)	62	7 (11.3)	NR (NE, NE)	1.116 (0.446, 2.792)	0.8137
vCPS < 10%	100	18 (18.0)	NR (NE, NE)	122	21 (17.2)	NR (NE, NE)	0.861 (0.458, 1.619)	0.6389
Missing	76	14 (18.4)	NR (11.8, NE)	72	12 (16.7)	NR (2.8, NE)	0.773 (0.352, 1.701)	0.5178
Interaction								0.8679

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Constipation

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	22 (14.0)	NR (NE, NE)	161	19 (11.8)	NR (NE, NE)	0.901 (0.486, 1.671)	0.7392
>= 65 Years	99	14 (14.1)	NR (NE, NE)	95	4 (4.2)	NR (NE, NE)	2.997 (0.985, 9.117)	0.0412
Interaction								0.0731
Gender								
Male	217	31 (14.3)	NR (NE, NE)	215	18 (8.4)	NR (NE, NE)	1.399 (0.781, 2.506)	0.2534
Female	39	5 (12.8)	NR (NE, NE)	41	5 (12.2)	NR (3.5, NE)	0.759 (0.216, 2.668)	0.6640
Interaction								0.4531

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Constipation

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	27 (14.4)	NR (NE, NE)	192	18 (9.4)	NR (NE, NE)	1.290 (0.709, 2.347)	0.4001
Non-Smoker	68	9 (13.2)	NR (NE, NE)	63	5 (7.9)	NR (NE, NE)	1.216 (0.405, 3.648)	0.7268
Interaction								0.9712
ICC Options								
Paclitaxel	83	12 (14.5)	NR (NE, NE)	85	5 (5.9)	NR (NE, NE)	2.479 (0.873, 7.039)	0.0757
Docetaxel	56	8 (14.3)	NR (NE, NE)	53	6 (11.3)	NR (NE, NE)	1.213 (0.420, 3.503)	0.7203
Irinotecan	117	16 (13.7)	NR (NE, NE)	118	12 (10.2)	NR (NE, NE)	0.823 (0.384, 1.762)	0.6136
Interaction								0.2623

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Constipation

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	5 (7.8)	NR (NE, NE)	63	9 (14.3)	NR (NE, NE)	0.446 (0.149, 1.336)	0.1363
1	192	31 (16.1)	NR (NE, NE)	193	14 (7.3)	NR (NE, NE)	1.826 (0.970, 3.438)	0.0571
Interaction								0.0220
Region #1								
Asia	201	29 (14.4)	NR (NE, NE)	203	19 (9.4)	NR (NE, NE)	1.230 (0.688, 2.200)	0.4812
Europe/North America	55	7 (12.7)	NR (NE, NE)	53	4 (7.5)	NR (NE, NE)	1.497 (0.437, 5.128)	0.5166
Interaction								0.7673

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Constipation

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	24 (13.6)	NR (NE, NE)	178	14 (7.9)	NR (NE, NE)	1.339 (0.691, 2.597)	0.3837
Japan	25	5 (20.0)	NR (NE, NE)	25	5 (20.0)	NR (2.1, NE)	0.985 (0.284, 3.413)	0.9806
Europe/North America	55	7 (12.7)	NR (NE, NE)	53	4 (7.5)	NR (NE, NE)	1.497 (0.437, 5.128)	0.5166
Interaction								0.8127
Race								
Asian and other	203	29 (14.3)	NR (NE, NE)	212	19 (9.0)	NR (NE, NE)	1.262 (0.706, 2.257)	0.4284
White	53	7 (13.2)	NR (NE, NE)	44	4 (9.1)	NR (NE, NE)	1.356 (0.396, 4.646)	0.6252
Interaction								0.9163

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Constipation

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	12 (15.0)	NR (NE, NE)	62	6 (9.7)	NR (3.5, NE)	1.163 (0.433, 3.125)	0.7627
vCPS < 10%	100	14 (14.0)	NR (NE, NE)	122	11 (9.0)	NR (NE, NE)	1.330 (0.603, 2.934)	0.4764
Missing	76	10 (13.2)	NR (NE, NE)	72	6 (8.3)	NR (NE, NE)	1.233 (0.446, 3.414)	0.6837
Interaction								0.9841

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Diarrhea

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	9 (5.7)	NR (NE, NE)	161	14 (8.7)	NR (5.8, NE)	0.442 (0.190, 1.025)	0.0503
>= 65 Years	99	5 (5.1)	NR (NE, NE)	95	9 (9.5)	NR (5.2, NE)	0.408 (0.134, 1.240)	0.1019
Interaction								0.8411
Gender								
Male	217	13 (6.0)	NR (NE, NE)	215	19 (8.8)	NR (5.8, NE)	0.475 (0.233, 0.967)	0.0353
Female	39	1 (2.6)	NR (NE, NE)	41	4 (9.8)	NR (3.7, NE)	0.195 (0.022, 1.767)	0.1066
Interaction								0.4471

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Diarrhea

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	13 (6.9)	NR (NE, NE)	192	20 (10.4)	NR (5.8, NE)	0.475 (0.235, 0.959)	0.0333
Non-Smoker	68	1 (1.5)	NR (NE, NE)	63	3 (4.8)	NR (NE, NE)	0.247 (0.026, 2.379)	0.1887
Interaction								0.4880
ICC Options								
Paclitaxel	83	4 (4.8)	NR (NE, NE)	85	5 (5.9)	NR (5.8, NE)	0.765 (0.205, 2.864)	0.6904
Docetaxel	56	2 (3.6)	NR (NE, NE)	53	3 (5.7)	NR (NE, NE)	0.553 (0.092, 3.314)	0.5102
Irinotecan	117	8 (6.8)	NR (NE, NE)	118	15 (12.7)	NR (3.7, NE)	0.308 (0.128, 0.737)	0.0051
Interaction								0.3865

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Diarrhea

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	3 (4.7)	NR (NE, NE)	63	9 (14.3)	NR (5.2, NE)	0.248 (0.067, 0.920)	0.0231
1	192	11 (5.7)	NR (NE, NE)	193	14 (7.3)	NR (5.8, NE)	0.549 (0.248, 1.216)	0.1332
Interaction								0.2843
Region #1								
Asia	201	9 (4.5)	NR (NE, NE)	203	16 (7.9)	NR (5.8, NE)	0.356 (0.155, 0.817)	0.0110
Europe/North America	55	5 (9.1)	NR (NE, NE)	53	7 (13.2)	NR (NE, NE)	0.627 (0.198, 1.983)	0.4193
Interaction								0.5292

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Diarrhea

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	6 (3.4)	NR (NE, NE)	178	13 (7.3)	NR (5.8, NE)	0.285 (0.106, 0.764)	0.0080
Japan	25	3 (12.0)	NR (4.0, NE)	25	3 (12.0)	NR (5.2, NE)	0.809 (0.159, 4.107)	0.7982
Europe/North America	55	5 (9.1)	NR (NE, NE)	53	7 (13.2)	NR (NE, NE)	0.627 (0.198, 1.983)	0.4193
Interaction								0.4860
Race								
Asian and other	203	9 (4.4)	NR (NE, NE)	212	16 (7.5)	NR (5.8, NE)	0.364 (0.158, 0.835)	0.0130
White	53	5 (9.4)	NR (NE, NE)	44	7 (15.9)	NR (3.7, NE)	0.562 (0.178, 1.782)	0.3179
Interaction								0.6474

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Diarrhea

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	5 (6.3)	NR (NE, NE)	62	4 (6.5)	NR (5.8, NE)	0.671 (0.176, 2.549)	0.5551
vCPS < 10%	100	5 (5.0)	NR (NE, NE)	122	12 (9.8)	NR (NE, NE)	0.417 (0.146, 1.187)	0.0893
Missing	76	4 (5.3)	NR (NE, NE)	72	7 (9.7)	NR (5.2, NE)	0.366 (0.106, 1.259)	0.0965
Interaction								0.8567

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Financial Difficulties

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	18 (11.5)	28.4 (NE, NE)	161	12 (7.5)	NR (NE, NE)	1.174 (0.559, 2.466)	0.6682
>= 65 Years	99	7 (7.1)	NR (NE, NE)	95	16 (16.8)	NR (NE, NE)	0.341 (0.140, 0.832)	0.0126
Interaction								0.0415
Gender								
Male	217	23 (10.6)	28.4 (NE, NE)	215	21 (9.8)	NR (NE, NE)	0.853 (0.468, 1.553)	0.5994
Female	39	2 (5.1)	NR (NE, NE)	41	7 (17.1)	NR (3.0, NE)	0.210 (0.043, 1.033)	0.0336
Interaction								0.1510

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Financial Difficulties

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	19 (10.1)	28.4 (NE, NE)	192	19 (9.9)	NR (NE, NE)	0.791 (0.414, 1.510)	0.4726
Non-Smoker	68	6 (8.8)	NR (NE, NE)	63	9 (14.3)	NR (NE, NE)	0.487 (0.172, 1.376)	0.1604
Interaction								0.4306
ICC Options								
Paclitaxel	83	8 (9.6)	NR (NE, NE)	85	9 (10.6)	NR (NE, NE)	0.817 (0.315, 2.121)	0.6744
Docetaxel	56	8 (14.3)	NR (NE, NE)	53	5 (9.4)	NR (NE, NE)	1.473 (0.482, 4.503)	0.4931
Irinotecan	117	9 (7.7)	28.4 (NE, NE)	118	14 (11.9)	NR (NE, NE)	0.406 (0.169, 0.975)	0.0356
Interaction								0.1625

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Financial Difficulties

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	6 (9.4)	28.4 (NE, NE)	63	4 (6.3)	NR (NE, NE)	0.980 (0.262, 3.667)	0.9759
1	192	19 (9.9)	NR (NE, NE)	193	24 (12.4)	NR (NE, NE)	0.643 (0.351, 1.177)	0.1442
Interaction								0.4895
Region #1								
Asia	201	22 (10.9)	28.4 (NE, NE)	203	23 (11.3)	NR (NE, NE)	0.745 (0.411, 1.348)	0.3239
Europe/North America	55	3 (5.5)	NR (NE, NE)	53	5 (9.4)	NR (NE, NE)	0.444 (0.106, 1.866)	0.2534
Interaction								0.6371

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Financial Difficulties

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	19 (10.8)	28.4 (NE, NE)	178	23 (12.9)	NR (NE, NE)	0.634 (0.341, 1.177)	0.1409
Japan	25	3 (12.0)	NR (NE, NE)	25	0 (0.0)	NR (NE, NE)	71668956.901 (0.000, NE)	0.1057
Europe/North America	55	3 (5.5)	NR (NE, NE)	53	5 (9.4)	NR (NE, NE)	0.444 (0.106, 1.866)	0.2534
Interaction								0.9705
Race								
Asian and other	203	22 (10.8)	28.4 (NE, NE)	212	24 (11.3)	NR (NE, NE)	0.729 (0.405, 1.313)	0.2859
White	53	3 (5.7)	NR (NE, NE)	44	4 (9.1)	NR (NE, NE)	0.516 (0.115, 2.316)	0.3772
Interaction								0.7718

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Financial Difficulties

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	6 (7.5)	NR (NE, NE)	62	10 (16.1)	NR (NE, NE)	0.335 (0.120, 0.932)	0.0264
vCPS < 10%	100	14 (14.0)	NR (NE, NE)	122	11 (9.0)	NR (NE, NE)	1.321 (0.599, 2.915)	0.4867
Missing	76	5 (6.6)	28.4 (NE, NE)	72	7 (9.7)	NR (NE, NE)	0.473 (0.138, 1.618)	0.2184
Interaction								0.0661

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Global Health Status/QOL

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	19 (24.7)	9.1 (3.7, NE)	77	18 (23.4)	NR (3.5, NE)	0.958 (0.502, 1.827)	0.8942
>= 65 Years	62	13 (21.0)	NR (NE, NE)	61	12 (19.7)	NR (NE, NE)	0.996 (0.454, 2.187)	0.9928
Interaction								0.9777
Gender								
Male	118	30 (25.4)	NR (9.1, NE)	111	27 (24.3)	NR (NE, NE)	0.956 (0.568, 1.610)	0.8647
Female	21	2 (9.5)	NR (NE, NE)	27	3 (11.1)	NR (NE, NE)	0.862 (0.144, 5.163)	0.8699
Interaction								0.8372

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Global Health Status/QOL

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	27 (26.0)	NR (9.1, NE)	105	24 (22.9)	NR (NE, NE)	1.105 (0.637, 1.916)	0.7193
Non-Smoker	35	5 (14.3)	NR (NE, NE)	33	6 (18.2)	NR (3.5, NE)	0.598 (0.181, 1.975)	0.3852
Interaction								0.3086
ICC Options								
Paclitaxel	83	21 (25.3)	9.1 (3.7, NE)	85	15 (17.6)	NR (NE, NE)	1.432 (0.738, 2.780)	0.2812
Docetaxel	56	11 (19.6)	NR (NE, NE)	53	15 (28.3)	NR (3.5, NE)	0.582 (0.266, 1.273)	0.1627
Interaction								0.0670

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Global Health Status/QOL

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	11 (25.6)	NR (3.7, NE)	42	8 (19.0)	NR (NE, NE)	1.106 (0.442, 2.767)	0.8256
1	96	21 (21.9)	NR (NE, NE)	96	22 (22.9)	NR (3.5, NE)	0.910 (0.500, 1.654)	0.7532
Interaction								0.7153
Region #1								
Asia	103	26 (25.2)	NR (NE, NE)	105	27 (25.7)	NR (3.5, NE)	0.880 (0.513, 1.510)	0.6371
Europe/North America	36	6 (16.7)	NR (9.1, NE)	33	3 (9.1)	NR (NE, NE)	1.684 (0.416, 6.813)	0.4573
Interaction								0.3298

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Global Health Status/QOL

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	17 (21.8)	NR (NE, NE)	80	20 (25.0)	NR (3.5, NE)	0.778 (0.408, 1.487)	0.4388
Japan	25	9 (36.0)	NR (2.1, NE)	25	7 (28.0)	NR (1.6, NE)	1.131 (0.416, 3.076)	0.8074
Europe/North America	36	6 (16.7)	NR (9.1, NE)	33	3 (9.1)	NR (NE, NE)	1.684 (0.416, 6.813)	0.4573
Interaction								0.4949
Race								
Asian and other	105	26 (24.8)	NR (NE, NE)	114	28 (24.6)	NR (NE, NE)	0.885 (0.519, 1.511)	0.6494
White	34	6 (17.6)	NR (9.1, NE)	24	2 (8.3)	NR (NE, NE)	2.171 (0.434, 10.853)	0.3312
Interaction								0.2497

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Global Health Status/QOL

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	10 (22.2)	NR (3.7, NE)	34	6 (17.6)	NR (NE, NE)	1.233 (0.447, 3.400)	0.6826
vCPS < 10%	53	14 (26.4)	NR (2.8, NE)	56	14 (25.0)	NR (NE, NE)	0.921 (0.439, 1.934)	0.8236
Missing	41	8 (19.5)	NR (3.5, NE)	48	10 (20.8)	NR (3.5, NE)	0.816 (0.320, 2.080)	0.6650
Interaction								0.8835

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Physical Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	14 (18.2)	NR (3.7, NE)	77	21 (27.3)	4.5 (2.3, NE)	0.590 (0.299, 1.165)	0.1234
>= 65 Years	62	12 (19.4)	NR (NE, NE)	61	13 (21.3)	4.9 (2.8, NE)	0.731 (0.331, 1.616)	0.4345
Interaction								0.7157
Gender								
Male	118	23 (19.5)	NR (NE, NE)	111	29 (26.1)	NR (3.5, NE)	0.629 (0.363, 1.088)	0.0927
Female	21	3 (14.3)	NR (NE, NE)	27	5 (18.5)	10.0 (1.7, NE)	0.988 (0.221, 4.416)	0.9869
Interaction								0.8789

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Physical Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	20 (19.2)	NR (NE, NE)	105	32 (30.5)	4.9 (2.8, NE)	0.540 (0.308, 0.947)	0.0283
Non-Smoker	35	6 (17.1)	NR (2.9, NE)	33	2 (6.1)	NR (NE, NE)	2.268 (0.457, 11.255)	0.3021
Interaction								0.1034
ICC Options								
Paclitaxel	83	14 (16.9)	NR (3.7, NE)	85	22 (25.9)	4.9 (2.8, NE)	0.589 (0.301, 1.155)	0.1177
Docetaxel	56	12 (21.4)	NR (2.9, NE)	53	12 (22.6)	NR (3.5, NE)	0.808 (0.362, 1.804)	0.6009
Interaction								0.6248

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Physical Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	7 (16.3)	NR (NE, NE)	42	12 (28.6)	NR (2.3, NE)	0.413 (0.162, 1.056)	0.0557
1	96	19 (19.8)	NR (NE, NE)	96	22 (22.9)	10.0 (3.5, NE)	0.778 (0.421, 1.441)	0.4218
Interaction								0.2564
Region #1								
Asia	103	19 (18.4)	NR (NE, NE)	105	26 (24.8)	10.0 (3.5, NE)	0.603 (0.333, 1.092)	0.0902
Europe/North America	36	7 (19.4)	NR (3.6, NE)	33	8 (24.2)	3.5 (1.5, NE)	0.751 (0.271, 2.080)	0.5784
Interaction								0.7402

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Physical Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	15 (19.2)	NR (NE, NE)	80	17 (21.3)	10.0 (4.5, NE)	0.777 (0.387, 1.557)	0.4739
Japan	25	4 (16.0)	NR (NE, NE)	25	9 (36.0)	4.9 (1.7, NE)	0.337 (0.103, 1.107)	0.0581
Europe/North America	36	7 (19.4)	NR (3.6, NE)	33	8 (24.2)	3.5 (1.5, NE)	0.751 (0.271, 2.080)	0.5784
Interaction								0.4161
Race								
Asian and other	105	20 (19.0)	NR (NE, NE)	114	27 (23.7)	10.0 (4.5, NE)	0.635 (0.355, 1.135)	0.1209
White	34	6 (17.6)	NR (3.6, NE)	24	7 (29.2)	3.5 (1.5, NE)	0.632 (0.212, 1.888)	0.4050
Interaction								0.9778

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Physical Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	9 (20.0)	NR (3.7, NE)	34	10 (29.4)	10.0 (1.7, NE)	0.591 (0.240, 1.458)	0.2468
vCPS < 10%	53	11 (20.8)	NR (NE, NE)	56	11 (19.6)	NR (3.5, NE)	0.952 (0.412, 2.201)	0.9083
Missing	41	6 (14.6)	NR (2.8, NE)	48	13 (27.1)	3.5 (1.7, NE)	0.434 (0.164, 1.148)	0.0819
Interaction								0.5290

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Role Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	18 (23.4)	9.1 (9.1, NE)	77	19 (24.7)	10.0 (2.7, NE)	0.860 (0.450, 1.644)	0.6445
>= 65 Years	62	17 (27.4)	NR (3.1, NE)	61	23 (37.7)	3.8 (1.4, NE)	0.632 (0.336, 1.187)	0.1428
Interaction								0.4457
Gender								
Male	118	29 (24.6)	NR (9.1, NE)	111	35 (31.5)	4.9 (2.7, NE)	0.683 (0.416, 1.120)	0.1228
Female	21	6 (28.6)	NR (0.2, NE)	27	7 (25.9)	10.0 (2.7, NE)	1.245 (0.400, 3.872)	0.7014
Interaction								0.3736

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Role Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	28 (26.9)	NR (9.1, NE)	105	34 (32.4)	4.9 (2.3, NE)	0.768 (0.464, 1.269)	0.2936
Non-Smoker	35	7 (20.0)	NR (2.3, NE)	33	8 (24.2)	3.8 (2.7, NE)	0.656 (0.238, 1.810)	0.4053
Interaction								0.6609
ICC Options								
Paclitaxel	83	24 (28.9)	NR (9.1, NE)	85	32 (37.6)	3.3 (1.7, 10.0)	0.658 (0.387, 1.120)	0.1156
Docetaxel	56	11 (19.6)	NR (NE, NE)	53	10 (18.9)	NR (3.5, NE)	0.995 (0.422, 2.345)	0.9899
Interaction								0.4977

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Role Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	7 (16.3)	NR (9.1, NE)	42	15 (35.7)	3.3 (2.3, NE)	0.308 (0.123, 0.771)	0.0071
1	96	28 (29.2)	NR (2.3, NE)	96	27 (28.1)	4.9 (3.3, NE)	1.023 (0.603, 1.736)	0.9323
Interaction								0.0327
Region #1								
Asia	103	26 (25.2)	NR (NE, NE)	105	35 (33.3)	3.8 (2.3, NE)	0.636 (0.382, 1.060)	0.0752
Europe/North America	36	9 (25.0)	9.1 (3.1, NE)	33	7 (21.2)	NR (2.7, NE)	1.109 (0.410, 3.002)	0.8367
Interaction								0.2551

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Role Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	18 (23.1)	NR (NE, NE)	80	24 (30.0)	3.8 (2.3, NE)	0.656 (0.356, 1.210)	0.1689
Japan	25	8 (32.0)	NR (0.8, NE)	25	11 (44.0)	3.3 (1.3, NE)	0.634 (0.252, 1.590)	0.3072
Europe/North America	36	9 (25.0)	9.1 (3.1, NE)	33	7 (21.2)	NR (2.7, NE)	1.109 (0.410, 3.002)	0.8367
Interaction								0.5013
Race								
Asian and other	105	28 (26.7)	NR (NE, NE)	114	37 (32.5)	3.8 (2.3, NE)	0.682 (0.416, 1.118)	0.1214
White	34	7 (20.6)	9.1 (3.1, NE)	24	5 (20.8)	NR (2.7, NE)	1.007 (0.317, 3.198)	0.9899
Interaction								0.4299

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Role Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	11 (24.4)	NR (9.1, NE)	34	12 (35.3)	10.0 (1.4, NE)	0.611 (0.268, 1.391)	0.2305
vCPS < 10%	53	16 (30.2)	NR (2.3, NE)	56	16 (28.6)	3.8 (2.3, NE)	1.002 (0.501, 2.005)	0.9951
Missing	41	8 (19.5)	NR (NE, NE)	48	14 (29.2)	3.5 (1.7, NE)	0.599 (0.250, 1.434)	0.2392
Interaction								0.5694

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Emotional Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	11 (14.3)	9.1 (7.0, NE)	77	11 (14.3)	NR (NE, NE)	0.933 (0.403, 2.161)	0.8704
>= 65 Years	62	9 (14.5)	NR (NE, NE)	61	12 (19.7)	NR (NE, NE)	0.683 (0.287, 1.627)	0.3849
Interaction								0.5833
Gender								
Male	118	17 (14.4)	NR (9.1, NE)	111	18 (16.2)	NR (NE, NE)	0.763 (0.392, 1.485)	0.4214
Female	21	3 (14.3)	NR (NE, NE)	27	5 (18.5)	NR (1.4, NE)	0.759 (0.181, 3.182)	0.7025
Interaction								0.9619

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Emotional Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	15 (14.4)	NR (9.1, NE)	105	16 (15.2)	NR (NE, NE)	0.875 (0.431, 1.773)	0.7087
Non-Smoker	35	5 (14.3)	NR (2.2, NE)	33	7 (21.2)	NR (1.4, NE)	0.455 (0.144, 1.440)	0.1690
Interaction								0.3533
ICC Options								
Paclitaxel	83	12 (14.5)	NR (9.1, NE)	85	12 (14.1)	NR (NE, NE)	0.958 (0.430, 2.135)	0.9170
Docetaxel	56	8 (14.3)	NR (NE, NE)	53	11 (20.8)	NR (2.9, NE)	0.561 (0.224, 1.406)	0.2052
Interaction								0.3410

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Emotional Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	5 (11.6)	NR (7.0, NE)	42	6 (14.3)	NR (4.5, NE)	0.669 (0.203, 2.208)	0.5031
1	96	15 (15.6)	NR (NE, NE)	96	17 (17.7)	NR (NE, NE)	0.806 (0.402, 1.615)	0.5410
Interaction								0.7529
Region #1								
Asia	103	15 (14.6)	NR (NE, NE)	105	15 (14.3)	NR (NE, NE)	0.883 (0.431, 1.810)	0.7331
Europe/North America	36	5 (13.9)	NR (9.1, NE)	33	8 (24.2)	NR (1.4, NE)	0.480 (0.155, 1.490)	0.1946
Interaction								0.4743

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Emotional Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	10 (12.8)	NR (NE, NE)	80	11 (13.8)	NR (4.5, NE)	0.841 (0.357, 1.982)	0.6908
Japan	25	5 (20.0)	NR (7.0, NE)	25	4 (16.0)	NR (NE, NE)	1.049 (0.276, 3.980)	0.9432
Europe/North America	36	5 (13.9)	NR (9.1, NE)	33	8 (24.2)	NR (1.4, NE)	0.480 (0.155, 1.490)	0.1946
Interaction								0.7693
Race								
Asian and other	105	15 (14.3)	NR (NE, NE)	114	17 (14.9)	NR (NE, NE)	0.803 (0.400, 1.612)	0.5344
White	34	5 (14.7)	NR (9.1, NE)	24	6 (25.0)	NR (1.7, NE)	0.575 (0.174, 1.907)	0.3602
Interaction								0.7258

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Emotional Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	4 (8.9)	NR (9.1, NE)	34	2 (5.9)	NR (NE, NE)	1.335 (0.243, 7.326)	0.7385
vCPS < 10%	53	9 (17.0)	NR (NE, NE)	56	13 (23.2)	NR (4.5, NE)	0.664 (0.284, 1.555)	0.3392
Missing	41	7 (17.1)	NR (7.0, NE)	48	8 (16.7)	NR (NE, NE)	0.877 (0.315, 2.439)	0.8001
Interaction								0.7267

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Cognitive Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	16 (20.8)	9.1 (9.1, NE)	77	17 (22.1)	10.0 (3.3, NE)	0.829 (0.417, 1.649)	0.5890
>= 65 Years	62	14 (22.6)	NR (NE, NE)	61	10 (16.4)	NR (NE, NE)	1.355 (0.601, 3.053)	0.4586
Interaction								0.4526
Gender								
Male	118	25 (21.2)	NR (9.1, NE)	111	23 (20.7)	NR (NE, NE)	0.915 (0.518, 1.616)	0.7574
Female	21	5 (23.8)	NR (1.6, NE)	27	4 (14.8)	10.0 (NE, NE)	2.017 (0.480, 8.480)	0.3252
Interaction								0.4411

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Cognitive Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	19 (18.3)	NR (9.1, NE)	105	23 (21.9)	10.0 (10.0, NE)	0.774 (0.421, 1.426)	0.4053
Non-Smoker	35	11 (31.4)	2.8 (2.1, NE)	33	4 (12.1)	NR (NE, NE)	2.087 (0.663, 6.565)	0.1951
Interaction								0.1562
ICC Options								
Paclitaxel	83	17 (20.5)	NR (9.1, NE)	85	17 (20.0)	10.0 (3.6, NE)	0.927 (0.473, 1.818)	0.8248
Docetaxel	56	13 (23.2)	NR (3.5, NE)	53	10 (18.9)	NR (NE, NE)	1.123 (0.491, 2.565)	0.7814
Interaction								0.8458

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Cognitive Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	11 (25.6)	NR (9.1, NE)	42	13 (31.0)	3.6 (2.8, NE)	0.622 (0.276, 1.402)	0.2387
1	96	19 (19.8)	NR (NE, NE)	96	14 (14.6)	10.0 (10.0, NE)	1.319 (0.661, 2.632)	0.4279
Interaction								0.1677
Region #1								
Asia	103	24 (23.3)	NR (NE, NE)	105	22 (21.0)	10.0 (10.0, NE)	0.978 (0.547, 1.748)	0.9394
Europe/North America	36	6 (16.7)	9.1 (2.8, NE)	33	5 (15.2)	NR (NE, NE)	0.954 (0.290, 3.144)	0.9385
Interaction								0.9047

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Cognitive Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	17 (21.8)	NR (NE, NE)	80	16 (20.0)	10.0 (10.0, NE)	0.998 (0.504, 1.977)	0.9963
Japan	25	7 (28.0)	NR (2.1, NE)	25	6 (24.0)	3.6 (3.3, NE)	0.981 (0.326, 2.952)	0.9720
Europe/North America	36	6 (16.7)	9.1 (2.8, NE)	33	5 (15.2)	NR (NE, NE)	0.954 (0.290, 3.144)	0.9385
Interaction								0.9834
Race								
Asian and other	105	24 (22.9)	NR (NE, NE)	114	23 (20.2)	10.0 (10.0, NE)	0.976 (0.550, 1.733)	0.9330
White	34	6 (17.6)	9.1 (2.8, NE)	24	4 (16.7)	NR (1.5, NE)	1.001 (0.282, 3.562)	0.9983
Interaction								0.8403

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Cognitive Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	10 (22.2)	NR (9.1, NE)	34	6 (17.6)	NR (10.0, NE)	1.139 (0.413, 3.143)	0.8003
vCPS < 10%	53	9 (17.0)	NR (3.5, NE)	56	11 (19.6)	NR (3.3, NE)	0.737 (0.305, 1.780)	0.4940
Missing	41	11 (26.8)	NR (1.6, NE)	48	10 (20.8)	NR (2.1, NE)	1.296 (0.550, 3.055)	0.5435
Interaction								0.6307

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Social Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	12 (15.6)	NR (NE, NE)	77	18 (23.4)	NR (3.1, NE)	0.565 (0.271, 1.175)	0.1175
>= 65 Years	62	13 (21.0)	NR (NE, NE)	61	13 (21.3)	NR (3.6, NE)	0.905 (0.418, 1.958)	0.7973
Interaction								0.3764
Gender								
Male	118	20 (16.9)	NR (NE, NE)	111	27 (24.3)	NR (4.7, NE)	0.621 (0.348, 1.109)	0.0996
Female	21	5 (23.8)	NR (0.7, NE)	27	4 (14.8)	NR (2.3, NE)	1.533 (0.407, 5.773)	0.5229
Interaction								0.2175

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Social Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	18 (17.3)	NR (NE, NE)	105	27 (25.7)	NR (3.6, NE)	0.620 (0.341, 1.128)	0.1102
Non-Smoker	35	7 (20.0)	NR (3.0, NE)	33	4 (12.1)	NR (NE, NE)	1.270 (0.371, 4.347)	0.7002
Interaction								0.2980
ICC Options								
Paclitaxel	83	15 (18.1)	NR (NE, NE)	85	18 (21.2)	NR (4.7, NE)	0.784 (0.395, 1.559)	0.4829
Docetaxel	56	10 (17.9)	NR (NE, NE)	53	13 (24.5)	NR (2.8, NE)	0.640 (0.280, 1.463)	0.2802
Interaction								0.6690

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Social Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	4 (9.3)	NR (NE, NE)	42	8 (19.0)	NR (3.1, NE)	0.380 (0.114, 1.267)	0.1008
1	96	21 (21.9)	NR (NE, NE)	96	23 (24.0)	NR (4.7, NE)	0.843 (0.466, 1.525)	0.5669
Interaction								0.2788
Region #1								
Asia	103	21 (20.4)	NR (NE, NE)	105	24 (22.9)	NR (3.6, NE)	0.761 (0.423, 1.369)	0.3556
Europe/North America	36	4 (11.1)	NR (NE, NE)	33	7 (21.2)	NR (4.7, NE)	0.536 (0.157, 1.832)	0.3075
Interaction								0.5473

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Social Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	16 (20.5)	NR (NE, NE)	80	17 (21.3)	NR (3.1, NE)	0.845 (0.426, 1.675)	0.6259
Japan	25	5 (20.0)	NR (NE, NE)	25	7 (28.0)	NR (1.3, NE)	0.581 (0.183, 1.846)	0.3491
Europe/North America	36	4 (11.1)	NR (NE, NE)	33	7 (21.2)	NR (4.7, NE)	0.536 (0.157, 1.832)	0.3075
Interaction								0.7070
Race								
Asian and other	105	22 (21.0)	NR (NE, NE)	114	25 (21.9)	NR (3.6, NE)	0.803 (0.452, 1.427)	0.4497
White	34	3 (8.8)	NR (NE, NE)	24	6 (25.0)	NR (1.4, NE)	0.395 (0.099, 1.584)	0.1716
Interaction								0.3106

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Social Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	5 (11.1)	NR (NE, NE)	34	7 (20.6)	NR (2.3, NE)	0.476 (0.150, 1.509)	0.1967
vCPS < 10%	53	10 (18.9)	NR (NE, NE)	56	12 (21.4)	NR (3.1, NE)	0.794 (0.343, 1.840)	0.5842
Missing	41	10 (24.4)	NR (2.1, NE)	48	12 (25.0)	4.7 (2.8, NE)	0.908 (0.392, 2.104)	0.8175
Interaction								0.6434

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Fatigue

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	27 (35.1)	3.7 (2.8, NE)	77	28 (36.4)	2.7 (1.7, 4.5)	0.790 (0.464, 1.345)	0.3767
>= 65 Years	62	26 (41.9)	3.5 (1.4, NE)	61	22 (36.1)	2.2 (1.7, NE)	1.045 (0.587, 1.861)	0.8782
Interaction								0.5506
Gender								
Male	118	45 (38.1)	3.7 (2.8, 11.8)	111	45 (40.5)	2.3 (1.7, 3.8)	0.779 (0.513, 1.182)	0.2299
Female	21	8 (38.1)	2.8 (0.2, NE)	27	5 (18.5)	3.3 (1.7, NE)	2.131 (0.690, 6.588)	0.1737
Interaction								0.0939

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Fatigue

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	42 (40.4)	3.5 (2.1, NE)	105	40 (38.1)	2.3 (1.7, NE)	1.011 (0.654, 1.563)	0.9600
Non-Smoker	35	11 (31.4)	11.8 (2.0, NE)	33	10 (30.3)	3.5 (1.4, NE)	0.554 (0.227, 1.354)	0.1863
Interaction								0.3415
ICC Options								
Paclitaxel	83	34 (41.0)	3.7 (2.1, 11.8)	85	31 (36.5)	2.7 (1.7, 4.5)	0.981 (0.602, 1.601)	0.9393
Docetaxel	56	19 (33.9)	3.5 (2.1, NE)	53	19 (35.8)	2.3 (1.4, NE)	0.790 (0.415, 1.505)	0.4619
Interaction								0.5303

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Fatigue

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	16 (37.2)	7.0 (3.5, NE)	42	18 (42.9)	2.3 (1.4, NE)	0.544 (0.274, 1.078)	0.0732
1	96	37 (38.5)	2.9 (1.4, NE)	96	32 (33.3)	2.7 (1.7, NE)	1.205 (0.750, 1.936)	0.4302
Interaction								0.0817
Region #1								
Asia	103	38 (36.9)	7.0 (2.8, NE)	105	43 (41.0)	2.2 (1.7, 3.5)	0.718 (0.462, 1.117)	0.1313
Europe/North America	36	15 (41.7)	2.8 (0.7, NE)	33	7 (21.2)	NR (1.7, NE)	2.155 (0.872, 5.323)	0.0857
Interaction								0.0367

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Fatigue

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	26 (33.3)	3.7 (2.1, NE)	80	31 (38.8)	2.3 (1.5, 4.5)	0.717 (0.424, 1.210)	0.1991
Japan	25	12 (48.0)	7.0 (0.8, NE)	25	12 (48.0)	1.7 (1.6, NE)	0.774 (0.340, 1.763)	0.5332
Europe/North America	36	15 (41.7)	2.8 (0.7, NE)	33	7 (21.2)	NR (1.7, NE)	2.155 (0.872, 5.323)	0.0857
Interaction								0.1098
Race								
Asian and other	105	40 (38.1)	7.0 (2.8, NE)	114	43 (37.7)	2.3 (1.7, 3.8)	0.809 (0.524, 1.250)	0.3283
White	34	13 (38.2)	2.8 (0.7, NE)	24	7 (29.2)	NR (1.7, NE)	1.493 (0.591, 3.770)	0.3888
Interaction								0.2601

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Fatigue

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	15 (33.3)	9.1 (2.8, NE)	34	10 (29.4)	NR (2.1, NE)	1.040 (0.466, 2.320)	0.9219
vCPS < 10%	53	25 (47.2)	2.1 (1.4, NE)	56	24 (42.9)	2.3 (1.5, 3.8)	1.038 (0.592, 1.819)	0.8955
Missing	41	13 (31.7)	7.0 (2.8, NE)	48	16 (33.3)	2.1 (1.7, 3.5)	0.663 (0.301, 1.460)	0.2905
Interaction								0.7579

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Nausea and Vomiting

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	17 (22.1)	NR (3.6, NE)	77	8 (10.4)	NR (NE, NE)	1.895 (0.816, 4.398)	0.1275
>= 65 Years	62	9 (14.5)	NR (NE, NE)	61	7 (11.5)	NR (5.2, NE)	1.096 (0.405, 2.967)	0.8566
Interaction								0.3986
Gender								
Male	118	21 (17.8)	NR (NE, NE)	111	13 (11.7)	NR (NE, NE)	1.355 (0.678, 2.709)	0.3864
Female	21	5 (23.8)	NR (0.7, NE)	27	2 (7.4)	NR (NE, NE)	3.568 (0.692, 18.397)	0.1028
Interaction								0.3978

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Nausea and Vomiting

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	19 (18.3)	NR (NE, NE)	105	12 (11.4)	NR (5.2, NE)	1.534 (0.743, 3.164)	0.2412
Non-Smoker	35	7 (20.0)	NR (2.9, NE)	33	3 (9.1)	NR (3.2, NE)	1.591 (0.410, 6.170)	0.4972
Interaction								0.9841
ICC Options								
Paclitaxel	83	16 (19.3)	NR (NE, NE)	85	11 (12.9)	NR (5.2, NE)	1.418 (0.658, 3.057)	0.3691
Docetaxel	56	10 (17.9)	NR (3.6, NE)	53	4 (7.5)	NR (2.9, NE)	1.844 (0.571, 5.950)	0.2975
Interaction								0.6037

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Nausea and Vomiting

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	5 (11.6)	NR (NE, NE)	42	4 (9.5)	NR (5.2, NE)	0.948 (0.253, 3.548)	0.9372
1	96	21 (21.9)	NR (3.6, NE)	96	11 (11.5)	NR (NE, NE)	1.820 (0.876, 3.780)	0.1008
Interaction								0.4265
Region #1								
Asia	103	19 (18.4)	NR (NE, NE)	105	9 (8.6)	NR (NE, NE)	1.892 (0.855, 4.188)	0.1079
Europe/North America	36	7 (19.4)	NR (2.1, NE)	33	6 (18.2)	NR (2.2, NE)	1.026 (0.343, 3.066)	0.9635
Interaction								0.3425

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Nausea and Vomiting

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	16 (20.5)	NR (NE, NE)	80	8 (10.0)	NR (NE, NE)	1.852 (0.792, 4.332)	0.1459
Japan	25	3 (12.0)	NR (NE, NE)	25	1 (4.0)	NR (5.2, NE)	2.671 (0.276, 25.818)	0.3773
Europe/North America	36	7 (19.4)	NR (2.1, NE)	33	6 (18.2)	NR (2.2, NE)	1.026 (0.343, 3.066)	0.9635
Interaction								0.6064
Race								
Asian and other	105	20 (19.0)	NR (NE, NE)	114	10 (8.8)	NR (NE, NE)	1.873 (0.875, 4.007)	0.0987
White	34	6 (17.6)	NR (2.1, NE)	24	5 (20.8)	NR (2.2, NE)	0.896 (0.272, 2.951)	0.8562
Interaction								0.2693

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Nausea and Vomiting

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	7 (15.6)	NR (NE, NE)	34	1 (2.9)	NR (NE, NE)	5.508 (0.677, 44.827)	0.0720
vCPS < 10%	53	11 (20.8)	NR (3.6, NE)	56	8 (14.3)	NR (3.2, NE)	1.247 (0.501, 3.103)	0.6344
Missing	41	8 (19.5)	NR (2.8, NE)	48	6 (12.5)	NR (3.5, NE)	1.529 (0.529, 4.423)	0.4234
Interaction								0.4944

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Pain

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	20 (26.0)	NR (7.0, NE)	77	15 (19.5)	NR (3.8, NE)	1.336 (0.683, 2.614)	0.3921
>= 65 Years	62	13 (21.0)	11.8 (11.8, NE)	61	15 (24.6)	4.9 (3.2, NE)	0.702 (0.328, 1.504)	0.3564
Interaction								0.2565
Gender								
Male	118	30 (25.4)	NR (7.0, NE)	111	26 (23.4)	NR (3.6, NE)	0.986 (0.581, 1.671)	0.9567
Female	21	3 (14.3)	NR (1.6, NE)	27	4 (14.8)	10.0 (NE, NE)	1.236 (0.249, 6.137)	0.7931
Interaction								0.9318

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Pain

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	28 (26.9)	NR (7.0, NE)	105	26 (24.8)	10.0 (3.8, NE)	1.059 (0.620, 1.807)	0.8324
Non-Smoker	35	5 (14.3)	NR (11.8, NE)	33	4 (12.1)	NR (2.7, NE)	0.742 (0.185, 2.972)	0.6710
Interaction								0.7343
ICC Options								
Paclitaxel	83	20 (24.1)	11.8 (7.0, NE)	85	21 (24.7)	10.0 (3.6, NE)	0.905 (0.489, 1.674)	0.7496
Docetaxel	56	13 (23.2)	NR (2.1, NE)	53	9 (17.0)	NR (NE, NE)	1.312 (0.561, 3.071)	0.5247
Interaction								0.6322

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Pain

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	13 (30.2)	11.8 (7.0, NE)	42	8 (19.0)	NR (3.6, NE)	1.280 (0.527, 3.109)	0.5823
1	96	20 (20.8)	NR (NE, NE)	96	22 (22.9)	10.0 (4.9, NE)	0.867 (0.472, 1.590)	0.6398
Interaction								0.4201
Region #1								
Asia	103	24 (23.3)	NR (7.0, NE)	105	25 (23.8)	4.9 (3.6, NE)	0.799 (0.454, 1.407)	0.4317
Europe/North America	36	9 (25.0)	NR (2.0, NE)	33	5 (15.2)	NR (2.7, NE)	1.788 (0.599, 5.336)	0.2891
Interaction								0.1733

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Pain

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	18 (23.1)	NR (NE, NE)	80	20 (25.0)	10.0 (3.2, NE)	0.846 (0.447, 1.600)	0.6008
Japan	25	6 (24.0)	11.8 (7.0, NE)	25	5 (20.0)	4.9 (3.6, NE)	0.679 (0.199, 2.323)	0.5345
Europe/North America	36	9 (25.0)	NR (2.0, NE)	33	5 (15.2)	NR (2.7, NE)	1.788 (0.599, 5.336)	0.2891
Interaction								0.4055
Race								
Asian and other	105	25 (23.8)	NR (7.0, NE)	114	26 (22.8)	10.0 (3.6, NE)	0.839 (0.482, 1.461)	0.5310
White	34	8 (23.5)	NR (2.0, NE)	24	4 (16.7)	NR (2.7, NE)	1.706 (0.514, 5.669)	0.3766
Interaction								0.2527

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Pain

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	8 (17.8)	NR (NE, NE)	34	8 (23.5)	10.0 (2.6, NE)	0.666 (0.249, 1.779)	0.4118
vCPS < 10%	53	15 (28.3)	NR (2.9, NE)	56	12 (21.4)	NR (3.8, NE)	1.285 (0.601, 2.747)	0.5128
Missing	41	10 (24.4)	11.8 (7.0, NE)	48	10 (20.8)	4.9 (2.8, NE)	0.974 (0.392, 2.419)	0.9549
Interaction								0.6164

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Dyspnoea

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	17 (22.1)	NR (3.6, NE)	77	16 (20.8)	NR (3.5, NE)	0.912 (0.460, 1.810)	0.7919
>= 65 Years	62	8 (12.9)	NR (NE, NE)	61	10 (16.4)	NR (3.3, NE)	0.676 (0.266, 1.719)	0.4063
Interaction								0.6826
Gender								
Male	118	22 (18.6)	NR (NE, NE)	111	21 (18.9)	NR (3.8, NE)	0.868 (0.477, 1.581)	0.6416
Female	21	3 (14.3)	NR (NE, NE)	27	5 (18.5)	NR (1.7, NE)	0.692 (0.163, 2.932)	0.6144
Interaction								0.6792

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Dyspnoea

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	21 (20.2)	NR (NE, NE)	105	24 (22.9)	NR (3.3, NE)	0.791 (0.439, 1.424)	0.4307
Non-Smoker	35	4 (11.4)	NR (NE, NE)	33	2 (6.1)	NR (3.8, NE)	1.449 (0.264, 7.944)	0.6676
Interaction								0.4886
ICC Options								
Paclitaxel	83	17 (20.5)	NR (NE, NE)	85	15 (17.6)	NR (3.5, NE)	1.082 (0.539, 2.170)	0.8232
Docetaxel	56	8 (14.3)	NR (NE, NE)	53	11 (20.8)	NR (2.9, NE)	0.531 (0.212, 1.331)	0.1690
Interaction								0.2216

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Dyspnoea

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	7 (16.3)	NR (NE, NE)	42	8 (19.0)	NR (2.8, NE)	0.673 (0.243, 1.865)	0.4406
1	96	18 (18.8)	NR (NE, NE)	96	18 (18.8)	NR (3.3, NE)	0.909 (0.472, 1.750)	0.7737
Interaction								0.5892
Region #1								
Asia	103	21 (20.4)	NR (NE, NE)	105	21 (20.0)	NR (3.8, NE)	0.851 (0.464, 1.562)	0.6000
Europe/North America	36	4 (11.1)	NR (NE, NE)	33	5 (15.2)	NR (2.8, NE)	0.681 (0.182, 2.554)	0.5671
Interaction								0.8511

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Dyspnoea

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	15 (19.2)	NR (3.6, NE)	80	14 (17.5)	NR (3.8, NE)	0.990 (0.477, 2.052)	0.9778
Japan	25	6 (24.0)	NR (3.1, NE)	25	7 (28.0)	NR (1.7, NE)	0.757 (0.252, 2.271)	0.6147
Europe/North America	36	4 (11.1)	NR (NE, NE)	33	5 (15.2)	NR (2.8, NE)	0.681 (0.182, 2.554)	0.5671
Interaction								0.7480
Race								
Asian and other	105	22 (21.0)	NR (NE, NE)	114	22 (19.3)	NR (3.8, NE)	0.896 (0.495, 1.621)	0.7147
White	34	3 (8.8)	NR (NE, NE)	24	4 (16.7)	NR (2.8, NE)	0.524 (0.117, 2.358)	0.3920
Interaction								0.6024

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Dyspnoea

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	7 (15.6)	NR (NE, NE)	34	9 (26.5)	NR (1.7, NE)	0.561 (0.209, 1.508)	0.2419
vCPS < 10%	53	12 (22.6)	NR (3.6, NE)	56	8 (14.3)	NR (3.5, NE)	1.585 (0.645, 3.897)	0.3084
Missing	41	6 (14.6)	NR (3.6, NE)	48	9 (18.8)	NR (2.8, NE)	0.608 (0.213, 1.731)	0.3421
Interaction								0.1838

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Insomnia

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	12 (15.6)	NR (NE, NE)	77	10 (13.0)	NR (NE, NE)	1.017 (0.438, 2.362)	0.9677
>= 65 Years	62	13 (21.0)	NR (NE, NE)	61	8 (13.1)	NR (4.9, NE)	1.534 (0.634, 3.708)	0.3353
Interaction								0.4798
Gender								
Male	118	21 (17.8)	NR (NE, NE)	111	16 (14.4)	NR (NE, NE)	1.114 (0.581, 2.138)	0.7425
Female	21	4 (19.0)	NR (1.4, NE)	27	2 (7.4)	NR (NE, NE)	2.438 (0.444, 13.378)	0.2894
Interaction								0.3733

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Insomnia

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	17 (16.3)	NR (NE, NE)	105	16 (15.2)	NR (NE, NE)	0.997 (0.503, 1.976)	0.9920
Non-Smoker	35	8 (22.9)	NR (2.9, NE)	33	2 (6.1)	NR (NE, NE)	3.040 (0.645, 14.330)	0.1386
Interaction								0.1887
ICC Options								
Paclitaxel	83	16 (19.3)	NR (3.7, NE)	85	8 (9.4)	NR (NE, NE)	2.022 (0.864, 4.733)	0.0964
Docetaxel	56	9 (16.1)	NR (NE, NE)	53	10 (18.9)	NR (2.3, NE)	0.674 (0.271, 1.676)	0.3847
Interaction								0.0825

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Insomnia

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	9 (20.9)	NR (NE, NE)	42	7 (16.7)	NR (NE, NE)	1.113 (0.413, 2.996)	0.8288
1	96	16 (16.7)	NR (NE, NE)	96	11 (11.5)	NR (4.9, NE)	1.356 (0.629, 2.924)	0.4333
Interaction								0.6166
Region #1								
Asia	103	21 (20.4)	NR (NE, NE)	105	14 (13.3)	NR (4.9, NE)	1.305 (0.662, 2.572)	0.4357
Europe/North America	36	4 (11.1)	NR (NE, NE)	33	4 (12.1)	NR (NE, NE)	0.915 (0.229, 3.666)	0.9004
Interaction								0.6773

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Insomnia

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	14 (17.9)	NR (3.7, NE)	80	8 (10.0)	NR (NE, NE)	1.599 (0.670, 3.816)	0.2830
Japan	25	7 (28.0)	NR (2.8, NE)	25	6 (24.0)	NR (1.7, NE)	0.990 (0.331, 2.962)	0.9849
Europe/North America	36	4 (11.1)	NR (NE, NE)	33	4 (12.1)	NR (NE, NE)	0.915 (0.229, 3.666)	0.9004
Interaction								0.7187
Race								
Asian and other	105	21 (20.0)	NR (NE, NE)	114	15 (13.2)	NR (4.9, NE)	1.271 (0.654, 2.470)	0.4750
White	34	4 (11.8)	NR (NE, NE)	24	3 (12.5)	NR (NE, NE)	1.029 (0.230, 4.601)	0.9699
Interaction								0.8214

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Insomnia

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	7 (15.6)	NR (3.7, NE)	34	5 (14.7)	NR (NE, NE)	0.893 (0.281, 2.836)	0.8461
vCPS < 10%	53	9 (17.0)	NR (NE, NE)	56	6 (10.7)	NR (NE, NE)	1.445 (0.514, 4.064)	0.4796
Missing	41	9 (22.0)	NR (2.8, NE)	48	7 (14.6)	NR (4.9, NE)	1.449 (0.538, 3.899)	0.4564
Interaction								0.8021

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Appetite Loss

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	18 (23.4)	9.1 (3.7, NE)	77	12 (15.6)	NR (NE, NE)	1.355 (0.652, 2.817)	0.4119
>= 65 Years	62	9 (14.5)	NR (11.8, NE)	61	8 (13.1)	NR (5.2, NE)	0.867 (0.324, 2.320)	0.7766
Interaction								0.4906
Gender								
Male	118	24 (20.3)	NR (9.1, NE)	111	16 (14.4)	NR (NE, NE)	1.261 (0.667, 2.384)	0.4735
Female	21	3 (14.3)	NR (NE, NE)	27	4 (14.8)	NR (3.5, NE)	0.777 (0.170, 3.559)	0.7447
Interaction								0.5058

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Appetite Loss

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	17 (16.3)	NR (9.1, NE)	105	17 (16.2)	NR (5.2, NE)	0.921 (0.469, 1.808)	0.8113
Non-Smoker	35	10 (28.6)	11.8 (1.5, NE)	33	3 (9.1)	NR (3.8, NE)	2.245 (0.608, 8.298)	0.2087
Interaction								0.2351
ICC Options								
Paclitaxel	83	19 (22.9)	11.8 (9.1, NE)	85	13 (15.3)	NR (5.2, NE)	1.422 (0.700, 2.888)	0.3267
Docetaxel	56	8 (14.3)	NR (NE, NE)	53	7 (13.2)	NR (NE, NE)	0.879 (0.316, 2.444)	0.8037
Interaction								0.3545

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Appetite Loss

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	8 (18.6)	11.8 (9.1, NE)	42	5 (11.9)	NR (5.2, NE)	1.172 (0.380, 3.612)	0.7820
1	96	19 (19.8)	NR (NE, NE)	96	15 (15.6)	NR (NE, NE)	1.177 (0.598, 2.317)	0.6346
Interaction								0.8187
Region #1								
Asia	103	18 (17.5)	NR (11.8, NE)	105	19 (18.1)	NR (5.2, NE)	0.776 (0.405, 1.487)	0.4416
Europe/North America	36	9 (25.0)	9.1 (2.8, NE)	33	1 (3.0)	NR (NE, NE)	8.591 (1.082, 68.217)	0.0145
Interaction								0.0253

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Appetite Loss

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	15 (19.2)	NR (NE, NE)	80	13 (16.3)	NR (3.8, NE)	1.046 (0.497, 2.200)	0.9050
Japan	25	3 (12.0)	NR (3.5, NE)	25	6 (24.0)	NR (2.2, NE)	0.335 (0.082, 1.368)	0.1100
Europe/North America	36	9 (25.0)	9.1 (2.8, NE)	33	1 (3.0)	NR (NE, NE)	8.591 (1.082, 68.217)	0.0145
Interaction								0.0362
Race								
Asian and other	105	19 (18.1)	NR (11.8, NE)	114	19 (16.7)	NR (5.2, NE)	0.860 (0.453, 1.634)	0.6442
White	34	8 (23.5)	9.1 (2.8, NE)	24	1 (4.2)	NR (NE, NE)	6.347 (0.789, 51.044)	0.0460
Interaction								0.0608

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Appetite Loss

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	10 (22.2)	NR (3.7, NE)	34	4 (11.8)	NR (3.5, NE)	1.725 (0.539, 5.526)	0.3507
vCPS < 10%	53	11 (20.8)	NR (3.5, NE)	56	7 (12.5)	NR (NE, NE)	1.566 (0.606, 4.047)	0.3483
Missing	41	6 (14.6)	11.8 (11.8, NE)	48	9 (18.8)	NR (2.8, NE)	0.582 (0.195, 1.740)	0.3239
Interaction								0.3621

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Constipation

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	12 (15.6)	NR (NE, NE)	77	10 (13.0)	NR (3.5, NE)	1.145 (0.494, 2.653)	0.7506
>= 65 Years	62	8 (12.9)	NR (NE, NE)	61	1 (1.6)	NR (NE, NE)	8.181 (1.023, 65.417)	0.0173
Interaction								0.0923
Gender								
Male	118	19 (16.1)	NR (NE, NE)	111	7 (6.3)	NR (NE, NE)	2.600 (1.093, 6.187)	0.0242
Female	21	1 (4.8)	NR (NE, NE)	27	4 (14.8)	NR (3.5, NE)	0.254 (0.027, 2.355)	0.1894
Interaction								0.0598

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Constipation

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	15 (14.4)	NR (NE, NE)	105	9 (8.6)	NR (NE, NE)	1.759 (0.769, 4.020)	0.1729
Non-Smoker	35	5 (14.3)	NR (2.9, NE)	33	2 (6.1)	NR (NE, NE)	1.912 (0.371, 9.860)	0.4277
Interaction								0.9290
ICC Options								
Paclitaxel	83	12 (14.5)	NR (NE, NE)	85	5 (5.9)	NR (NE, NE)	2.479 (0.873, 7.039)	0.0757
Docetaxel	56	8 (14.3)	NR (NE, NE)	53	6 (11.3)	NR (NE, NE)	1.213 (0.420, 3.503)	0.7203
Interaction								0.3402

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Constipation

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	2 (4.7)	NR (NE, NE)	42	3 (7.1)	NR (NE, NE)	0.539 (0.090, 3.241)	0.4929
1	96	18 (18.8)	NR (NE, NE)	96	8 (8.3)	NR (NE, NE)	2.430 (1.056, 5.592)	0.0297
Interaction								0.1380
Region #1								
Asia	103	17 (16.5)	NR (NE, NE)	105	11 (10.5)	NR (NE, NE)	1.530 (0.716, 3.267)	0.2660
Europe/North America	36	3 (8.3)	NR (NE, NE)	33	0 (0.0)	NR (NE, NE)	71243685.741 (0.000, NE)	0.1052
Interaction								0.9885

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Constipation

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	12 (15.4)	NR (NE, NE)	80	6 (7.5)	NR (NE, NE)	2.046 (0.768, 5.453)	0.1414
Japan	25	5 (20.0)	NR (NE, NE)	25	5 (20.0)	NR (2.1, NE)	0.985 (0.284, 3.413)	0.9806
Europe/North America	36	3 (8.3)	NR (NE, NE)	33	0 (0.0)	NR (NE, NE)	71243685.741 (0.000, NE)	0.1052
Interaction								0.5769

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Constipation

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	17 (16.2)	NR (NE, NE)	114	11 (9.6)	NR (NE, NE)	1.595 (0.747, 3.407)	0.2212
White	34	3 (8.8)	NR (NE, NE)	24	0 (0.0)	NR (NE, NE)	62214220.686 (0.000, NE)	0.1342
Interaction								0.9895
Baseline PD-L1 Status								
vCPS >= 10%	45	7 (15.6)	NR (NE, NE)	34	5 (14.7)	NR (3.5, NE)	1.036 (0.327, 3.279)	0.9516
vCPS < 10%	53	9 (17.0)	NR (NE, NE)	56	3 (5.4)	NR (NE, NE)	3.100 (0.839, 11.453)	0.0726
Missing	41	4 (9.8)	NR (NE, NE)	48	3 (6.3)	NR (NE, NE)	1.567 (0.351, 7.001)	0.5500
Interaction								0.4684

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Diarrhea

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	3 (3.9)	--	77	6 (7.8)	--	--	--
>= 65 Years	62	3 (4.8)	--	61	2 (3.3)	--	--	--
Interaction								--
Gender								
Male	118	6 (5.1)	NR (NE, NE)	111	7 (6.3)	NR (5.8, NE)	0.691 (0.231, 2.063)	0.5044
Female	21	0 (0.0)	NR (NE, NE)	27	1 (3.7)	NR (NE, NE)	0.000 (0.000, NE)	0.3613
Interaction								0.9939

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Diarrhea

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	5 (4.8)	NR (NE, NE)	105	8 (7.6)	NR (5.8, NE)	0.559 (0.182, 1.714)	0.3018
Non-Smoker	35	1 (2.9)	NR (NE, NE)	33	0 (0.0)	NR (NE, NE)	21508137.653 (0.000, NE)	0.4054
Interaction								0.9930
ICC Options								
Paclitaxel	83	4 (4.8)	--	85	5 (5.9)	--	--	--
Docetaxel	56	2 (3.6)	--	53	3 (5.7)	--	--	--
Interaction								--

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Diarrhea

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	2 (4.7)	--	42	3 (7.1)	--	--	--
1	96	4 (4.2)	--	96	5 (5.2)	--	--	--
Interaction								--
Region #1								
Asia	103	6 (5.8)	NR (NE, NE)	105	7 (6.7)	NR (5.8, NE)	0.696 (0.232, 2.083)	0.5139
Europe/North America	36	0 (0.0)	NR (NE, NE)	33	1 (3.0)	NR (NE, NE)	0.000 (0.000, NE)	0.3173
Interaction								0.9922

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Diarrhea

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	3 (3.8)	--	80	4 (5.0)	--	--	--
Japan	25	3 (12.0)	--	25	3 (12.0)	--	--	--
Europe/North America	36	0 (0.0)	--	33	1 (3.0)	--	--	--
Interaction								--
Race								
Asian and other	105	6 (5.7)	NR (NE, NE)	114	7 (6.1)	NR (5.8, NE)	0.715 (0.239, 2.144)	0.5478
White	34	0 (0.0)	NR (NE, NE)	24	1 (4.2)	NR (NE, NE)	0.000 (0.000, NE)	0.2850
Interaction								0.9921

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Diarrhea

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	2 (4.4)	--	34	3 (8.8)	--	--	--
vCPS < 10%	53	3 (5.7)	--	56	1 (1.8)	--	--	--
Missing	41	1 (2.4)	--	48	4 (8.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Financial Difficulties

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	10 (13.0)	NR (NE, NE)	77	7 (9.1)	NR (NE, NE)	1.311 (0.499, 3.447)	0.5785
>= 65 Years	62	6 (9.7)	NR (NE, NE)	61	7 (11.5)	NR (NE, NE)	0.772 (0.259, 2.300)	0.6394
Interaction								0.4946
Gender								
Male	118	15 (12.7)	NR (NE, NE)	111	10 (9.0)	NR (NE, NE)	1.345 (0.604, 2.995)	0.4624
Female	21	1 (4.8)	NR (2.8, NE)	27	4 (14.8)	NR (3.0, NE)	0.227 (0.025, 2.065)	0.1518
Interaction								0.1947

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Financial Difficulties

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	12 (11.5)	NR (NE, NE)	105	11 (10.5)	NR (NE, NE)	1.076 (0.474, 2.440)	0.8598
Non-Smoker	35	4 (11.4)	NR (NE, NE)	33	3 (9.1)	NR (3.0, NE)	0.983 (0.220, 4.397)	0.9819
Interaction								0.9602
ICC Options								
Paclitaxel	83	8 (9.6)	NR (NE, NE)	85	9 (10.6)	NR (NE, NE)	0.817 (0.315, 2.121)	0.6744
Docetaxel	56	8 (14.3)	NR (NE, NE)	53	5 (9.4)	NR (NE, NE)	1.473 (0.482, 4.503)	0.4931
Interaction								0.4254

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Financial Difficulties

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	4 (9.3)	NR (NE, NE)	42	1 (2.4)	NR (NE, NE)	3.050 (0.340, 27.394)	0.2948
1	96	12 (12.5)	NR (NE, NE)	96	13 (13.5)	NR (NE, NE)	0.880 (0.401, 1.930)	0.7465
Interaction								0.2493
Region #1								
Asia	103	14 (13.6)	NR (NE, NE)	105	11 (10.5)	NR (NE, NE)	1.192 (0.541, 2.628)	0.6594
Europe/North America	36	2 (5.6)	NR (NE, NE)	33	3 (9.1)	NR (NE, NE)	0.508 (0.085, 3.055)	0.4487
Interaction								0.4860

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Financial Difficulties

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	11 (14.1)	NR (NE, NE)	80	11 (13.8)	NR (NE, NE)	0.964 (0.418, 2.225)	0.9312
Japan	25	3 (12.0)	NR (NE, NE)	25	0 (0.0)	NR (NE, NE)	71668956.901 (0.000, NE)	0.1057
Europe/North America	36	2 (5.6)	NR (NE, NE)	33	3 (9.1)	NR (NE, NE)	0.508 (0.085, 3.055)	0.4487
Interaction								0.8944
Race								
Asian and other	105	14 (13.3)	NR (NE, NE)	114	12 (10.5)	NR (NE, NE)	1.136 (0.525, 2.457)	0.7439
White	34	2 (5.9)	NR (NE, NE)	24	2 (8.3)	NR (NE, NE)	0.662 (0.093, 4.719)	0.6766
Interaction								0.7012

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 16MAY2024 03:12 t-14-02-06-02-01-02-b-s-eff-tteqs-subgrp-c30-itts-fa.rtf

Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Financial Difficulties

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	6 (13.3)	NR (NE, NE)	34	6 (17.6)	NR (3.0, NE)	0.661 (0.212, 2.066)	0.4705
vCPS < 10%	53	6 (11.3)	NR (NE, NE)	56	4 (7.1)	NR (NE, NE)	1.434 (0.404, 5.088)	0.5736
Missing	41	4 (9.8)	NR (NE, NE)	48	4 (8.3)	NR (NE, NE)	1.187 (0.297, 4.744)	0.8065
Interaction								0.6440

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

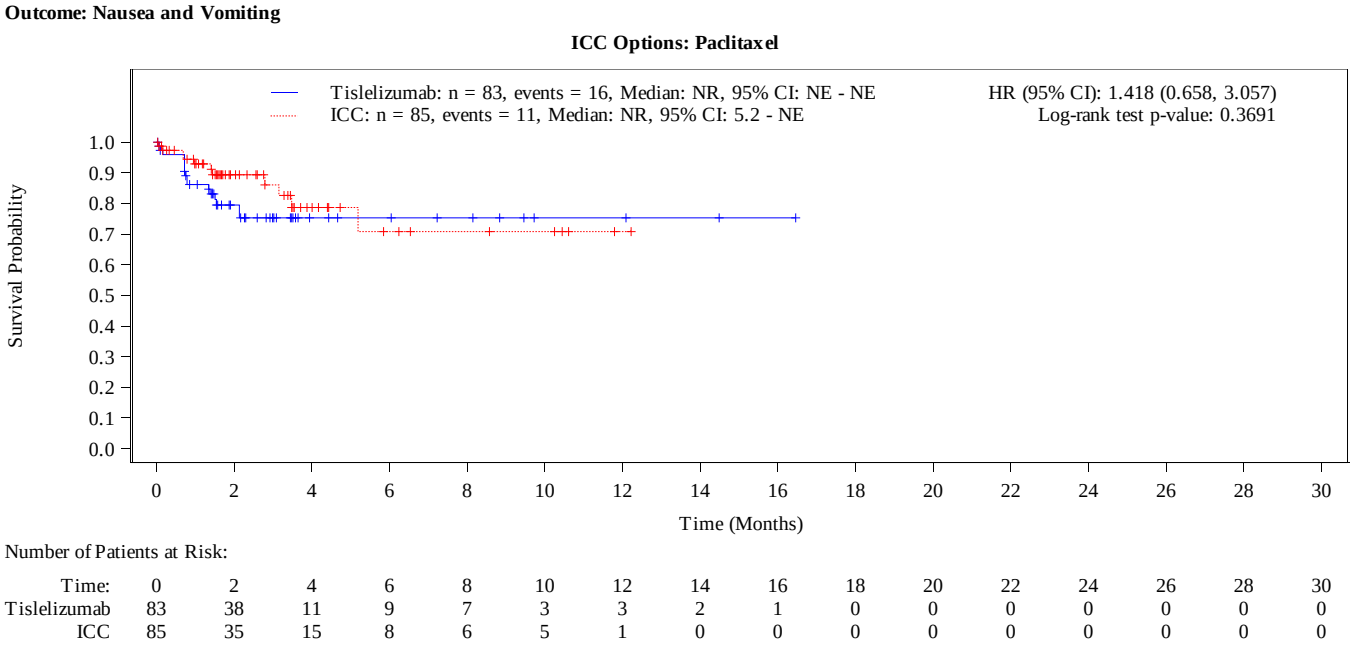
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

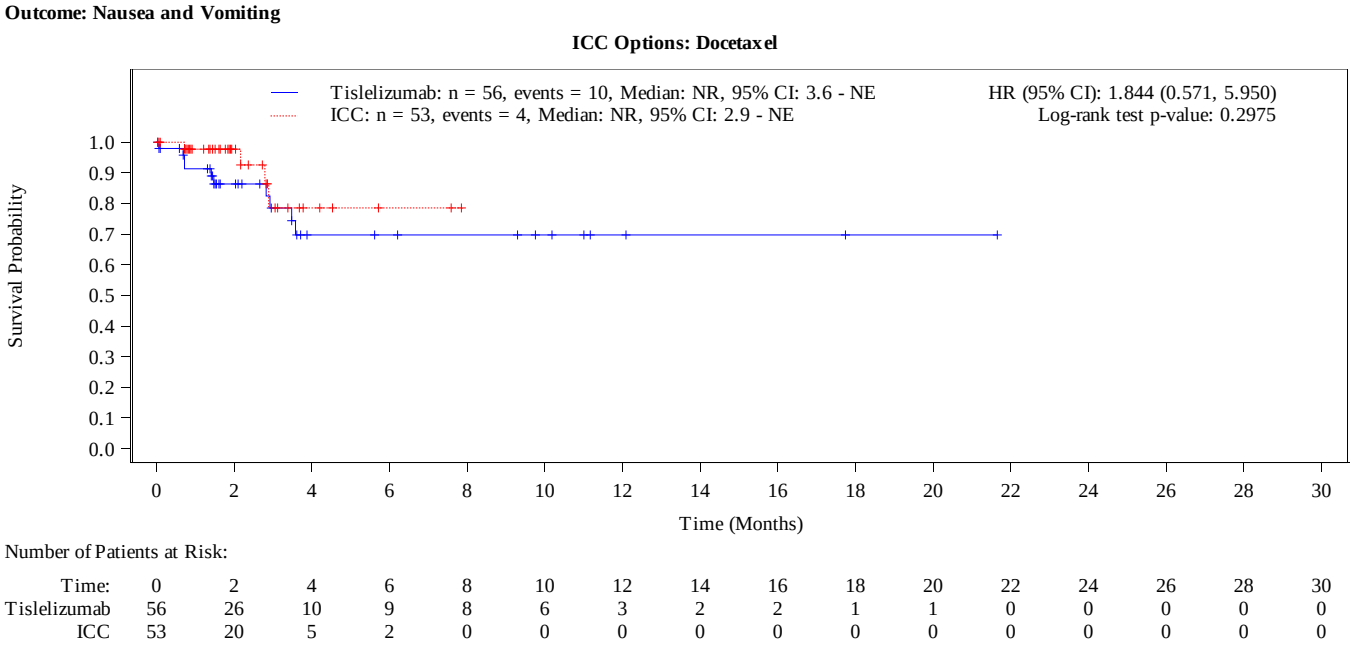
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 16MAY2024 03:12 t-14-02-06-02-01-02-b-s-eff-tteqs-subgrp-c30-itts-fa.rtf

Figure 14.2.7.1.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set



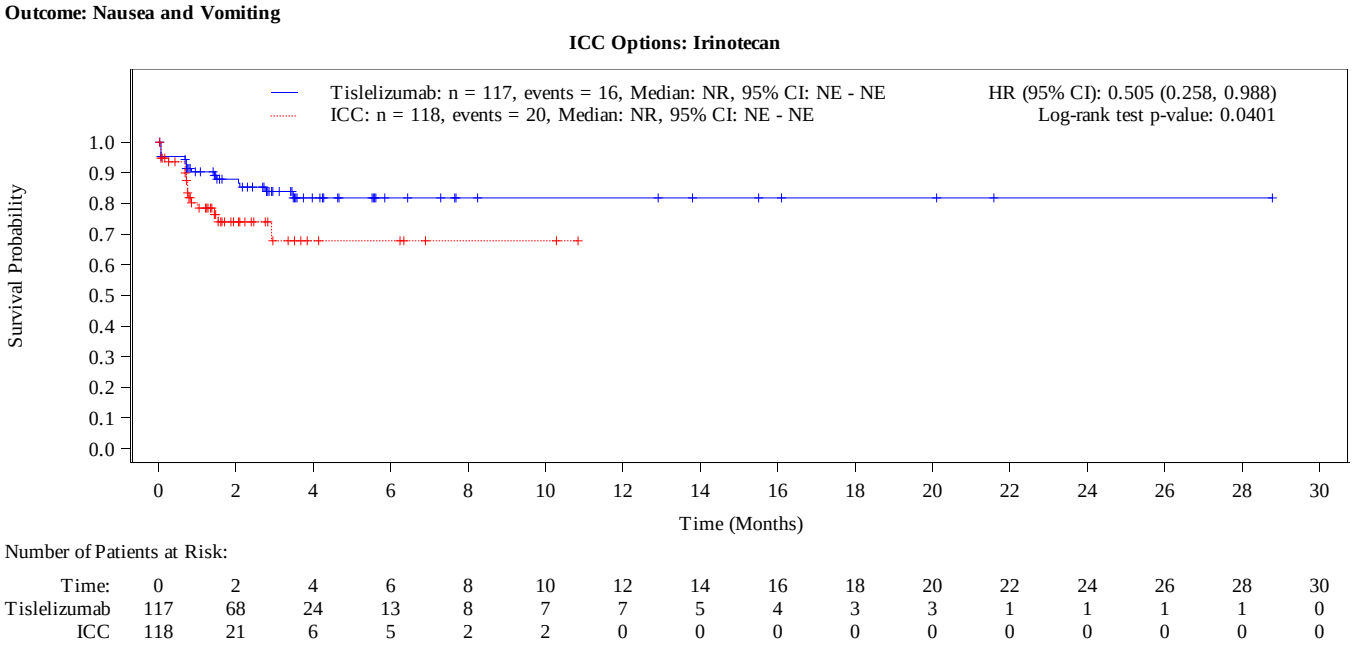
Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 16MAY2024 03:40 f-14-02-07-01-02-s-km-tteqs-subgrp-c30-itt-fa.rtf

Figure 14.2.7.1.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set



Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 16MAY2024 03:40 f-14-02-07-01-02-s-km-tteqs-subgrp-c30-itt-fa.rtf

Figure 14.2.7.1.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set



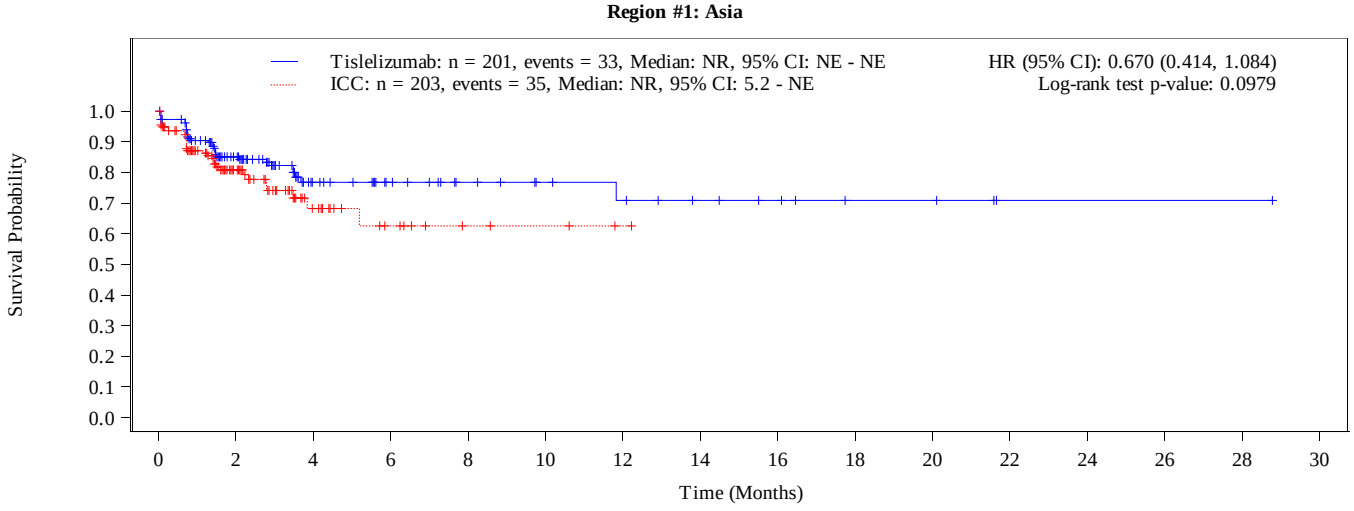
Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	117	68	24	13	8	7	7	5	4	3	3	1	1	1	1	0
ICC	118	21	6	5	2	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 16MAY2024 03:40 f-14-02-07-01-02-s-km-tteqs-subgrp-c30-itt-fa.rtf

Figure 14.2.7.1.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Appetite Loss



Number of Patients at Risk:

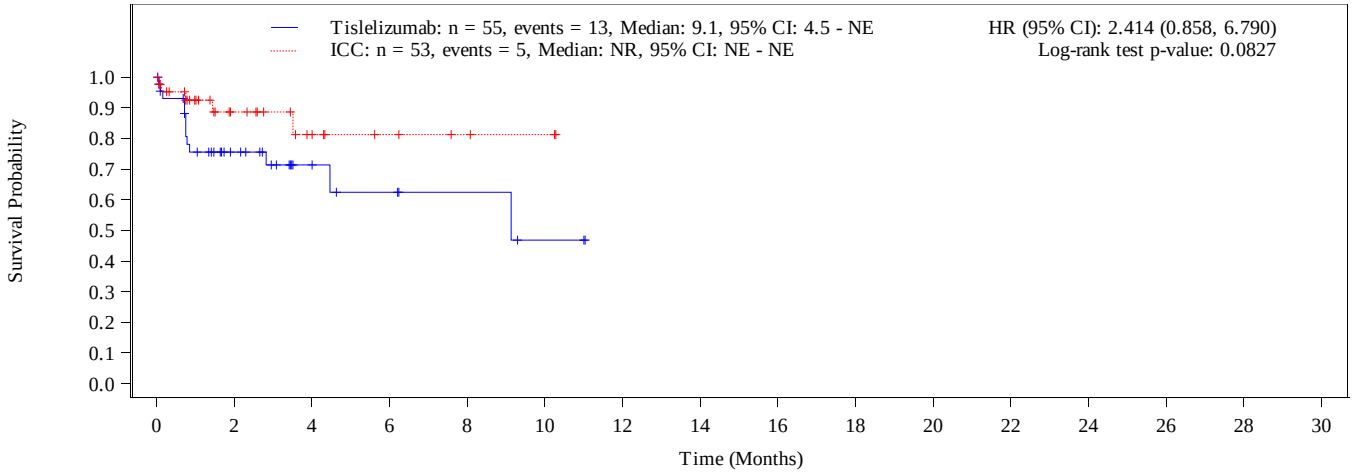
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	201	104	39	27	18	14	12	9	7	4	4	1	1	1	1	0
ICC	203	59	19	9	4	3	1	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 16MAY2024 03:40 f-14-02-07-01-02-s-km-tteqs-subgrp-c30-itt-fa.rtf

Figure 14.2.7.1.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Appetite Loss

Region #1: Europe/North America



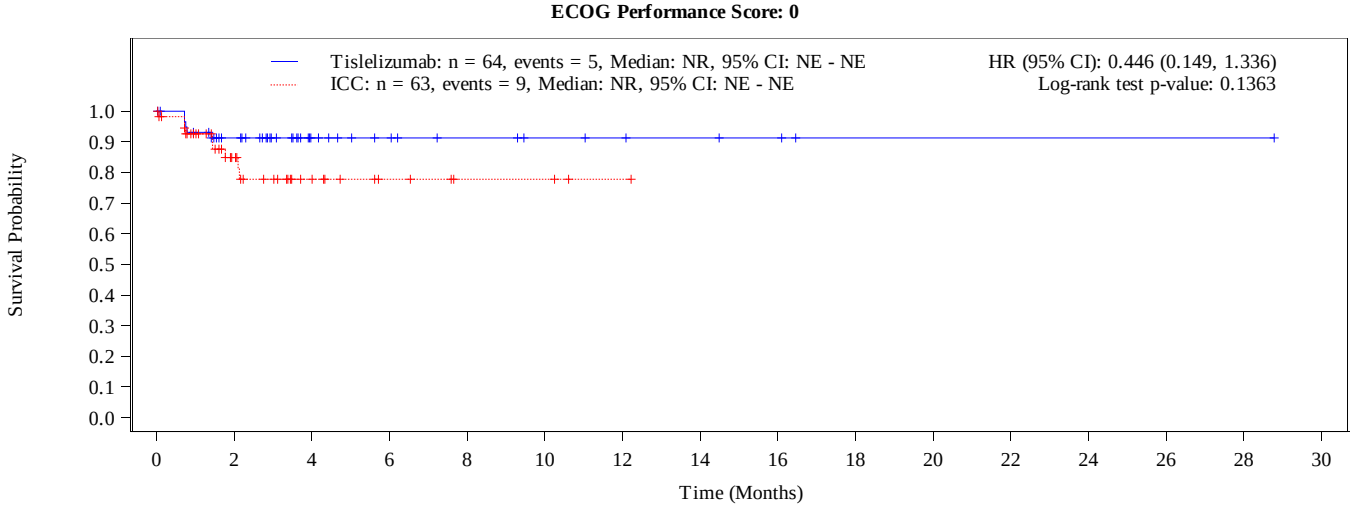
Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	55	22	9	6	4	2	0	0	0	0	0	0	0	0	0	0
ICC	53	18	9	5	3	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 16MAY2024 03:40 f-14-02-07-01-02-s-km-tteqs-subgrp-c30-itt-fa.rtf

Figure 14.2.7.1.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Constipation



Number of Patients at Risk:

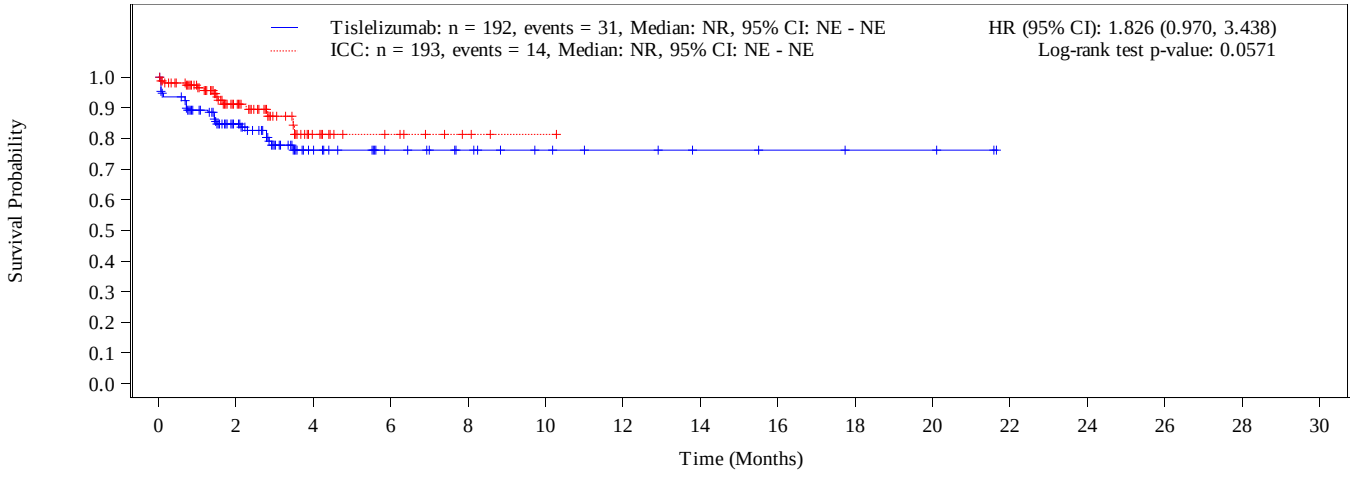
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	64	42	16	11	8	6	5	4	3	1	1	1	1	1	1	0
ICC	63	27	12	6	3	3	1	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 16MAY2024 03:40 f-14-02-07-01-02-s-km-tteqs-subgrp-c30-itt-fa.rtf

Figure 14.2.7.1.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Constipation

ECOG Performance Score: 1



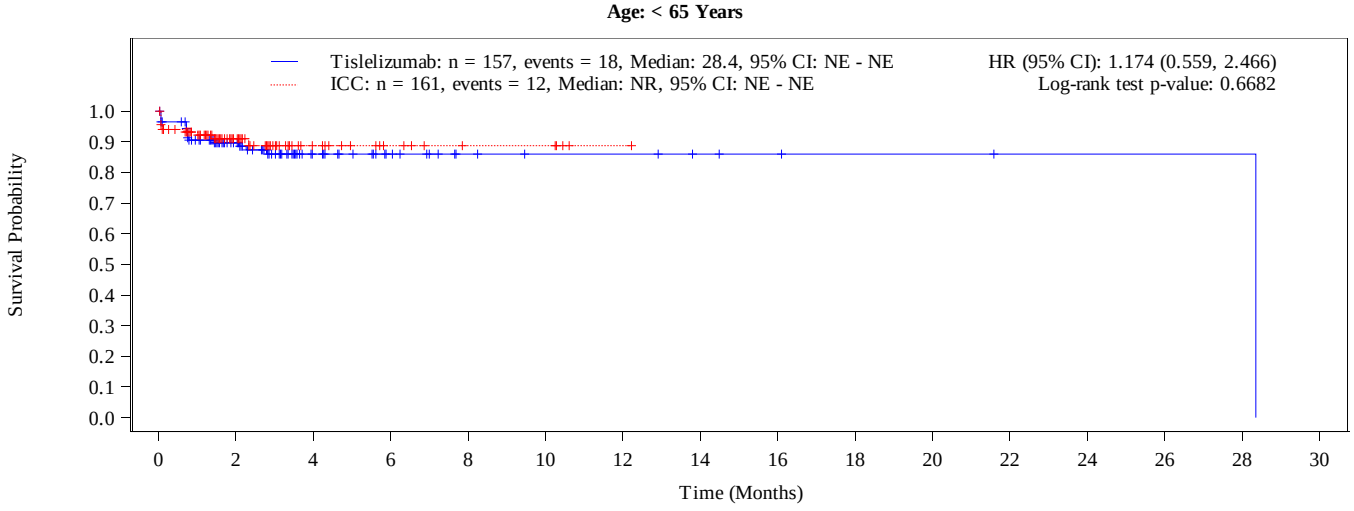
Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	192	86	28	18	13	9	7	5	4	3	3	0	0	0	0	0
ICC	193	60	17	9	3	1	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 16MAY2024 03:40 f-14-02-07-01-02-s-km-tteqs-subgrp-c30-itt-fa.rtf

Figure 14.2.7.1.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Financial Difficulties

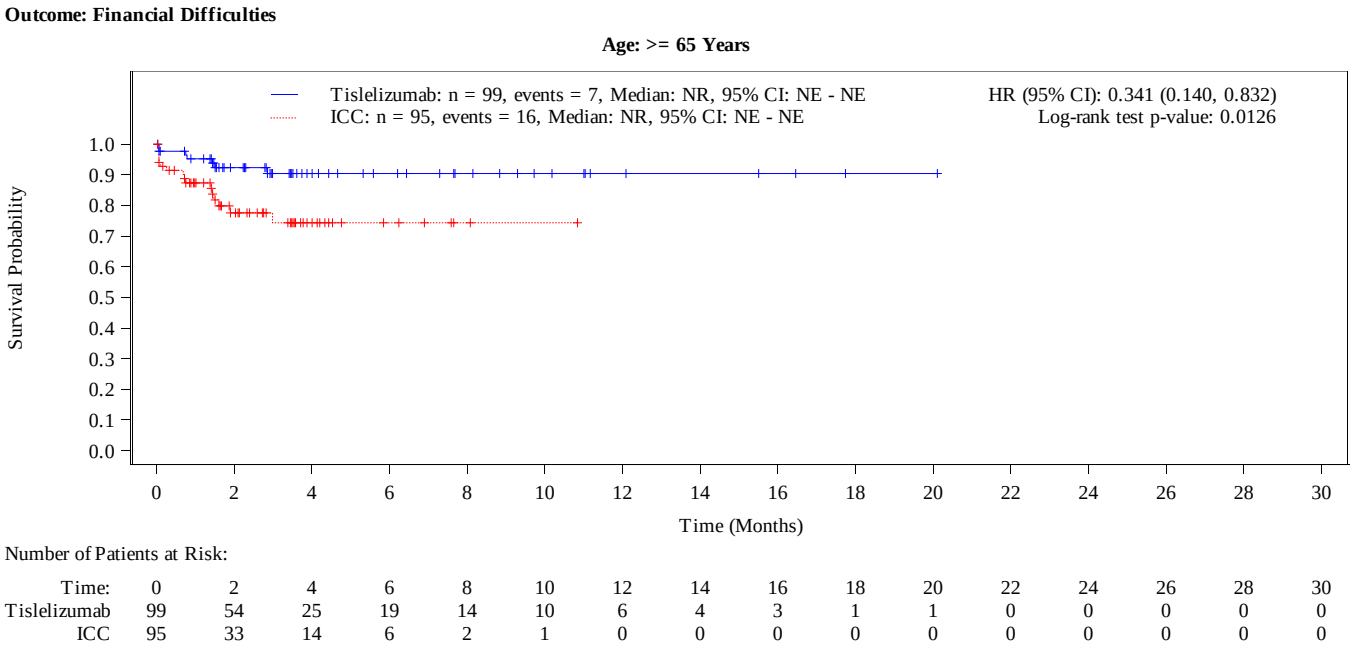


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	157	82	28	15	8	6	6	4	3	2	2	1	1	1	1	0
ICC	161	47	17	9	5	5	1	0	0	0	0	0	0	0	0	0

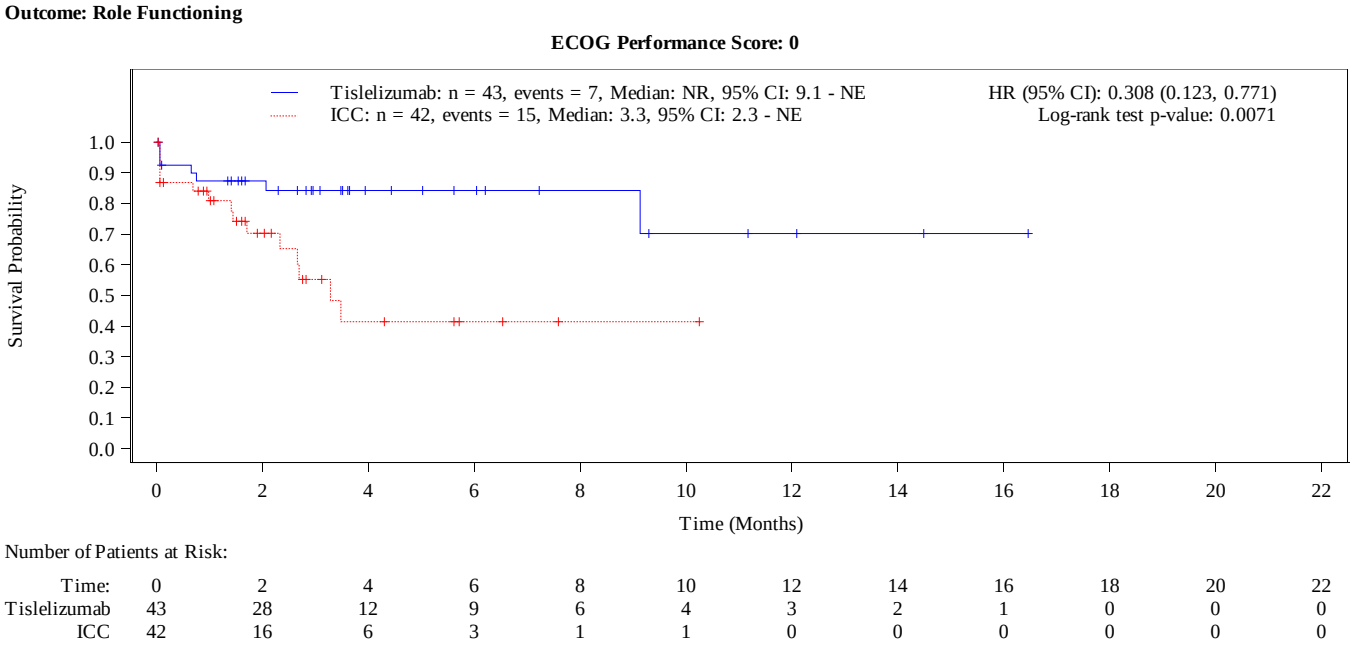
Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 16MAY2024 03:40 f-14-02-07-01-02-s-km-tteqs-subgrp-c30-itt-fa.rtf

Figure 14.2.7.1.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set



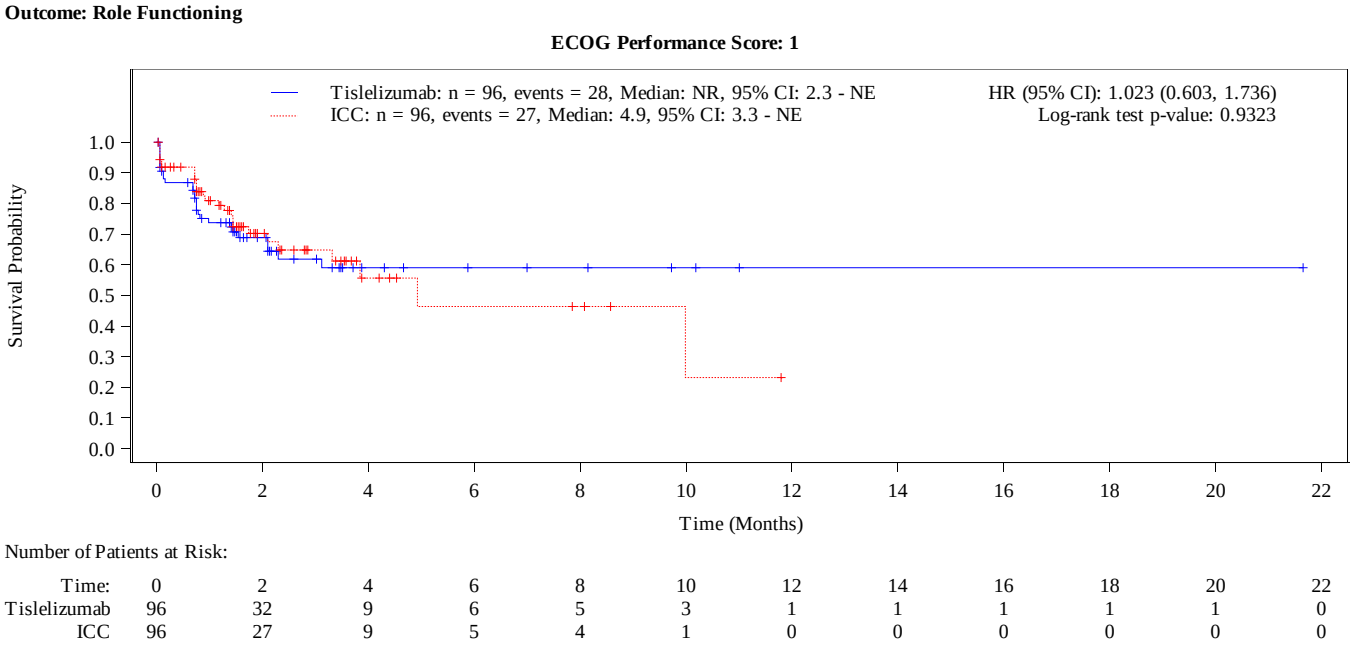
Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 16MAY2024 03:40 f-14-02-07-01-02-s-km-tteqs-subgrp-c30-itt-fa.rtf

Figure 14.2.7.1.2.b.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 16MAY2024 03:40 f-14-02-07-01-02-b-s-km-tteqs-subgrp-c30-itts-fa.rtf

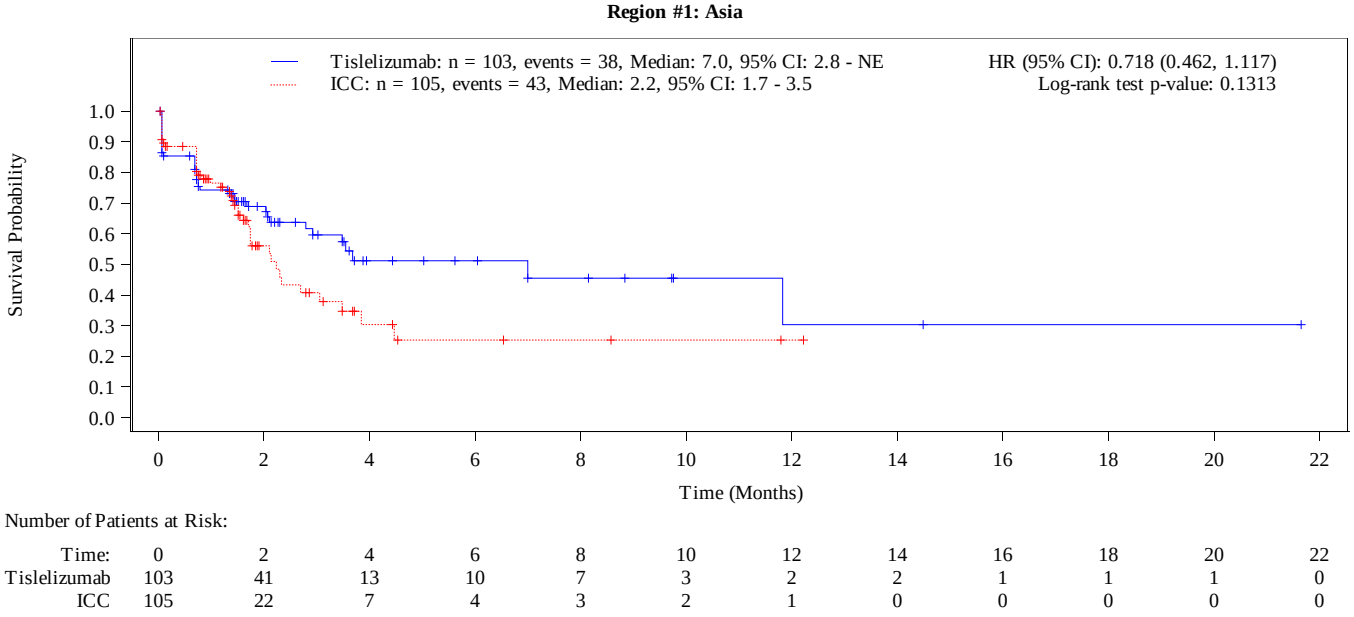
Figure 14.2.7.1.2.b.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 16MAY2024 03:40 f-14-02-07-01-02-b-s-km-tteqs-subgrp-c30-itts-fa.rtf

Figure 14.2.7.1.2.b.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Fatigue



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	103	41	13	10	7	3	2	2	1	1	1	0
ICC	105	22	7	4	3	2	1	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
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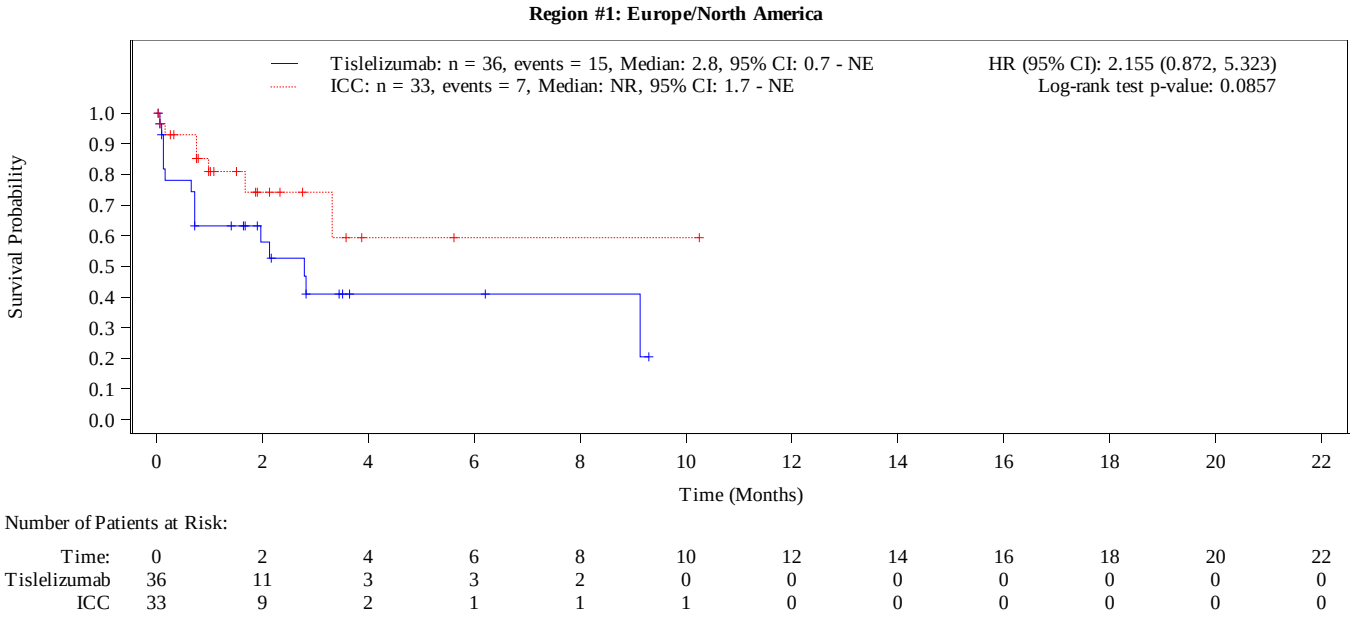
Figure 14.2.7.1.2.b.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Fatigue



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	36	11	3	3	2	0	0	0	0	0	0	0
ICC	33	9	2	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
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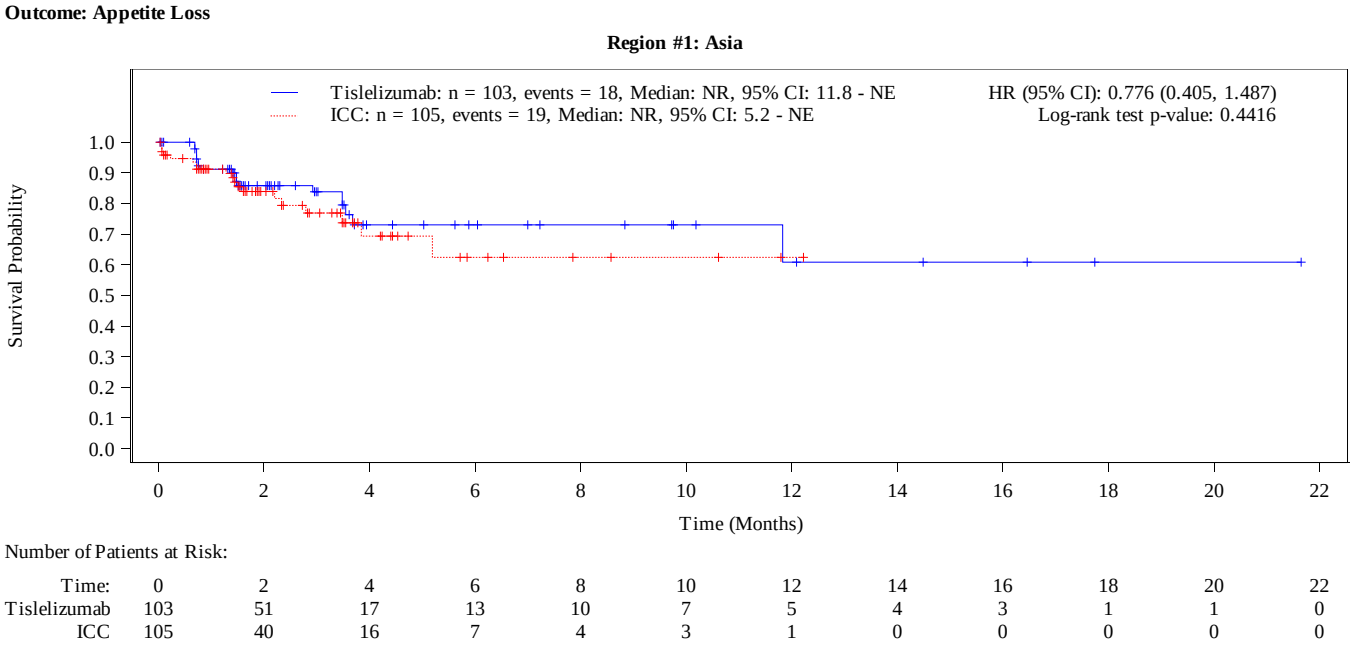
Figure 14.2.7.1.2.b.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
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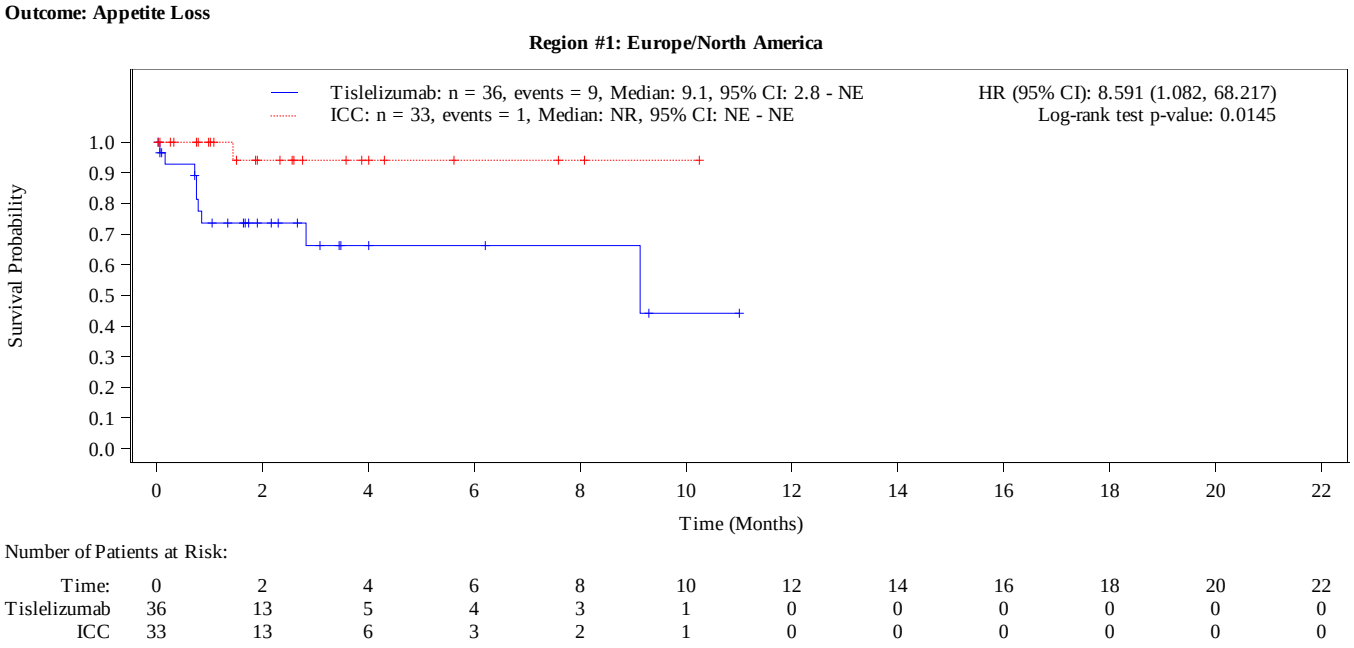
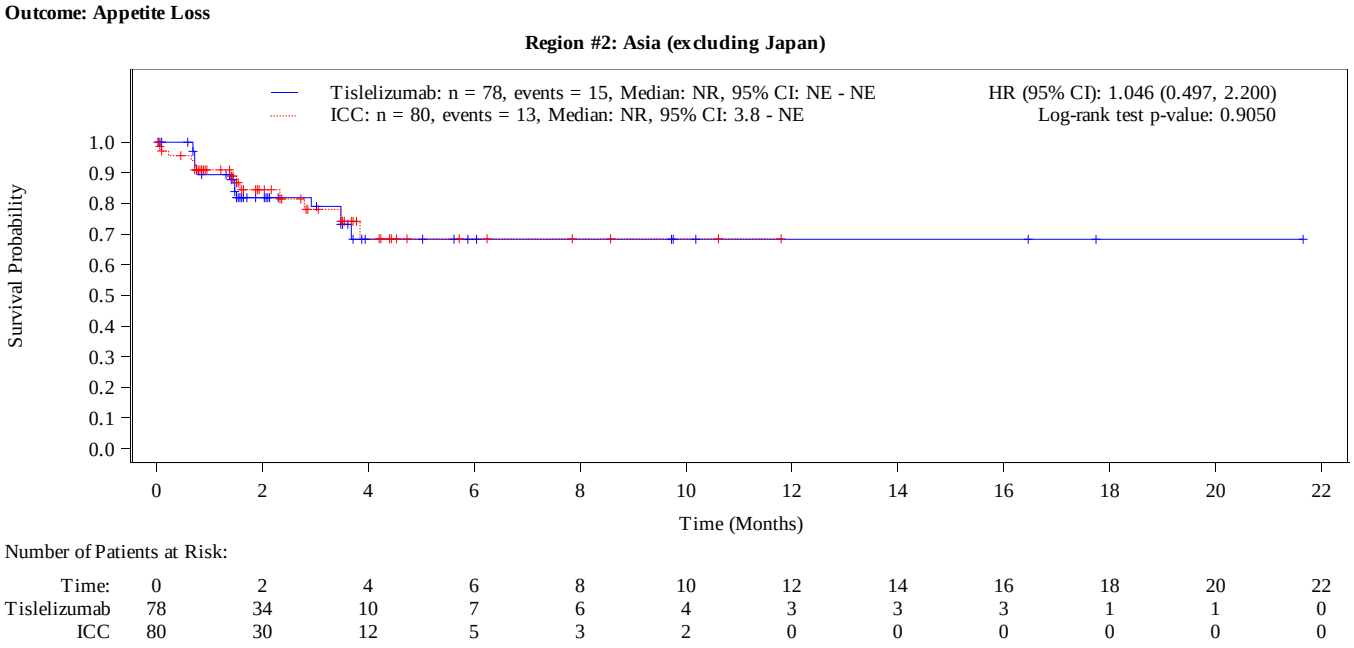
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 16MAY2024 03:40 f-14-02-07-01-02-b-s-km-tteqs-subgrp-c30-itts-fa.rtf

Figure 14.2.7.1.2.b.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan



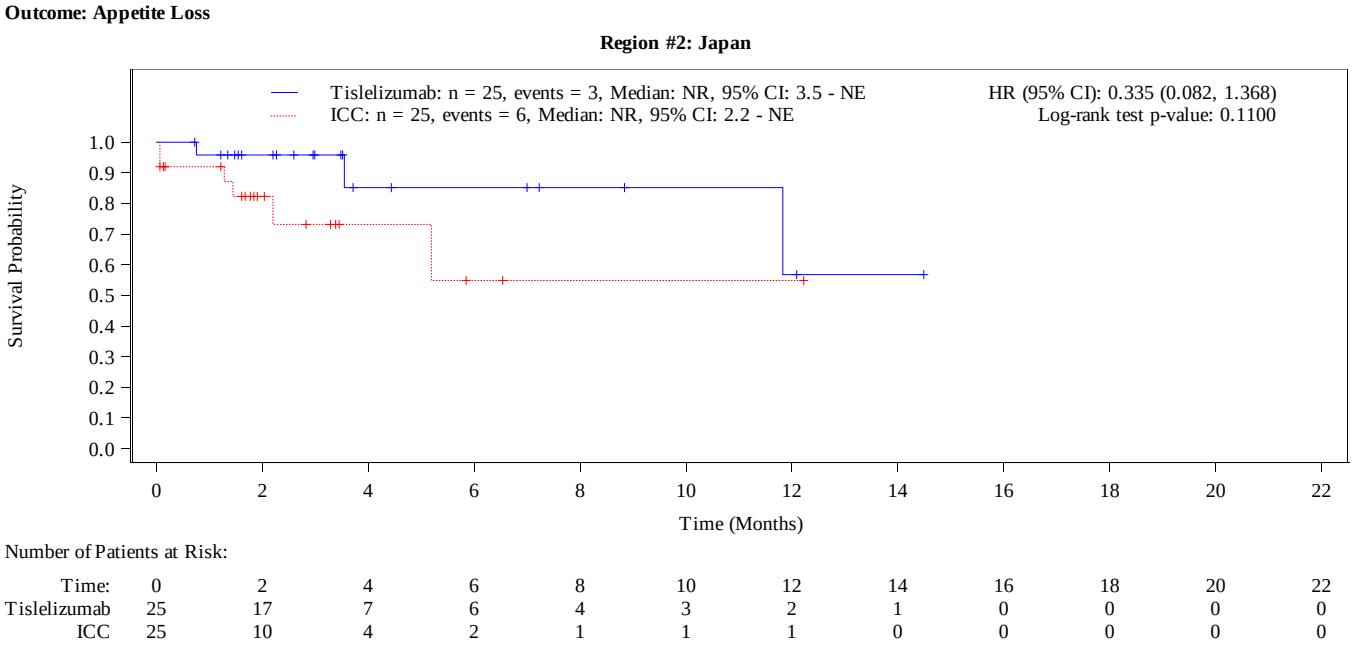
Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 16MAY2024 03:40 f-14-02-07-01-02-b-s-km-tteqs-subgrp-c30-itts-fa.rtf

Figure 14.2.7.1.2.b.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 16MAY2024 03:40 f-14-02-07-01-02-b-s-km-tteqs-subgrp-c30-itts-fa.rtf

Figure 14.2.7.1.2.b.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

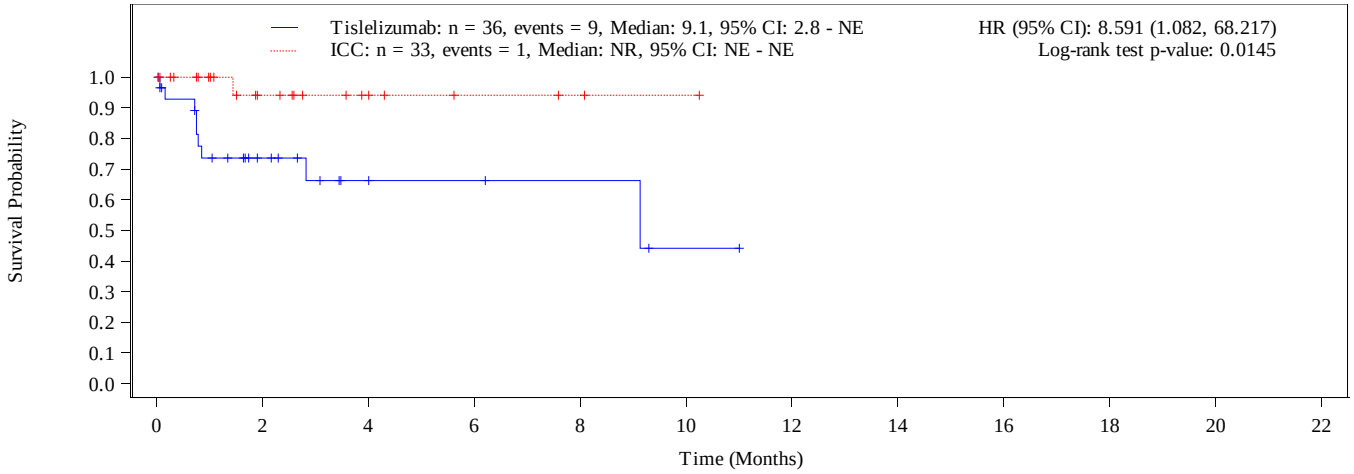


Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 16MAY2024 03:40 f-14-02-07-01-02-b-s-km-tteqs-subgrp-c30-itts-fa.rtf

Figure 14.2.7.1.2.b.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Appetite Loss

Region #2: Europe/North America



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	36	13	5	4	3	1	0	0	0	0	0	0
ICC	33	13	6	3	2	1	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 16MAY2024 03:40 f-14-02-07-01-02-b-s-km-tteqs-subgrp-c30-itts-fa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: QLQ-OES18 index-score

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	239		246	
	Mean (SD)	14.7 (11.81)		16.3 (13.20)	
	Median	12.8		13.3	
	Min, Max	0, 68		0, 62	
Cycle 1	n	138	131	131	126
	Mean (SD)	15.5 (12.35)	-0.1 (8.15)	17.5 (13.70)	1.0 (8.91)
	Median	13.1	0.0	15.0	0.0
	Min, Max	0, 59	-24, 34	0, 68	-32, 51
Cycle 2	n	221	210	173	170
	Mean (SD)	15.9 (14.77)	2.5 (11.34)	16.9 (12.93)	2.1 (9.61)
	Median	11.7	0.6	14.4	1.4
	Min, Max	0, 90	-24, 90	0, 69	-34, 38
Cycle 3	n	179	169	90	88
	Mean (SD)	14.7 (11.63)	1.3 (9.36)	15.3 (11.99)	1.1 (10.55)
	Median	11.9	0.0	12.4	0.7
	Min, Max	0, 54	-27, 43	0, 53	-31, 40

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-qs-chg-oes-itt-fa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: QLQ-OES18 index-score

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	145	137	74	73
	Mean (SD)	13.3 (11.03)	0.7 (9.70)	15.1 (10.70)	1.4 (10.53)
	Median	11.7	0.0	12.1	1.4
	Min, Max	0, 53	-40, 37	0, 43	-35, 30
Cycle 5	n	110	104	45	43
	Mean (SD)	11.9 (10.67)	-1.0 (10.15)	14.3 (16.29)	0.9 (13.29)
	Median	10.0	0.0	8.9	0.0
	Min, Max	0, 52	-38, 29	0, 82	-37, 52
Cycle 6	n	98	93	37	35
	Mean (SD)	11.1 (10.90)	-0.6 (8.63)	15.5 (15.36)	3.0 (12.05)
	Median	9.2	0.0	10.0	1.4
	Min, Max	0, 54	-23, 31	0, 67	-20, 41
End of Treatment	n	70	68	83	81
	Mean (SD)	19.7 (17.35)	6.7 (14.37)	22.2 (16.44)	7.7 (13.19)
	Median	15.0	3.9	18.6	6.1
	Min, Max	0, 71	-23, 55	0, 83	-28, 69

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-qs-chg-oes-itt-fa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: QLQ-OES18 index-score

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	105	101	96	95
	Mean (SD)	20.0 (16.74)	5.8 (14.30)	21.9 (14.53)	6.9 (12.18)
	Median	15.3	1.9	19.2	4.4
	Min, Max	0, 74	-25, 46	0, 70	-20, 45
Worst Post-Baseline Value	n	244	228	225	218
	Mean (SD)	23.3 (16.80)	9.4 (13.89)	24.7 (16.48)	9.1 (12.45)
	Median	20.1	6.1	21.1	6.9
	Min, Max	0, 90	-18, 90	0, 83	-20, 69

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-qs-chg-oes-itt-fa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Dysphagia

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	240		248	
	Mean (SD)	35.3 (35.22)		34.8 (34.57)	
	Median	33.3		22.2	
	Min, Max	0, 100		0, 100	
Cycle 1	n	138	132	132	129
	Mean (SD)	38.2 (38.09)	-0.7 (23.97)	43.4 (35.82)	4.8 (20.45)
	Median	22.2	0.0	33.3	0.0
	Min, Max	0, 100	-100, 100	0, 100	-67, 100
Cycle 2	n	224	213	174	171
	Mean (SD)	35.7 (37.52)	1.5 (26.06)	37.9 (34.56)	6.5 (28.68)
	Median	22.2	0.0	33.3	0.0
	Min, Max	0, 100	-100, 100	0, 100	-100, 100
Cycle 3	n	180	170	91	89
	Mean (SD)	37.3 (38.00)	5.1 (28.07)	38.2 (34.55)	4.6 (29.14)
	Median	22.2	0.0	33.3	0.0
	Min, Max	0, 100	-100, 100	0, 100	-78, 100

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-qs-chg-oes-itt-fa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Dysphagia

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	146	138	76	74
	Mean (SD)	34.2 (37.56)	1.4 (27.14)	39.6 (35.76)	5.3 (35.19)
	Median	22.2	0.0	33.3	0.0
	Min, Max	0, 100	-100, 100	0, 100	-100, 100
Cycle 5	n	110	104	45	43
	Mean (SD)	36.5 (39.54)	2.7 (29.36)	37.3 (39.29)	-0.9 (39.54)
	Median	22.2	0.0	22.2	0.0
	Min, Max	0, 100	-67, 100	0, 100	-100, 100
Cycle 6	n	99	93	37	35
	Mean (SD)	33.8 (38.55)	1.6 (28.50)	36.0 (36.23)	2.7 (37.15)
	Median	11.1	0.0	33.3	0.0
	Min, Max	0, 100	-100, 100	0, 100	-100, 100
End of Treatment	n	71	69	83	81
	Mean (SD)	41.3 (37.00)	8.1 (34.56)	42.2 (37.05)	3.3 (28.94)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-100, 78	0, 100	-100, 78

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-qs-chg-oes-itt-fa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Dysphagia

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	106	102	96	95
	Mean (SD)	45.4 (38.00)	5.9 (33.30)	51.3 (35.81)	12.6 (35.48)
	Median	38.9	0.0	44.4	0.0
	Min, Max	0, 100	-100, 100	0, 100	-100, 100
Worst Post-Baseline Value	n	246	231	226	221
	Mean (SD)	51.7 (38.52)	17.9 (30.65)	52.5 (35.03)	17.6 (30.85)
	Median	44.4	11.1	44.4	11.1
	Min, Max	0, 100	-100, 100	0, 100	-56, 100

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-qs-chg-oes-itt-fa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Eating

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	240		246	
	Mean (SD)	17.6 (19.83)		19.6 (21.10)	
	Median	8.3		16.7	
	Min, Max	0, 100		0, 100	
Cycle 1	n	138	132	131	126
	Mean (SD)	19.3 (22.82)	1.5 (13.46)	20.2 (22.46)	-0.4 (15.34)
	Median	8.3	0.0	16.7	0.0
	Min, Max	0, 100	-50, 58	0, 100	-50, 75
Cycle 2	n	222	211	174	171
	Mean (SD)	19.0 (23.29)	3.0 (17.79)	19.8 (22.94)	1.5 (16.67)
	Median	8.3	0.0	16.7	0.0
	Min, Max	0, 100	-67, 100	0, 100	-50, 75
Cycle 3	n	180	170	90	88
	Mean (SD)	17.0 (21.21)	1.0 (19.29)	14.7 (19.15)	-2.8 (17.68)
	Median	8.3	0.0	8.3	0.0
	Min, Max	0, 100	-83, 75	0, 92	-50, 67

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-qs-chg-oes-itt-fa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Eating

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	146	138	75	73
	Mean (SD)	14.6 (18.36)	-0.2 (17.16)	17.9 (21.60)	2.5 (19.68)
	Median	8.3	0.0	8.3	0.0
	Min, Max	0, 100	-67, 83	0, 100	-42, 75
Cycle 5	n	110	104	45	43
	Mean (SD)	12.1 (15.79)	-2.9 (16.62)	15.7 (22.49)	2.1 (21.60)
	Median	8.3	0.0	8.3	0.0
	Min, Max	0, 75	-67, 42	0, 100	-58, 67
Cycle 6	n	99	93	37	35
	Mean (SD)	12.2 (15.76)	-2.5 (15.92)	18.7 (26.60)	6.7 (22.94)
	Median	8.3	0.0	8.3	0.0
	Min, Max	0, 67	-67, 42	0, 100	-58, 67
End of Treatment	n	70	68	83	81
	Mean (SD)	26.9 (28.59)	9.4 (22.99)	26.5 (25.74)	9.2 (22.54)
	Median	16.7	0.0	16.7	8.3
	Min, Max	0, 100	-33, 100	0, 100	-42, 75

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-qs-chg-oes-itt-fa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Eating

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	105	101	96	95
	Mean (SD)	23.5 (24.37)	6.7 (22.14)	25.0 (22.56)	6.1 (17.29)
	Median	16.7	0.0	16.7	8.3
	Min, Max	0, 100	-67, 75	0, 92	-58, 42
Worst Post-Baseline Value	n	245	230	225	218
	Mean (SD)	30.4 (26.83)	14.1 (22.00)	31.3 (25.98)	11.7 (20.51)
	Median	25.0	8.3	25.0	8.3
	Min, Max	0, 100	-67, 100	0, 100	-50, 75

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-qs-chg-oes-itt-fa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Reflux

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	240		248	
	Mean (SD)	12.2 (17.48)		12.7 (17.96)	
	Median	0.0		0.0	
	Min, Max	0, 100		0, 100	
Cycle 1	n	138	132	132	129
	Mean (SD)	12.6 (18.44)	-0.8 (13.64)	13.4 (17.77)	1.8 (15.90)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 67	0, 67	-67, 50
Cycle 2	n	224	213	174	171
	Mean (SD)	11.2 (17.04)	-0.1 (16.23)	12.8 (18.91)	1.8 (18.35)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-50, 83
Cycle 3	n	181	171	91	89
	Mean (SD)	10.6 (17.57)	-0.8 (16.25)	12.3 (18.73)	1.5 (19.08)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-50, 83	0, 83	-33, 67

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-qs-chg-oes-itt-fa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Reflux

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	146	138	76	74
	Mean (SD)	9.1 (15.91)	-1.6 (14.78)	11.4 (16.60)	0.5 (15.35)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 83	-50, 83	0, 67	-33, 50
Cycle 5	n	110	104	45	43
	Mean (SD)	7.7 (12.91)	-1.4 (16.77)	10.4 (18.56)	0.0 (18.18)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 50	-83, 33	0, 67	-50, 50
Cycle 6	n	99	93	37	35
	Mean (SD)	7.6 (13.10)	0.2 (14.22)	12.6 (21.66)	1.4 (22.28)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 50	-67, 33	0, 83	-50, 67
End of Treatment	n	71	69	83	81
	Mean (SD)	15.3 (23.70)	5.1 (21.06)	17.9 (21.74)	6.2 (21.80)
	Median	0.0	0.0	16.7	0.0
	Min, Max	0, 100	-50, 83	0, 83	-67, 83

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-qs-chg-oes-itt-fa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Reflux

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	106	102	96	95
	Mean (SD)	14.5 (18.12)	3.6 (18.85)	14.2 (16.92)	1.9 (18.97)
	Median	16.7	0.0	16.7	0.0
	Min, Max	0, 83	-50, 50	0, 67	-67, 67
Worst Post-Baseline Value	n	246	231	226	221
	Mean (SD)	20.5 (22.98)	8.8 (20.49)	21.7 (22.49)	10.0 (20.82)
	Median	16.7	0.0	16.7	0.0
	Min, Max	0, 100	-50, 100	0, 100	-67, 83

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-qs-chg-oes-itt-fa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Pain

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	240		248	
	Mean (SD)	11.8 (14.64)		11.9 (18.20)	
	Median	11.1		0.0	
	Min, Max	0, 67		0, 100	
Cycle 1	n	138	132	132	129
	Mean (SD)	11.7 (14.42)	-1.0 (11.61)	12.8 (19.42)	1.3 (13.01)
	Median	11.1	0.0	0.0	0.0
	Min, Max	0, 78	-44, 44	0, 100	-44, 89
Cycle 2	n	224	213	174	171
	Mean (SD)	12.2 (17.90)	1.1 (15.43)	10.3 (15.30)	-0.3 (11.01)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-44, 22
Cycle 3	n	181	171	91	89
	Mean (SD)	11.1 (16.28)	-0.1 (13.15)	8.9 (13.73)	0.2 (11.00)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-44, 44	0, 78	-44, 33

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-qs-chg-oes-itt-fa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Pain

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	146	138	76	74
	Mean (SD)	9.1 (12.46)	-1.8 (13.87)	7.6 (10.14)	1.4 (12.47)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 56	-67, 33	0, 33	-22, 33
Cycle 5	n	110	104	45	43
	Mean (SD)	8.4 (11.96)	-1.6 (13.88)	7.4 (11.84)	1.3 (13.33)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 56	-67, 44	0, 33	-22, 33
Cycle 6	n	99	93	37	35
	Mean (SD)	7.7 (12.03)	-1.1 (14.29)	8.1 (14.26)	1.9 (15.36)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-56, 56	0, 67	-22, 67
End of Treatment	n	71	69	83	81
	Mean (SD)	17.9 (23.44)	6.4 (20.15)	17.0 (20.63)	6.4 (17.47)
	Median	11.1	0.0	11.1	0.0
	Min, Max	0, 100	-33, 89	0, 100	-44, 67

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-qs-chg-oes-itt-fa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Pain

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	106	102	96	95
	Mean (SD)	15.5 (17.66)	4.1 (17.96)	14.8 (18.07)	4.2 (15.31)
	Median	11.1	0.0	11.1	0.0
	Min, Max	0, 67	-44, 67	0, 78	-22, 44
Worst Post-Baseline Value	n	246	231	226	221
	Mean (SD)	20.3 (21.35)	9.2 (18.50)	19.2 (19.78)	7.9 (14.86)
	Median	11.1	0.0	11.1	0.0
	Min, Max	0, 100	-33, 100	0, 100	-22, 89

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-qs-chg-oes-itt-fa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Trouble swallowing saliva

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	240		248	
	Mean (SD)	11.7 (23.08)		11.2 (24.30)	
	Median	0.0		0.0	
	Min, Max	0, 100		0, 100	
Cycle 1	n	138	132	132	129
	Mean (SD)	12.1 (21.29)	-1.8 (22.30)	10.6 (24.13)	1.0 (23.55)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 100	0, 100	-67, 100
Cycle 2	n	223	212	174	171
	Mean (SD)	13.0 (25.02)	2.8 (26.01)	10.3 (22.27)	1.4 (25.91)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 100	0, 100	-100, 100
Cycle 3	n	181	171	91	89
	Mean (SD)	12.5 (24.65)	1.9 (29.53)	10.6 (24.28)	2.2 (28.34)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 100	0, 100	-100, 100

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-qs-chg-oes-itt-fa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Trouble swallowing saliva

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	146	138	76	74
	Mean (SD)	8.2 (18.18)	-1.7 (26.81)	11.0 (21.35)	-0.5 (26.74)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 100	0, 100	-100, 67
Cycle 5	n	110	104	45	43
	Mean (SD)	6.7 (20.09)	-4.2 (23.08)	7.4 (23.45)	-2.3 (19.78)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 100	0, 100	-100, 33
Cycle 6	n	99	93	37	35
	Mean (SD)	5.7 (17.20)	-3.9 (19.57)	9.0 (25.64)	-1.9 (22.78)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 33	0, 100	-100, 67
End of Treatment	n	71	69	83	81
	Mean (SD)	15.0 (26.30)	5.8 (27.98)	17.7 (29.60)	9.5 (28.50)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-qs-chg-oes-itt-fa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Trouble swallowing saliva

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	106	102	96	95
	Mean (SD)	13.8 (26.77)	2.9 (31.50)	12.2 (25.19)	1.8 (30.12)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 100	0, 100	-100, 100
Worst Post-Baseline Value	n	246	231	226	221
	Mean (SD)	27.2 (33.86)	15.7 (35.14)	22.6 (32.31)	12.1 (31.86)
	Median	16.7	0.0	0.0	0.0
	Min, Max	0, 100	-100, 100	0, 100	-100, 100

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-qs-chg-oes-itt-fa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Choked when swallowing

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	240		248	
	Mean (SD)	14.2 (18.88)		14.2 (22.11)	
	Median	0.0		0.0	
	Min, Max	0, 67		0, 100	
Cycle 1	n	138	132	131	128
	Mean (SD)	13.5 (21.93)	-1.3 (20.76)	13.5 (21.79)	-4.2 (20.06)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 67
Cycle 2	n	224	213	174	171
	Mean (SD)	15.2 (22.05)	1.6 (21.42)	14.9 (22.24)	0.6 (24.38)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-100, 67
Cycle 3	n	181	171	91	89
	Mean (SD)	13.8 (21.07)	-1.2 (22.55)	13.6 (24.83)	2.6 (25.24)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-33, 100

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-qs-chg-oes-itt-fa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Choked when swallowing

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	146	138	76	74
	Mean (SD)	11.2 (19.68)	-2.7 (22.80)	11.4 (18.50)	-0.9 (22.05)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 67	-67, 67
Cycle 5	n	110	104	45	43
	Mean (SD)	10.9 (19.21)	-4.2 (24.00)	11.9 (24.78)	-0.0 (20.57)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 67	0, 100	-67, 67
Cycle 6	n	99	93	37	35
	Mean (SD)	10.1 (16.81)	-3.2 (22.01)	9.9 (17.33)	0.0 (21.39)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-67, 67	0, 67	-33, 67
End of Treatment	n	71	69	83	81
	Mean (SD)	15.5 (25.72)	4.3 (27.36)	18.9 (29.54)	5.8 (27.78)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-qs-chg-oes-itt-fa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Choked when swallowing

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	106	102	96	95
	Mean (SD)	16.7 (26.13)	2.0 (29.23)	18.1 (26.01)	3.9 (24.24)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 67
Worst Post-Baseline Value	n	246	231	225	220
	Mean (SD)	26.8 (29.09)	12.6 (29.34)	25.5 (29.59)	10.3 (27.68)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-qs-chg-oes-itt-fa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Dry mouth

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	239		248	
	Mean (SD)	16.3 (20.24)		19.9 (24.34)	
	Median	0.0		0.0	
	Min, Max	0, 100		0, 100	
Cycle 1	n	138	131	132	129
	Mean (SD)	18.1 (20.19)	1.3 (18.21)	22.2 (23.90)	2.6 (21.49)
	Median	0.0	0.0	33.3	0.0
	Min, Max	0, 100	-33, 67	0, 100	-67, 100
Cycle 2	n	224	212	174	171
	Mean (SD)	19.5 (25.49)	4.6 (23.52)	21.8 (23.41)	3.3 (24.16)
	Median	0.0	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100
Cycle 3	n	181	171	91	89
	Mean (SD)	17.5 (22.92)	1.8 (23.22)	20.9 (24.67)	1.5 (25.08)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 67

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-qs-chg-oes-itt-fa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Dry mouth

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	146	138	76	74
	Mean (SD)	17.8 (22.88)	5.6 (23.34)	18.4 (20.65)	0.9 (28.12)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 67	-100, 67
Cycle 5	n	110	104	45	43
	Mean (SD)	13.3 (18.73)	0.6 (20.24)	15.6 (23.14)	-2.3 (25.61)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-67, 67	0, 100	-67, 67
Cycle 6	n	99	93	37	35
	Mean (SD)	13.1 (20.10)	1.1 (20.53)	20.7 (26.47)	5.7 (26.18)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 67	0, 100	-33, 67
End of Treatment	n	71	69	83	81
	Mean (SD)	21.1 (25.97)	9.2 (29.64)	25.7 (24.04)	9.9 (25.52)
	Median	0.0	0.0	33.3	0.0
	Min, Max	0, 100	-67, 100	0, 100	-33, 100

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-qs-chg-oes-itt-fa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Dry mouth

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	106	102	96	95
	Mean (SD)	22.0 (25.98)	6.2 (28.04)	28.8 (28.04)	12.6 (28.43)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100
Worst Post-Baseline Value	n	246	230	226	221
	Mean (SD)	32.4 (27.83)	17.0 (26.93)	35.1 (27.88)	16.4 (28.18)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-qs-chg-oes-itt-fa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Trouble with taste

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	239		247	
	Mean (SD)	7.9 (18.00)		14.0 (24.80)	
	Median	0.0		0.0	
	Min, Max	0, 100		0, 100	
Cycle 1	n	138	131	131	127
	Mean (SD)	10.1 (17.83)	2.3 (19.48)	12.2 (21.96)	0.5 (19.69)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 67	0, 100	-67, 67
Cycle 2	n	223	211	174	171
	Mean (SD)	9.7 (20.51)	3.2 (22.31)	17.2 (25.27)	3.5 (23.17)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 67
Cycle 3	n	179	169	90	88
	Mean (SD)	9.1 (17.94)	2.2 (21.56)	13.7 (24.93)	-0.0 (26.26)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 67	0, 100	-100, 67

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-qs-chg-oes-itt-fa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Trouble with taste

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	145	137	76	73
	Mean (SD)	8.5 (17.91)	2.9 (18.73)	15.8 (25.22)	5.0 (25.86)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 67
Cycle 5	n	110	104	45	43
	Mean (SD)	5.2 (13.69)	-1.6 (18.22)	14.1 (25.11)	3.1 (27.04)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-100, 67	0, 100	-100, 67
Cycle 6	n	99	93	37	35
	Mean (SD)	4.7 (12.61)	-1.8 (20.48)	18.0 (30.02)	8.6 (24.71)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-100, 67	0, 100	-33, 100
End of Treatment	n	71	69	83	81
	Mean (SD)	14.6 (23.05)	7.2 (24.83)	20.1 (29.88)	9.1 (28.39)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 67	0, 100	-67, 100

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-qs-chg-oes-itt-fa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Trouble with taste

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	105	101	96	95
	Mean (SD)	18.4 (28.11)	13.5 (29.13)	20.1 (27.98)	7.7 (21.44)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-33, 67
Worst Post-Baseline Value	n	245	229	225	219
	Mean (SD)	21.6 (27.48)	14.6 (27.07)	26.7 (29.88)	12.5 (27.95)
	Median	0.0	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-qs-chg-oes-itt-fa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Trouble with coughing

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	239		248	
	Mean (SD)	11.0 (20.60)		13.2 (22.37)	
	Median	0.0		0.0	
	Min, Max	0, 100		0, 100	
Cycle 1	n	138	131	132	129
	Mean (SD)	11.4 (19.93)	-0.5 (16.53)	16.4 (23.11)	2.8 (17.69)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 33	0, 100	-67, 33
Cycle 2	n	224	212	173	170
	Mean (SD)	14.1 (23.27)	4.4 (21.81)	13.7 (22.14)	2.9 (20.78)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 67
Cycle 3	n	181	171	91	89
	Mean (SD)	11.6 (19.73)	2.7 (18.59)	12.8 (21.53)	2.2 (22.36)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 67	0, 100	-67, 100

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-qs-chg-oes-itt-fa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Trouble with coughing

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	146	138	75	74
	Mean (SD)	12.3 (19.58)	4.1 (19.92)	12.4 (19.59)	1.4 (23.69)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-67, 67	0, 67	-67, 67
Cycle 5	n	110	104	45	43
	Mean (SD)	10.9 (18.68)	3.2 (20.52)	14.1 (25.11)	7.0 (27.75)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-67, 67	0, 100	-67, 100
Cycle 6	n	98	93	37	35
	Mean (SD)	10.2 (19.39)	3.9 (20.17)	12.6 (25.28)	4.8 (29.31)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-67, 67	0, 100	-67, 100
End of Treatment	n	71	69	83	81
	Mean (SD)	18.8 (26.86)	8.7 (29.51)	22.5 (29.04)	12.8 (28.17)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-qs-chg-oes-itt-fa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Trouble with coughing

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	106	102	96	95
	Mean (SD)	16.0 (24.44)	6.5 (23.94)	22.2 (29.68)	13.3 (31.28)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 100
Worst Post-Baseline Value	n	246	230	226	221
	Mean (SD)	25.1 (28.08)	14.9 (25.77)	29.6 (30.00)	17.8 (27.25)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-qs-chg-oes-itt-fa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Trouble talking

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	240		248	
	Mean (SD)	9.6 (20.59)		11.3 (21.79)	
	Median	0.0		0.0	
	Min, Max	0, 100		0, 100	
Cycle 1	n	138	132	132	129
	Mean (SD)	8.5 (20.56)	-0.5 (15.94)	12.9 (23.89)	-0.8 (21.03)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 67	0, 100	-100, 100
Cycle 2	n	224	213	174	171
	Mean (SD)	11.3 (23.65)	3.6 (19.76)	10.0 (20.35)	0.4 (17.71)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-100, 67
Cycle 3	n	181	171	91	89
	Mean (SD)	9.4 (20.28)	2.3 (17.18)	9.9 (20.78)	-0.4 (20.41)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-100, 100

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-qs-chg-oes-itt-fa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Trouble talking

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	146	138	76	74
	Mean (SD)	8.4 (18.70)	1.2 (15.81)	9.6 (18.71)	-1.8 (17.35)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 67	-67, 33
Cycle 5	n	110	104	45	43
	Mean (SD)	7.6 (20.02)	-0.6 (20.24)	9.6 (22.04)	1.6 (20.51)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 67
Cycle 6	n	99	93	37	35
	Mean (SD)	6.7 (18.43)	-0.4 (15.92)	9.0 (21.73)	-0.0 (21.39)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 67
End of Treatment	n	71	69	83	81
	Mean (SD)	12.2 (26.57)	2.9 (21.95)	14.1 (24.48)	5.3 (24.98)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-qs-chg-oes-itt-fa.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Trouble talking

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	106	102	96	95
	Mean (SD)	15.7 (28.44)	7.2 (23.28)	12.2 (23.75)	4.9 (26.62)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100
Worst Post-Baseline Value	n	246	231	226	221
	Mean (SD)	19.1 (29.21)	11.0 (25.16)	19.6 (27.64)	8.3 (23.28)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-qs-chg-oes-itt-fa.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: QLQ-OES18 index-score

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	127		132	
	Mean (SD)	16.3 (11.65)		17.2 (13.93)	
	Median	15.0		13.9	
	Min, Max	0, 68		0, 62	
Cycle 1	n	82	77	81	78
	Mean (SD)	17.2 (11.88)	0.1 (7.10)	17.5 (14.39)	0.4 (8.97)
	Median	14.9	0.0	14.4	0.0
	Min, Max	0, 58	-24, 34	0, 68	-21, 51
Cycle 2	n	123	113	97	96
	Mean (SD)	17.8 (15.42)	3.1 (10.20)	16.3 (13.41)	1.0 (9.14)
	Median	13.9	1.1	12.8	0.6
	Min, Max	0, 88	-14, 53	0, 69	-34, 36
Cycle 3	n	97	88	56	55
	Mean (SD)	17.2 (12.24)	2.3 (10.58)	14.3 (11.55)	-0.7 (8.68)
	Median	13.9	0.4	11.4	0.0
	Min, Max	0, 54	-27, 43	0, 44	-31, 20

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-b-qs-chg-oes-itts-fa.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: QLQ-OES18 index-score

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	76	68	50	50
	Mean (SD)	16.6 (11.47)	2.4 (10.73)	15.0 (10.34)	0.6 (10.43)
	Median	14.6	0.0	12.1	1.7
	Min, Max	0, 53	-40, 37	0, 43	-35, 26
Cycle 5	n	57	52	32	31
	Mean (SD)	15.3 (10.84)	1.1 (10.12)	15.4 (18.73)	1.1 (14.94)
	Median	13.3	0.1	8.1	0.0
	Min, Max	0, 44	-38, 29	0, 82	-37, 52
Cycle 6	n	54	49	26	25
	Mean (SD)	13.4 (12.11)	0.5 (9.59)	16.2 (17.38)	3.0 (13.55)
	Median	10.8	0.0	9.9	1.4
	Min, Max	0, 54	-21, 31	0, 67	-20, 41
End of Treatment	n	37	35	46	45
	Mean (SD)	23.7 (17.89)	9.6 (13.77)	22.4 (16.81)	6.8 (14.09)
	Median	24.2	6.1	17.9	5.0
	Min, Max	0, 71	-15, 55	0, 83	-28, 69

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-b-qs-chg-oes-itts-fa.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: QLQ-OES18 index-score

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	62	58	61	60
	Mean (SD)	24.4 (17.65)	8.5 (14.84)	21.0 (15.10)	6.2 (11.28)
	Median	18.6	4.2	16.9	3.8
	Min, Max	0, 74	-25, 46	0, 66	-20, 45
Worst Post-Baseline Value	n	136	124	127	122
	Mean (SD)	25.7 (17.57)	10.6 (13.56)	25.3 (17.41)	8.8 (13.09)
	Median	22.2	6.7	20.8	6.7
	Min, Max	0, 88	-13, 55	0, 83	-20, 69

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-b-qs-chg-oes-itts-fa.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Dysphagia

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		134	
	Mean (SD)	46.3 (36.35)		38.8 (36.35)	
	Median	44.4		33.3	
	Min, Max	0, 100		0, 100	
Cycle 1	n	82	78	82	81
	Mean (SD)	50.1 (39.24)	-1.9 (23.65)	46.2 (37.67)	3.4 (20.23)
	Median	44.4	0.0	44.4	0.0
	Min, Max	0, 100	-100, 67	0, 100	-44, 100
Cycle 2	n	124	114	97	96
	Mean (SD)	44.8 (39.92)	1.2 (26.83)	41.2 (36.11)	7.2 (27.31)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-100, 100	0, 100	-67, 100
Cycle 3	n	97	88	57	56
	Mean (SD)	49.4 (38.72)	7.2 (30.70)	39.4 (35.95)	3.4 (29.05)
	Median	44.4	0.0	33.3	0.0
	Min, Max	0, 100	-100, 100	0, 100	-78, 67

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-b-qs-chg-oes-itts-fa.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Dysphagia

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	76	68	52	51
	Mean (SD)	48.4 (38.56)	4.6 (27.83)	41.7 (37.27)	2.8 (32.95)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-100, 100	0, 100	-89, 67
Cycle 5	n	57	52	32	31
	Mean (SD)	52.4 (41.24)	5.3 (28.73)	39.2 (40.01)	-1.4 (38.89)
	Median	44.4	0.0	33.3	0.0
	Min, Max	0, 100	-67, 100	0, 100	-100, 89
Cycle 6	n	54	49	26	25
	Mean (SD)	44.2 (41.32)	1.4 (27.37)	37.6 (37.72)	0.4 (35.21)
	Median	44.4	0.0	33.3	0.0
	Min, Max	0, 100	-67, 100	0, 100	-100, 67
End of Treatment	n	37	35	46	45
	Mean (SD)	54.1 (35.92)	9.8 (35.01)	50.2 (39.39)	1.7 (32.56)
	Median	55.6	11.1	50.0	0.0
	Min, Max	0, 100	-89, 78	0, 100	-100, 78

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-b-qs-chg-oes-itts-fa.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Dysphagia

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	62	58	61	60
	Mean (SD)	54.3 (36.94)	5.4 (33.25)	55.6 (37.79)	11.5 (37.27)
	Median	66.7	0.0	55.6	0.0
	Min, Max	0, 100	-67, 100	0, 100	-100, 100
Worst Post-Baseline Value	n	136	125	128	125
	Mean (SD)	60.1 (38.05)	16.8 (32.63)	56.3 (36.53)	17.2 (30.41)
	Median	66.7	11.1	55.6	11.1
	Min, Max	0, 100	-100, 100	0, 100	-44, 100

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-b-qs-chg-oes-itts-fa.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Eating

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		132	
	Mean (SD)	20.4 (20.57)		20.8 (23.38)	
	Median	16.7		16.7	
	Min, Max	0, 100		0, 100	
Cycle 1	n	82	78	81	78
	Mean (SD)	22.7 (25.54)	2.4 (15.13)	21.0 (23.13)	-0.5 (13.91)
	Median	16.7	0.0	8.3	0.0
	Min, Max	0, 100	-50, 58	0, 92	-33, 33
Cycle 2	n	124	114	97	96
	Mean (SD)	21.6 (24.97)	3.3 (16.47)	19.3 (23.44)	0.1 (16.15)
	Median	16.7	0.0	16.7	0.0
	Min, Max	0, 100	-33, 67	0, 92	-50, 50
Cycle 3	n	98	89	56	55
	Mean (SD)	20.0 (24.86)	0.8 (21.76)	13.1 (15.56)	-5.3 (16.77)
	Median	8.3	0.0	8.3	0.0
	Min, Max	0, 100	-83, 75	0, 67	-50, 25

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-b-qs-chg-oes-itts-fa.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Eating

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	76	68	51	50
	Mean (SD)	18.4 (20.34)	1.2 (17.05)	17.5 (21.10)	0.5 (19.95)
	Median	8.3	0.0	8.3	0.0
	Min, Max	0, 100	-25, 83	0, 83	-42, 58
Cycle 5	n	57	52	32	31
	Mean (SD)	14.3 (17.66)	-1.1 (14.76)	17.2 (25.66)	1.9 (25.34)
	Median	8.3	0.0	8.3	0.0
	Min, Max	0, 75	-42, 42	0, 100	-58, 67
Cycle 6	n	54	49	26	25
	Mean (SD)	14.8 (16.64)	-0.2 (13.97)	21.5 (30.20)	7.7 (26.45)
	Median	8.3	0.0	8.3	0.0
	Min, Max	0, 58	-25, 42	0, 100	-58, 67
End of Treatment	n	37	35	46	45
	Mean (SD)	33.1 (30.14)	12.1 (21.99)	27.7 (28.92)	9.4 (25.29)
	Median	25.0	8.3	16.7	8.3
	Min, Max	0, 100	-25, 67	0, 100	-42, 75

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-b-qs-chg-oes-itts-fa.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Eating

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	62	58	61	60
	Mean (SD)	28.0 (24.61)	8.5 (19.46)	24.7 (25.18)	5.3 (17.96)
	Median	25.0	4.2	16.7	8.3
	Min, Max	0, 100	-25, 67	0, 92	-58, 42
Worst Post-Baseline Value	n	136	125	127	122
	Mean (SD)	33.8 (28.40)	15.1 (21.15)	33.2 (27.44)	12.2 (21.94)
	Median	25.0	8.3	25.0	8.3
	Min, Max	0, 100	-50, 83	0, 100	-50, 75

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-b-qs-chg-oes-itts-fa.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Reflux

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		134	
	Mean (SD)	11.6 (16.93)		11.6 (18.42)	
	Median	0.0		0.0	
	Min, Max	0, 83		0, 100	
Cycle 1	n	82	78	82	81
	Mean (SD)	12.0 (20.33)	-0.2 (14.83)	13.2 (18.65)	2.3 (17.43)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 67	0, 67	-67, 50
Cycle 2	n	124	114	97	96
	Mean (SD)	10.6 (17.05)	-0.0 (14.37)	12.7 (20.09)	3.3 (20.47)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-50, 67	0, 100	-50, 83
Cycle 3	n	98	89	57	56
	Mean (SD)	12.4 (20.91)	1.3 (19.17)	11.4 (17.86)	2.4 (19.44)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-50, 83	0, 83	-33, 67

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-b-qs-chg-oes-itts-fa.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Reflux

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	76	68	52	51
	Mean (SD)	9.4 (17.92)	-1.5 (17.21)	12.5 (16.13)	3.3 (15.28)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 83	-50, 83	0, 67	-33, 50
Cycle 5	n	57	52	32	31
	Mean (SD)	8.5 (13.03)	0.3 (17.92)	10.4 (17.84)	1.1 (20.61)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 33	-83, 33	0, 67	-50, 50
Cycle 6	n	54	49	26	25
	Mean (SD)	7.4 (12.81)	1.0 (16.10)	12.2 (21.89)	2.7 (25.77)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 50	-67, 33	0, 83	-50, 67
End of Treatment	n	37	35	46	45
	Mean (SD)	16.7 (25.46)	7.1 (20.33)	15.6 (21.49)	4.8 (24.00)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-17, 83	0, 83	-67, 83

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-b-qs-chg-oes-itts-fa.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Reflux

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	62	58	61	60
	Mean (SD)	14.5 (16.66)	2.6 (19.19)	14.2 (16.34)	2.2 (19.28)
	Median	16.7	0.0	16.7	0.0
	Min, Max	0, 67	-33, 50	0, 67	-67, 33
Worst Post-Baseline Value	n	136	125	128	125
	Mean (SD)	20.2 (24.96)	8.9 (21.12)	23.2 (22.93)	12.0 (23.05)
	Median	16.7	0.0	16.7	16.7
	Min, Max	0, 100	-33, 83	0, 100	-67, 83

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-b-qs-chg-oes-itts-fa.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Pain

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		134	
	Mean (SD)	11.5 (13.97)		12.9 (19.69)	
	Median	11.1		11.1	
	Min, Max	0, 67		0, 100	
Cycle 1	n	82	78	82	81
	Mean (SD)	11.9 (15.40)	-0.1 (12.60)	13.6 (21.21)	1.4 (14.95)
	Median	11.1	0.0	0.0	0.0
	Min, Max	0, 78	-44, 44	0, 100	-44, 89
Cycle 2	n	124	114	97	96
	Mean (SD)	12.5 (18.07)	1.7 (16.14)	10.7 (17.34)	-0.9 (11.01)
	Median	0.0	0.0	11.1	0.0
	Min, Max	0, 100	-33, 100	0, 100	-44, 22
Cycle 3	n	98	89	57	56
	Mean (SD)	11.8 (17.02)	-0.2 (14.21)	8.5 (13.53)	-1.1 (8.83)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-44, 44	0, 78	-22, 17

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-b-qs-chg-oes-itts-fa.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Pain

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	76	68	52	51
	Mean (SD)	9.6 (13.00)	-1.0 (15.45)	7.5 (9.77)	0.0 (11.76)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 44	-67, 33	0, 33	-22, 33
Cycle 5	n	57	52	32	31
	Mean (SD)	9.6 (13.52)	0.0 (15.40)	7.6 (11.79)	0.7 (14.33)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 56	-67, 44	0, 33	-22, 33
Cycle 6	n	54	49	26	25
	Mean (SD)	8.2 (13.51)	-0.2 (15.96)	9.0 (16.03)	1.8 (17.77)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-56, 56	0, 67	-22, 67
End of Treatment	n	37	35	46	45
	Mean (SD)	22.8 (27.08)	11.1 (23.65)	16.9 (22.92)	4.9 (16.68)
	Median	11.1	0.0	11.1	0.0
	Min, Max	0, 100	-33, 89	0, 100	-33, 67

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-b-qs-chg-oes-itts-fa.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Pain

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	62	58	61	60
	Mean (SD)	17.7 (18.82)	7.3 (20.02)	13.8 (18.77)	2.6 (15.36)
	Median	11.1	5.6	11.1	0.0
	Min, Max	0, 67	-33, 67	0, 78	-22, 44
Worst Post-Baseline Value	n	136	125	128	125
	Mean (SD)	21.7 (22.44)	10.8 (20.15)	20.1 (21.60)	7.8 (15.22)
	Median	22.2	11.1	11.1	11.1
	Min, Max	0, 100	-33, 100	0, 100	-22, 89

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-b-qs-chg-oes-itts-fa.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Trouble swallowing saliva

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		134	
	Mean (SD)	12.8 (24.07)		11.7 (24.61)	
	Median	0.0		0.0	
	Min, Max	0, 100		0, 100	
Cycle 1	n	82	78	82	81
	Mean (SD)	11.4 (18.31)	-1.7 (17.73)	11.4 (25.78)	1.2 (24.41)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-100, 33	0, 100	-67, 100
Cycle 2	n	123	113	97	96
	Mean (SD)	14.6 (26.36)	3.8 (26.63)	9.6 (21.49)	0.0 (26.05)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 100	0, 100	-100, 100
Cycle 3	n	98	89	57	56
	Mean (SD)	11.9 (24.52)	-0.4 (31.58)	9.9 (23.54)	-3.0 (28.62)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 100	0, 100	-100, 100

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-b-qs-chg-oes-itts-fa.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Trouble swallowing saliva

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	76	68	52	51
	Mean (SD)	10.1 (19.64)	-1.0 (31.00)	9.0 (17.61)	-5.9 (27.25)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 100	0, 67	-100, 67
Cycle 5	n	57	52	32	31
	Mean (SD)	9.4 (22.50)	-1.9 (25.06)	9.4 (27.09)	-4.3 (22.35)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 100	0, 100	-100, 33
Cycle 6	n	54	49	26	25
	Mean (SD)	6.8 (19.83)	-3.4 (19.54)	12.8 (29.93)	-2.7 (27.08)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 33	0, 100	-100, 67
End of Treatment	n	37	35	46	45
	Mean (SD)	12.6 (18.17)	3.8 (23.94)	18.8 (32.70)	11.1 (31.78)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-67, 67	0, 100	-67, 100

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-b-qs-chg-oes-itts-fa.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Trouble swallowing saliva

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	62	58	61	60
	Mean (SD)	18.8 (30.55)	5.2 (35.21)	9.8 (22.23)	1.7 (27.74)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 100	0, 100	-100, 100
Worst Post-Baseline Value	n	136	125	128	125
	Mean (SD)	27.5 (33.43)	16.0 (32.95)	23.7 (33.50)	12.5 (33.24)
	Median	33.3	0.0	0.0	0.0
	Min, Max	0, 100	-100, 100	0, 100	-100, 100

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-b-qs-chg-oes-itts-fa.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Choked when swallowing

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		134	
	Mean (SD)	14.1 (19.89)		15.7 (24.08)	
	Median	0.0		0.0	
	Min, Max	0, 67		0, 100	
Cycle 1	n	82	78	81	80
	Mean (SD)	15.0 (22.32)	-0.4 (17.40)	11.1 (20.41)	-5.8 (20.39)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 67	0, 100	-67, 67
Cycle 2	n	124	114	97	96
	Mean (SD)	16.1 (22.69)	2.6 (18.36)	10.7 (18.97)	-3.1 (24.70)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 67	0, 100	-100, 67
Cycle 3	n	98	89	57	56
	Mean (SD)	12.9 (21.21)	-1.9 (23.76)	11.1 (22.12)	1.8 (21.48)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-33, 100

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-b-qs-chg-oes-itts-fa.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Choked when swallowing

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	76	68	52	51
	Mean (SD)	11.8 (20.87)	-1.5 (21.88)	10.9 (18.34)	-0.0 (22.11)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 67	-67, 67
Cycle 5	n	57	52	32	31
	Mean (SD)	12.3 (18.51)	-0.6 (23.33)	12.5 (27.76)	1.1 (21.92)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-67, 33	0, 100	-67, 67
Cycle 6	n	54	49	26	25
	Mean (SD)	9.3 (16.40)	-2.7 (21.34)	7.7 (17.15)	-1.3 (20.37)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-67, 33	0, 67	-33, 67
End of Treatment	n	37	35	46	45
	Mean (SD)	16.2 (24.37)	4.8 (25.75)	18.1 (26.95)	5.2 (28.39)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-67, 67	0, 100	-67, 100

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-b-qs-chg-oes-itts-fa.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Choked when swallowing

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	62	58	61	60
	Mean (SD)	18.3 (28.10)	4.0 (29.34)	15.3 (26.23)	3.3 (23.53)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 67
Worst Post-Baseline Value	n	136	125	127	124
	Mean (SD)	26.7 (28.92)	12.8 (27.04)	24.9 (29.69)	9.7 (28.12)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-b-qs-chg-oes-itts-fa.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Dry mouth

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	127		134	
	Mean (SD)	18.1 (20.47)		19.9 (24.90)	
	Median	0.0		0.0	
	Min, Max	0, 100		0, 100	
Cycle 1	n	82	77	82	81
	Mean (SD)	18.7 (22.28)	0.4 (18.33)	21.5 (24.21)	2.1 (20.65)
	Median	0.0	0.0	33.3	0.0
	Min, Max	0, 100	-33, 67	0, 100	-67, 100
Cycle 2	n	124	113	97	96
	Mean (SD)	22.0 (27.51)	5.3 (23.39)	18.9 (23.52)	-0.0 (21.08)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 67	0, 100	-67, 67
Cycle 3	n	98	89	57	56
	Mean (SD)	20.7 (24.18)	3.7 (20.37)	16.4 (22.82)	-2.4 (22.79)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 67	0, 100	-67, 33

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-b-qs-chg-oes-itts-fa.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Dry mouth

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	76	68	52	51
	Mean (SD)	21.1 (26.58)	7.4 (26.29)	16.0 (19.23)	0.0 (27.49)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 67	-100, 67
Cycle 5	n	57	52	32	31
	Mean (SD)	14.6 (18.92)	0.0 (18.67)	14.6 (25.31)	-2.2 (27.13)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-67, 33	0, 100	-67, 67
Cycle 6	n	54	49	26	25
	Mean (SD)	14.8 (23.05)	2.0 (20.87)	17.9 (27.05)	5.3 (26.67)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 67	0, 100	-33, 67
End of Treatment	n	37	35	46	45
	Mean (SD)	27.0 (29.23)	17.1 (26.04)	21.7 (23.54)	7.4 (26.49)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-33, 100

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-b-qs-chg-oes-itts-fa.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Dry mouth

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	62	58	61	60
	Mean (SD)	27.4 (29.89)	10.9 (31.46)	26.2 (31.10)	12.8 (31.35)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100
Worst Post-Baseline Value	n	136	124	128	125
	Mean (SD)	37.0 (30.54)	19.6 (27.22)	33.9 (28.98)	15.2 (29.18)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-b-qs-chg-oes-itts-fa.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Trouble with taste

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	127		133	
	Mean (SD)	8.7 (20.23)		15.3 (26.75)	
	Median	0.0		0.0	
	Min, Max	0, 100		0, 100	
Cycle 1	n	82	77	81	79
	Mean (SD)	11.0 (18.93)	3.0 (20.36)	12.8 (23.90)	0.0 (19.97)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 67	0, 100	-67, 67
Cycle 2	n	124	113	97	96
	Mean (SD)	10.2 (21.75)	3.8 (23.88)	18.2 (28.88)	2.4 (24.78)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 67
Cycle 3	n	97	88	56	55
	Mean (SD)	11.3 (20.35)	4.5 (25.36)	12.5 (25.87)	-3.0 (25.88)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 67	0, 100	-100, 67

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-b-qs-chg-oes-itts-fa.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Trouble with taste

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	76	68	52	50
	Mean (SD)	11.4 (21.47)	6.4 (20.97)	17.3 (27.61)	4.0 (27.47)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 67
Cycle 5	n	57	52	32	31
	Mean (SD)	5.3 (12.26)	-1.3 (19.76)	15.6 (28.06)	3.2 (30.25)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 33	-100, 33	0, 100	-100, 67
Cycle 6	n	54	49	26	25
	Mean (SD)	6.8 (15.02)	-0.7 (24.99)	16.7 (33.00)	6.7 (27.22)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-100, 67	0, 100	-33, 100
End of Treatment	n	37	35	46	45
	Mean (SD)	18.0 (25.57)	12.4 (25.67)	16.7 (27.89)	5.2 (24.57)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 67	0, 100	-67, 67

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-b-qs-chg-oes-itts-fa.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Trouble with taste

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	62	58	61	60
	Mean (SD)	24.2 (29.67)	20.7 (29.83)	18.0 (30.17)	7.8 (18.78)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-33, 67
Worst Post-Baseline Value	n	136	124	127	123
	Mean (SD)	24.5 (29.04)	17.5 (29.89)	26.2 (31.32)	10.6 (27.10)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-b-qs-chg-oes-itts-fa.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Trouble with coughing

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	127		134	
	Mean (SD)	10.0 (18.46)		14.4 (23.64)	
	Median	0.0		0.0	
	Min, Max	0, 67		0, 100	
Cycle 1	n	82	77	82	81
	Mean (SD)	10.2 (17.91)	0.0 (15.29)	15.4 (22.34)	1.2 (17.03)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-33, 33	0, 100	-67, 33
Cycle 2	n	124	113	97	96
	Mean (SD)	14.0 (24.08)	4.7 (22.21)	12.4 (21.69)	1.0 (19.62)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 67
Cycle 3	n	98	89	57	56
	Mean (SD)	13.6 (21.32)	4.9 (19.17)	14.0 (23.53)	1.2 (24.59)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 67	0, 100	-67, 100

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-b-qs-chg-oes-itts-fa.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Trouble with coughing

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	76	68	51	51
	Mean (SD)	14.5 (21.32)	5.4 (19.62)	13.7 (20.20)	1.3 (27.46)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-33, 67	0, 67	-67, 67
Cycle 5	n	57	52	32	31
	Mean (SD)	15.2 (21.89)	7.1 (22.23)	15.6 (28.06)	7.5 (31.87)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-33, 67	0, 100	-67, 100
Cycle 6	n	54	49	26	25
	Mean (SD)	11.7 (21.63)	5.4 (19.66)	15.4 (28.64)	6.7 (34.69)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-33, 67	0, 100	-67, 100
End of Treatment	n	37	35	46	45
	Mean (SD)	19.8 (27.73)	12.4 (26.92)	22.5 (29.02)	13.3 (27.89)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-33, 100

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-b-qs-chg-oes-itts-fa.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Trouble with coughing

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	62	58	61	60
	Mean (SD)	21.0 (28.46)	9.2 (26.34)	22.4 (30.86)	11.7 (32.37)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100
Worst Post-Baseline Value	n	136	124	128	125
	Mean (SD)	25.7 (29.25)	16.9 (26.03)	31.5 (31.11)	18.4 (29.77)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-b-qs-chg-oes-itts-fa.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Trouble talking

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		134	
	Mean (SD)	10.4 (22.04)		11.7 (22.11)	
	Median	0.0		0.0	
	Min, Max	0, 100		0, 100	
Cycle 1	n	82	78	82	81
	Mean (SD)	9.3 (21.77)	-0.4 (14.71)	13.0 (23.86)	-1.2 (17.83)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 67	0, 100	-67, 67
Cycle 2	n	124	114	97	96
	Mean (SD)	12.1 (25.62)	4.1 (19.90)	9.6 (19.81)	0.0 (14.51)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 67	-33, 33
Cycle 3	n	98	89	57	56
	Mean (SD)	10.9 (21.82)	4.5 (20.84)	9.9 (19.89)	0.0 (15.57)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 67	-67, 33

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-b-qs-chg-oes-itts-fa.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Trouble talking

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	76	68	52	51
	Mean (SD)	11.0 (20.65)	4.4 (19.87)	9.6 (17.88)	-1.3 (19.96)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 67	-67, 33
Cycle 5	n	57	52	32	31
	Mean (SD)	11.1 (23.85)	3.2 (23.11)	11.5 (24.84)	3.2 (23.34)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 67
Cycle 6	n	54	49	26	25
	Mean (SD)	9.9 (23.01)	2.0 (18.52)	11.5 (24.84)	2.7 (23.41)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 67
End of Treatment	n	37	35	46	45
	Mean (SD)	16.2 (30.04)	5.7 (22.12)	15.9 (24.08)	5.2 (26.55)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-b-qs-chg-oes-itts-fa.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Trouble talking

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	62	58	61	60
	Mean (SD)	19.4 (30.51)	10.9 (24.49)	9.8 (22.23)	3.3 (25.08)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100
Worst Post-Baseline Value	n	136	125	128	125
	Mean (SD)	22.1 (30.96)	13.6 (26.47)	21.4 (28.60)	9.6 (24.25)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-03-01-b-qs-chg-oes-itts-fa.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Dysphagia									
Cycle 4	138		2.38 (2.25)	74		7.87 (2.88)	-5.48 (-12.51, 1.55)	-0.20 (-0.46, 0.06)	0.1258
Cycle 6	93		2.23 (2.70)	35		2.39 (4.10)	-0.16 (-9.73, 9.42)	-0.01 (-0.34, 0.33)	0.9740
Overall Treatment Effect	228	35.32 (35.22)	3.05 (1.61)	208	34.83 (34.57)	5.45 (1.98)	-2.40 (-7.19, 2.39)	-0.12 (-0.36, 0.12)	0.3258

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Only patients with baseline and postbaseline value are included in analysis.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab.

[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Negative differences favor tislelizumab.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-03-01-01-eff-mmrmqs-o18-itt-fa.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Eating									
Cycle 4	138		0.32 (1.44)	73		2.41 (1.86)	-2.09 (-6.60, 2.41)	-0.12 (-0.38, 0.14)	0.3613
Cycle 6	93		0.01 (1.57)	35		4.88 (2.22)	-4.87 (-10.11, 0.36)	-0.27 (-0.56, 0.02)	0.0680
Overall Treatment Effect	227	17.57 (19.83)	0.44 (1.06)	205	19.61 (21.10)	1.24 (1.24)	-0.80 (-3.81, 2.22)	-0.06 (-0.28, 0.16)	0.6028

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Negative differences favor tislelizumab.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-03-01-01-eff-mmrmqs-o18-itt-fa.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Reflux									
Cycle 4	138		-1.99 (1.16)	74		1.86 (1.51)	-3.85 (-7.48, -0.22)	-0.28 (-0.55, -0.02)	0.0378
Cycle 6	93		-1.14 (1.47)	35		-0.01 (2.23)	-1.13 (-6.32, 4.05)	-0.07 (-0.41, 0.26)	0.6670
Overall Treatment Effect	228	12.22 (17.48)	-1.15 (0.91)	208	12.70 (17.96)	1.03 (1.10)	-2.17 (-4.82, 0.48)	-0.19 (-0.43, 0.04)	0.1076

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Negative differences favor tislelizumab.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-03-01-01-eff-mmrmqs-o18-itt-fa.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Pain (OES18)									
Cycle 4	138		-1.34 (1.01)	74		0.41 (1.34)	-1.75 (-4.97, 1.48)	-0.15 (-0.42, 0.12)	0.2864
Cycle 6	93		-0.74 (1.31)	35		2.14 (2.02)	-2.89 (-7.60, 1.83)	-0.21 (-0.56, 0.13)	0.2284
Overall Treatment Effect	228	11.76 (14.64)	-0.26 (0.72)	208	11.92 (18.20)	0.81 (0.91)	-1.07 (-3.23, 1.09)	-0.12 (-0.37, 0.13)	0.3301

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Negative differences favor tislelizumab.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-03-01-01-eff-mmrmqs-o18-itt-fa.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Trouble swallowing saliva									
Cycle 4	138		-1.83 (1.68)	74		-0.99 (2.24)	-0.84 (-6.26, 4.57)	-0.04 (-0.32, 0.23)	0.7597
Cycle 6	93		-3.92 (1.66)	35		-3.17 (2.56)	-0.75 (-6.68, 5.18)	-0.04 (-0.39, 0.30)	0.8030
Overall Treatment Effect	228	11.67 (23.08)	-1.09 (1.10)	208	11.16 (24.30)	-1.37 (1.36)	0.28 (-2.95, 3.52)	0.02 (-0.22, 0.26)	0.8638

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Negative differences favor tislelizumab.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-03-01-01-eff-mmrmqs-o18-itt-fa.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Choked when swallowing									
Cycle 4	138		-3.14 (1.60)	74		-1.82 (2.11)	-1.33 (-6.44, 3.79)	-0.07 (-0.34, 0.20)	0.6103
Cycle 6	93		-3.99 (1.68)	35		-1.03 (2.60)	-2.96 (-8.99, 3.08)	-0.17 (-0.52, 0.18)	0.3346
Overall Treatment Effect	228	14.17 (18.88)	-2.07 (1.07)	207	14.25 (22.11)	-0.48 (1.31)	-1.59 (-4.74, 1.56)	-0.12 (-0.36, 0.12)	0.3202

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Only patients with baseline and postbaseline value are included in analysis.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab.

[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Negative differences favor tislelizumab.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-03-01-01-eff-mmrmqs-o18-itt-fa.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Dry mouth									
Cycle 4	138		2.87 (1.87)	74		1.92 (2.45)	0.95 (-5.00, 6.90)	0.04 (-0.23, 0.31)	0.7530
Cycle 6	93		0.35 (2.01)	35		5.52 (3.06)	-5.17 (-12.30, 1.97)	-0.24 (-0.58, 0.09)	0.1546
Overall Treatment Effect	227	16.32 (20.24)	0.79 (1.21)	208	19.89 (24.34)	2.63 (1.47)	-1.84 (-5.38, 1.69)	-0.12 (-0.36, 0.11)	0.3062

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Negative differences favor tislelizumab.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-03-01-01-eff-mmrmqs-o18-itt-fa.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Trouble with taste									
Cycle 4	137		1.07 (1.72)	73		7.03 (2.21)	-5.97 (-11.38, -0.56)	-0.29 (-0.55, -0.03)	0.0307
Cycle 6	93		-0.58 (1.97)	35		9.34 (2.79)	-9.93 (-16.57, -3.29)	-0.44 (-0.74, -0.14)	0.0036
Overall Treatment Effect	226	7.95 (18.00)	-0.06 (1.25)	206	14.04 (24.80)	4.53 (1.49)	-4.59 (-8.24, -0.93)	-0.29 (-0.52, -0.06)	0.0140

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Negative differences favor tislelizumab.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-03-01-01-eff-mmrmqs-o18-itt-fa.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Trouble with coughing									
Cycle 4	138		3.02 (1.66)	74		2.90 (2.21)	0.12 (-5.23, 5.48)	0.01 (-0.27, 0.28)	0.9647
Cycle 6	93		4.13 (2.12)	35		5.12 (3.25)	-0.98 (-8.58, 6.61)	-0.04 (-0.38, 0.30)	0.7989
Overall Treatment Effect	227	11.02 (20.60)	2.53 (1.14)	208	13.17 (22.37)	4.13 (1.44)	-1.60 (-5.06, 1.86)	-0.12 (-0.37, 0.13)	0.3636

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Negative differences favor tislelizumab.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-03-01-01-eff-mmrmqs-o18-itt-fa.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Trouble talking									
Cycle 4	138		0.43 (1.27)	74		-0.17 (1.62)	0.60 (-3.32, 4.51)	0.04 (-0.22, 0.30)	0.7644
Cycle 6	93		0.35 (1.40)	35		0.02 (1.93)	0.34 (-4.24, 4.91)	0.02 (-0.26, 0.30)	0.8847
Overall Treatment Effect	228	9.58 (20.59)	0.65 (1.05)	208	11.29 (21.79)	0.27 (1.23)	0.38 (-2.61, 3.38)	0.03 (-0.20, 0.25)	0.8010

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Negative differences favor tislelizumab.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-03-01-01-eff-mmrmqs-o18-itt-fa.rtf

Table 14.2.6.3.1.1.b:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Dysphagia									
Cycle 4	68		5.56 (3.24)	51		3.69 (3.72)	1.86 (-7.77, 11.50)	0.07 (-0.28, 0.41)	0.7031
Cycle 6	49		2.02 (3.58)	25		0.09 (4.65)	1.94 (-9.59, 13.47)	0.07 (-0.34, 0.47)	0.7397
Overall Treatment Effect	123	46.27 (36.35)	3.90 (2.23)	119	38.81 (36.35)	3.34 (2.56)	0.56 (-5.97, 7.08)	0.03 (-0.29, 0.34)	0.8660

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

Only patients with baseline and postbaseline value are included in analysis.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab.

[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Negative differences favor tislelizumab.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

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Table 14.2.6.3.1.1.b:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Eating									
Cycle 4	68		1.52 (2.12)	50		0.17 (2.45)	1.35 (-4.97, 7.67)	0.07 (-0.27, 0.42)	0.6726
Cycle 6	49		0.93 (2.32)	25		3.85 (2.98)	-2.92 (-10.31, 4.47)	-0.15 (-0.53, 0.23)	0.4349
Overall Treatment Effect	123	20.44 (20.57)	1.09 (1.40)	116	20.83 (23.38)	-0.59 (1.57)	1.68 (-2.32, 5.68)	0.12 (-0.17, 0.42)	0.4077

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Negative differences favor tislelizumab.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-03-01-01-b-eff-mmrmqs-o18-itts-fa.rtf

Table 14.2.6.3.1.1.b:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Reflux									
Cycle 4	68		-1.37 (1.75)	51		4.28 (2.02)	-5.65 (-10.84, -0.47)	-0.37 (-0.72, -0.03)	0.0328
Cycle 6	49		-0.56 (2.28)	25		1.48 (2.99)	-2.04 (-9.42, 5.34)	-0.11 (-0.50, 0.28)	0.5846
Overall Treatment Effect	123	11.59 (16.93)	-0.35 (1.39)	119	11.57 (18.42)	2.57 (1.58)	-2.93 (-6.94, 1.08)	-0.22 (-0.52, 0.08)	0.1516

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Negative differences favor tislelizumab.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-03-01-01-b-eff-mmrmqs-o18-itts-fa.rtf

Table 14.2.6.3.1.1.b:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Pain (OES18)									
Cycle 4	68		-0.44 (1.53)	51		-0.47 (1.76)	0.04 (-4.51, 4.58)	0.00 (-0.34, 0.35)	0.9874
Cycle 6	49		1.45 (2.09)	25		2.83 (2.76)	-1.37 (-8.21, 5.47)	-0.08 (-0.49, 0.33)	0.6914
Overall Treatment Effect	123	11.55 (13.97)	0.66 (1.09)	119	12.85 (19.69)	0.51 (1.27)	0.14 (-3.06, 3.35)	0.01 (-0.30, 0.33)	0.9300

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Negative differences favor tislelizumab.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-03-01-01-b-eff-mmrmqs-o18-itts-fa.rtf

Table 14.2.6.3.1.1.b:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Trouble swallowing saliva									
Cycle 4	68		-0.78 (2.43)	51		-3.92 (2.81)	3.14 (-4.12, 10.40)	0.16 (-0.20, 0.52)	0.3935
Cycle 6	49		-3.35 (2.58)	25		-4.80 (3.44)	1.45 (-7.03, 9.93)	0.07 (-0.35, 0.50)	0.7353
Overall Treatment Effect	123	12.76 (24.07)	-0.73 (1.53)	119	11.69 (24.61)	-3.13 (1.79)	2.40 (-2.09, 6.89)	0.17 (-0.15, 0.49)	0.2930

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Negative differences favor tislelizumab.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-03-01-01-b-eff-mmrmqs-o18-itts-fa.rtf

Table 14.2.6.3.1.1.b:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Choked when swallowing									
Cycle 4	68		-2.80 (2.26)	51		-2.54 (2.62)	-0.26 (-7.02, 6.51)	-0.01 (-0.37, 0.35)	0.9403
Cycle 6	49		-4.18 (2.32)	25		-4.23 (3.22)	0.05 (-7.79, 7.89)	0.00 (-0.46, 0.47)	0.9902
Overall Treatment Effect	123	14.06 (19.89)	-1.73 (1.35)	118	15.67 (24.08)	-2.64 (1.59)	0.91 (-3.08, 4.89)	0.07 (-0.25, 0.40)	0.6528

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Negative differences favor tislelizumab.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-03-01-01-b-eff-mmrmqs-o18-itts-fa.rtf

Table 14.2.6.3.1.1.b:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Dry mouth									
Cycle 4	68		7.27 (2.86)	51		0.19 (3.26)	7.08 (-1.39, 15.55)	0.29 (-0.06, 0.63)	0.1007
Cycle 6	49		2.18 (2.97)	25		2.86 (4.05)	-0.69 (-10.58, 9.21)	-0.03 (-0.47, 0.41)	0.8906
Overall Treatment Effect	122	18.11 (20.47)	2.93 (1.62)	119	19.90 (24.90)	0.14 (1.85)	2.78 (-1.90, 7.46)	0.18 (-0.13, 0.49)	0.2425

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Negative differences favor tislelizumab.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-03-01-01-b-eff-mmrmqs-o18-itts-fa.rtf

Table 14.2.6.3.1.1.b:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Trouble with taste									
Cycle 4	68		6.21 (2.74)	50		7.71 (3.10)	-1.49 (-9.59, 6.60)	-0.06 (-0.38, 0.26)	0.7158
Cycle 6	49		5.09 (3.17)	25		8.24 (3.83)	-3.15 (-12.94, 6.64)	-0.11 (-0.45, 0.23)	0.5249
Overall Treatment Effect	122	8.66 (20.23)	2.85 (1.95)	117	15.29 (26.75)	3.90 (2.14)	-1.05 (-6.63, 4.53)	-0.05 (-0.35, 0.24)	0.7103

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Negative differences favor tislelizumab.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-03-01-01-b-eff-mmrmqs-o18-itts-fa.rtf

Table 14.2.6.3.1.1.b:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Trouble with coughing									
Cycle 4	68		5.18 (2.54)	51		2.66 (2.93)	2.52 (-5.09, 10.13)	0.12 (-0.24, 0.47)	0.5131
Cycle 6	49		7.18 (3.18)	25		7.19 (4.20)	-0.01 (-10.42, 10.40)	-0.00 (-0.40, 0.40)	0.9987
Overall Treatment Effect	122	9.97 (18.46)	4.49 (1.66)	119	14.43 (23.64)	4.05 (1.94)	0.44 (-4.49, 5.36)	0.03 (-0.29, 0.35)	0.8615

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Negative differences favor tislelizumab.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-03-01-01-b-eff-mmrmqs-o18-itts-fa.rtf

Table 14.2.6.3.1.1.b:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Trouble talking									
Cycle 4	68		3.68 (2.12)	51		-0.23 (2.40)	3.92 (-2.32, 10.16)	0.20 (-0.12, 0.52)	0.2166
Cycle 6	49		3.74 (2.09)	25		0.99 (2.46)	2.75 (-3.53, 9.03)	0.14 (-0.18, 0.47)	0.3881
Overall Treatment Effect	123	10.42 (22.04)	2.75 (1.53)	119	11.69 (22.11)	0.34 (1.70)	2.41 (-1.97, 6.78)	0.16 (-0.13, 0.46)	0.2797

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Negative differences favor tislelizumab.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-03-01-01-b-eff-mmrmqs-o18-itts-fa.rtf

Table 14.2.6.3.1.2:
Analyses of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Dysphagia	256	63 (24.6)	NR (NE, NE)	256	63 (24.6)	NR (3.3, NE)	0.786 (0.552, 1.120)	0.1746
Eating	256	35 (13.7)	NR (NE, NE)	256	27 (10.5)	NR (NE, NE)	1.105 (0.666, 1.836)	0.6971
Reflux	256	32 (12.5)	NR (15.1, NE)	256	45 (17.6)	NR (NE, NE)	0.522 (0.328, 0.830)	0.0049
Pain	256	49 (19.1)	NR (NE, NE)	256	44 (17.2)	NR (NE, NE)	0.949 (0.626, 1.439)	0.8048
Trouble Swallowing Saliva	256	23 (9.0)	NR (NE, NE)	256	17 (6.6)	NR (NE, NE)	1.118 (0.593, 2.108)	0.7283
Choked When Swallowing	256	23 (9.0)	NR (NE, NE)	256	23 (9.0)	NR (NE, NE)	0.831 (0.463, 1.492)	0.5322
Dry Mouth	256	50 (19.5)	NR (11.8, NE)	256	37 (14.5)	NR (NE, NE)	1.047 (0.678, 1.615)	0.8346
Trouble With Taste	256	35 (13.7)	NR (NE, NE)	256	30 (11.7)	NR (NE, NE)	0.863 (0.525, 1.419)	0.5590

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-tte-qlq.sas 16MAY2024 03:12 t-14-02-06-03-01-02-eff-tte-qlq-o18-itt-fa.rtf

Table 14.2.6.3.1.2:
Analyses of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Trouble With Coughing	256	43 (16.8)	NR (NE, NE)	256	30 (11.7)	NR (NE, NE)	1.200 (0.749, 1.921)	0.4451
Trouble Talking	256	25 (9.8)	NR (NE, NE)	256	11 (4.3)	NR (NE, NE)	2.001 (0.982, 4.077)	0.0508

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-tte-qlq.sas 16MAY2024 03:12 t-14-02-06-03-01-02-eff-tte-qlq-o18-itt-fa.rtf

Table 14.2.6.3.1.2.b:
Analyses of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Dysphagia	139	39 (28.1)	NR (NE, NE)	138	37 (26.8)	NR (4.9, NE)	0.968 (0.617, 1.520)	0.8866
Eating	139	22 (15.8)	NR (NE, NE)	138	17 (12.3)	NR (5.2, NE)	1.181 (0.623, 2.236)	0.6091
Reflux	139	19 (13.7)	NR (NE, NE)	138	27 (19.6)	NR (NE, NE)	0.606 (0.336, 1.092)	0.0901
Pain	139	32 (23.0)	NR (NE, NE)	138	25 (18.1)	NR (4.9, NE)	1.327 (0.783, 2.249)	0.2855
Trouble Swallowing Saliva	139	12 (8.6)	NR (NE, NE)	138	7 (5.1)	NR (NE, NE)	1.652 (0.646, 4.226)	0.2886
Choked When Swallowing	139	13 (9.4)	NR (NE, NE)	138	13 (9.4)	NR (NE, NE)	0.910 (0.417, 1.985)	0.8132
Dry Mouth	139	28 (20.1)	NR (11.8, NE)	138	18 (13.0)	NR (NE, NE)	1.464 (0.803, 2.669)	0.2079
Trouble With Taste	139	23 (16.5)	NR (NE, NE)	138	15 (10.9)	NR (NE, NE)	1.362 (0.707, 2.623)	0.3510

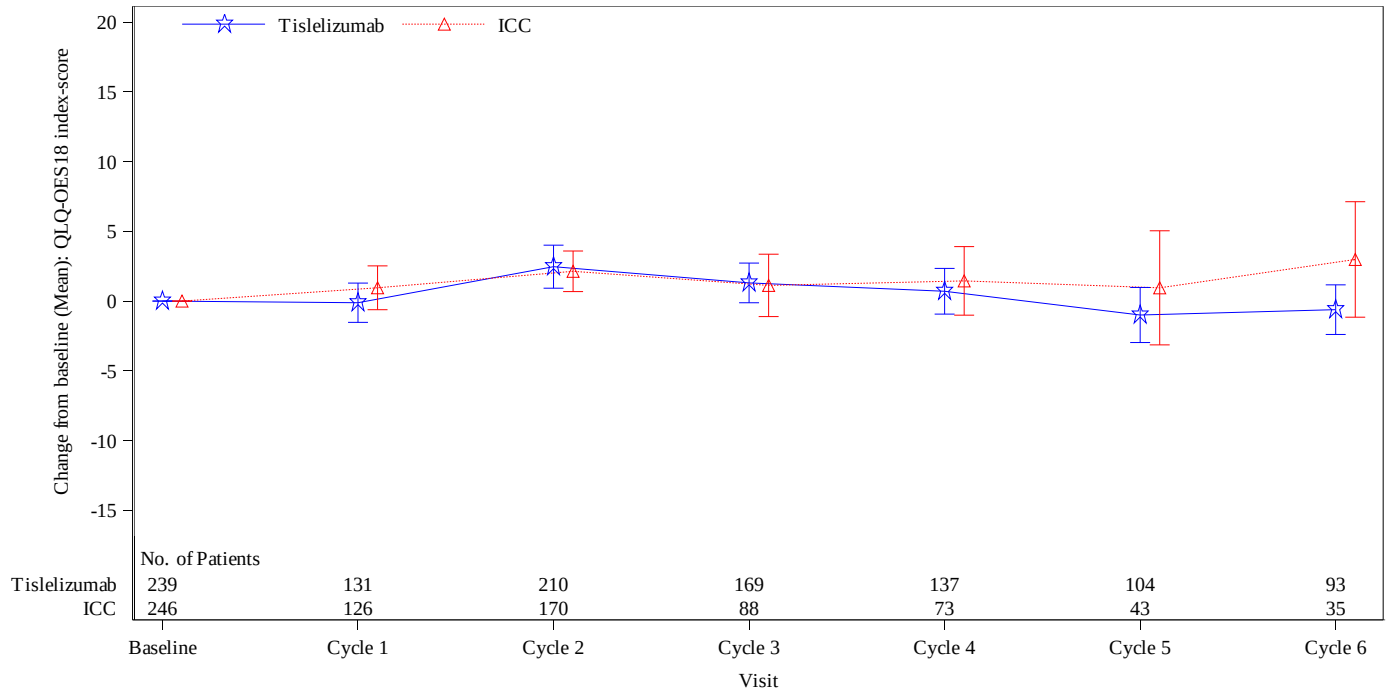
Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-tte-qlq.sas 16MAY2024 03:12 t-14-02-06-03-01-02-b-eff-tte-qlq-o18-itts-fa.rtf

Table 14.2.6.3.1.2.b:
Analyses of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Trouble With Coughing	139	26 (18.7)	NR (NE, NE)	138	18 (13.0)	NR (4.9, NE)	1.379 (0.754, 2.521)	0.2929
Trouble Talking	139	17 (12.2)	NR (NE, NE)	138	6 (4.3)	NR (NE, NE)	2.605 (1.023, 6.633)	0.0368

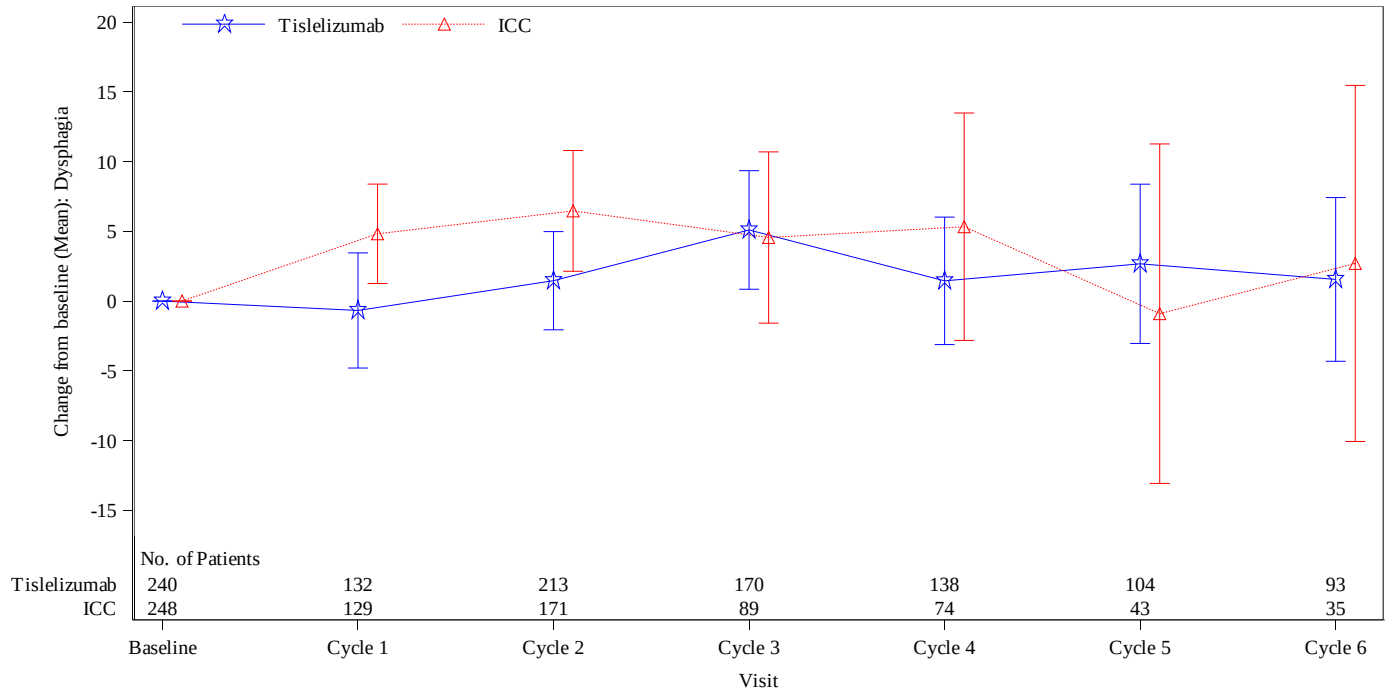
Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-tte-qlq.sas 16MAY2024 03:12 t-14-02-06-03-01-02-b-eff-tte-qlq-o18-itts-fa.rtf

Figure 14.2.7.2:
Summary of EORTC QLQ-OES18 Scores by Visit
ITT Analysis Set



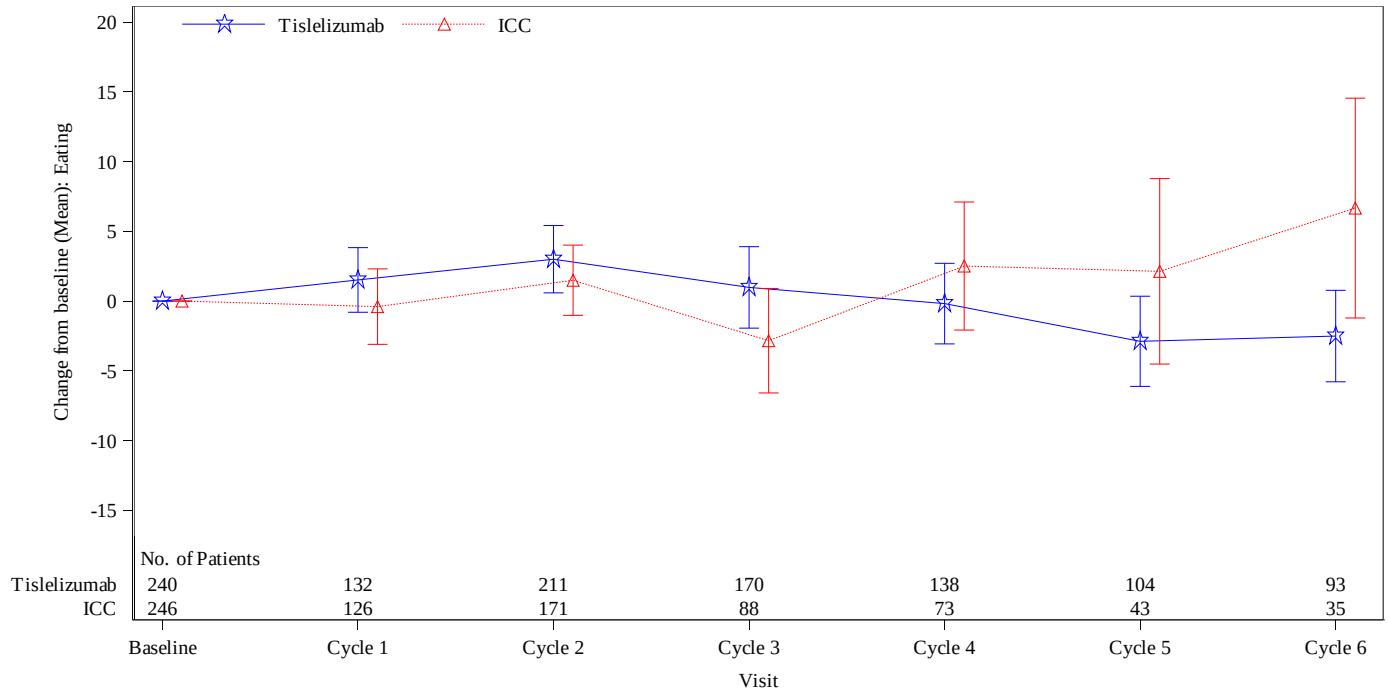
Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Datapoints represent means and 95% CI.
Increases in scores for index score, dysphagia, eating, reflux, pain, trouble swallowing saliva, choked when swallowing, dry mouth, trouble with taste, trouble with coughing and trouble talking are deteriorations for OES18.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-series.sas 15MAY2024 20:01 f-14-02-07-02-series-oes18-itt-fa.rtf

Figure 14.2.7.2:
Summary of EORTC QLQ-OES18 Scores by Visit
ITT Analysis Set



Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Datapoints represent means and 95% CI.
Increases in scores for index score, dysphagia, eating, reflux, pain, trouble swallowing saliva, choked when swallowing, dry mouth, trouble with taste, trouble with coughing and trouble talking are deteriorations for OES18.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-series.sas 15MAY2024 20:01 f-14-02-07-02-series-oes18-itt-fa.rtf

Figure 14.2.7.2:
Summary of EORTC QLQ-OES18 Scores by Visit
ITT Analysis Set



Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
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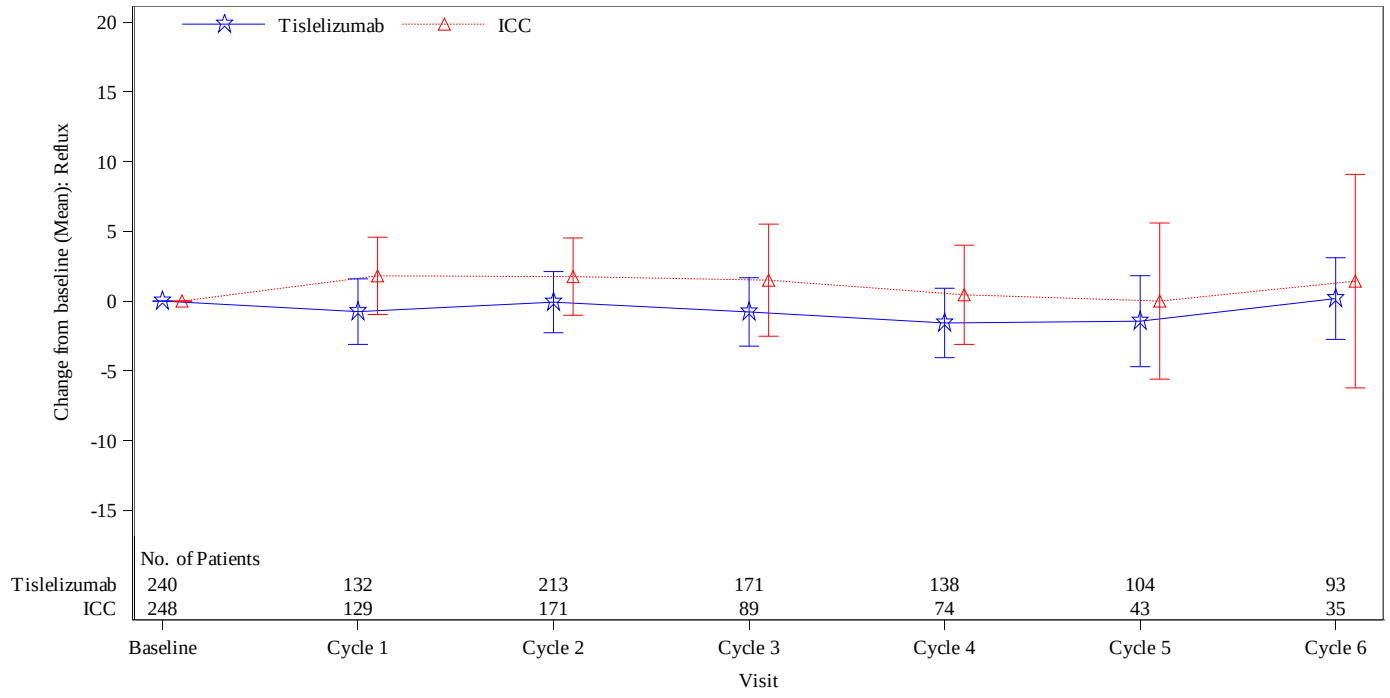

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
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Figure 14.2.7.2:
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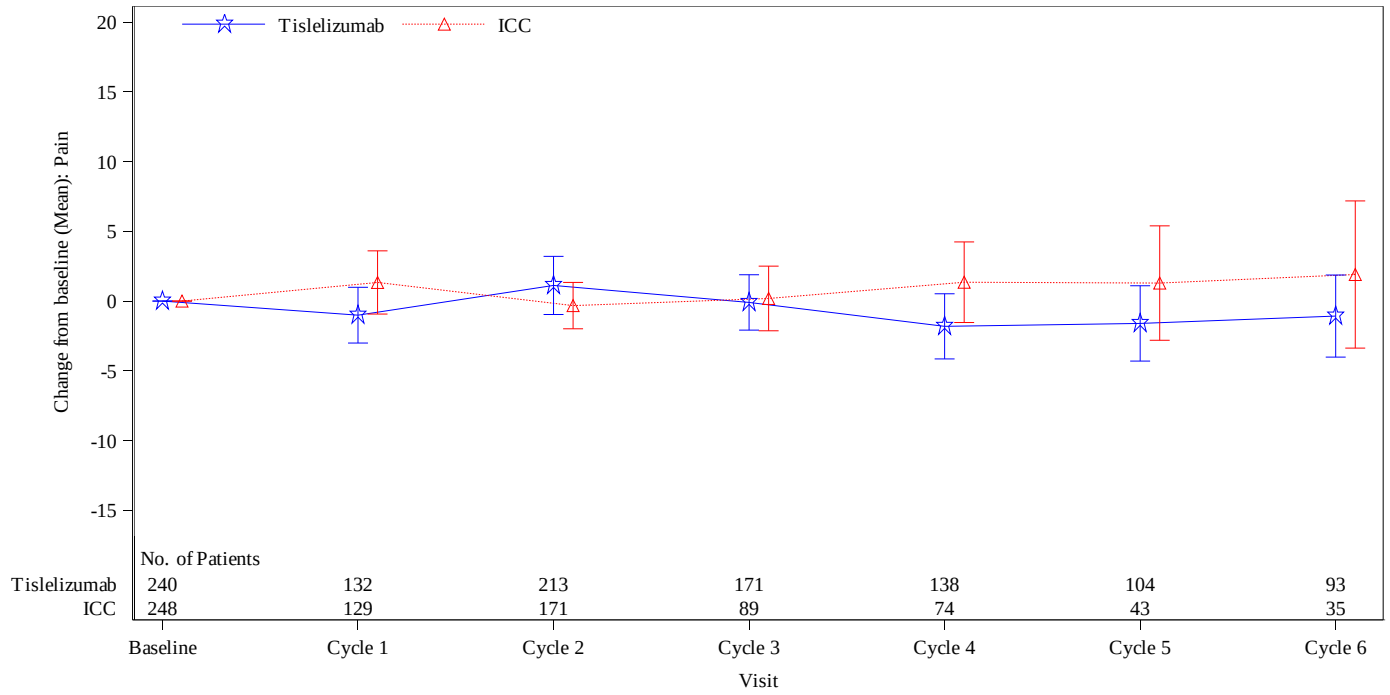

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
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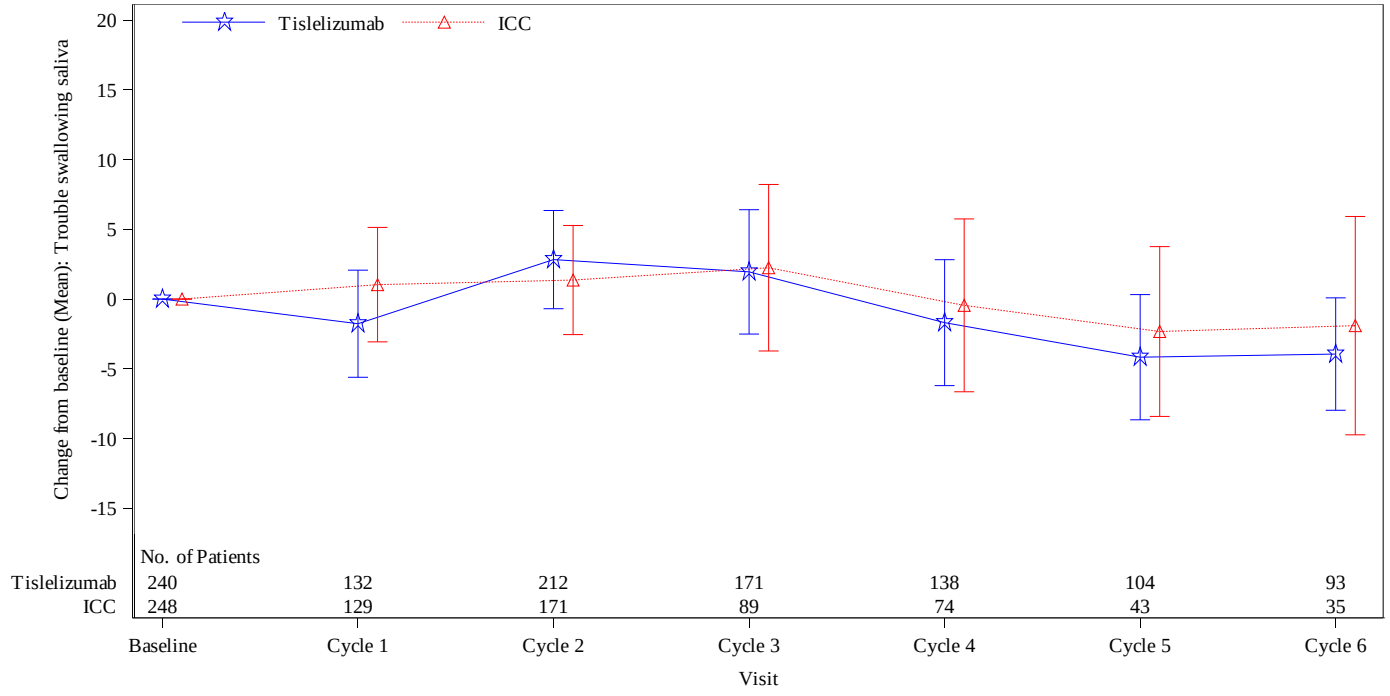
ITT Analysis Set



Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
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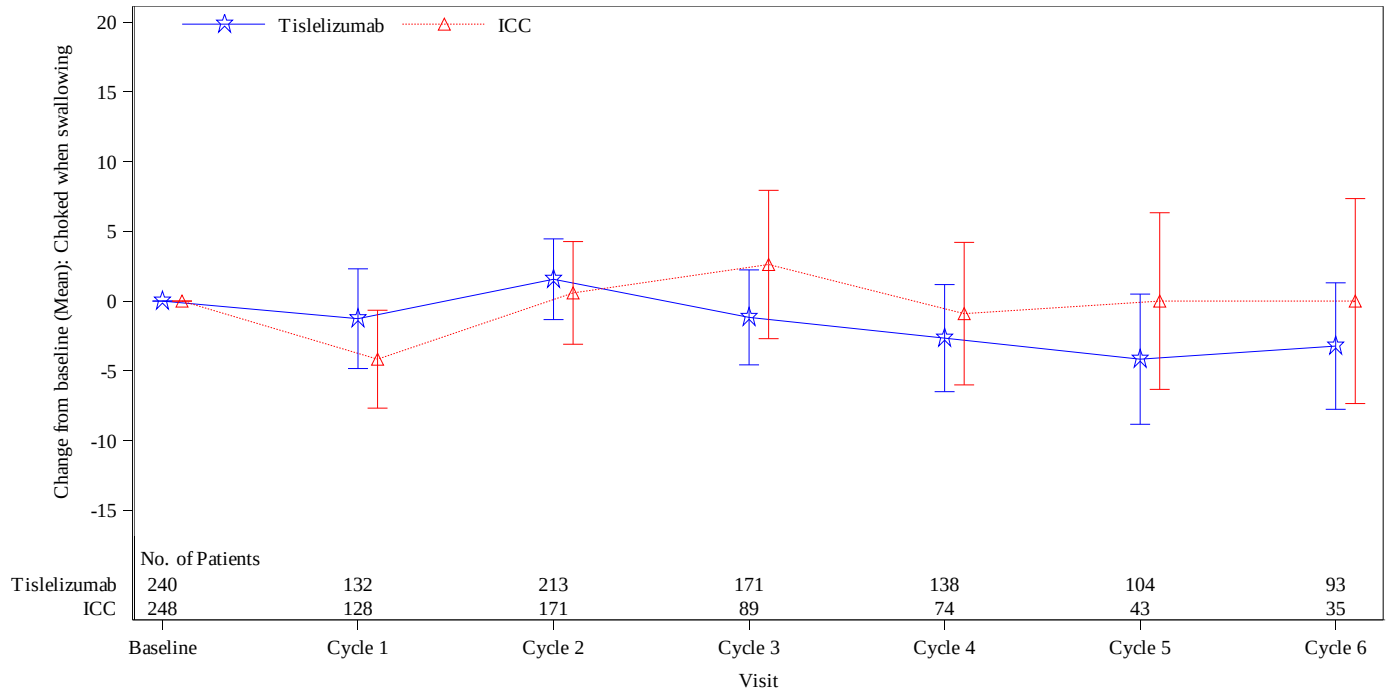

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
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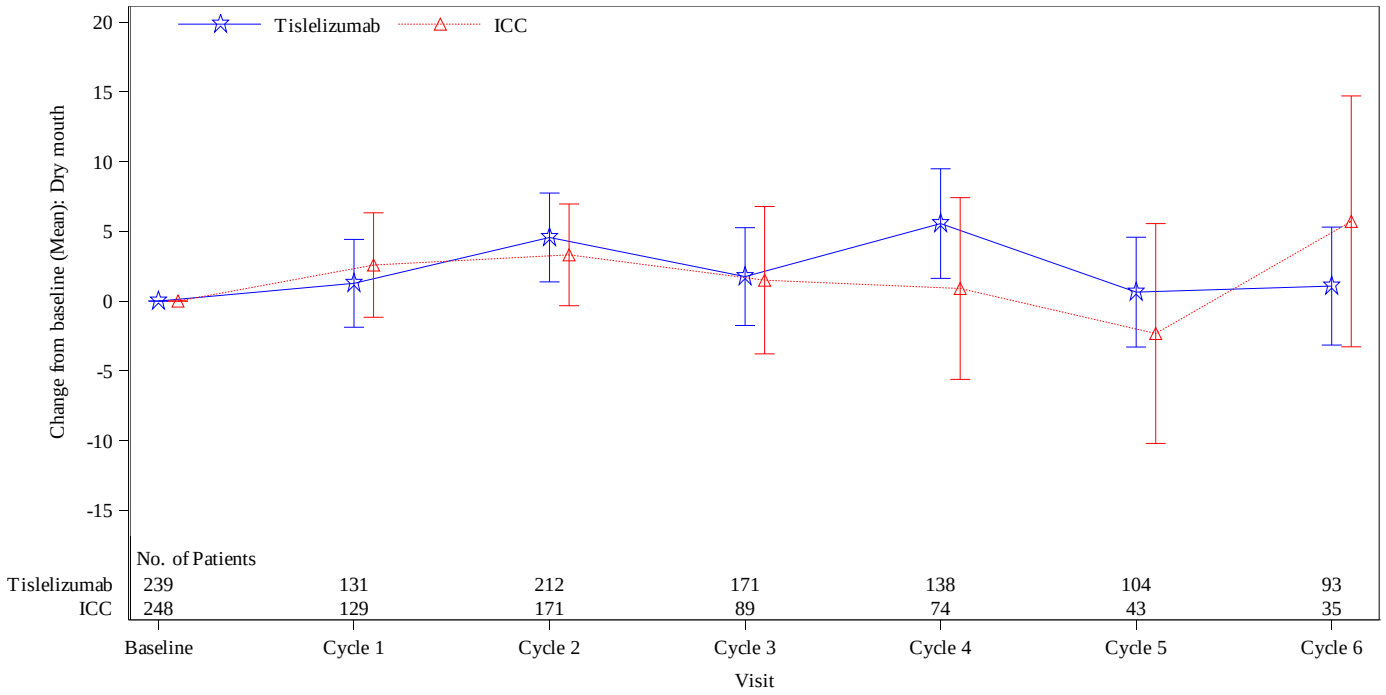

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
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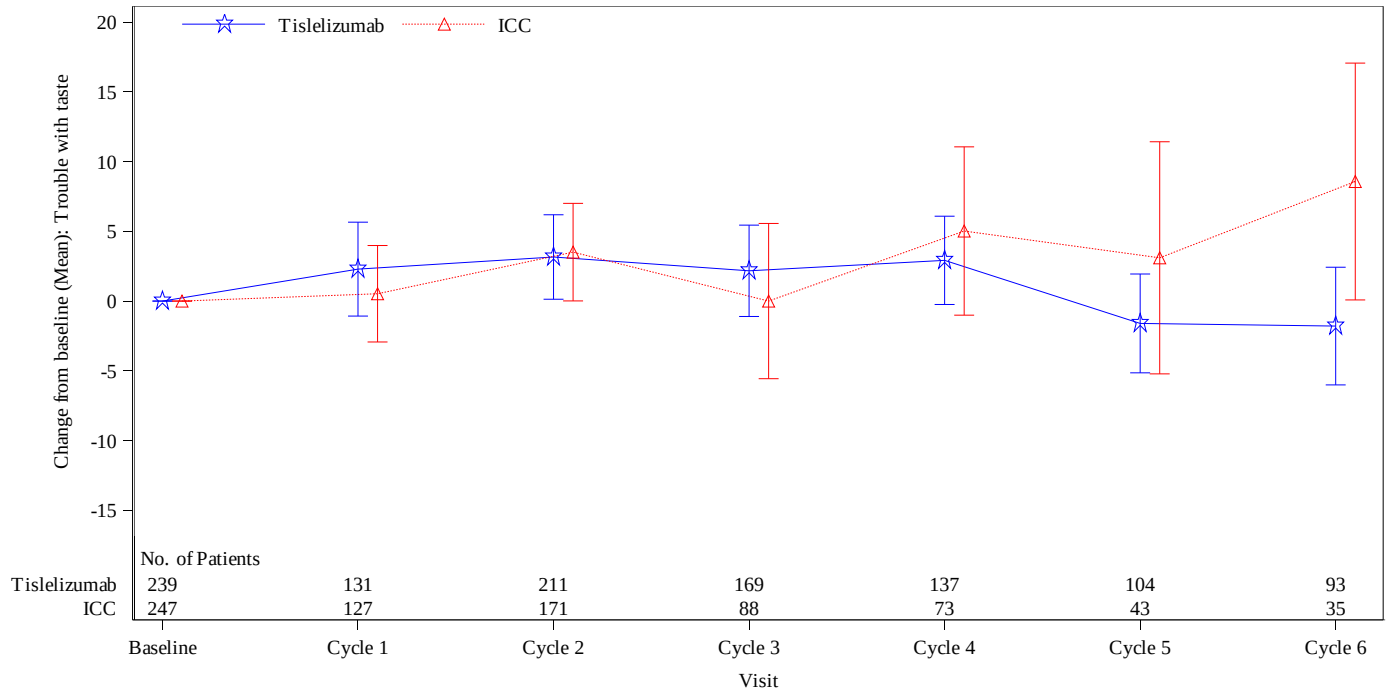

Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
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unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-series.sas 15MAY2024 20:01 f-14-02-07-02-series-oes18-itt-fa.rtf

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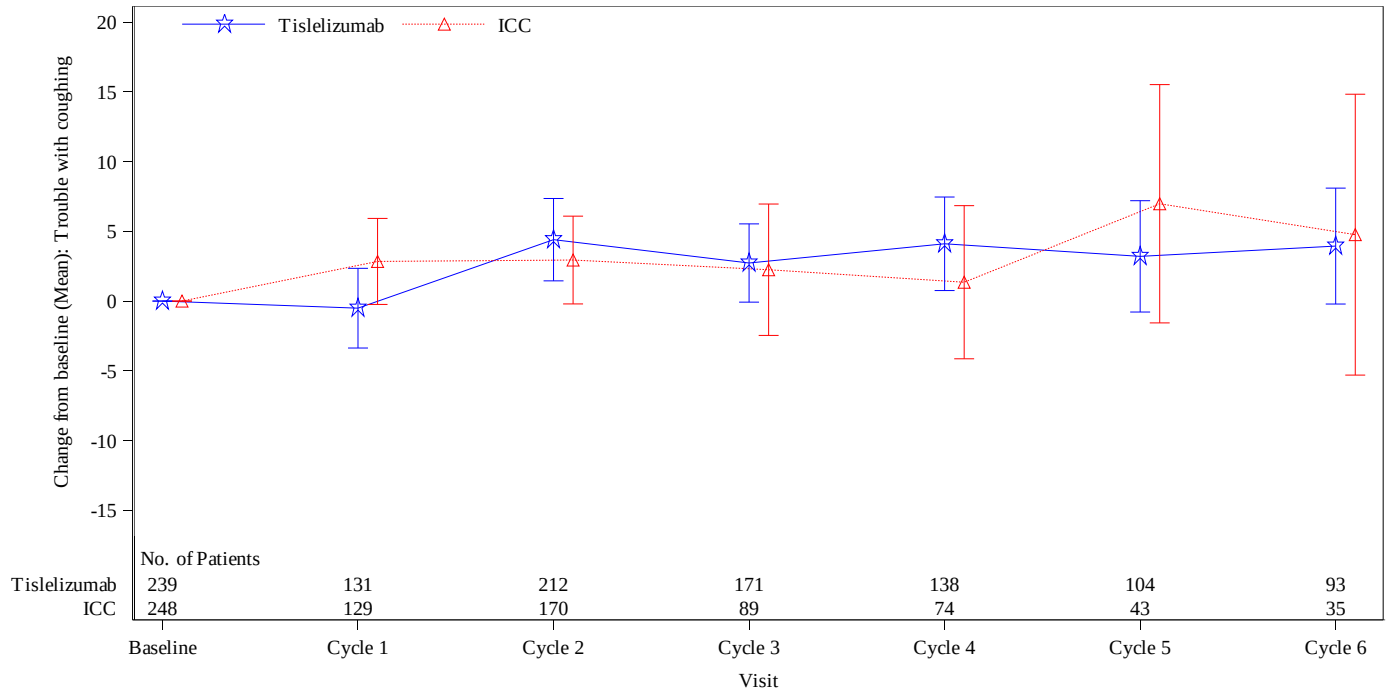
ITT Analysis Set



Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
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unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-series.sas 15MAY2024 20:01 f-14-02-07-02-series-oes18-itt-fa.rtf

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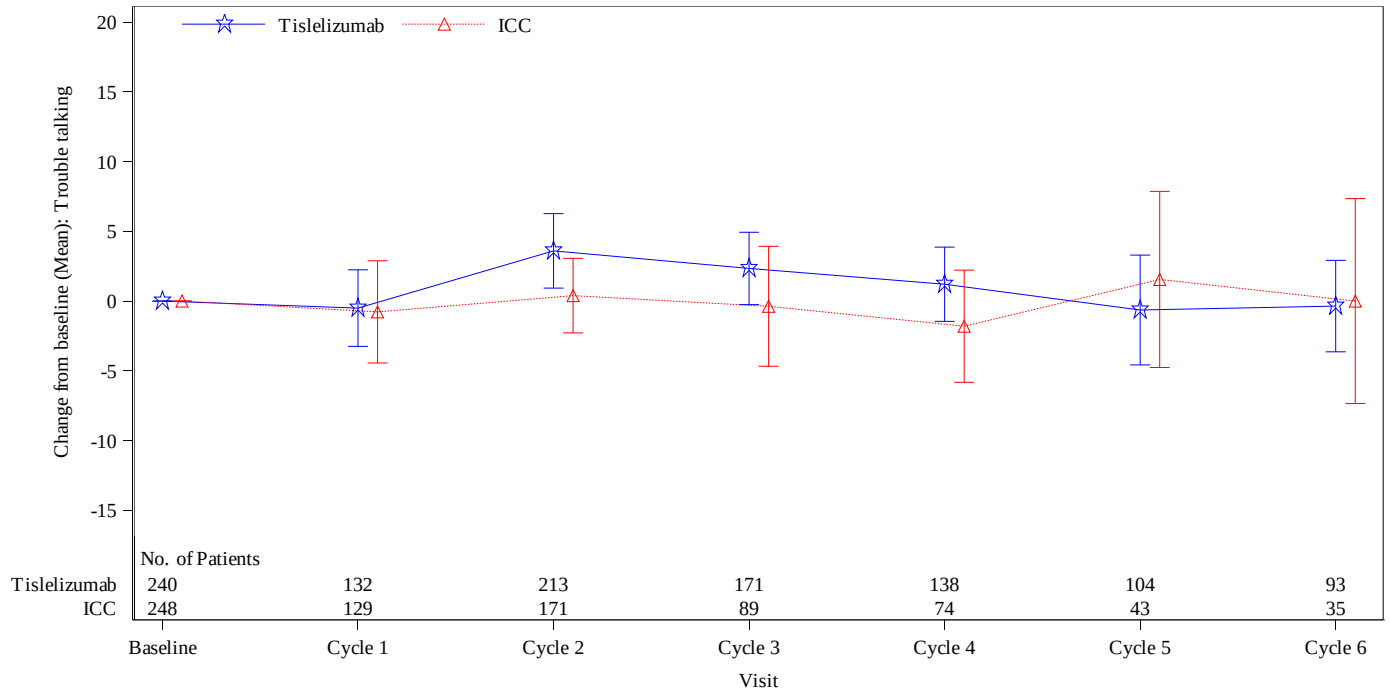
ITT Analysis Set



Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
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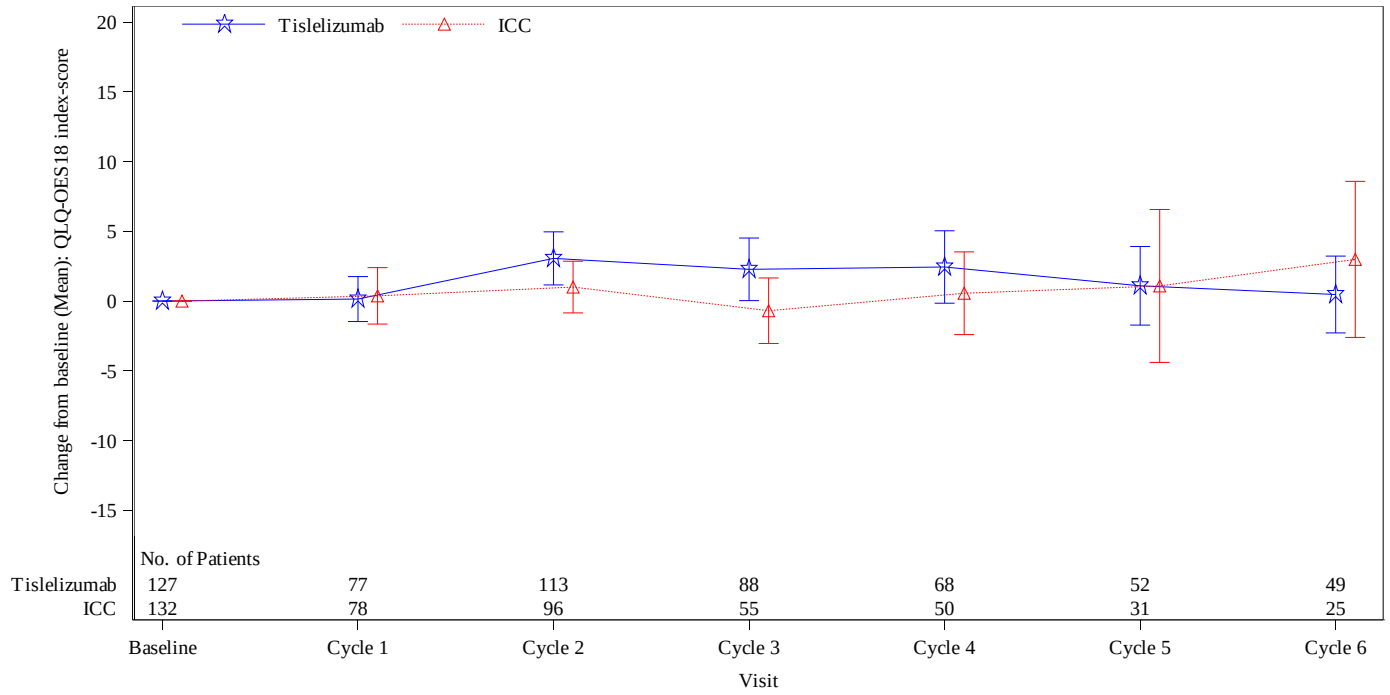
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-series.sas 15MAY2024 20:01 f-14-02-07-02-series-oes18-itt-fa.rtf

Figure 14.2.7.2.b:
Summary of EORTC QLQ-OES18 Scores by Visit
ITT Analysis Set - Subpopulation without Irinotecan



Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
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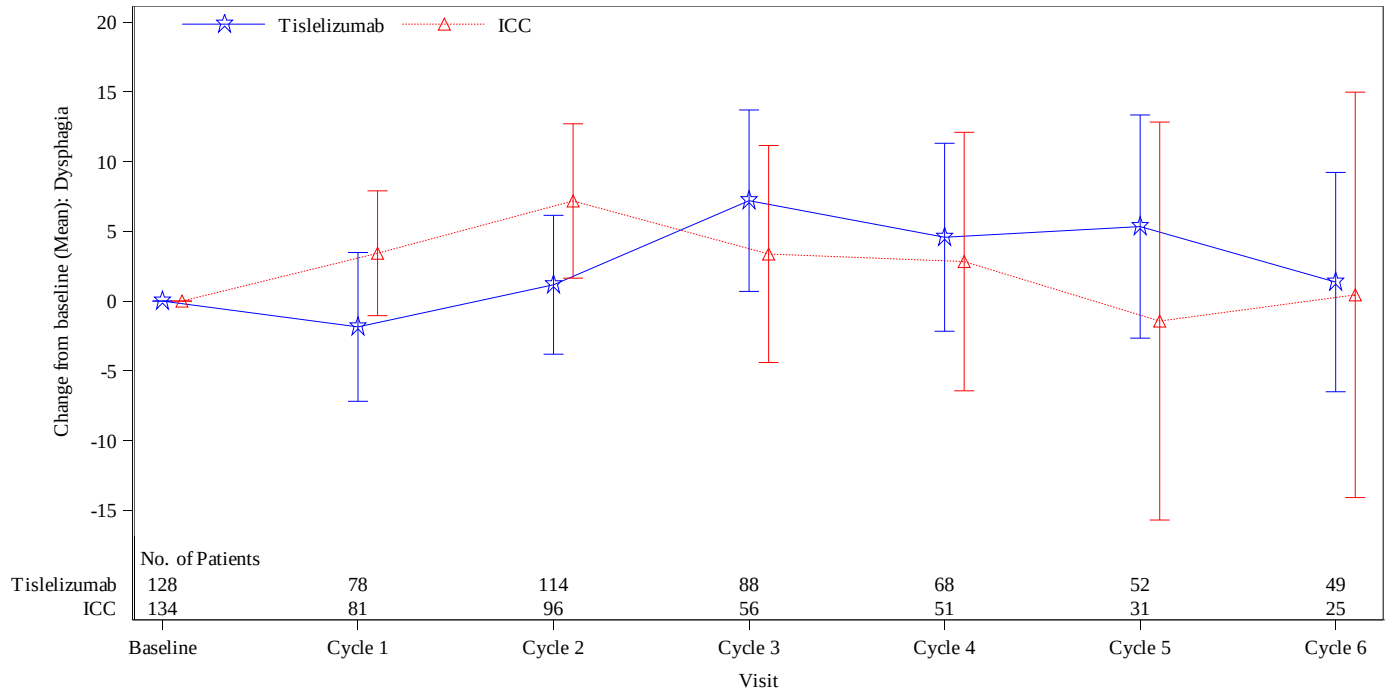
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-series.sas 15MAY2024 20:01 f-14-02-07-02-b-series-oes18-itts-fa.rtf

Figure 14.2.7.2.b:
Summary of EORTC QLQ-OES18 Scores by Visit
ITT Analysis Set - Subpopulation without Irinotecan



Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
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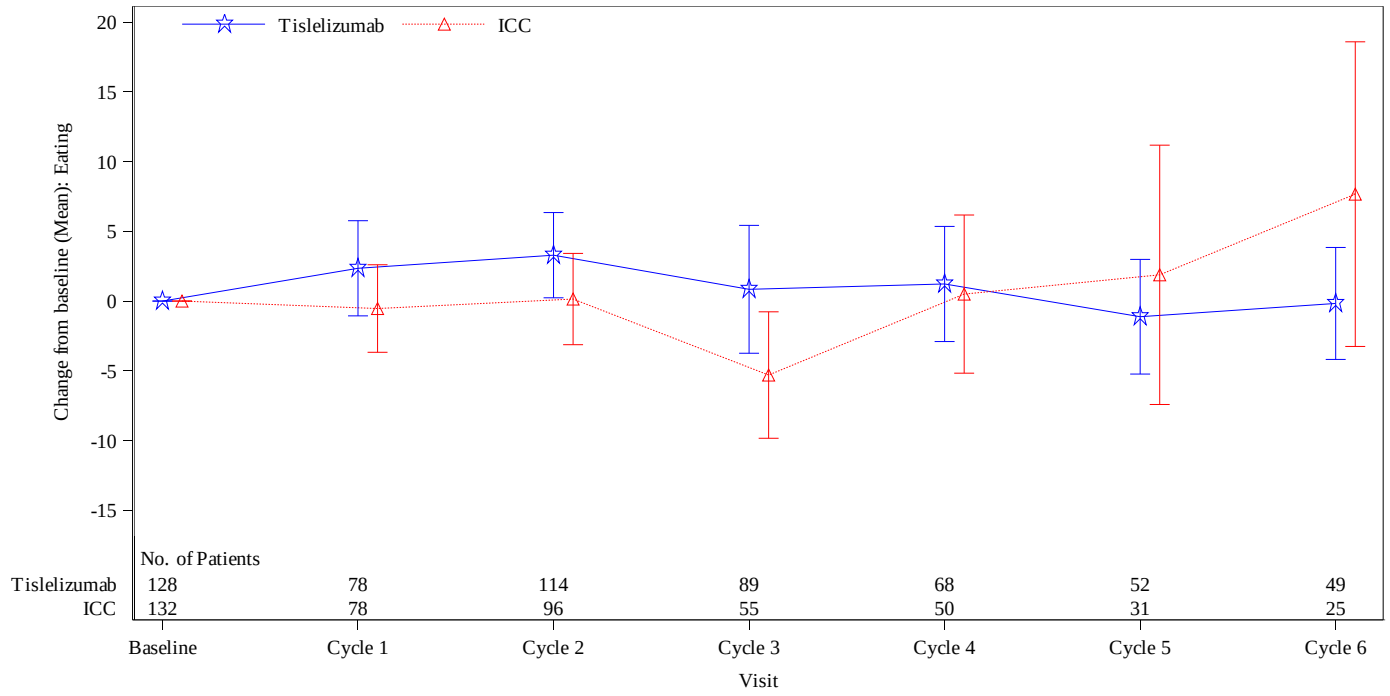
Figure 14.2.7.2.b:
Summary of EORTC QLQ-OES18 Scores by Visit
ITT Analysis Set - Subpopulation without Irinotecan



Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
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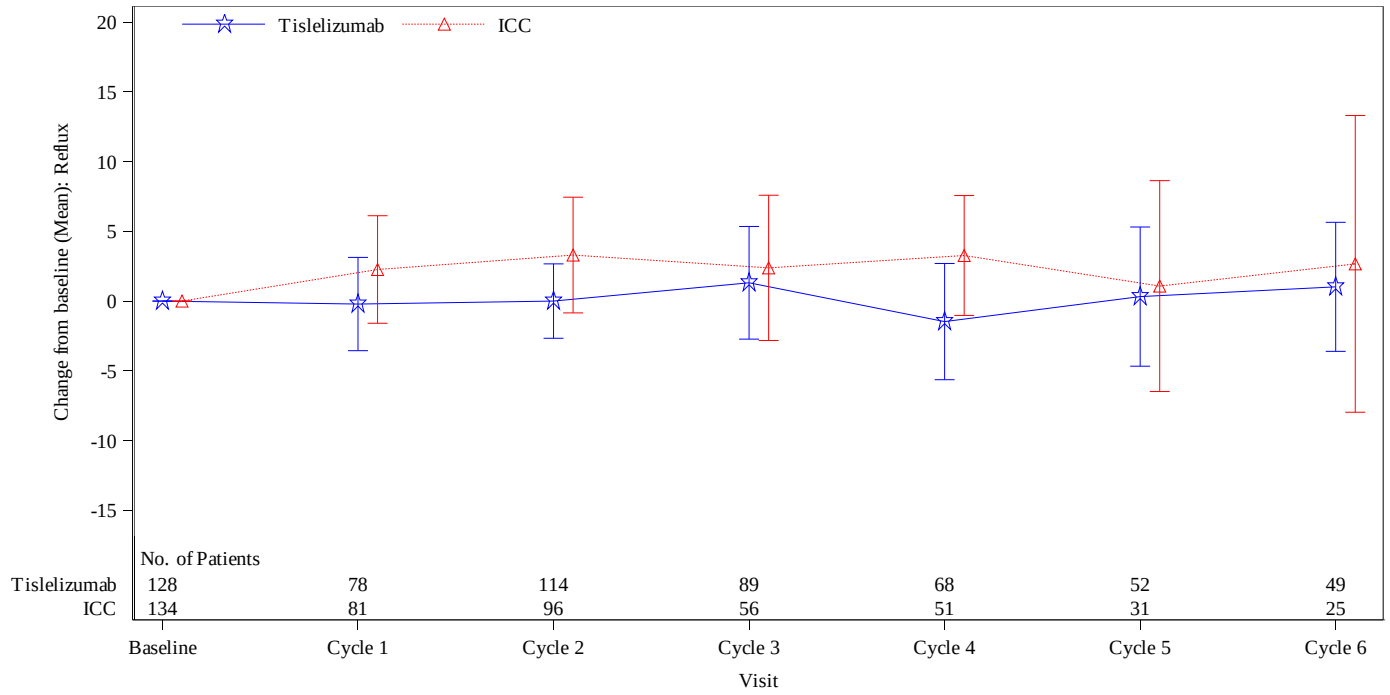

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Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
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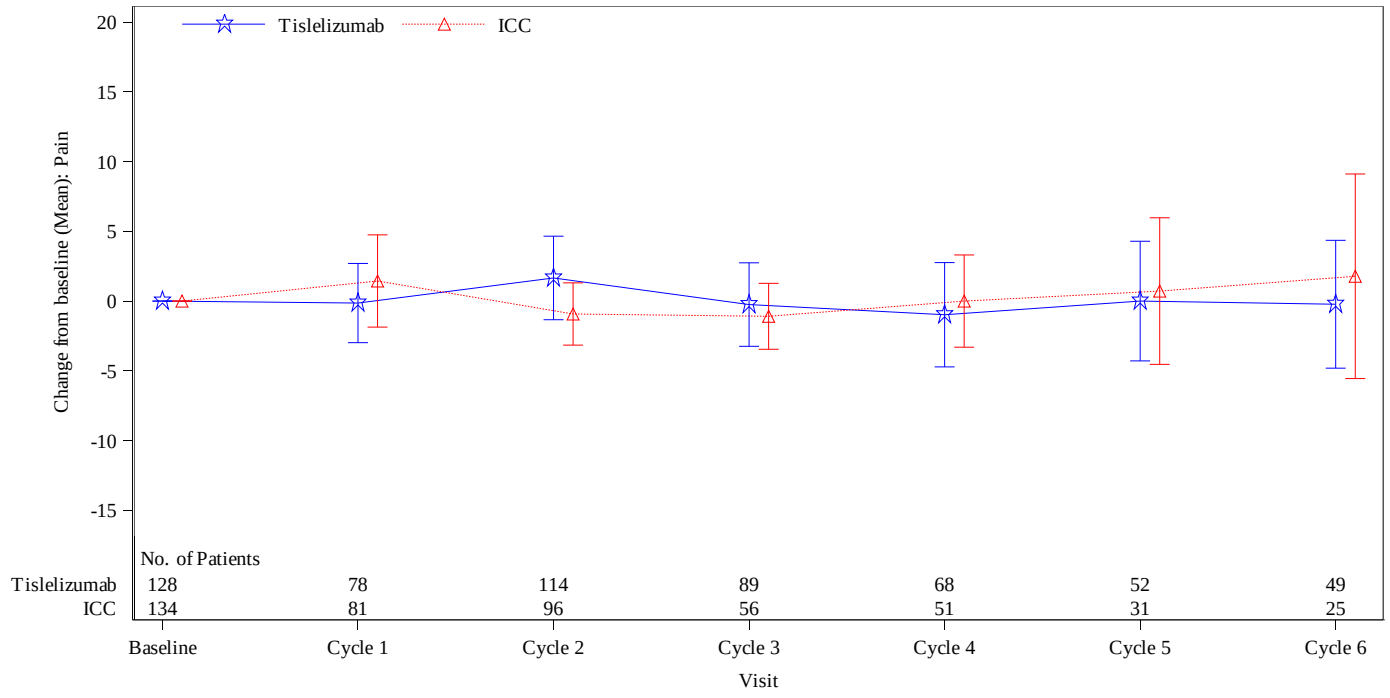

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Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
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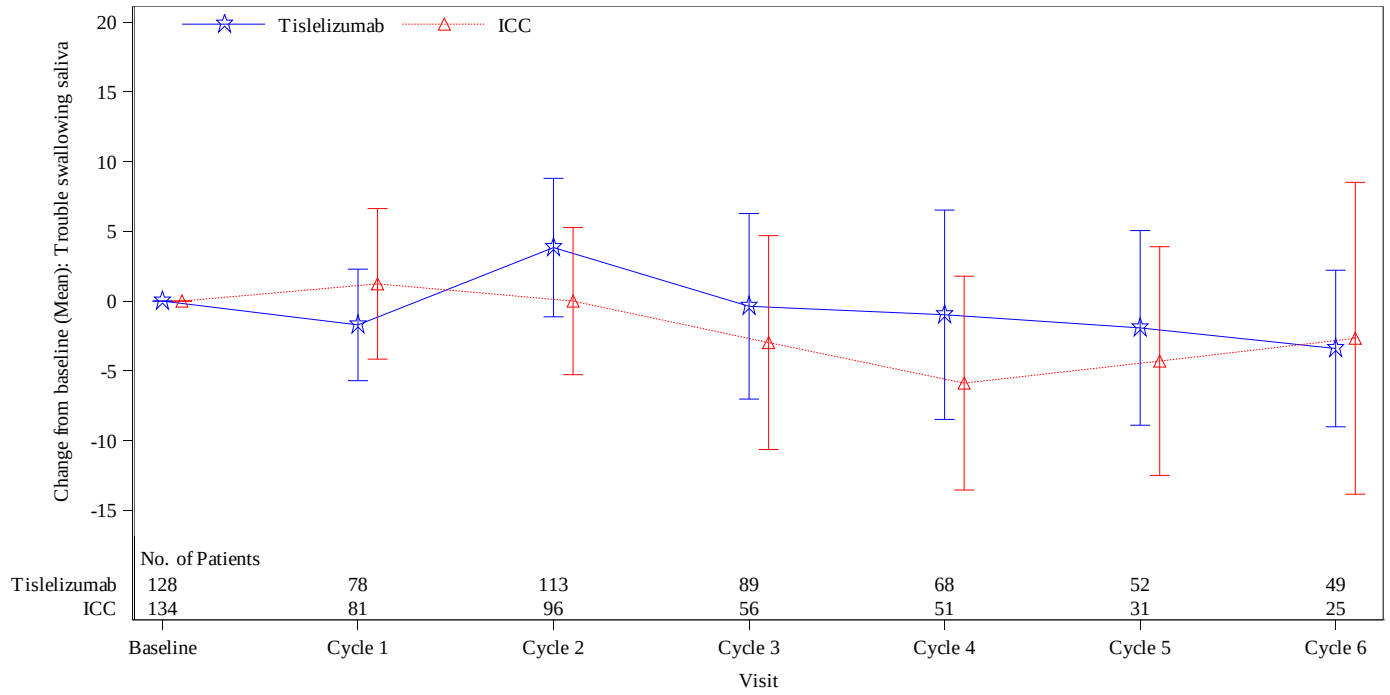
ITT Analysis Set - Subpopulation without Irinotecan



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Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
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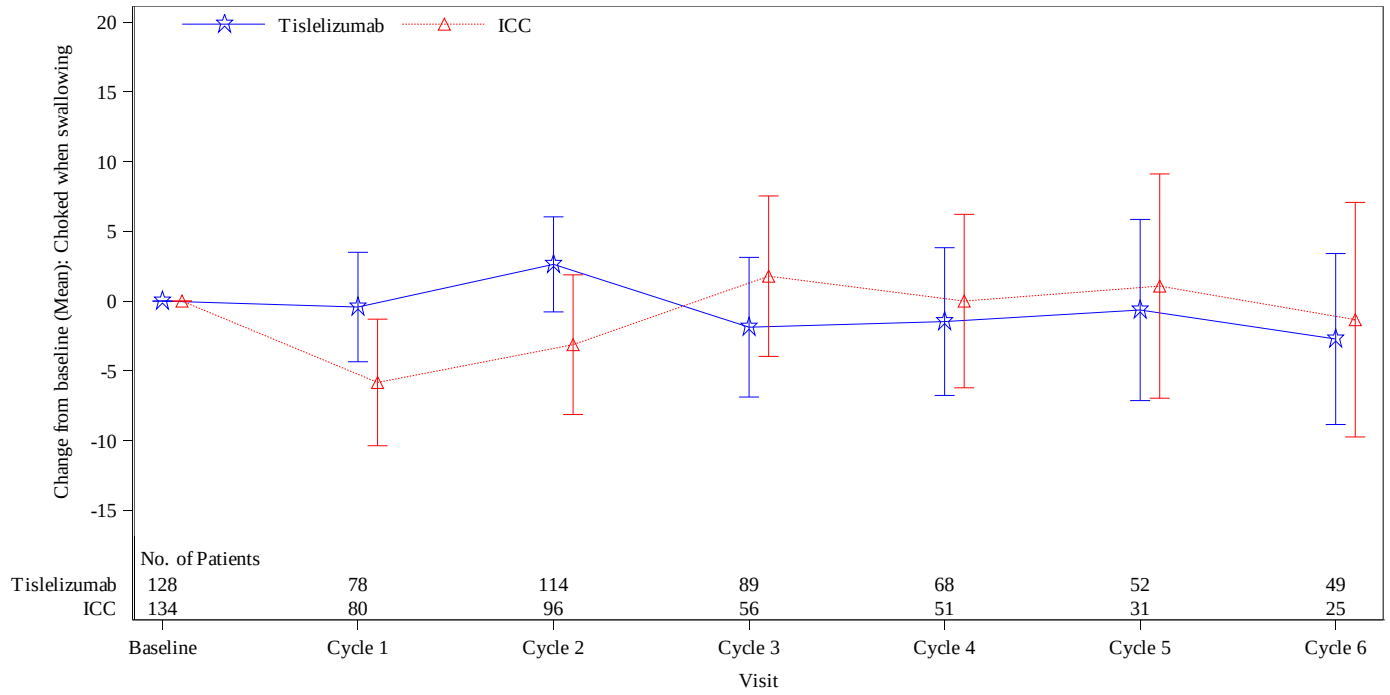

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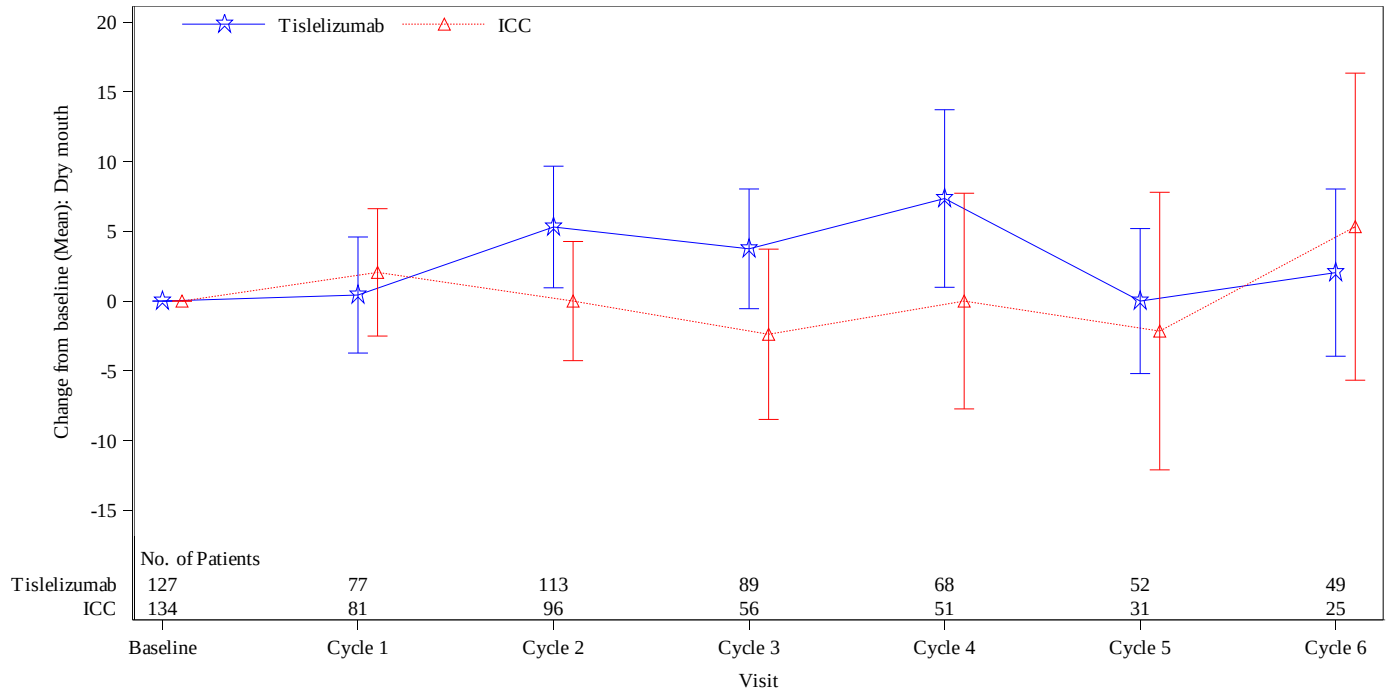
ITT Analysis Set - Subpopulation without Irinotecan



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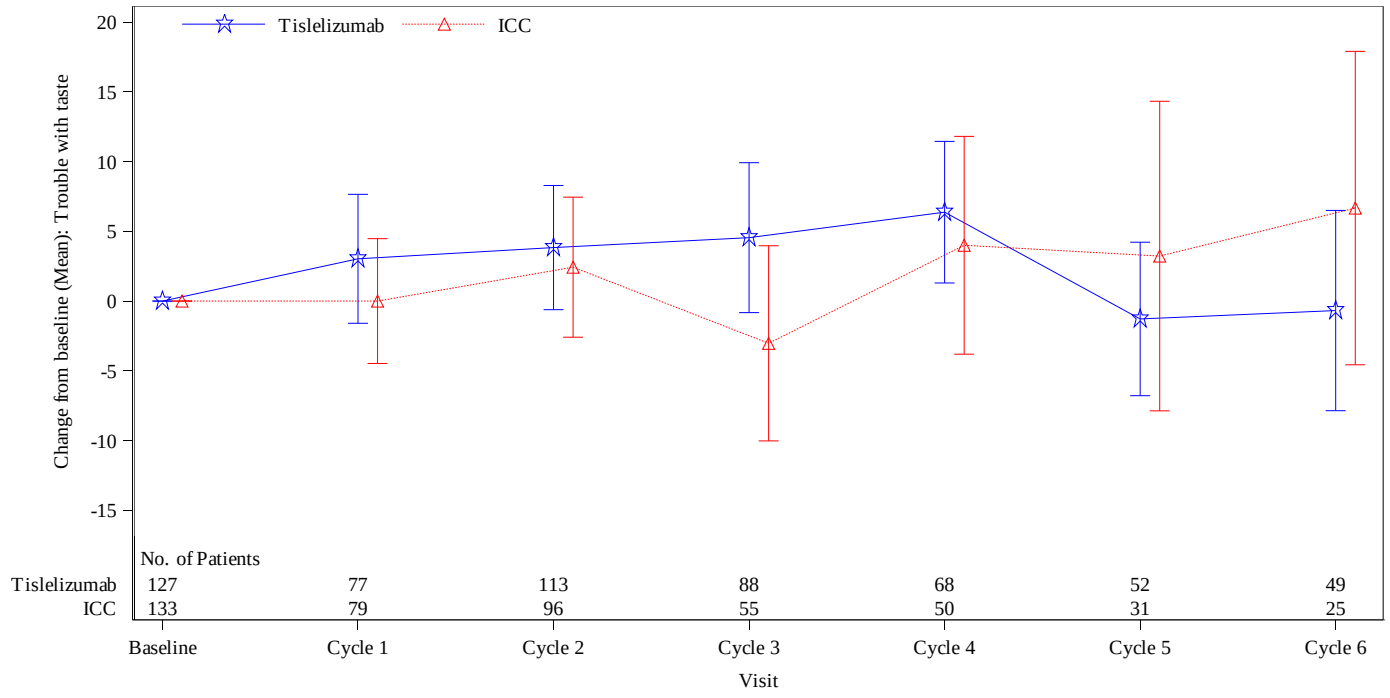
ITT Analysis Set - Subpopulation without Irinotecan



Source: Listing 16.2.6.6.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
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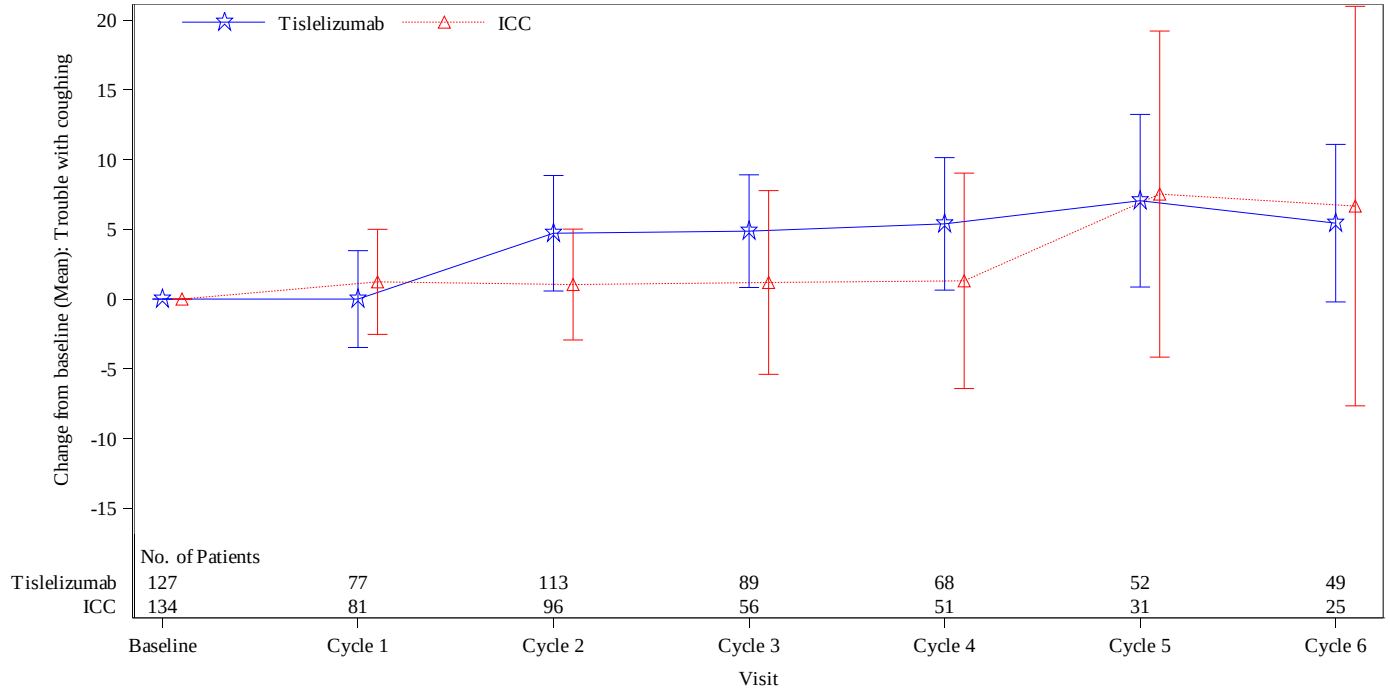
ITT Analysis Set - Subpopulation without Irinotecan



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ITT Analysis Set - Subpopulation without Irinotecan

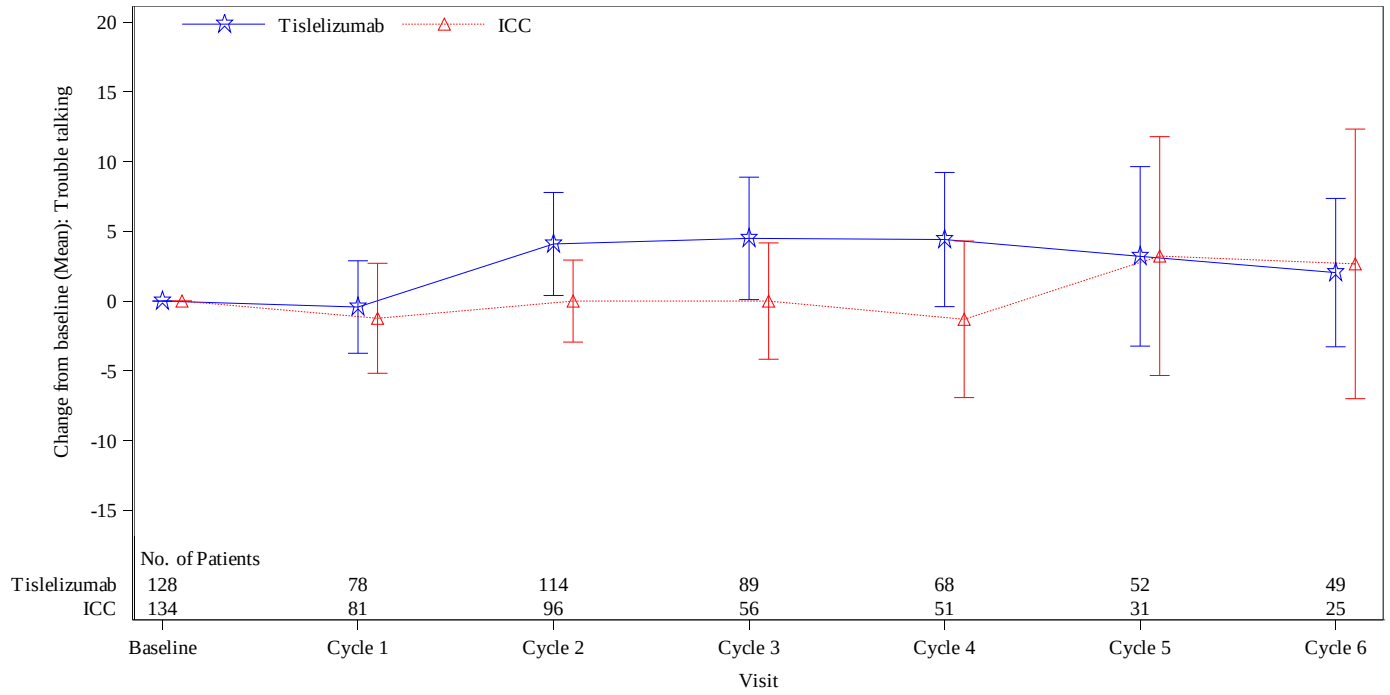

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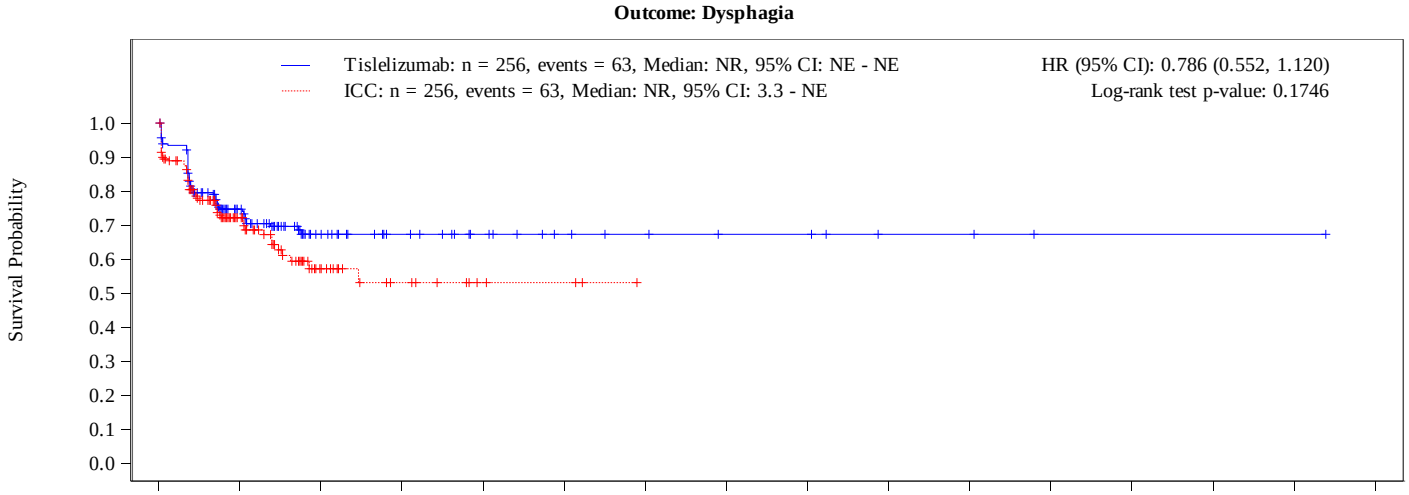
Figure 14.2.7.2.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set

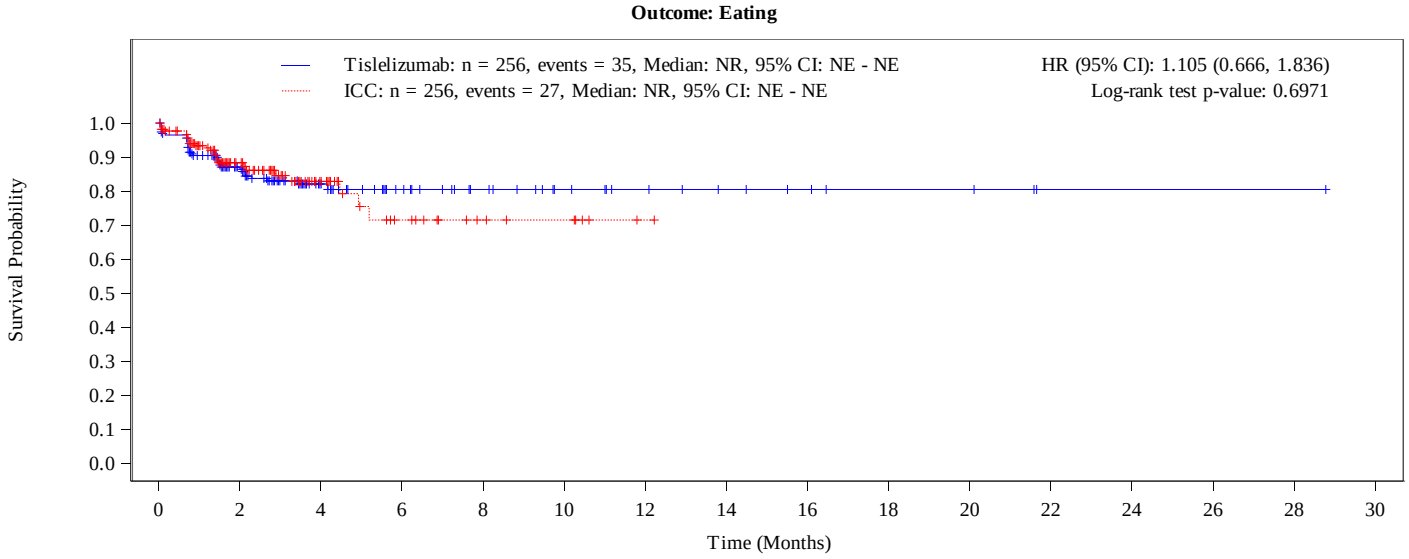


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	256	108	36	23	15	10	8	6	6	3	3	1	1	1	1	0
ICC	256	64	21	10	4	3	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-02-02-km-qs-o18-itt-fa.rtf

Figure 14.2.7.2.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set

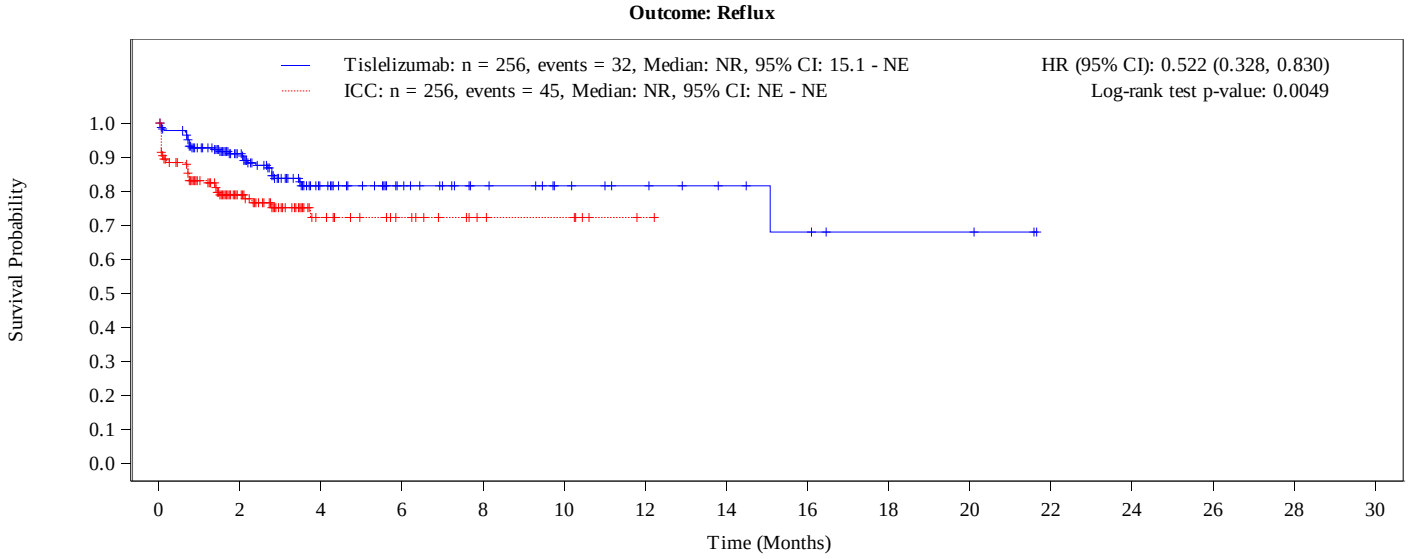


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	256	133	52	33	23	16	12	8	6	4	4	1	1	1	1	0
ICC	256	84	31	15	8	6	1	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-02-02-km-qs-o18-itt-fa.rtf

Figure 14.2.7.2.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set

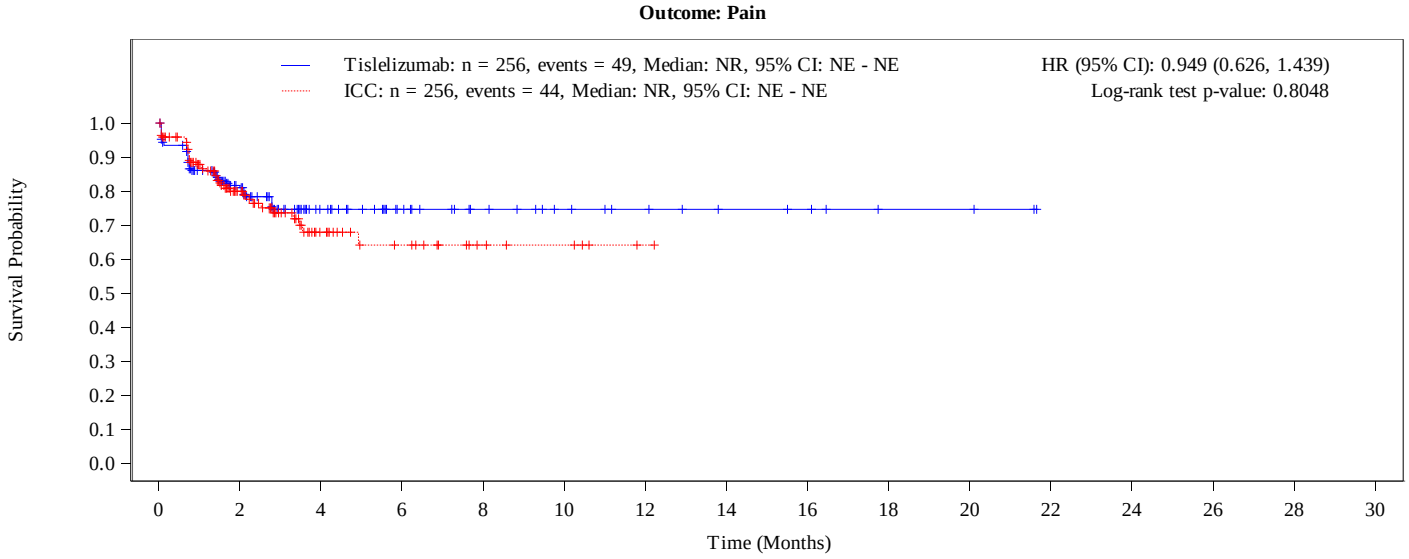


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	256	138	48	30	19	14	11	7	5	3	3	0	0	0	0	0
ICC	256	75	23	15	7	6	1	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-02-02-km-qs-o18-itt-fa.rtf

Figure 14.2.7.2.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set

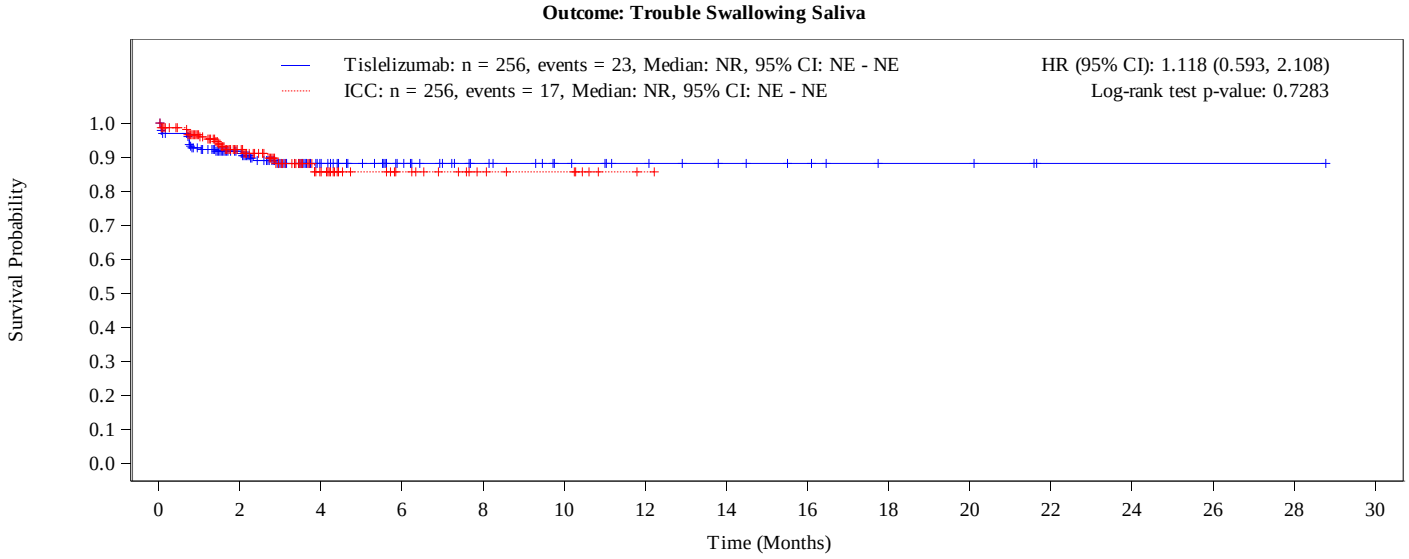


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	256	126	43	27	18	13	10	7	6	3	3	0	0	0	0	0
ICC	256	76	25	15	7	5	1	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-02-02-km-qs-o18-itt-fa.rtf

Figure 14.2.7.2.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set

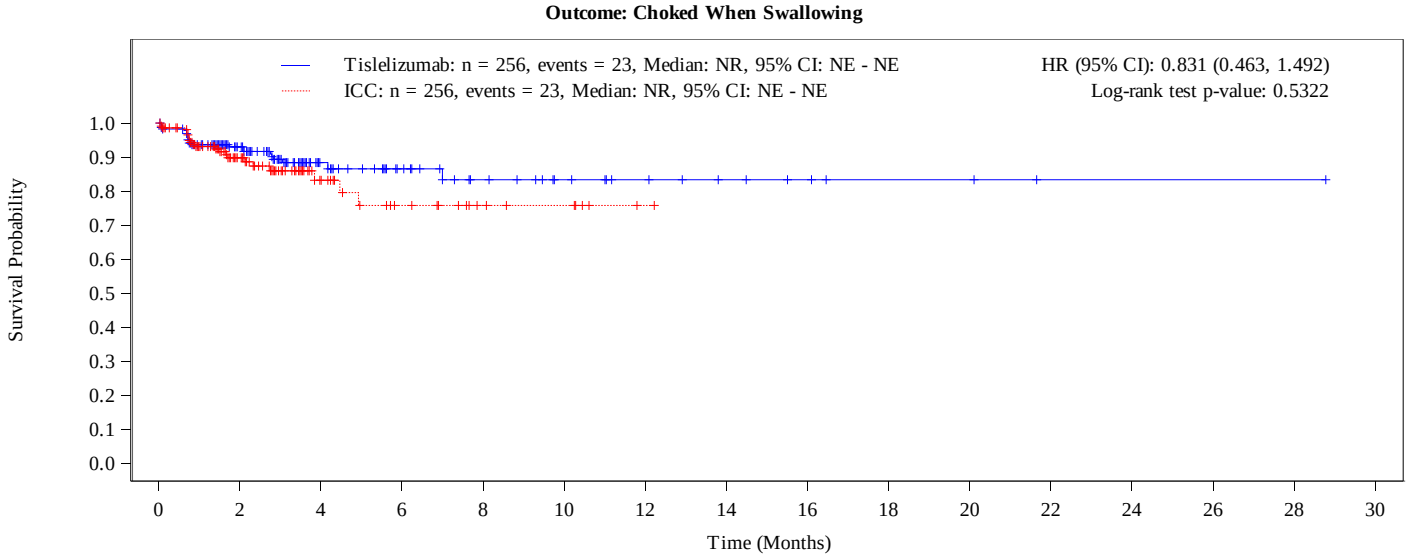


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	256	140	53	34	23	17	13	9	7	4	4	1	1	1	1	0
ICC	256	86	32	17	9	7	1	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-02-02-km-qs-o18-itt-fa.rtf

Figure 14.2.7.2.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set

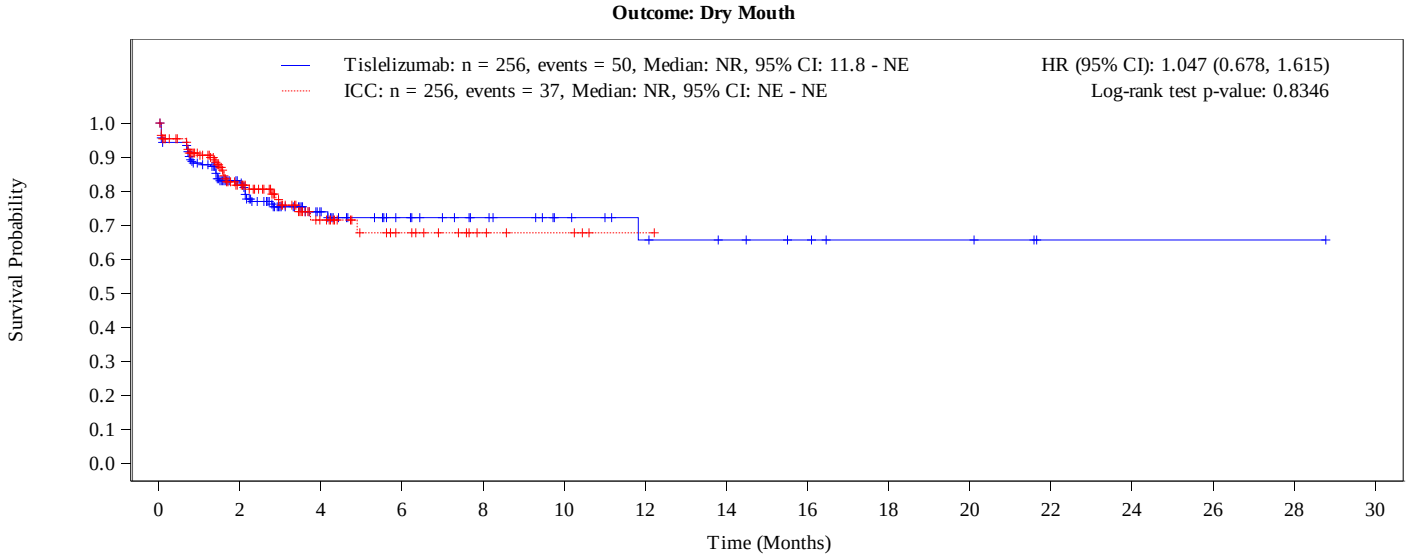


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	256	140	48	32	21	15	11	7	5	3	3	1	1	1	1	0
ICC	256	82	28	16	8	6	1	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-02-02-km-qs-o18-itt-fa.rtf

Figure 14.2.7.2.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set

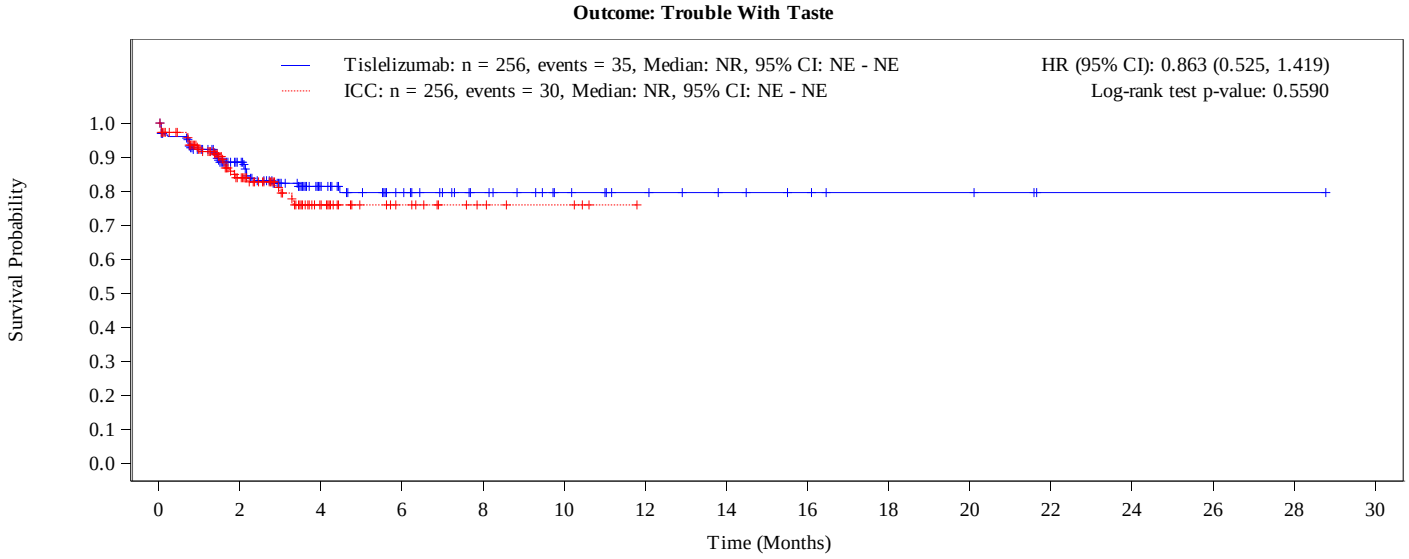


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	256	126	44	28	20	14	10	8	6	4	4	1	1	1	1	0
ICC	256	75	27	14	6	4	1	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-02-02-km-qs-o18-itt-fa.rtf

Figure 14.2.7.2.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set

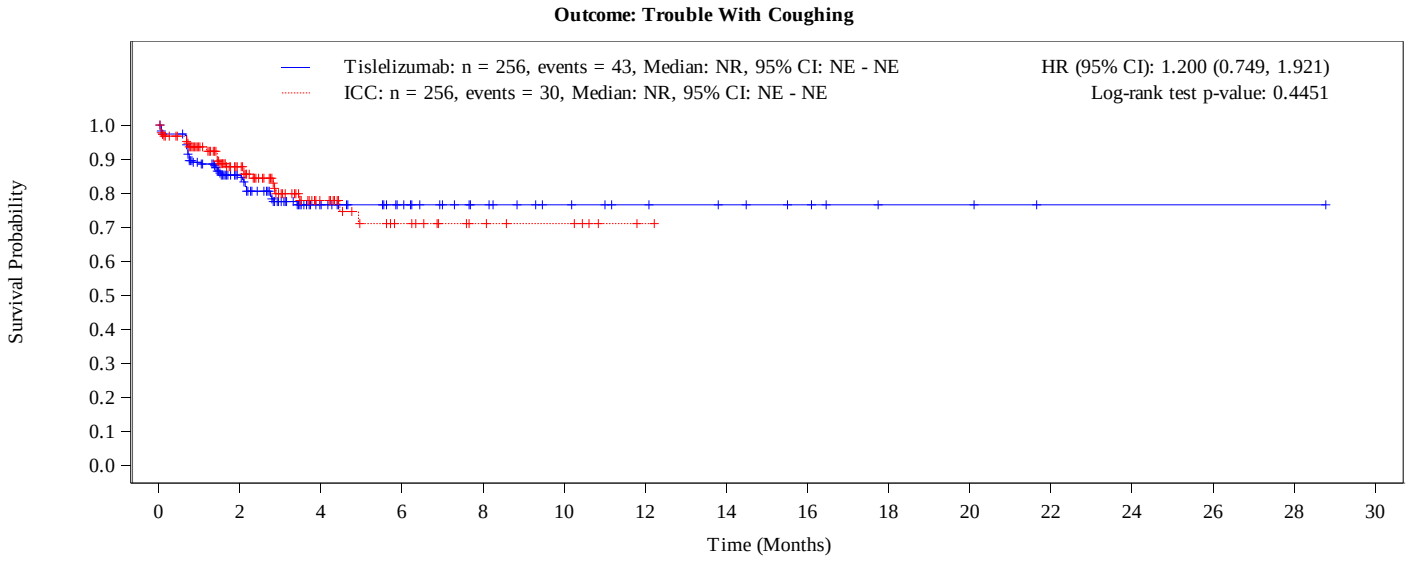


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	256	136	51	33	23	16	12	8	6	4	4	1	1	1	1	0
ICC	256	78	27	13	6	4	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-02-02-km-qs-o18-itt-fa.rtf

Figure 14.2.7.2.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set

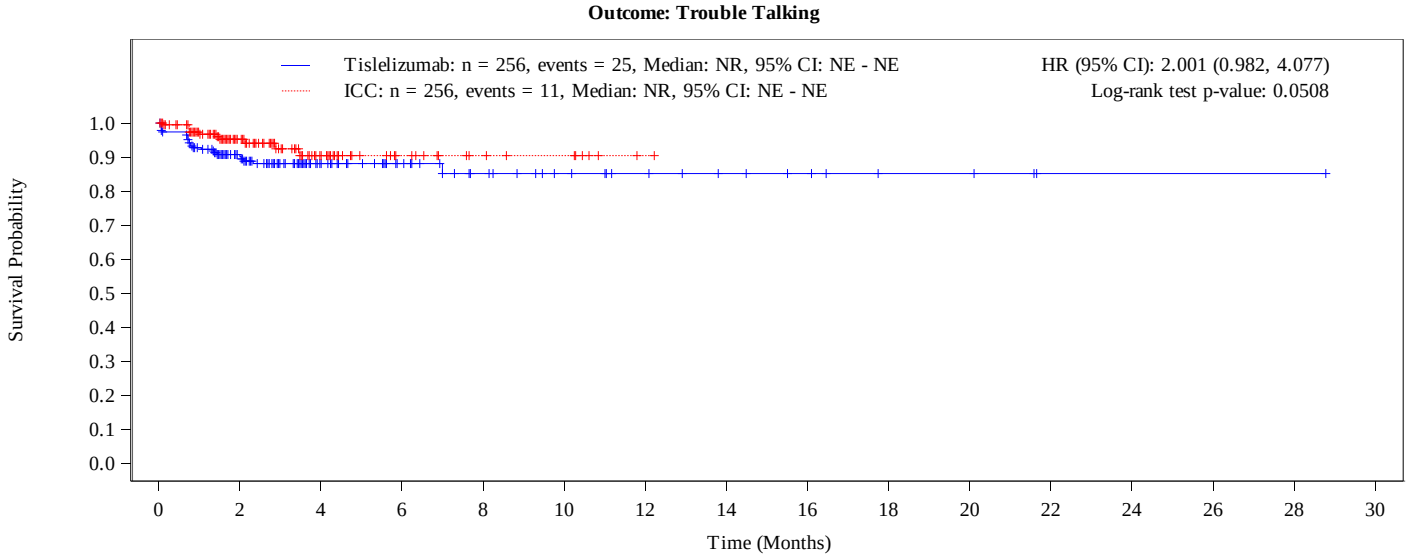


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	256	128	42	28	18	13	10	8	6	3	3	1	1	1	1	0
ICC	256	86	30	16	8	6	1	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-02-02-km-qs-o18-itt-fa.rtf

Figure 14.2.7.2.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set

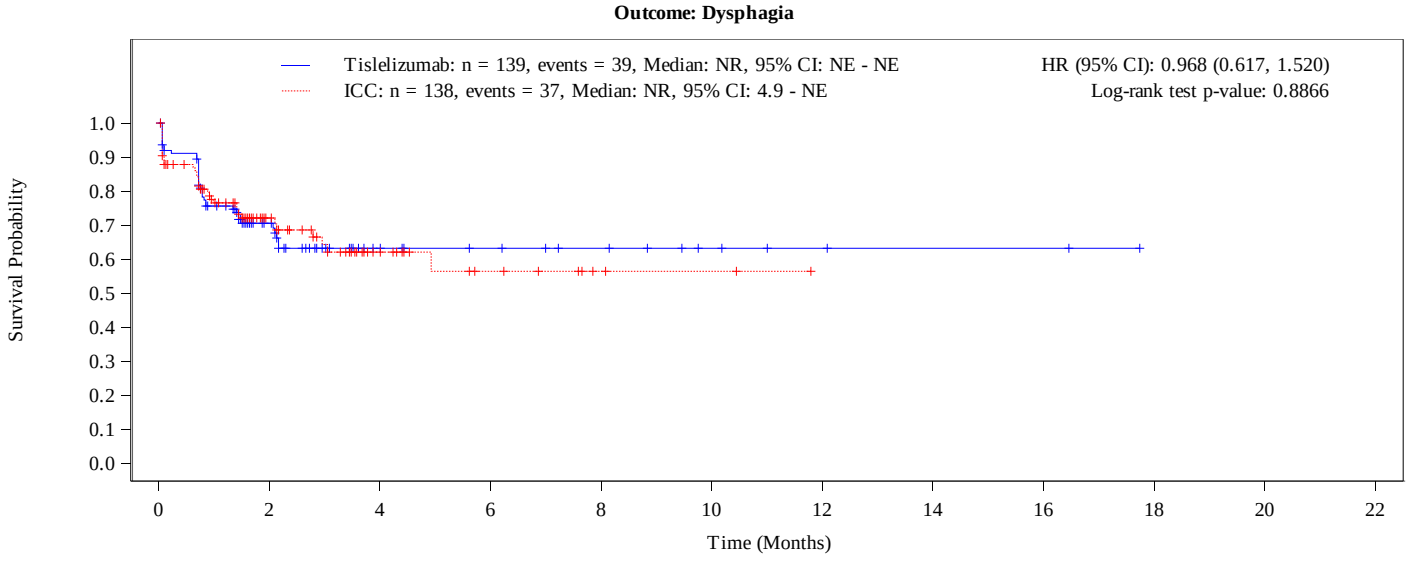


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	256	140	54	35	23	17	13	9	7	4	4	1	1	1	1	0
ICC	256	87	34	17	9	7	1	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-02-02-km-qs-o18-itt-fa.rtf

Figure 14.2.7.2.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation without Irinotecan

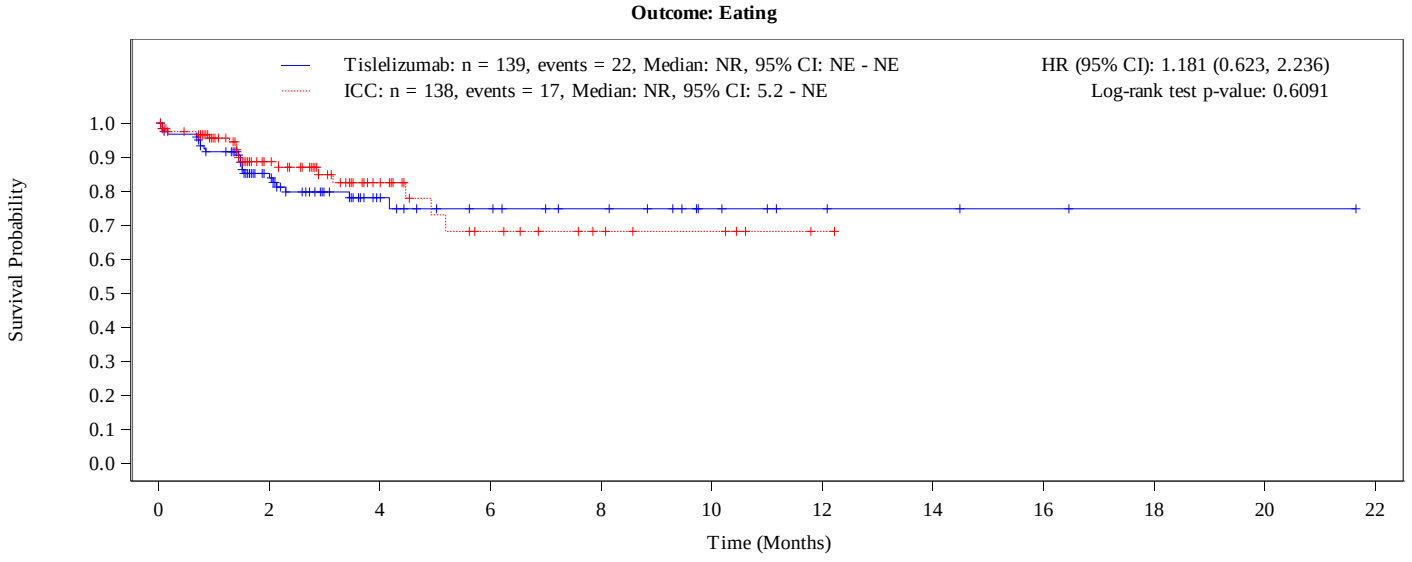


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	139	50	16	12	9	5	3	2	2	0	0	0
ICC	138	43	17	8	3	2	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-02-02-b-km-qs-o18-itts-fa.rtf

Figure 14.2.7.2.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation without Irinotecan

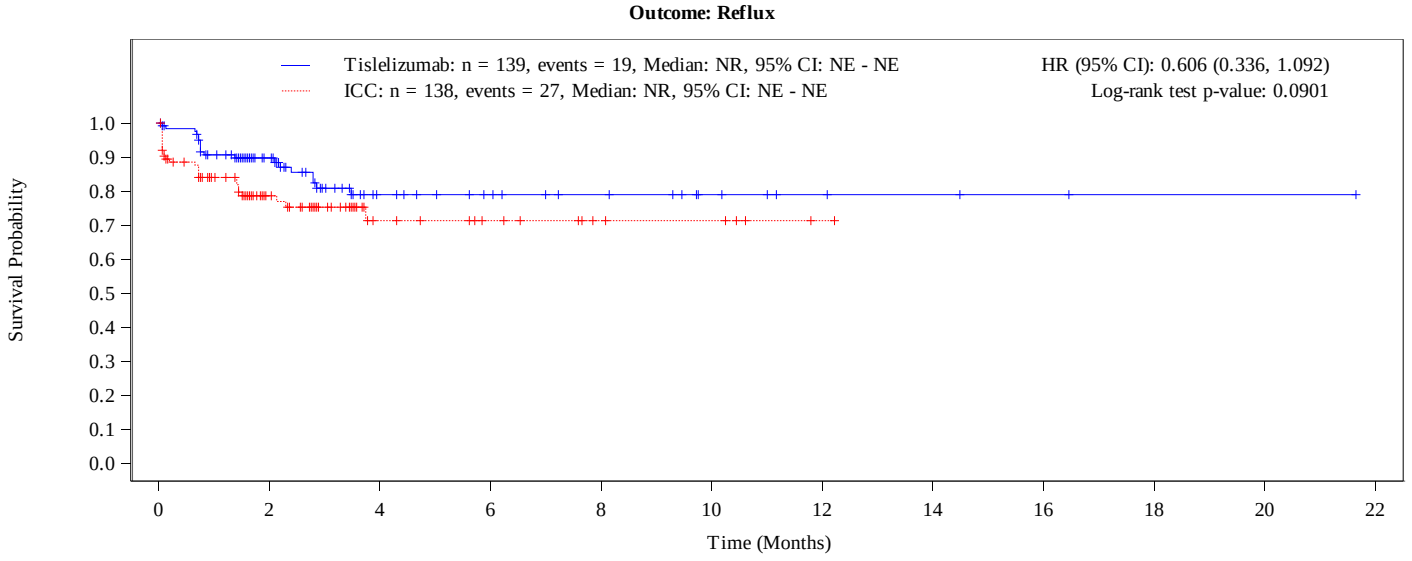


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	139	65	25	18	14	8	5	3	2	1	1	0
ICC	138	56	24	12	7	5	1	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-02-02-b-km-qs-o18-itts-fa.rtf

Figure 14.2.7.2.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation without Irinotecan

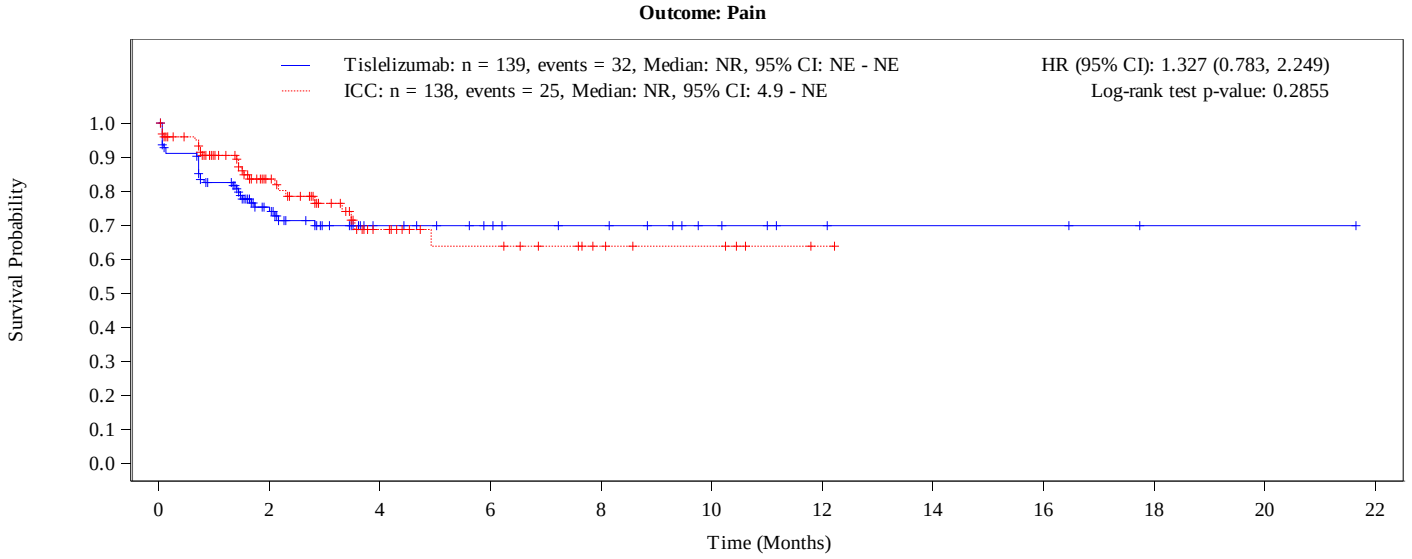


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	139	69	23	17	13	8	5	3	2	1	1	0
ICC	138	50	16	11	6	5	1	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-02-02-b-km-qs-o18-itts-fa.rtf

Figure 14.2.7.2.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation without Irinotecan

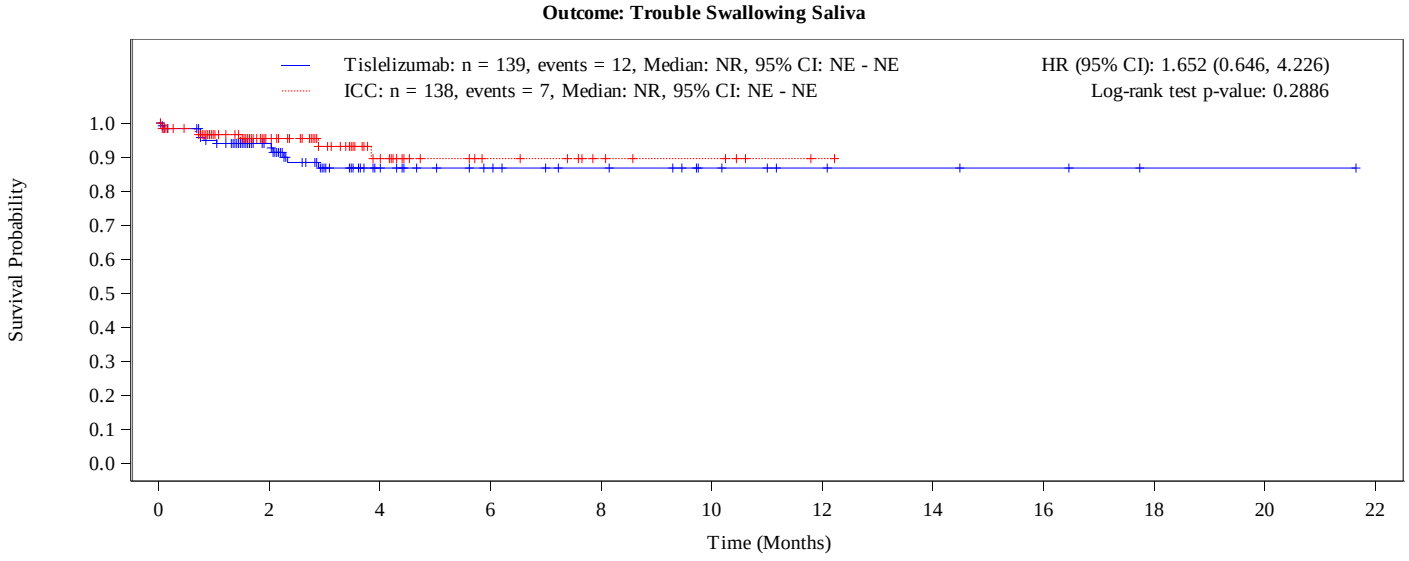


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	139	59	20	15	12	7	4	3	3	1	1	0
ICC	138	52	20	13	7	5	1	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-02-02-b-km-qs-o18-itts-fa.rtf

Figure 14.2.7.2.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation without Irinotecan

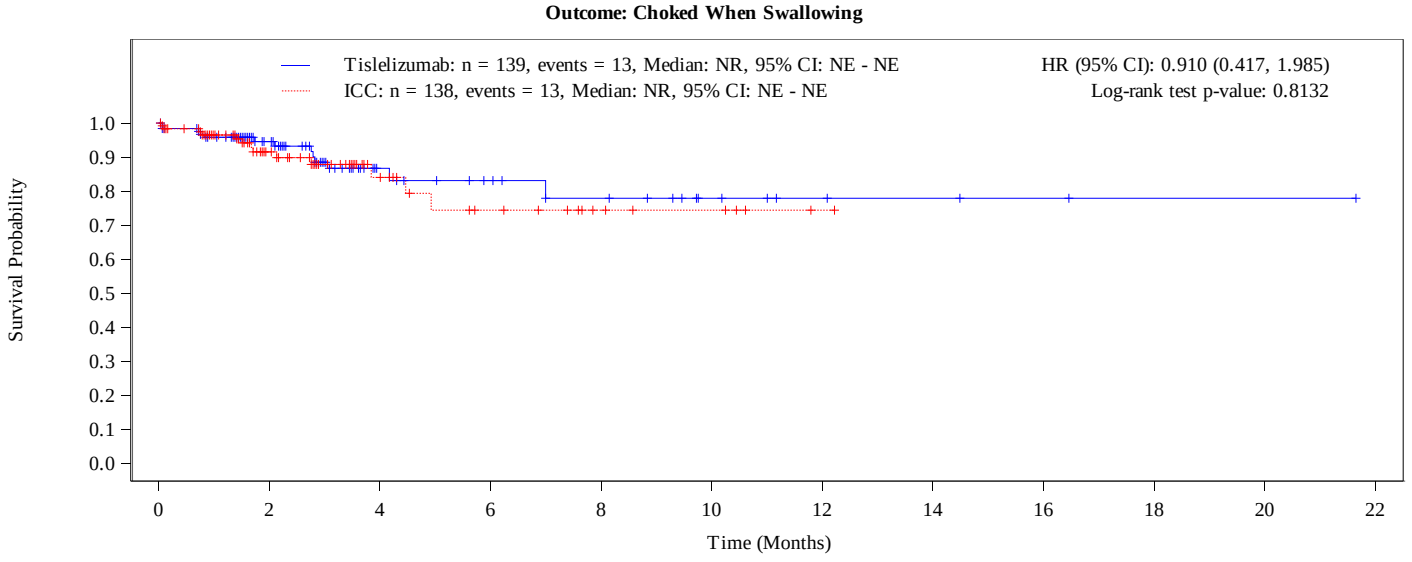


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	139	72	26	18	14	9	6	4	3	1	1	0
ICC	138	59	24	12	7	5	1	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-02-02-b-km-qs-o18-itts-fa.rtf

Figure 14.2.7.2.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation without Irinotecan

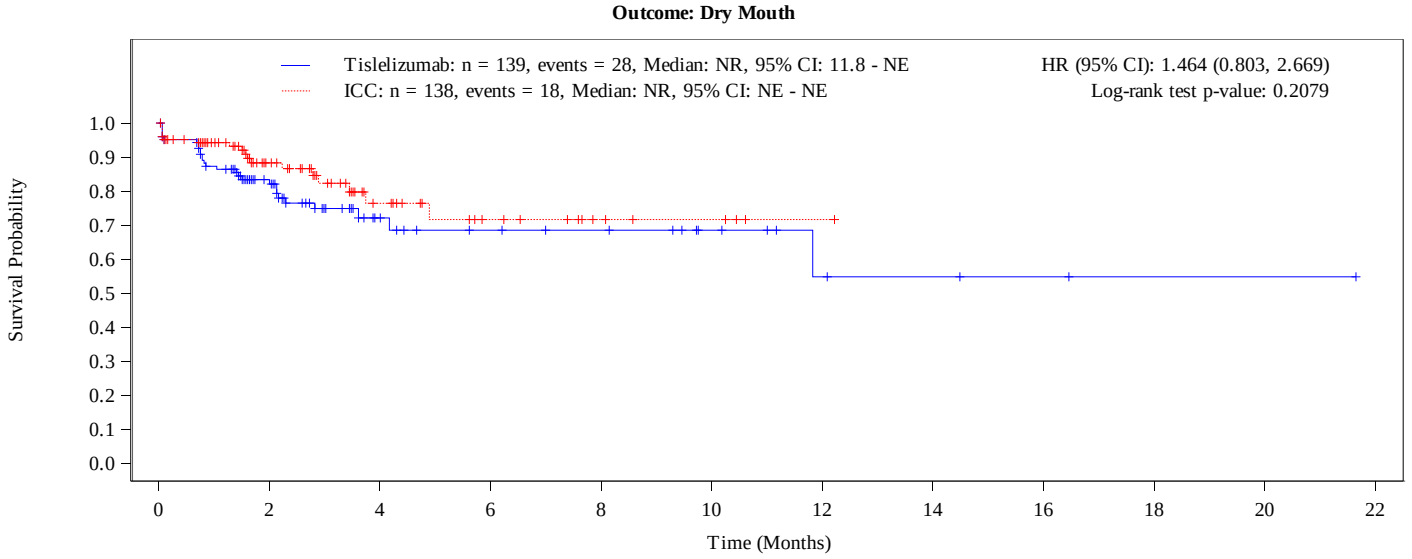


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	139	72	24	18	14	8	5	3	2	1	1	0
ICC	138	56	22	13	7	5	1	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-02-02-b-km-qs-o18-itts-fa.rtf

Figure 14.2.7.2.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation without Irinotecan

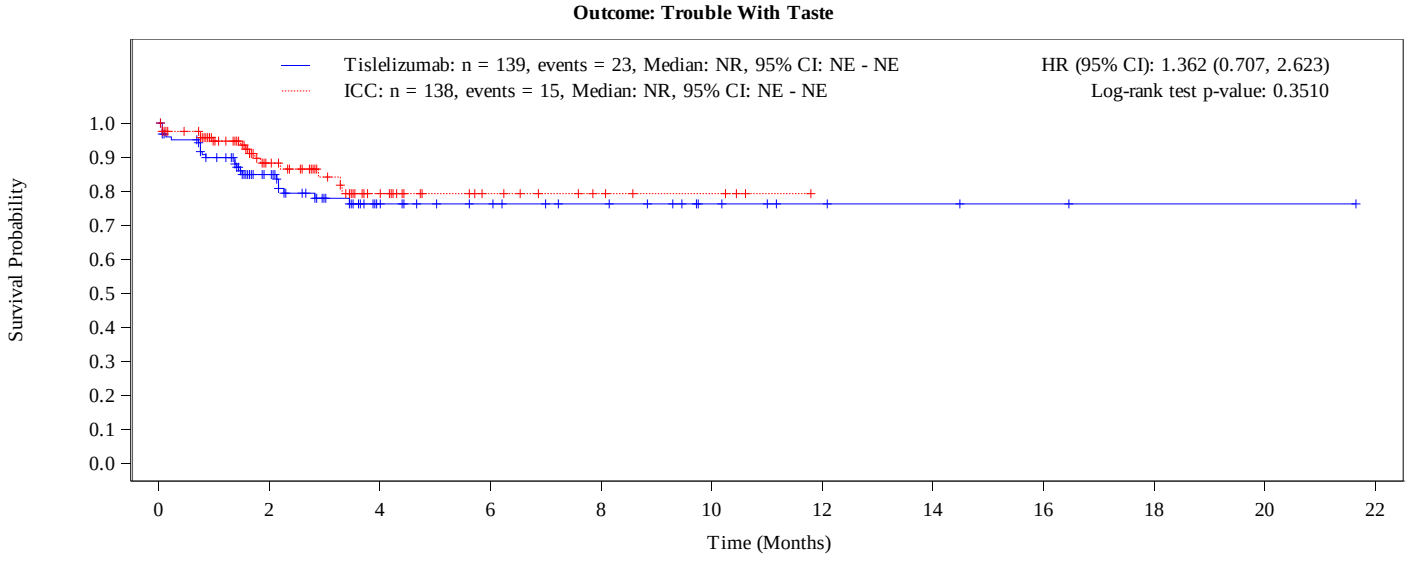


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	139	64	21	15	13	8	4	3	2	1	1	0
ICC	138	55	22	12	6	4	1	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-02-02-b-km-qs-o18-itts-fa.rtf

Figure 14.2.7.2.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation without Irinotecan

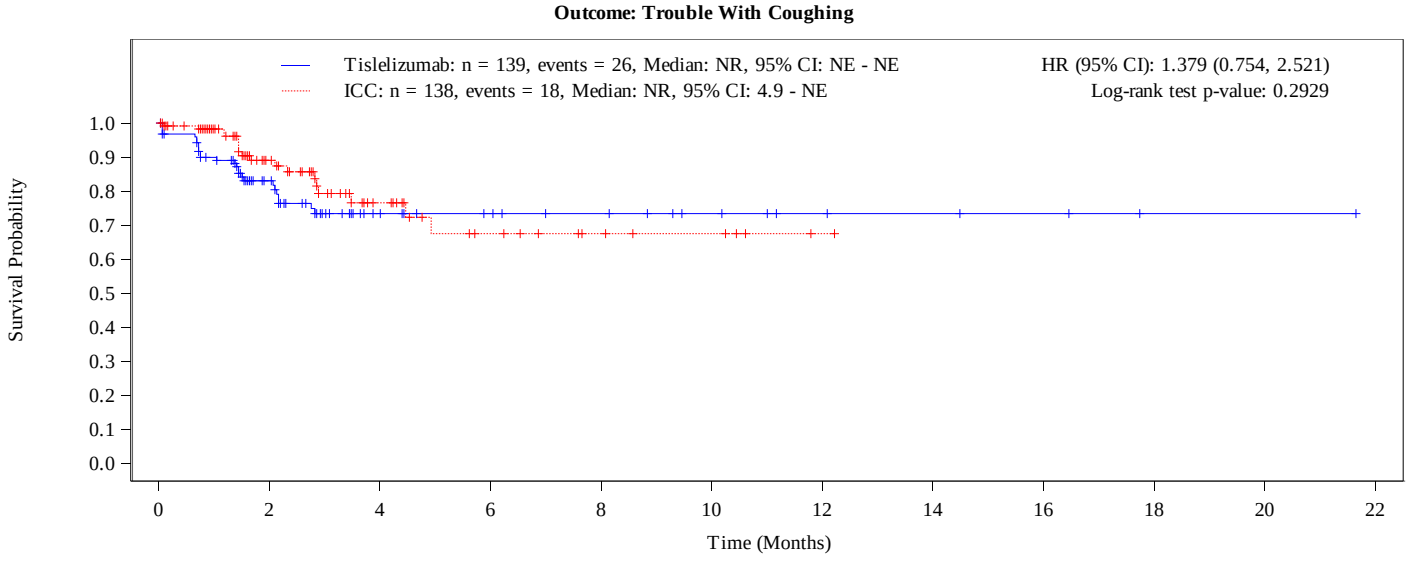


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	139	66	24	18	14	8	5	3	2	1	1	0
ICC	138	54	23	11	6	4	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-02-02-b-km-qs-o18-itts-fa.rtf

Figure 14.2.7.2.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation without Irinotecan

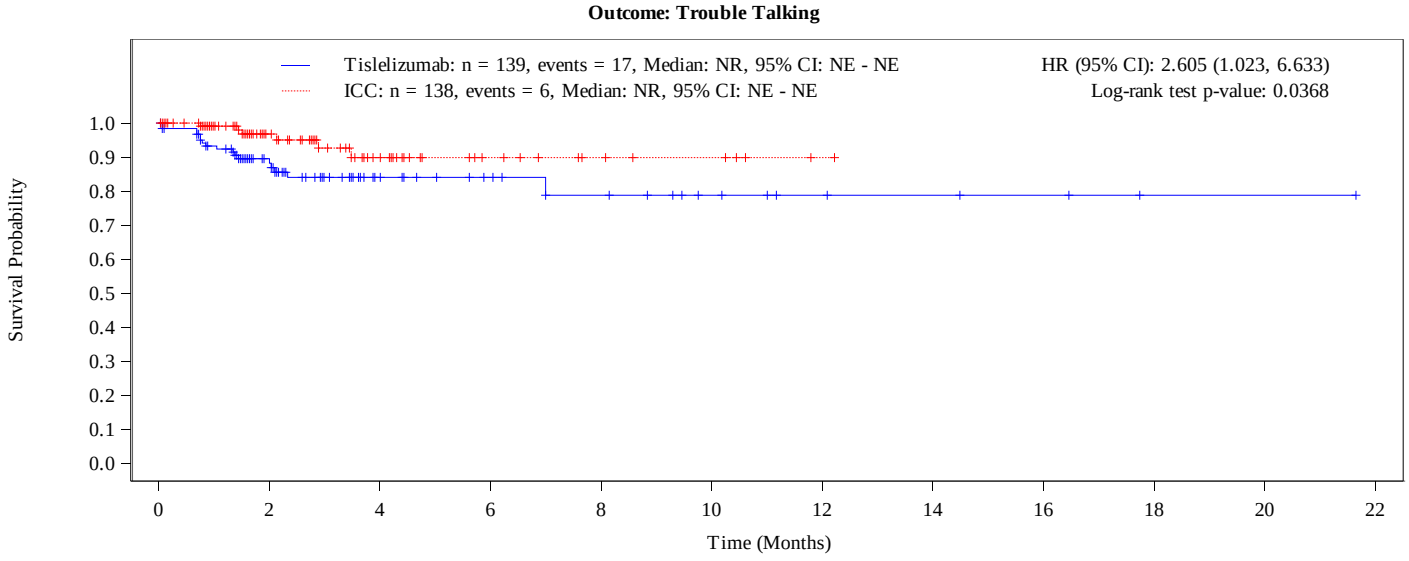


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	139	64	20	15	12	8	5	4	3	1	1	0
ICC	138	57	23	12	7	5	1	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-02-02-b-km-qs-o18-itts-fa.rtf

Figure 14.2.7.2.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	139	68	25	18	14	9	6	4	3	1	1	0
ICC	138	58	25	12	7	5	1	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-02-02-b-km-qs-o18-itts-fa.rtf

Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Dysphagia

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	40 (25.5)	NR (NE, NE)	161	35 (21.7)	NR (3.7, NE)	0.907 (0.575, 1.430)	0.6690
>= 65 Years	99	23 (23.2)	NR (NE, NE)	95	28 (29.5)	NR (2.1, NE)	0.645 (0.371, 1.122)	0.1132
Interaction								0.3590
Gender								
Male	217	57 (26.3)	NR (NE, NE)	215	54 (25.1)	NR (3.1, NE)	0.827 (0.569, 1.201)	0.3096
Female	39	6 (15.4)	NR (NE, NE)	41	9 (22.0)	NR (1.4, NE)	0.597 (0.212, 1.677)	0.3197
Interaction								0.4200

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Dysphagia

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	47 (25.0)	NR (NE, NE)	192	50 (26.0)	NR (3.1, NE)	0.761 (0.510, 1.134)	0.1714
Non-Smoker	68	16 (23.5)	NR (NE, NE)	63	13 (20.6)	NR (2.6, NE)	0.889 (0.426, 1.853)	0.7497
Interaction								0.7924
ICC Options								
Paclitaxel	83	25 (30.1)	NR (2.1, NE)	85	23 (27.1)	NR (3.1, NE)	1.060 (0.601, 1.868)	0.8374
Docetaxel	56	14 (25.0)	NR (2.2, NE)	53	14 (26.4)	NR (2.1, NE)	0.863 (0.411, 1.811)	0.6919
Irinotecan	117	24 (20.5)	NR (NE, NE)	118	26 (22.0)	3.7 (2.6, NE)	0.565 (0.321, 0.995)	0.0423
Interaction								0.3352

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 16MAY2024 03:12 t-14-02-06-03-01-02-s-eff-tteqs-subgrp-o18-itt-fa.rtf

Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Dysphagia

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	17 (26.6)	NR (NE, NE)	63	21 (33.3)	4.9 (3.0, NE)	0.644 (0.339, 1.223)	0.1687
1	192	46 (24.0)	NR (NE, NE)	193	42 (21.8)	NR (3.7, NE)	0.859 (0.564, 1.307)	0.4708
Interaction								0.4615
Region #1								
Asia	201	52 (25.9)	NR (NE, NE)	203	49 (24.1)	NR (3.7, NE)	0.827 (0.559, 1.224)	0.3338
Europe/North America	55	11 (20.0)	NR (NE, NE)	53	14 (26.4)	NR (2.8, NE)	0.631 (0.286, 1.392)	0.2461
Interaction								0.5920

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 16MAY2024 03:12 t-14-02-06-03-01-02-s-eff-tteqs-subgrp-o18-itt-fa.rtf

Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Dysphagia

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	45 (25.6)	NR (NE, NE)	178	42 (23.6)	NR (3.1, NE)	0.814 (0.534, 1.242)	0.3307
Japan	25	7 (28.0)	NR (0.8, NE)	25	7 (28.0)	4.9 (4.9, NE)	0.952 (0.333, 2.727)	0.9250
Europe/North America	55	11 (20.0)	NR (NE, NE)	53	14 (26.4)	NR (2.8, NE)	0.631 (0.286, 1.392)	0.2461
Interaction								0.8629
Race								
Asian and other	203	52 (25.6)	NR (NE, NE)	212	51 (24.1)	NR (3.7, NE)	0.813 (0.551, 1.198)	0.2861
White	53	11 (20.8)	NR (NE, NE)	44	12 (27.3)	3.3 (2.8, NE)	0.670 (0.295, 1.522)	0.3318
Interaction								0.7251

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 16MAY2024 03:12 t-14-02-06-03-01-02-s-eff-tteqs-subgrp-o18-itt-fa.rtf

Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Dysphagia

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	17 (21.3)	NR (NE, NE)	62	10 (16.1)	NR (3.0, NE)	1.010 (0.460, 2.217)	0.9809
vCPS < 10%	100	30 (30.0)	NR (NE, NE)	122	31 (25.4)	NR (3.1, NE)	1.019 (0.616, 1.685)	0.9401
Missing	76	16 (21.1)	NR (NE, NE)	72	22 (30.6)	4.9 (1.0, NE)	0.489 (0.256, 0.935)	0.0243
Interaction								0.1481

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Eating

Subgroup	Tislelizumab (N = 256) Total No. of Patients	Tislelizumab (N = 256) Patients with events n (%)	Tislelizumab (N = 256) Median time to event (95% CI) [a]	ICC (N = 256) Total No. of Patients	ICC (N = 256) Patients with events n (%)	ICC (N = 256) Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	23 (14.6)	NR (NE, NE)	161	11 (6.8)	NR (NE, NE)	1.716 (0.835, 3.526)	0.1344
>= 65 Years	99	12 (12.1)	NR (NE, NE)	95	16 (16.8)	5.2 (4.9, NE)	0.524 (0.245, 1.117)	0.0878
Interaction								0.0387
Gender								
Male	217	32 (14.7)	NR (NE, NE)	215	21 (9.8)	NR (NE, NE)	1.177 (0.677, 2.045)	0.5620
Female	39	3 (7.7)	NR (NE, NE)	41	6 (14.6)	NR (NE, NE)	0.435 (0.109, 1.740)	0.2233
Interaction								0.1180

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 16MAY2024 03:12 t-14-02-06-03-01-02-s-eff-tteqs-subgrp-o18-itt-fa.rtf

Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Eating

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	27 (14.4)	NR (NE, NE)	192	23 (12.0)	NR (NE, NE)	0.935 (0.535, 1.635)	0.8147
Non-Smoker	68	8 (11.8)	NR (NE, NE)	63	4 (6.3)	NR (NE, NE)	1.470 (0.441, 4.904)	0.5261
Interaction								0.5931
ICC Options								
Paclitaxel	83	16 (19.3)	NR (NE, NE)	85	11 (12.9)	NR (4.9, NE)	1.428 (0.663, 3.078)	0.3598
Docetaxel	56	6 (10.7)	NR (NE, NE)	53	6 (11.3)	NR (NE, NE)	0.743 (0.238, 2.321)	0.6076
Irinotecan	117	13 (11.1)	NR (NE, NE)	118	10 (8.5)	NR (NE, NE)	0.981 (0.427, 2.257)	0.9643
Interaction								0.5639

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 16MAY2024 03:12 t-14-02-06-03-01-02-s-eff-tteqs-subgrp-o18-itt-fa.rtf

Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Eating

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	7 (10.9)	NR (NE, NE)	63	8 (12.7)	NR (5.2, NE)	0.694 (0.250, 1.924)	0.4787
1	192	28 (14.6)	NR (NE, NE)	193	19 (9.8)	NR (NE, NE)	1.135 (0.632, 2.037)	0.6702
Interaction								0.3915
Region #1								
Asia	201	26 (12.9)	NR (NE, NE)	203	20 (9.9)	NR (5.2, NE)	0.988 (0.550, 1.777)	0.9688
Europe/North America	55	9 (16.4)	NR (NE, NE)	53	7 (13.2)	NR (2.9, NE)	1.026 (0.381, 2.763)	0.9596
Interaction								0.9882

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Eating

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	23 (13.1)	NR (NE, NE)	178	14 (7.9)	NR (NE, NE)	1.257 (0.644, 2.450)	0.5000
Japan	25	3 (12.0)	NR (NE, NE)	25	6 (24.0)	5.2 (4.9, NE)	0.404 (0.100, 1.639)	0.1874
Europe/North America	55	9 (16.4)	NR (NE, NE)	53	7 (13.2)	NR (2.9, NE)	1.026 (0.381, 2.763)	0.9596
Interaction								0.3307
Race								
Asian and other	203	27 (13.3)	NR (NE, NE)	212	20 (9.4)	NR (NE, NE)	1.055 (0.590, 1.888)	0.8553
White	53	8 (15.1)	NR (NE, NE)	44	7 (15.9)	NR (2.9, NE)	0.798 (0.288, 2.208)	0.6621
Interaction								0.6279

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Eating

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	13 (16.3)	NR (NE, NE)	62	9 (14.5)	NR (NE, NE)	0.865 (0.369, 2.029)	0.7370
vCPS < 10%	100	15 (15.0)	NR (NE, NE)	122	12 (9.8)	NR (4.5, NE)	1.209 (0.564, 2.589)	0.6237
Missing	76	7 (9.2)	NR (NE, NE)	72	6 (8.3)	NR (4.9, NE)	0.884 (0.295, 2.648)	0.8252
Interaction								0.7247

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Reflux

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	14 (8.9)	NR (NE, NE)	161	28 (17.4)	NR (NE, NE)	0.369 (0.193, 0.705)	0.0015
>= 65 Years	99	18 (18.2)	15.1 (15.1, NE)	95	17 (17.9)	NR (NE, NE)	0.745 (0.379, 1.465)	0.3889
Interaction								0.0798
Gender								
Male	217	24 (11.1)	NR (15.1, NE)	215	34 (15.8)	NR (NE, NE)	0.493 (0.289, 0.839)	0.0074
Female	39	8 (20.5)	NR (2.8, NE)	41	11 (26.8)	NR (1.4, NE)	0.581 (0.232, 1.454)	0.2330
Interaction								0.8334

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Reflux

Subgroup	Tislelizumab (N = 256) Total No. of Patients	Tislelizumab (N = 256) Patients with events n (%)	Tislelizumab (N = 256) Median time to event (95% CI) [a]	ICC (N = 256) Total No. of Patients	ICC (N = 256) Patients with events n (%)	ICC (N = 256) Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Smoking Status								
Former/Current Smoker	188	27 (14.4)	NR (15.1, NE)	192	32 (16.7)	NR (NE, NE)	0.634 (0.377, 1.067)	0.0811
Non-Smoker	68	5 (7.4)	NR (NE, NE)	63	13 (20.6)	NR (2.3, NE)	0.237 (0.083, 0.673)	0.0031
Interaction								0.0647
ICC Options								
Paclitaxel	83	11 (13.3)	NR (NE, NE)	85	16 (18.8)	NR (NE, NE)	0.591 (0.274, 1.276)	0.1728
Docetaxel	56	8 (14.3)	NR (NE, NE)	53	11 (20.8)	NR (NE, NE)	0.598 (0.239, 1.493)	0.2615
Irinotecan	117	13 (11.1)	NR (15.1, NE)	118	18 (15.3)	NR (NE, NE)	0.413 (0.195, 0.872)	0.0157
Interaction								0.7883

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Reflux

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	11 (17.2)	NR (NE, NE)	63	9 (14.3)	NR (NE, NE)	0.971 (0.401, 2.353)	0.9476
1	192	21 (10.9)	NR (15.1, NE)	193	36 (18.7)	NR (NE, NE)	0.397 (0.229, 0.690)	0.0006
Interaction								0.1404
Region #1								
Asia	201	22 (10.9)	NR (15.1, NE)	203	35 (17.2)	NR (NE, NE)	0.427 (0.247, 0.738)	0.0015
Europe/North America	55	10 (18.2)	NR (NE, NE)	53	10 (18.9)	NR (NE, NE)	0.803 (0.334, 1.933)	0.6222
Interaction								0.2140

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Reflux

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	17 (9.7)	NR (15.1, NE)	178	35 (19.7)	NR (NE, NE)	0.315 (0.173, 0.574)	<0.0001
Japan	25	5 (20.0)	NR (NE, NE)	25	0 (0.0)	NR (NE, NE)	66175219.847 (0.000, NE)	0.0462
Europe/North America	55	10 (18.2)	NR (NE, NE)	53	10 (18.9)	NR (NE, NE)	0.803 (0.334, 1.933)	0.6222
Interaction								0.2040
Race								
Asian and other	203	23 (11.3)	NR (15.1, NE)	212	38 (17.9)	NR (NE, NE)	0.425 (0.250, 0.722)	0.0010
White	53	9 (17.0)	NR (NE, NE)	44	7 (15.9)	NR (NE, NE)	0.950 (0.353, 2.556)	0.9187
Interaction								0.1443

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Reflux

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	10 (12.5)	NR (15.1, NE)	62	10 (16.1)	NR (3.7, NE)	0.525 (0.212, 1.301)	0.1545
vCPS < 10%	100	13 (13.0)	NR (NE, NE)	122	21 (17.2)	NR (NE, NE)	0.551 (0.274, 1.106)	0.0864
Missing	76	9 (11.8)	NR (NE, NE)	72	14 (19.4)	NR (NE, NE)	0.454 (0.195, 1.054)	0.0550
Interaction								0.8681

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Pain

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	33 (21.0)	NR (NE, NE)	161	23 (14.3)	NR (NE, NE)	1.154 (0.676, 1.970)	0.5950
>= 65 Years	99	16 (16.2)	NR (NE, NE)	95	21 (22.1)	NR (3.3, NE)	0.587 (0.304, 1.131)	0.1045
Interaction								0.1140
Gender								
Male	217	42 (19.4)	NR (NE, NE)	215	36 (16.7)	NR (NE, NE)	0.912 (0.583, 1.427)	0.6861
Female	39	7 (17.9)	NR (NE, NE)	41	8 (19.5)	NR (1.8, NE)	0.799 (0.287, 2.220)	0.6649
Interaction								0.7241

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Pain

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	39 (20.7)	NR (NE, NE)	192	35 (18.2)	NR (4.9, NE)	0.941 (0.595, 1.487)	0.7916
Non-Smoker	68	10 (14.7)	NR (NE, NE)	63	9 (14.3)	NR (NE, NE)	0.755 (0.304, 1.875)	0.5414
Interaction								0.6525
ICC Options								
Paclitaxel	83	24 (28.9)	NR (NE, NE)	85	15 (17.6)	NR (4.9, NE)	1.690 (0.886, 3.224)	0.1030
Docetaxel	56	8 (14.3)	NR (NE, NE)	53	10 (18.9)	NR (3.5, NE)	0.664 (0.261, 1.687)	0.3822
Irinotecan	117	17 (14.5)	NR (NE, NE)	118	19 (16.1)	NR (NE, NE)	0.546 (0.279, 1.068)	0.0702
Interaction								0.0444

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Pain

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	11 (17.2)	NR (NE, NE)	63	15 (23.8)	NR (3.5, NE)	0.572 (0.262, 1.251)	0.1519
1	192	38 (19.8)	NR (NE, NE)	193	29 (15.0)	NR (4.9, NE)	1.046 (0.644, 1.701)	0.8538
Interaction								0.1629
Region #1								
Asia	201	39 (19.4)	NR (NE, NE)	203	31 (15.3)	NR (NE, NE)	0.998 (0.621, 1.604)	0.9941
Europe/North America	55	10 (18.2)	NR (NE, NE)	53	13 (24.5)	3.5 (2.5, NE)	0.636 (0.277, 1.458)	0.2762
Interaction								0.3087

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Pain

Subgroup	Tislelizumab (N = 256) Total No. of Patients	Tislelizumab (N = 256) Patients with events n (%)	Tislelizumab (N = 256) Median time to event (95% CI) [a]	ICC (N = 256) Total No. of Patients	ICC (N = 256) Patients with events n (%)	ICC (N = 256) Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Region #2								
Asia (excluding Japan)	176	29 (16.5)	NR (NE, NE)	178	27 (15.2)	NR (NE, NE)	0.824 (0.486, 1.397)	0.4676
Japan	25	10 (40.0)	NR (1.4, NE)	25	4 (16.0)	NR (4.9, NE)	2.542 (0.795, 8.127)	0.0973
Europe/North America	55	10 (18.2)	NR (NE, NE)	53	13 (24.5)	3.5 (2.5, NE)	0.636 (0.277, 1.458)	0.2762
Interaction								0.1489
Race								
Asian and other	203	39 (19.2)	NR (NE, NE)	212	32 (15.1)	NR (NE, NE)	0.987 (0.617, 1.579)	0.9553
White	53	10 (18.9)	NR (NE, NE)	44	12 (27.3)	3.5 (1.8, NE)	0.630 (0.271, 1.468)	0.2750
Interaction								0.2988

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Pain

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	13 (16.3)	NR (NE, NE)	62	14 (22.6)	NR (2.5, NE)	0.483 (0.225, 1.035)	0.0547
vCPS < 10%	100	21 (21.0)	NR (NE, NE)	122	23 (18.9)	NR (3.5, NE)	0.925 (0.510, 1.675)	0.7940
Missing	76	15 (19.7)	NR (NE, NE)	72	7 (9.7)	NR (4.9, NE)	1.776 (0.723, 4.363)	0.1976
Interaction								0.1226

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Trouble Swallowing Saliva

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	15 (9.6)	NR (NE, NE)	161	10 (6.2)	NR (NE, NE)	1.179 (0.527, 2.635)	0.6870
>= 65 Years	99	8 (8.1)	NR (NE, NE)	95	7 (7.4)	NR (NE, NE)	0.928 (0.336, 2.569)	0.8864
Interaction								0.7596
Gender								
Male	217	18 (8.3)	NR (NE, NE)	215	14 (6.5)	NR (NE, NE)	1.008 (0.500, 2.033)	0.9815
Female	39	5 (12.8)	NR (NE, NE)	41	3 (7.3)	NR (NE, NE)	1.463 (0.347, 6.175)	0.6014
Interaction								0.5862

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Trouble Swallowing Saliva

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	13 (6.9)	NR (NE, NE)	192	14 (7.3)	NR (NE, NE)	0.763 (0.358, 1.629)	0.4829
Non-Smoker	68	10 (14.7)	NR (NE, NE)	63	3 (4.8)	NR (3.8, NE)	2.396 (0.655, 8.759)	0.1714
Interaction								0.1077
ICC Options								
Paclitaxel	83	9 (10.8)	NR (NE, NE)	85	3 (3.5)	NR (NE, NE)	2.977 (0.804, 11.028)	0.0859
Docetaxel	56	3 (5.4)	NR (NE, NE)	53	4 (7.5)	NR (NE, NE)	0.612 (0.136, 2.756)	0.5181
Irinotecan	117	11 (9.4)	NR (NE, NE)	118	10 (8.5)	NR (NE, NE)	0.771 (0.324, 1.833)	0.5530
Interaction								0.1665

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Trouble Swallowing Saliva

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	8 (12.5)	NR (NE, NE)	63	3 (4.8)	NR (NE, NE)	2.323 (0.614, 8.782)	0.1984
1	192	15 (7.8)	NR (NE, NE)	193	14 (7.3)	NR (NE, NE)	0.818 (0.393, 1.700)	0.5885
Interaction								0.2128
Region #1								
Asia	201	18 (9.0)	NR (NE, NE)	203	13 (6.4)	NR (NE, NE)	1.077 (0.526, 2.208)	0.8371
Europe/North America	55	5 (9.1)	NR (NE, NE)	53	4 (7.5)	NR (NE, NE)	1.063 (0.285, 3.971)	0.9272
Interaction								0.9340

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Trouble Swallowing Saliva

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	15 (8.5)	NR (NE, NE)	178	13 (7.3)	NR (NE, NE)	0.888 (0.421, 1.874)	0.7539
Japan	25	3 (12.0)	NR (NE, NE)	25	0 (0.0)	NR (NE, NE)	67914557.359 (0.000, NE)	0.1172
Europe/North America	55	5 (9.1)	NR (NE, NE)	53	4 (7.5)	NR (NE, NE)	1.063 (0.285, 3.971)	0.9272
Interaction								0.9415
Race								
Asian and other	203	18 (8.9)	NR (NE, NE)	212	13 (6.1)	NR (NE, NE)	1.107 (0.541, 2.269)	0.7795
White	53	5 (9.4)	NR (NE, NE)	44	4 (9.1)	NR (NE, NE)	0.970 (0.260, 3.621)	0.9634
Interaction								0.9287

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Trouble Swallowing Saliva

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	5 (6.3)	NR (NE, NE)	62	5 (8.1)	NR (NE, NE)	0.594 (0.171, 2.060)	0.4061
vCPS < 10%	100	10 (10.0)	NR (NE, NE)	122	6 (4.9)	NR (NE, NE)	1.729 (0.626, 4.774)	0.2835
Missing	76	8 (10.5)	NR (NE, NE)	72	6 (8.3)	NR (NE, NE)	1.004 (0.347, 2.905)	0.9945
Interaction								0.3775

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Choked When Swallowing

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	16 (10.2)	NR (NE, NE)	161	11 (6.8)	NR (NE, NE)	1.108 (0.512, 2.398)	0.7938
>= 65 Years	99	7 (7.1)	NR (NE, NE)	95	12 (12.6)	NR (4.9, NE)	0.429 (0.168, 1.096)	0.0684
Interaction								0.1093
Gender								
Male	217	20 (9.2)	NR (NE, NE)	215	19 (8.8)	NR (NE, NE)	0.764 (0.406, 1.438)	0.4016
Female	39	3 (7.7)	NR (NE, NE)	41	4 (9.8)	NR (2.8, NE)	0.613 (0.136, 2.755)	0.5172
Interaction								0.7365

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Choked When Swallowing

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	20 (10.6)	NR (NE, NE)	192	17 (8.9)	NR (NE, NE)	0.899 (0.469, 1.723)	0.7481
Non-Smoker	68	3 (4.4)	NR (NE, NE)	63	6 (9.5)	NR (3.8, NE)	0.366 (0.091, 1.469)	0.1390
Interaction								0.1702
ICC Options								
Paclitaxel	83	8 (9.6)	NR (7.0, NE)	85	11 (12.9)	NR (4.9, NE)	0.668 (0.268, 1.666)	0.3832
Docetaxel	56	5 (8.9)	NR (NE, NE)	53	2 (3.8)	NR (NE, NE)	2.073 (0.398, 10.784)	0.3762
Irinotecan	117	10 (8.5)	NR (NE, NE)	118	10 (8.5)	NR (NE, NE)	0.740 (0.305, 1.790)	0.4992
Interaction								0.3994

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Choked When Swallowing

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	6 (9.4)	NR (NE, NE)	63	7 (11.1)	NR (4.5, NE)	0.648 (0.216, 1.943)	0.4337
1	192	17 (8.9)	NR (NE, NE)	193	16 (8.3)	NR (NE, NE)	0.781 (0.393, 1.552)	0.4773
Interaction								0.7255
Region #1								
Asia	201	18 (9.0)	NR (NE, NE)	203	16 (7.9)	NR (NE, NE)	0.788 (0.399, 1.557)	0.4904
Europe/North America	55	5 (9.1)	NR (NE, NE)	53	7 (13.2)	NR (NE, NE)	0.569 (0.180, 1.801)	0.3290
Interaction								0.6541

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Choked When Swallowing

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	14 (8.0)	NR (NE, NE)	178	13 (7.3)	NR (NE, NE)	0.774 (0.362, 1.658)	0.5079
Japan	25	4 (16.0)	NR (7.0, NE)	25	3 (12.0)	NR (4.9, NE)	0.937 (0.202, 4.343)	0.9334
Europe/North America	55	5 (9.1)	NR (NE, NE)	53	7 (13.2)	NR (NE, NE)	0.569 (0.180, 1.801)	0.3290
Interaction								0.8617
Race								
Asian and other	203	18 (8.9)	NR (NE, NE)	212	17 (8.0)	NR (NE, NE)	0.748 (0.382, 1.463)	0.3932
White	53	5 (9.4)	NR (NE, NE)	44	6 (13.6)	NR (NE, NE)	0.620 (0.189, 2.039)	0.4247
Interaction								0.7755

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Choked When Swallowing

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	6 (7.5)	NR (NE, NE)	62	6 (9.7)	NR (NE, NE)	0.586 (0.188, 1.825)	0.3494
vCPS < 10%	100	5 (5.0)	NR (NE, NE)	122	14 (11.5)	NR (4.5, NE)	0.321 (0.115, 0.895)	0.0220
Missing	76	12 (15.8)	NR (7.0, NE)	72	3 (4.2)	NR (4.9, NE)	3.266 (0.919, 11.608)	0.0521
Interaction								0.0209

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Dry Mouth

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	31 (19.7)	NR (NE, NE)	161	15 (9.3)	NR (NE, NE)	1.682 (0.907, 3.119)	0.0931
>= 65 Years	99	19 (19.2)	NR (11.8, NE)	95	22 (23.2)	NR (2.9, NE)	0.624 (0.333, 1.167)	0.1331
Interaction								0.0406
Gender								
Male	217	44 (20.3)	NR (11.8, NE)	215	31 (14.4)	NR (NE, NE)	1.083 (0.681, 1.720)	0.7336
Female	39	6 (15.4)	NR (NE, NE)	41	6 (14.6)	NR (1.9, NE)	0.847 (0.272, 2.637)	0.7735
Interaction								0.6993

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Dry Mouth

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	37 (19.7)	NR (NE, NE)	192	28 (14.6)	NR (4.9, NE)	1.076 (0.657, 1.761)	0.7696
Non-Smoker	68	13 (19.1)	NR (11.8, NE)	63	9 (14.3)	NR (NE, NE)	0.932 (0.392, 2.219)	0.8736
Interaction								0.8031
ICC Options								
Paclitaxel	83	19 (22.9)	11.8 (11.8, NE)	85	9 (10.6)	NR (NE, NE)	2.186 (0.984, 4.852)	0.0484
Docetaxel	56	9 (16.1)	NR (4.2, NE)	53	9 (17.0)	NR (2.9, NE)	0.765 (0.300, 1.951)	0.5695
Irinotecan	117	22 (18.8)	NR (NE, NE)	118	19 (16.1)	NR (3.0, NE)	0.710 (0.380, 1.327)	0.2772
Interaction								0.0587

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Dry Mouth

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	16 (25.0)	NR (11.8, NE)	63	5 (7.9)	NR (NE, NE)	2.380 (0.866, 6.544)	0.0818
1	192	34 (17.7)	NR (NE, NE)	193	32 (16.6)	NR (3.7, NE)	0.828 (0.510, 1.345)	0.4414
Interaction								0.0529
Region #1								
Asia	201	38 (18.9)	NR (NE, NE)	203	27 (13.3)	NR (NE, NE)	1.077 (0.655, 1.771)	0.7678
Europe/North America	55	12 (21.8)	NR (2.8, NE)	53	10 (18.9)	NR (1.9, NE)	0.932 (0.401, 2.165)	0.8697
Interaction								0.8779

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Dry Mouth

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	31 (17.6)	NR (NE, NE)	178	23 (12.9)	NR (4.9, NE)	1.021 (0.594, 1.756)	0.9392
Japan	25	7 (28.0)	11.8 (11.8, NE)	25	4 (16.0)	NR (NE, NE)	1.578 (0.455, 5.468)	0.4673
Europe/North America	55	12 (21.8)	NR (2.8, NE)	53	10 (18.9)	NR (1.9, NE)	0.932 (0.401, 2.165)	0.8697
Interaction								0.8167
Race								
Asian and other	203	38 (18.7)	NR (NE, NE)	212	28 (13.2)	NR (NE, NE)	1.069 (0.653, 1.748)	0.7889
White	53	12 (22.6)	NR (2.8, NE)	44	9 (20.5)	NR (1.9, NE)	0.916 (0.384, 2.182)	0.8416
Interaction								0.8850

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Dry Mouth

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	8 (10.0)	NR (NE, NE)	62	8 (12.9)	NR (3.7, NE)	0.494 (0.184, 1.328)	0.1522
vCPS < 10%	100	22 (22.0)	NR (4.2, NE)	122	20 (16.4)	NR (NE, NE)	1.089 (0.593, 1.999)	0.7823
Missing	76	20 (26.3)	11.8 (3.6, NE)	72	9 (12.5)	NR (NE, NE)	1.722 (0.778, 3.810)	0.1706
Interaction								0.1889

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Trouble With Taste

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	20 (12.7)	NR (NE, NE)	161	17 (10.6)	NR (NE, NE)	0.869 (0.453, 1.667)	0.6714
>= 65 Years	99	15 (15.2)	NR (NE, NE)	95	13 (13.7)	NR (NE, NE)	0.864 (0.409, 1.825)	0.6998
Interaction								0.9341
Gender								
Male	217	28 (12.9)	NR (NE, NE)	215	23 (10.7)	NR (NE, NE)	0.898 (0.515, 1.563)	0.7014
Female	39	7 (17.9)	NR (4.5, NE)	41	7 (17.1)	NR (1.9, NE)	0.730 (0.249, 2.139)	0.5605
Interaction								0.8422

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Trouble With Taste

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	26 (13.8)	NR (NE, NE)	192	26 (13.5)	NR (NE, NE)	0.739 (0.427, 1.278)	0.2755
Non-Smoker	68	9 (13.2)	NR (NE, NE)	63	4 (6.3)	NR (NE, NE)	1.670 (0.513, 5.436)	0.3858
Interaction								0.2760
ICC Options								
Paclitaxel	83	13 (15.7)	NR (NE, NE)	85	7 (8.2)	NR (NE, NE)	1.780 (0.709, 4.465)	0.2122
Docetaxel	56	10 (17.9)	NR (NE, NE)	53	8 (15.1)	NR (2.9, NE)	1.052 (0.413, 2.681)	0.9142
Irinotecan	117	12 (10.3)	NR (NE, NE)	118	15 (12.7)	NR (NE, NE)	0.438 (0.200, 0.959)	0.0334
Interaction								0.0618

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Trouble With Taste

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	7 (10.9)	NR (NE, NE)	63	8 (12.7)	NR (NE, NE)	0.583 (0.210, 1.623)	0.2952
1	192	28 (14.6)	NR (NE, NE)	193	22 (11.4)	NR (NE, NE)	0.974 (0.555, 1.708)	0.9264
Interaction								0.4762
Region #1								
Asia	201	24 (11.9)	NR (NE, NE)	203	19 (9.4)	NR (NE, NE)	0.949 (0.518, 1.739)	0.8646
Europe/North America	55	11 (20.0)	NR (4.5, NE)	53	11 (20.8)	NR (1.9, NE)	0.760 (0.328, 1.764)	0.5205
Interaction								0.7810

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Trouble With Taste

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	22 (12.5)	NR (NE, NE)	178	13 (7.3)	NR (NE, NE)	1.275 (0.640, 2.540)	0.4869
Japan	25	2 (8.0)	NR (NE, NE)	25	6 (24.0)	NR (2.2, NE)	0.259 (0.052, 1.298)	0.0770
Europe/North America	55	11 (20.0)	NR (4.5, NE)	53	11 (20.8)	NR (1.9, NE)	0.760 (0.328, 1.764)	0.5205
Interaction								0.1929
Race								
Asian and other	203	24 (11.8)	NR (NE, NE)	212	21 (9.9)	NR (NE, NE)	0.878 (0.487, 1.584)	0.6643
White	53	11 (20.8)	NR (4.5, NE)	44	9 (20.5)	NR (1.9, NE)	0.851 (0.351, 2.063)	0.7197
Interaction								0.9503

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Trouble With Taste

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	8 (10.0)	NR (NE, NE)	62	2 (3.2)	NR (NE, NE)	2.495 (0.528, 11.795)	0.2310
vCPS < 10%	100	17 (17.0)	NR (NE, NE)	122	19 (15.6)	NR (NE, NE)	0.838 (0.435, 1.617)	0.5969
Missing	76	10 (13.2)	NR (NE, NE)	72	9 (12.5)	NR (NE, NE)	0.780 (0.315, 1.930)	0.5880
Interaction								0.4761

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Trouble With Coughing

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	28 (17.8)	NR (NE, NE)	161	19 (11.8)	NR (NE, NE)	1.141 (0.635, 2.048)	0.6579
>= 65 Years	99	15 (15.2)	NR (NE, NE)	95	11 (11.6)	NR (4.9, NE)	1.073 (0.491, 2.344)	0.8589
Interaction								0.9220
Gender								
Male	217	36 (16.6)	NR (NE, NE)	215	27 (12.6)	NR (NE, NE)	1.024 (0.621, 1.690)	0.9244
Female	39	7 (17.9)	NR (NE, NE)	41	3 (7.3)	NR (NE, NE)	2.228 (0.575, 8.635)	0.2331
Interaction								0.3662

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Trouble With Coughing

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	37 (19.7)	NR (NE, NE)	192	27 (14.1)	NR (NE, NE)	1.169 (0.711, 1.923)	0.5341
Non-Smoker	68	6 (8.8)	NR (NE, NE)	63	3 (4.8)	NR (3.5, NE)	1.080 (0.266, 4.385)	0.9144
Interaction								0.8834
ICC Options								
Paclitaxel	83	12 (14.5)	NR (NE, NE)	85	13 (15.3)	NR (4.9, NE)	0.880 (0.401, 1.931)	0.7484
Docetaxel	56	14 (25.0)	NR (2.8, NE)	53	5 (9.4)	NR (3.5, NE)	2.704 (0.973, 7.516)	0.0460
Irinotecan	117	17 (14.5)	NR (NE, NE)	118	12 (10.2)	NR (NE, NE)	0.956 (0.452, 2.019)	0.9047
Interaction								0.1511

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Trouble With Coughing

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	13 (20.3)	NR (NE, NE)	63	7 (11.1)	NR (NE, NE)	1.548 (0.615, 3.895)	0.3474
1	192	30 (15.6)	NR (NE, NE)	193	23 (11.9)	NR (4.9, NE)	1.005 (0.583, 1.734)	0.9854
Interaction								0.5150
Region #1								
Asia	201	36 (17.9)	NR (NE, NE)	203	24 (11.8)	NR (NE, NE)	1.150 (0.684, 1.931)	0.5959
Europe/North America	55	7 (12.7)	NR (NE, NE)	53	6 (11.3)	NR (NE, NE)	0.972 (0.326, 2.904)	0.9598
Interaction								0.7254

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Trouble With Coughing

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	31 (17.6)	NR (NE, NE)	178	19 (10.7)	NR (NE, NE)	1.233 (0.695, 2.188)	0.4707
Japan	25	5 (20.0)	NR (NE, NE)	25	5 (20.0)	NR (4.9, NE)	0.881 (0.254, 3.063)	0.8422
Europe/North America	55	7 (12.7)	NR (NE, NE)	53	6 (11.3)	NR (NE, NE)	0.972 (0.326, 2.904)	0.9598
Interaction								0.8201
Race								
Asian and other	203	37 (18.2)	NR (NE, NE)	212	24 (11.3)	NR (NE, NE)	1.219 (0.728, 2.042)	0.4484
White	53	6 (11.3)	NR (NE, NE)	44	6 (13.6)	NR (2.9, NE)	0.728 (0.234, 2.266)	0.5814
Interaction								0.3837

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Trouble With Coughing

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	12 (15.0)	NR (NE, NE)	62	2 (3.2)	NR (NE, NE)	3.809 (0.852, 17.038)	0.0589
vCPS < 10%	100	18 (18.0)	NR (NE, NE)	122	18 (14.8)	NR (4.5, NE)	1.026 (0.533, 1.974)	0.9392
Missing	76	13 (17.1)	NR (NE, NE)	72	10 (13.9)	NR (3.5, NE)	0.889 (0.388, 2.034)	0.7781
Interaction								0.2821

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Trouble Talking

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	19 (12.1)	NR (NE, NE)	161	7 (4.3)	NR (NE, NE)	2.186 (0.916, 5.218)	0.0704
>= 65 Years	99	6 (6.1)	NR (NE, NE)	95	4 (4.2)	NR (NE, NE)	1.165 (0.328, 4.144)	0.8128
Interaction								0.4445
Gender								
Male	217	23 (10.6)	NR (NE, NE)	215	9 (4.2)	NR (NE, NE)	2.016 (0.930, 4.370)	0.0693
Female	39	2 (5.1)	NR (NE, NE)	41	2 (4.9)	NR (NE, NE)	0.935 (0.132, 6.644)	0.9468
Interaction								0.4084

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Trouble Talking

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	18 (9.6)	NR (NE, NE)	192	8 (4.2)	NR (NE, NE)	1.846 (0.801, 4.259)	0.1435
Non-Smoker	68	7 (10.3)	NR (NE, NE)	63	3 (4.8)	NR (3.5, NE)	1.703 (0.437, 6.629)	0.4355
Interaction								0.8734
ICC Options								
Paclitaxel	83	12 (14.5)	NR (7.0, NE)	85	3 (3.5)	NR (NE, NE)	3.900 (1.100, 13.823)	0.0226
Docetaxel	56	5 (8.9)	NR (NE, NE)	53	3 (5.7)	NR (3.5, NE)	1.307 (0.309, 5.532)	0.7149
Irinotecan	117	8 (6.8)	NR (NE, NE)	118	5 (4.2)	NR (NE, NE)	1.311 (0.428, 4.010)	0.6331
Interaction								0.2894

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Trouble Talking

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	6 (9.4)	NR (NE, NE)	63	2 (3.2)	NR (NE, NE)	2.238 (0.448, 11.172)	0.3136
1	192	19 (9.9)	NR (NE, NE)	193	9 (4.7)	NR (NE, NE)	1.727 (0.780, 3.825)	0.1715
Interaction								0.7128
Region #1								
Asia	201	20 (10.0)	NR (NE, NE)	203	7 (3.4)	NR (NE, NE)	2.201 (0.926, 5.233)	0.0667
Europe/North America	55	5 (9.1)	NR (NE, NE)	53	4 (7.5)	NR (NE, NE)	1.065 (0.285, 3.978)	0.9254
Interaction								0.3613

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Trouble Talking

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	17 (9.7)	NR (NE, NE)	178	6 (3.4)	NR (NE, NE)	2.278 (0.895, 5.794)	0.0750
Japan	25	3 (12.0)	NR (7.0, NE)	25	1 (4.0)	NR (NE, NE)	2.060 (0.204, 20.822)	0.5325
Europe/North America	55	5 (9.1)	NR (NE, NE)	53	4 (7.5)	NR (NE, NE)	1.065 (0.285, 3.978)	0.9254
Interaction								0.6580
Race								
Asian and other	203	20 (9.9)	NR (NE, NE)	212	7 (3.3)	NR (NE, NE)	2.254 (0.948, 5.358)	0.0585
White	53	5 (9.4)	NR (NE, NE)	44	4 (9.1)	NR (NE, NE)	0.966 (0.259, 3.610)	0.9594
Interaction								0.2858

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Trouble Talking

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	6 (7.5)	NR (NE, NE)	62	0 (0.0)	NR (NE, NE)	19657350.793 (0.000, NE)	0.0565
vCPS < 10%	100	15 (15.0)	NR (NE, NE)	122	5 (4.1)	NR (NE, NE)	3.212 (1.166, 8.847)	0.0167
Missing	76	4 (5.3)	NR (7.0, NE)	72	6 (8.3)	NR (3.5, NE)	0.432 (0.120, 1.553)	0.1859
Interaction								0.0745

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Dysphagia

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	25 (32.5)	NR (2.1, NE)	77	18 (23.4)	NR (3.1, NE)	1.362 (0.743, 2.498)	0.3076
>= 65 Years	62	14 (22.6)	NR (NE, NE)	61	19 (31.1)	NR (2.1, NE)	0.653 (0.327, 1.303)	0.2164
Interaction								0.1184
Gender								
Male	118	37 (31.4)	NR (2.2, NE)	111	31 (27.9)	NR (3.1, NE)	1.067 (0.662, 1.720)	0.7840
Female	21	2 (9.5)	NR (NE, NE)	27	6 (22.2)	NR (1.4, NE)	0.403 (0.081, 1.996)	0.2490
Interaction								0.2191

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Dysphagia

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	29 (27.9)	NR (NE, NE)	105	30 (28.6)	NR (3.0, NE)	0.933 (0.560, 1.554)	0.7853
Non-Smoker	35	10 (28.6)	NR (1.3, NE)	33	7 (21.2)	NR (1.4, NE)	1.065 (0.405, 2.801)	0.8962
Interaction								0.7410
ICC Options								
Paclitaxel	83	25 (30.1)	NR (2.1, NE)	85	23 (27.1)	NR (3.1, NE)	1.060 (0.601, 1.868)	0.8374
Docetaxel	56	14 (25.0)	NR (2.2, NE)	53	14 (26.4)	NR (2.1, NE)	0.863 (0.411, 1.811)	0.6919
Interaction								0.6606

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Dysphagia

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	12 (27.9)	NR (2.2, NE)	42	12 (28.6)	NR (3.0, NE)	0.891 (0.400, 1.984)	0.7734
1	96	27 (28.1)	NR (2.2, NE)	96	25 (26.0)	NR (2.8, NE)	1.023 (0.594, 1.763)	0.9327
Interaction								0.7664
Region #1								
Asia	103	31 (30.1)	NR (2.2, NE)	105	31 (29.5)	NR (2.8, NE)	0.929 (0.565, 1.529)	0.7683
Europe/North America	36	8 (22.2)	NR (2.1, NE)	33	6 (18.2)	NR (3.0, NE)	1.230 (0.427, 3.547)	0.6994
Interaction								0.6354

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Dysphagia

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	24 (30.8)	NR (2.1, NE)	80	24 (30.0)	NR (2.1, NE)	0.949 (0.538, 1.672)	0.8534
Japan	25	7 (28.0)	NR (0.8, NE)	25	7 (28.0)	4.9 (4.9, NE)	0.952 (0.333, 2.727)	0.9250
Europe/North America	36	8 (22.2)	NR (2.1, NE)	33	6 (18.2)	NR (3.0, NE)	1.230 (0.427, 3.547)	0.6994
Interaction								0.8889
Race								
Asian and other	105	31 (29.5)	NR (2.2, NE)	114	33 (28.9)	NR (2.8, NE)	0.905 (0.554, 1.478)	0.6827
White	34	8 (23.5)	NR (0.9, NE)	24	4 (16.7)	NR (3.0, NE)	1.606 (0.484, 5.336)	0.4319
Interaction								0.3781

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Dysphagia

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	11 (24.4)	NR (NE, NE)	34	7 (20.6)	NR (2.1, NE)	1.137 (0.439, 2.944)	0.7896
vCPS < 10%	53	20 (37.7)	NR (1.4, NE)	56	15 (26.8)	NR (2.8, NE)	1.350 (0.690, 2.643)	0.3716
Missing	41	8 (19.5)	NR (2.2, NE)	48	15 (31.3)	NR (1.0, NE)	0.584 (0.247, 1.378)	0.2029
Interaction								0.2765

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Eating

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	14 (18.2)	NR (4.2, NE)	77	7 (9.1)	NR (NE, NE)	1.935 (0.780, 4.798)	0.1457
>= 65 Years	62	8 (12.9)	NR (NE, NE)	61	10 (16.4)	5.2 (4.9, NE)	0.617 (0.242, 1.575)	0.3074
Interaction								0.1037
Gender								
Male	118	20 (16.9)	NR (NE, NE)	111	14 (12.6)	NR (5.2, NE)	1.255 (0.634, 2.485)	0.5130
Female	21	2 (9.5)	NR (NE, NE)	27	3 (11.1)	NR (NE, NE)	0.709 (0.118, 4.250)	0.7050
Interaction								0.4799

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Eating

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	17 (16.3)	NR (NE, NE)	105	14 (13.3)	NR (5.2, NE)	1.166 (0.575, 2.367)	0.6691
Non-Smoker	35	5 (14.3)	NR (NE, NE)	33	3 (9.1)	NR (3.2, NE)	1.170 (0.280, 4.900)	0.8284
Interaction								0.9406
ICC Options								
Paclitaxel	83	16 (19.3)	NR (NE, NE)	85	11 (12.9)	NR (4.9, NE)	1.428 (0.663, 3.078)	0.3598
Docetaxel	56	6 (10.7)	NR (NE, NE)	53	6 (11.3)	NR (NE, NE)	0.743 (0.238, 2.321)	0.6076
Interaction								0.3755

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Eating

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	5 (11.6)	NR (NE, NE)	42	5 (11.9)	NR (5.2, NE)	0.852 (0.246, 2.953)	0.8001
1	96	17 (17.7)	NR (4.2, NE)	96	12 (12.5)	NR (4.9, NE)	1.317 (0.629, 2.761)	0.4626
Interaction								0.5232
Region #1								
Asia	103	15 (14.6)	NR (NE, NE)	105	14 (13.3)	NR (4.9, NE)	0.954 (0.460, 1.978)	0.8990
Europe/North America	36	7 (19.4)	NR (2.1, NE)	33	3 (9.1)	NR (2.9, NE)	1.983 (0.512, 7.677)	0.3112
Interaction								0.3465

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Eating

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	12 (15.4)	NR (4.2, NE)	80	8 (10.0)	NR (NE, NE)	1.451 (0.592, 3.556)	0.4117
Japan	25	3 (12.0)	NR (NE, NE)	25	6 (24.0)	5.2 (4.9, NE)	0.404 (0.100, 1.639)	0.1874
Europe/North America	36	7 (19.4)	NR (2.1, NE)	33	3 (9.1)	NR (2.9, NE)	1.983 (0.512, 7.677)	0.3112
Interaction								0.1842
Race								
Asian and other	105	16 (15.2)	NR (NE, NE)	114	14 (12.3)	NR (4.9, NE)	1.059 (0.516, 2.171)	0.8756
White	34	6 (17.6)	NR (2.1, NE)	24	3 (12.5)	NR (2.9, NE)	1.399 (0.349, 5.604)	0.6336
Interaction								0.6952

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Eating

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	8 (17.8)	NR (NE, NE)	34	5 (14.7)	NR (NE, NE)	1.152 (0.376, 3.523)	0.8038
vCPS < 10%	53	9 (17.0)	NR (4.2, NE)	56	7 (12.5)	NR (4.5, NE)	1.165 (0.434, 3.129)	0.7617
Missing	41	5 (12.2)	NR (NE, NE)	48	5 (10.4)	NR (4.9, NE)	1.144 (0.331, 3.961)	0.8313
Interaction								0.9978

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Reflux

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	7 (9.1)	NR (NE, NE)	77	13 (16.9)	NR (NE, NE)	0.466 (0.185, 1.172)	0.0939
>= 65 Years	62	12 (19.4)	NR (NE, NE)	61	14 (23.0)	NR (3.7, NE)	0.701 (0.324, 1.518)	0.3616
Interaction								0.4577
Gender								
Male	118	14 (11.9)	NR (NE, NE)	111	21 (18.9)	NR (NE, NE)	0.536 (0.272, 1.056)	0.0651
Female	21	5 (23.8)	NR (2.2, NE)	27	6 (22.2)	NR (1.4, NE)	0.959 (0.292, 3.150)	0.9443
Interaction								0.4335

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Reflux

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	17 (16.3)	NR (NE, NE)	105	19 (18.1)	NR (NE, NE)	0.820 (0.426, 1.580)	0.5508
Non-Smoker	35	2 (5.7)	NR (NE, NE)	33	8 (24.2)	NR (1.4, NE)	0.165 (0.035, 0.778)	0.0088
Interaction								0.0482
ICC Options								
Paclitaxel	83	11 (13.3)	NR (NE, NE)	85	16 (18.8)	NR (NE, NE)	0.591 (0.274, 1.276)	0.1728
Docetaxel	56	8 (14.3)	NR (NE, NE)	53	11 (20.8)	NR (NE, NE)	0.598 (0.239, 1.493)	0.2615
Interaction								0.9618

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Reflux

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	8 (18.6)	NR (NE, NE)	42	5 (11.9)	NR (NE, NE)	1.395 (0.456, 4.270)	0.5566
1	96	11 (11.5)	NR (NE, NE)	96	22 (22.9)	NR (3.7, NE)	0.428 (0.207, 0.883)	0.0169
Interaction								0.0990
Region #1								
Asia	103	13 (12.6)	NR (NE, NE)	105	19 (18.1)	NR (NE, NE)	0.575 (0.283, 1.166)	0.1172
Europe/North America	36	6 (16.7)	NR (2.9, NE)	33	8 (24.2)	NR (1.4, NE)	0.614 (0.213, 1.771)	0.3590
Interaction								0.9073

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Reflux

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	8 (10.3)	NR (NE, NE)	80	19 (23.8)	NR (3.7, NE)	0.358 (0.156, 0.819)	0.0100
Japan	25	5 (20.0)	NR (NE, NE)	25	0 (0.0)	NR (NE, NE)	66175219.847 (0.000, NE)	0.0462
Europe/North America	36	6 (16.7)	NR (2.9, NE)	33	8 (24.2)	NR (1.4, NE)	0.614 (0.213, 1.771)	0.3590
Interaction								0.7083
Race								
Asian and other	105	14 (13.3)	NR (NE, NE)	114	22 (19.3)	NR (NE, NE)	0.558 (0.285, 1.092)	0.0814
White	34	5 (14.7)	NR (2.9, NE)	24	5 (20.8)	NR (1.5, NE)	0.711 (0.205, 2.461)	0.5875
Interaction								0.7102

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Reflux

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	6 (13.3)	NR (NE, NE)	34	6 (17.6)	NR (3.7, NE)	0.701 (0.225, 2.181)	0.5354
vCPS < 10%	53	7 (13.2)	NR (NE, NE)	56	11 (19.6)	NR (NE, NE)	0.529 (0.204, 1.368)	0.1794
Missing	41	6 (14.6)	NR (2.8, NE)	48	10 (20.8)	NR (NE, NE)	0.644 (0.234, 1.773)	0.3830
Interaction								0.9527

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Pain

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	20 (26.0)	NR (2.8, NE)	77	12 (15.6)	NR (3.5, NE)	1.698 (0.830, 3.475)	0.1394
>= 65 Years	62	12 (19.4)	NR (NE, NE)	61	13 (21.3)	NR (3.3, NE)	0.826 (0.376, 1.815)	0.6317
Interaction								0.1826
Gender								
Male	118	29 (24.6)	NR (NE, NE)	111	21 (18.9)	NR (4.9, NE)	1.274 (0.726, 2.235)	0.3918
Female	21	3 (14.3)	NR (1.7, NE)	27	4 (14.8)	NR (3.3, NE)	0.872 (0.193, 3.936)	0.8588
Interaction								0.6770

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Pain

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	28 (26.9)	NR (NE, NE)	105	19 (18.1)	NR (4.9, NE)	1.590 (0.888, 2.848)	0.1117
Non-Smoker	35	4 (11.4)	NR (NE, NE)	33	6 (18.2)	NR (1.5, NE)	0.415 (0.116, 1.477)	0.1598
Interaction								0.0608
ICC Options								
Paclitaxel	83	24 (28.9)	NR (NE, NE)	85	15 (17.6)	NR (4.9, NE)	1.690 (0.886, 3.224)	0.1030
Docetaxel	56	8 (14.3)	NR (NE, NE)	53	10 (18.9)	NR (3.5, NE)	0.664 (0.261, 1.687)	0.3822
Interaction								0.1036

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Pain

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	7 (16.3)	NR (NE, NE)	42	9 (21.4)	NR (3.5, NE)	0.643 (0.239, 1.730)	0.3716
1	96	25 (26.0)	NR (NE, NE)	96	16 (16.7)	NR (4.9, NE)	1.671 (0.892, 3.131)	0.1029
Interaction								0.0988
Region #1								
Asia	103	26 (25.2)	NR (NE, NE)	105	20 (19.0)	NR (4.9, NE)	1.271 (0.709, 2.277)	0.4149
Europe/North America	36	6 (16.7)	NR (NE, NE)	33	5 (15.2)	NR (3.3, NE)	1.166 (0.354, 3.839)	0.7996
Interaction								0.8245

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Pain

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	16 (20.5)	NR (NE, NE)	80	16 (20.0)	NR (3.5, NE)	0.986 (0.493, 1.972)	0.9681
Japan	25	10 (40.0)	NR (1.4, NE)	25	4 (16.0)	NR (4.9, NE)	2.542 (0.795, 8.127)	0.0973
Europe/North America	36	6 (16.7)	NR (NE, NE)	33	5 (15.2)	NR (3.3, NE)	1.166 (0.354, 3.839)	0.7996
Interaction								0.4055
Race								
Asian and other	105	26 (24.8)	NR (NE, NE)	114	21 (18.4)	NR (4.9, NE)	1.251 (0.704, 2.224)	0.4401
White	34	6 (17.6)	NR (NE, NE)	24	4 (16.7)	NR (3.3, NE)	1.303 (0.366, 4.637)	0.6809
Interaction								0.9409

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Pain

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	8 (17.8)	NR (NE, NE)	34	7 (20.6)	NR (NE, NE)	0.765 (0.277, 2.116)	0.6035
vCPS < 10%	53	14 (26.4)	NR (2.2, NE)	56	13 (23.2)	NR (2.8, NE)	1.115 (0.523, 2.376)	0.7761
Missing	41	10 (24.4)	NR (1.7, NE)	48	5 (10.4)	NR (3.5, NE)	2.485 (0.848, 7.283)	0.0801
Interaction								0.2747

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble Swallowing Saliva

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	7 (9.1)	NR (NE, NE)	77	3 (3.9)	NR (NE, NE)	2.105 (0.544, 8.149)	0.2697
>= 65 Years	62	5 (8.1)	NR (NE, NE)	61	4 (6.6)	NR (NE, NE)	1.068 (0.286, 3.987)	0.9219
Interaction								0.4975
Gender								
Male	118	10 (8.5)	NR (NE, NE)	111	7 (6.3)	NR (NE, NE)	1.238 (0.471, 3.254)	0.6641
Female	21	2 (9.5)	NR (2.9, NE)	27	0 (0.0)	NR (NE, NE)	76446444.086 (0.000, NE)	0.1720
Interaction								0.9918

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble Swallowing Saliva

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	9 (8.7)	NR (NE, NE)	105	6 (5.7)	NR (NE, NE)	1.450 (0.516, 4.079)	0.4776
Non-Smoker	35	3 (8.6)	NR (NE, NE)	33	1 (3.0)	NR (3.8, NE)	2.248 (0.233, 21.680)	0.4716
Interaction								0.7127
ICC Options								
Paclitaxel	83	9 (10.8)	NR (NE, NE)	85	3 (3.5)	NR (NE, NE)	2.977 (0.804, 11.028)	0.0859
Docetaxel	56	3 (5.4)	NR (NE, NE)	53	4 (7.5)	NR (NE, NE)	0.612 (0.136, 2.756)	0.5181
Interaction								0.1110

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble Swallowing Saliva

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	5 (11.6)	NR (NE, NE)	42	1 (2.4)	NR (NE, NE)	4.428 (0.516, 37.970)	0.1358
1	96	7 (7.3)	NR (NE, NE)	96	6 (6.3)	NR (NE, NE)	1.083 (0.364, 3.225)	0.8854
Interaction								0.2866
Region #1								
Asia	103	8 (7.8)	NR (NE, NE)	105	6 (5.7)	NR (NE, NE)	1.157 (0.401, 3.340)	0.7872
Europe/North America	36	4 (11.1)	NR (NE, NE)	33	1 (3.0)	NR (2.9, NE)	3.816 (0.426, 34.174)	0.1957
Interaction								0.3054

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble Swallowing Saliva

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	5 (6.4)	NR (NE, NE)	80	6 (7.5)	NR (NE, NE)	0.768 (0.234, 2.519)	0.6615
Japan	25	3 (12.0)	NR (NE, NE)	25	0 (0.0)	NR (NE, NE)	67914557.359 (0.000, NE)	0.1172
Europe/North America	36	4 (11.1)	NR (NE, NE)	33	1 (3.0)	NR (2.9, NE)	3.816 (0.426, 34.174)	0.1957
Interaction								0.4068
Race								
Asian and other	105	8 (7.6)	NR (NE, NE)	114	6 (5.3)	NR (NE, NE)	1.210 (0.419, 3.494)	0.7238
White	34	4 (11.8)	NR (NE, NE)	24	1 (4.2)	NR (2.9, NE)	3.285 (0.367, 29.405)	0.2573
Interaction								0.3885

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble Swallowing Saliva

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	3 (6.7)	--	34	2 (5.9)	--	--	--
vCPS < 10%	53	4 (7.5)	--	56	2 (3.6)	--	--	--
Missing	41	5 (12.2)	--	48	3 (6.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Choked When Swallowing

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	7 (9.1)	NR (7.0, NE)	77	5 (6.5)	NR (NE, NE)	1.302 (0.412, 4.115)	0.6526
>= 65 Years	62	6 (9.7)	NR (NE, NE)	61	8 (13.1)	NR (4.9, NE)	0.625 (0.216, 1.807)	0.3808
Interaction								0.3346
Gender								
Male	118	12 (10.2)	NR (NE, NE)	111	11 (9.9)	NR (NE, NE)	0.897 (0.395, 2.036)	0.7953
Female	21	1 (4.8)	NR (1.7, NE)	27	2 (7.4)	NR (2.8, NE)	0.561 (0.051, 6.210)	0.6331
Interaction								0.7045

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Choked When Swallowing

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	12 (11.5)	NR (7.0, NE)	105	10 (9.5)	NR (NE, NE)	1.102 (0.476, 2.555)	0.8193
Non-Smoker	35	1 (2.9)	NR (NE, NE)	33	3 (9.1)	NR (3.8, NE)	0.247 (0.026, 2.372)	0.1891
Interaction								0.1821
ICC Options								
Paclitaxel	83	8 (9.6)	NR (7.0, NE)	85	11 (12.9)	NR (4.9, NE)	0.668 (0.268, 1.666)	0.3832
Docetaxel	56	5 (8.9)	NR (NE, NE)	53	2 (3.8)	NR (NE, NE)	2.073 (0.398, 10.784)	0.3762
Interaction								0.2890

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Choked When Swallowing

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	5 (11.6)	NR (7.0, NE)	42	4 (9.5)	NR (4.5, NE)	1.051 (0.281, 3.925)	0.9406
1	96	8 (8.3)	NR (NE, NE)	96	9 (9.4)	NR (4.9, NE)	0.798 (0.308, 2.071)	0.6429
Interaction								0.7998
Region #1								
Asia	103	10 (9.7)	NR (NE, NE)	105	10 (9.5)	NR (4.9, NE)	0.821 (0.341, 1.979)	0.6599
Europe/North America	36	3 (8.3)	NR (NE, NE)	33	3 (9.1)	NR (2.8, NE)	0.844 (0.170, 4.193)	0.8347
Interaction								0.8861

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Choked When Swallowing

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	6 (7.7)	NR (NE, NE)	80	7 (8.8)	NR (4.5, NE)	0.779 (0.262, 2.320)	0.6531
Japan	25	4 (16.0)	NR (7.0, NE)	25	3 (12.0)	NR (4.9, NE)	0.937 (0.202, 4.343)	0.9334
Europe/North America	36	3 (8.3)	NR (NE, NE)	33	3 (9.1)	NR (2.8, NE)	0.844 (0.170, 4.193)	0.8347
Interaction								0.9694
Race								
Asian and other	105	10 (9.5)	NR (NE, NE)	114	11 (9.6)	NR (4.9, NE)	0.762 (0.322, 1.800)	0.5333
White	34	3 (8.8)	NR (NE, NE)	24	2 (8.3)	NR (NE, NE)	1.134 (0.189, 6.799)	0.8897
Interaction								0.6151

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Choked When Swallowing

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	2 (4.4)	NR (NE, NE)	34	3 (8.8)	NR (NE, NE)	0.471 (0.079, 2.821)	0.3986
vCPS < 10%	53	4 (7.5)	NR (4.2, NE)	56	7 (12.5)	NR (3.8, NE)	0.520 (0.152, 1.778)	0.2882
Missing	41	7 (17.1)	NR (7.0, NE)	48	3 (6.3)	NR (4.9, NE)	2.715 (0.701, 10.510)	0.1313
Interaction								0.1302

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Dry Mouth

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	18 (23.4)	NR (3.6, NE)	77	7 (9.1)	NR (NE, NE)	2.766 (1.152, 6.637)	0.0172
>= 65 Years	62	10 (16.1)	NR (11.8, NE)	61	11 (18.0)	NR (3.7, NE)	0.729 (0.302, 1.763)	0.4789
Interaction								0.0507
Gender								
Male	118	26 (22.0)	NR (11.8, NE)	111	16 (14.4)	NR (NE, NE)	1.448 (0.775, 2.706)	0.2408
Female	21	2 (9.5)	NR (NE, NE)	27	2 (7.4)	NR (NE, NE)	1.256 (0.176, 8.951)	0.8194
Interaction								0.8962

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Dry Mouth

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	20 (19.2)	NR (NE, NE)	105	16 (15.2)	NR (4.9, NE)	1.270 (0.658, 2.453)	0.4727
Non-Smoker	35	8 (22.9)	11.8 (2.3, NE)	33	2 (6.1)	NR (NE, NE)	2.695 (0.560, 12.979)	0.1979
Interaction								0.3263
ICC Options								
Paclitaxel	83	19 (22.9)	11.8 (11.8, NE)	85	9 (10.6)	NR (NE, NE)	2.186 (0.984, 4.852)	0.0484
Docetaxel	56	9 (16.1)	NR (4.2, NE)	53	9 (17.0)	NR (2.9, NE)	0.765 (0.300, 1.951)	0.5695
Interaction								0.0897

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Dry Mouth

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	13 (30.2)	11.8 (3.6, NE)	42	3 (7.1)	NR (NE, NE)	3.600 (1.022, 12.686)	0.0321
1	96	15 (15.6)	NR (NE, NE)	96	15 (15.6)	NR (3.7, NE)	1.009 (0.493, 2.065)	0.9803
Interaction								0.0747
Region #1								
Asia	103	22 (21.4)	NR (11.8, NE)	105	14 (13.3)	NR (4.9, NE)	1.479 (0.754, 2.900)	0.2499
Europe/North America	36	6 (16.7)	NR (2.8, NE)	33	4 (12.1)	NR (2.9, NE)	1.306 (0.368, 4.639)	0.6772
Interaction								0.9358

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Dry Mouth

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	15 (19.2)	NR (4.2, NE)	80	10 (12.5)	NR (4.9, NE)	1.552 (0.697, 3.458)	0.2755
Japan	25	7 (28.0)	11.8 (11.8, NE)	25	4 (16.0)	NR (NE, NE)	1.578 (0.455, 5.468)	0.4673
Europe/North America	36	6 (16.7)	NR (2.8, NE)	33	4 (12.1)	NR (2.9, NE)	1.306 (0.368, 4.639)	0.6772
Interaction								0.9957
Race								
Asian and other	105	22 (21.0)	NR (11.8, NE)	114	15 (13.2)	NR (4.9, NE)	1.438 (0.743, 2.781)	0.2757
White	34	6 (17.6)	NR (2.8, NE)	24	3 (12.5)	NR (2.9, NE)	1.458 (0.364, 5.839)	0.5911
Interaction								0.8974

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Dry Mouth

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	3 (6.7)	NR (NE, NE)	34	4 (11.8)	NR (3.4, NE)	0.483 (0.107, 2.171)	0.3321
vCPS < 10%	53	12 (22.6)	NR (4.2, NE)	56	8 (14.3)	NR (NE, NE)	1.484 (0.606, 3.632)	0.3815
Missing	41	13 (31.7)	11.8 (1.4, NE)	48	6 (12.5)	NR (NE, NE)	2.558 (0.959, 6.823)	0.0498
Interaction								0.1614

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble With Taste

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	14 (18.2)	NR (NE, NE)	77	8 (10.4)	NR (NE, NE)	1.651 (0.692, 3.940)	0.2510
>= 65 Years	62	9 (14.5)	NR (NE, NE)	61	7 (11.5)	NR (NE, NE)	1.127 (0.419, 3.033)	0.8124
Interaction								0.6178
Gender								
Male	118	20 (16.9)	NR (NE, NE)	111	11 (9.9)	NR (NE, NE)	1.614 (0.773, 3.371)	0.1968
Female	21	3 (14.3)	NR (1.4, NE)	27	4 (14.8)	NR (1.8, NE)	0.846 (0.187, 3.825)	0.8259
Interaction								0.4374

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble With Taste

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	17 (16.3)	NR (NE, NE)	105	14 (13.3)	NR (NE, NE)	1.142 (0.562, 2.322)	0.7122
Non-Smoker	35	6 (17.1)	NR (2.2, NE)	33	1 (3.0)	NR (NE, NE)	4.570 (0.550, 37.970)	0.1221
Interaction								0.2166
ICC Options								
Paclitaxel	83	13 (15.7)	NR (NE, NE)	85	7 (8.2)	NR (NE, NE)	1.780 (0.709, 4.465)	0.2122
Docetaxel	56	10 (17.9)	NR (NE, NE)	53	8 (15.1)	NR (2.9, NE)	1.052 (0.413, 2.681)	0.9142
Interaction								0.4199

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble With Taste

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	6 (14.0)	NR (NE, NE)	42	6 (14.3)	NR (NE, NE)	0.750 (0.241, 2.340)	0.6189
1	96	17 (17.7)	NR (NE, NE)	96	9 (9.4)	NR (NE, NE)	1.864 (0.830, 4.185)	0.1234
Interaction								0.2283
Region #1								
Asia	103	16 (15.5)	NR (NE, NE)	105	11 (10.5)	NR (NE, NE)	1.357 (0.629, 2.927)	0.4330
Europe/North America	36	7 (19.4)	NR (2.2, NE)	33	4 (12.1)	NR (2.9, NE)	1.574 (0.460, 5.382)	0.4654
Interaction								0.7785

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble With Taste

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	14 (17.9)	NR (NE, NE)	80	5 (6.3)	NR (NE, NE)	2.790 (1.005, 7.747)	0.0392
Japan	25	2 (8.0)	NR (NE, NE)	25	6 (24.0)	NR (2.2, NE)	0.259 (0.052, 1.298)	0.0770
Europe/North America	36	7 (19.4)	NR (2.2, NE)	33	4 (12.1)	NR (2.9, NE)	1.574 (0.460, 5.382)	0.4654
Interaction								0.0475
Race								
Asian and other	105	16 (15.2)	NR (NE, NE)	114	13 (11.4)	NR (NE, NE)	1.193 (0.573, 2.484)	0.6345
White	34	7 (20.6)	NR (2.2, NE)	24	2 (8.3)	NR (2.9, NE)	2.819 (0.585, 13.579)	0.1768
Interaction								0.3131

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble With Taste

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	4 (8.9)	NR (NE, NE)	34	2 (5.9)	NR (NE, NE)	1.465 (0.268, 8.016)	0.6560
vCPS < 10%	53	10 (18.9)	NR (NE, NE)	56	7 (12.5)	NR (NE, NE)	1.443 (0.549, 3.791)	0.4537
Missing	41	9 (22.0)	NR (2.2, NE)	48	6 (12.5)	NR (NE, NE)	1.712 (0.608, 4.820)	0.2999
Interaction								0.9659

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble With Coughing

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	16 (20.8)	NR (NE, NE)	77	11 (14.3)	NR (4.5, NE)	1.456 (0.674, 3.142)	0.3329
>= 65 Years	62	10 (16.1)	NR (NE, NE)	61	7 (11.5)	NR (4.9, NE)	1.191 (0.452, 3.141)	0.7224
Interaction								0.8039
Gender								
Male	118	22 (18.6)	NR (NE, NE)	111	16 (14.4)	NR (4.9, NE)	1.239 (0.651, 2.361)	0.5109
Female	21	4 (19.0)	NR (1.1, NE)	27	2 (7.4)	NR (NE, NE)	2.794 (0.512, 15.262)	0.2153
Interaction								0.4990

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble With Coughing

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	23 (22.1)	NR (NE, NE)	105	16 (15.2)	NR (4.9, NE)	1.502 (0.793, 2.845)	0.2058
Non-Smoker	35	3 (8.6)	NR (NE, NE)	33	2 (6.1)	NR (3.5, NE)	0.945 (0.157, 5.686)	0.9514
Interaction								0.6684
ICC Options								
Paclitaxel	83	12 (14.5)	NR (NE, NE)	85	13 (15.3)	NR (4.9, NE)	0.880 (0.401, 1.931)	0.7484
Docetaxel	56	14 (25.0)	NR (2.8, NE)	53	5 (9.4)	NR (3.5, NE)	2.704 (0.973, 7.516)	0.0460
Interaction								0.0869

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble With Coughing

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	11 (25.6)	NR (NE, NE)	42	4 (9.5)	NR (NE, NE)	2.472 (0.785, 7.786)	0.1084
1	96	15 (15.6)	NR (NE, NE)	96	14 (14.6)	NR (4.9, NE)	1.024 (0.494, 2.123)	0.9486
Interaction								0.2278
Region #1								
Asia	103	21 (20.4)	NR (NE, NE)	105	14 (13.3)	NR (4.9, NE)	1.437 (0.730, 2.827)	0.2886
Europe/North America	36	5 (13.9)	NR (NE, NE)	33	4 (12.1)	NR (2.9, NE)	1.071 (0.286, 4.007)	0.9191
Interaction								0.6787

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble With Coughing

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	16 (20.5)	NR (NE, NE)	80	9 (11.3)	NR (4.5, NE)	1.821 (0.804, 4.123)	0.1424
Japan	25	5 (20.0)	NR (NE, NE)	25	5 (20.0)	NR (4.9, NE)	0.881 (0.254, 3.063)	0.8422
Europe/North America	36	5 (13.9)	NR (NE, NE)	33	4 (12.1)	NR (2.9, NE)	1.071 (0.286, 4.007)	0.9191
Interaction								0.5658
Race								
Asian and other	105	22 (21.0)	NR (NE, NE)	114	14 (12.3)	NR (4.9, NE)	1.573 (0.804, 3.075)	0.1798
White	34	4 (11.8)	NR (NE, NE)	24	4 (16.7)	NR (2.9, NE)	0.699 (0.174, 2.808)	0.6118
Interaction								0.3035

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble With Coughing

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	6 (13.3)	NR (NE, NE)	34	2 (5.9)	NR (NE, NE)	2.357 (0.475, 11.694)	0.2785
vCPS < 10%	53	12 (22.6)	NR (NE, NE)	56	8 (14.3)	NR (4.5, NE)	1.524 (0.623, 3.731)	0.3512
Missing	41	8 (19.5)	NR (2.8, NE)	48	8 (16.7)	NR (3.5, NE)	1.145 (0.429, 3.055)	0.7846
Interaction								0.7839

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble Talking

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	11 (14.3)	NR (7.0, NE)	77	3 (3.9)	NR (NE, NE)	3.475 (0.968, 12.470)	0.0416
>= 65 Years	62	6 (9.7)	NR (NE, NE)	61	3 (4.9)	NR (NE, NE)	1.747 (0.436, 6.998)	0.4242
Interaction								0.4590
Gender								
Male	118	16 (13.6)	NR (NE, NE)	111	5 (4.5)	NR (NE, NE)	2.796 (1.023, 7.640)	0.0361
Female	21	1 (4.8)	NR (NE, NE)	27	1 (3.7)	NR (NE, NE)	1.243 (0.078, 19.934)	0.8776
Interaction								0.5379

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble Talking

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	13 (12.5)	NR (NE, NE)	105	5 (4.8)	NR (NE, NE)	2.492 (0.887, 6.998)	0.0726
Non-Smoker	35	4 (11.4)	NR (NE, NE)	33	1 (3.0)	NR (3.5, NE)	2.956 (0.330, 26.497)	0.3074
Interaction								0.8767
ICC Options								
Paclitaxel	83	12 (14.5)	NR (7.0, NE)	85	3 (3.5)	NR (NE, NE)	3.900 (1.100, 13.823)	0.0226
Docetaxel	56	5 (8.9)	NR (NE, NE)	53	3 (5.7)	NR (3.5, NE)	1.307 (0.309, 5.532)	0.7149
Interaction								0.2746

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble Talking

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	5 (11.6)	NR (7.0, NE)	42	1 (2.4)	NR (NE, NE)	3.944 (0.459, 33.859)	0.1769
1	96	12 (12.5)	NR (NE, NE)	96	5 (5.2)	NR (NE, NE)	2.342 (0.825, 6.652)	0.0989
Interaction								0.6527
Region #1								
Asia	103	13 (12.6)	NR (NE, NE)	105	4 (3.8)	NR (NE, NE)	2.899 (0.943, 8.915)	0.0516
Europe/North America	36	4 (11.1)	NR (NE, NE)	33	2 (6.1)	NR (2.9, NE)	1.790 (0.327, 9.807)	0.4960
Interaction								0.6504

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble Talking

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	10 (12.8)	NR (NE, NE)	80	3 (3.8)	NR (NE, NE)	3.336 (0.918, 12.127)	0.0518
Japan	25	3 (12.0)	NR (7.0, NE)	25	1 (4.0)	NR (NE, NE)	2.060 (0.204, 20.822)	0.5325
Europe/North America	36	4 (11.1)	NR (NE, NE)	33	2 (6.1)	NR (2.9, NE)	1.790 (0.327, 9.807)	0.4960
Interaction								0.8620
Race								
Asian and other	105	13 (12.4)	NR (NE, NE)	114	4 (3.5)	NR (NE, NE)	3.012 (0.979, 9.264)	0.0431
White	34	4 (11.8)	NR (NE, NE)	24	2 (8.3)	NR (2.9, NE)	1.538 (0.281, 8.422)	0.6169
Interaction								0.5255

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 16MAY2024 03:12 t-14-02-06-03-01-02-b-s-eff-tteqs-subgrp-o18-itts-fa.rtf

Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble Talking

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	5 (11.1)	NR (NE, NE)	34	0 (0.0)	NR (NE, NE)	22692498.345 (0.000, NE)	0.0537
vCPS < 10%	53	9 (17.0)	NR (NE, NE)	56	2 (3.6)	NR (NE, NE)	4.593 (0.992, 21.259)	0.0318
Missing	41	3 (7.3)	NR (7.0, NE)	48	4 (8.3)	NR (3.5, NE)	0.697 (0.154, 3.156)	0.6381
Interaction								0.2636

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

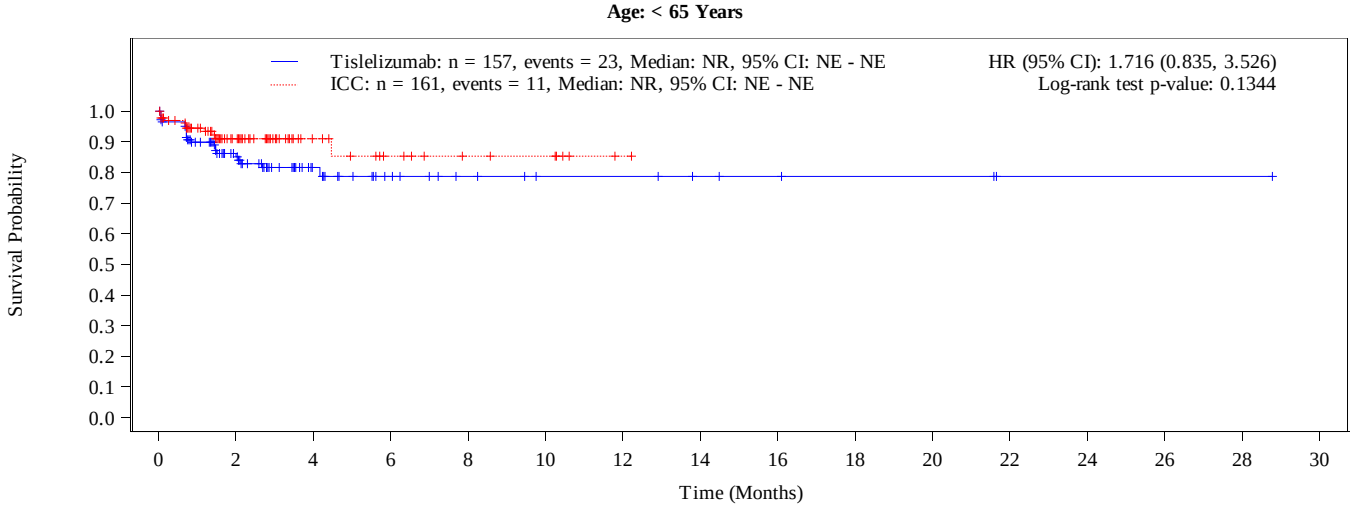
[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 16MAY2024 03:12 t-14-02-06-03-01-02-b-s-eff-tteqs-subgrp-o18-itts-fa.rtf

Figure 14.2.7.2.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Eating



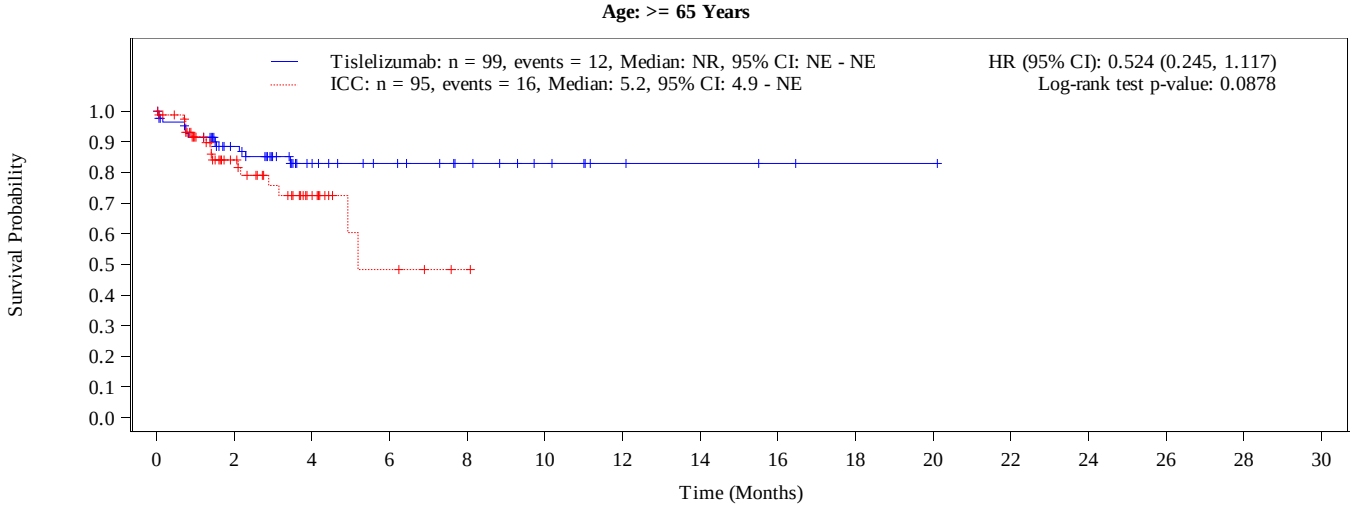
Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	157	79	28	15	10	7	7	5	4	3	3	1	1	1	1	0
ICC	161	49	18	11	7	6	1	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 16MAY2024 03:40 f-14-02-07-02-02-s-km-tteqs-subgrp-o18-itt-fa.rtf

Figure 14.2.7.2.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Eating



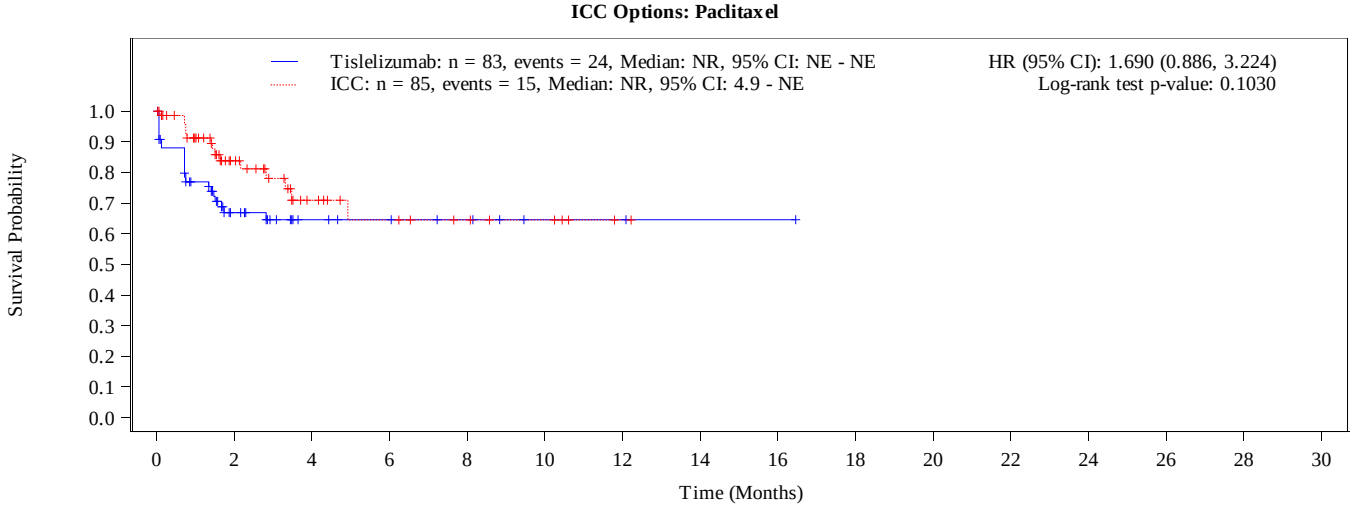
Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	99	54	24	18	13	9	5	3	2	1	1	0	0	0	0	0
ICC	95	35	13	4	1	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 16MAY2024 03:40 f-14-02-07-02-02-s-km-tteqs-subgrp-o18-itt-fa.rtf

Figure 14.2.7.2.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Pain

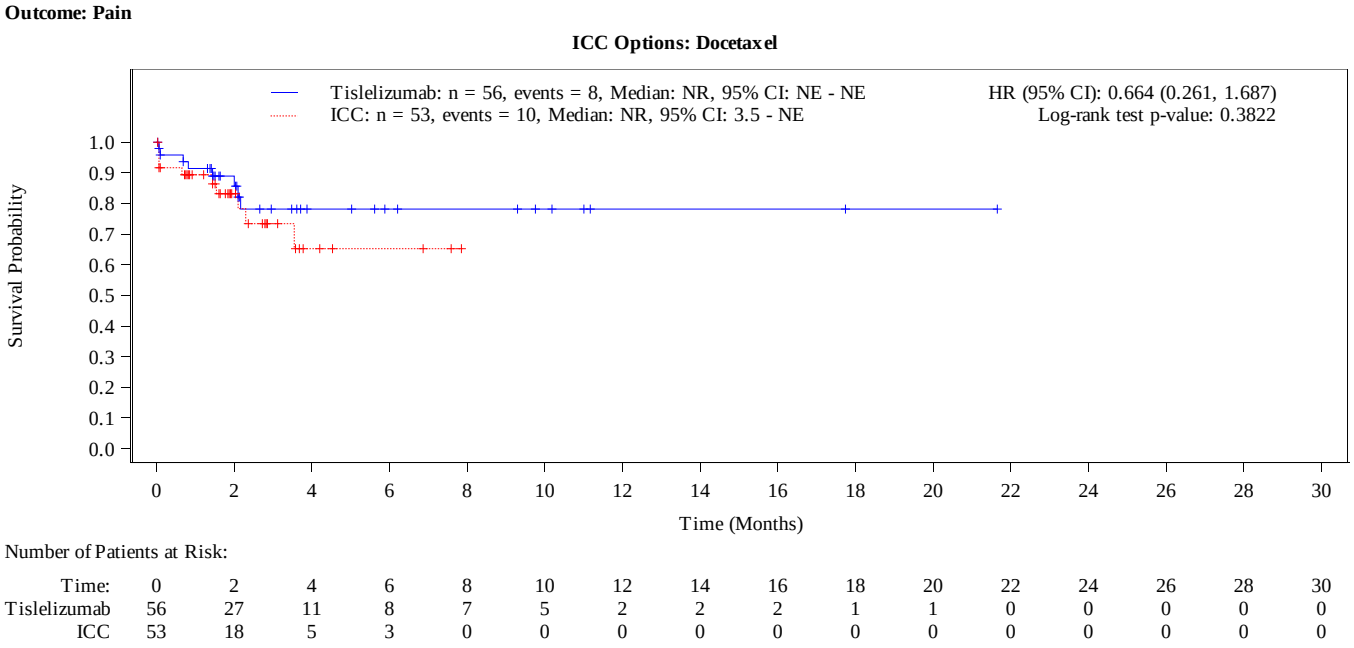


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	83	32	9	7	5	2	2	1	1	0	0	0	0	0	0	0
ICC	85	34	15	10	7	5	1	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 16MAY2024 03:40 f-14-02-07-02-02-s-km-tteqs-subgrp-o18-itt-fa.rtf

Figure 14.2.7.2.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set



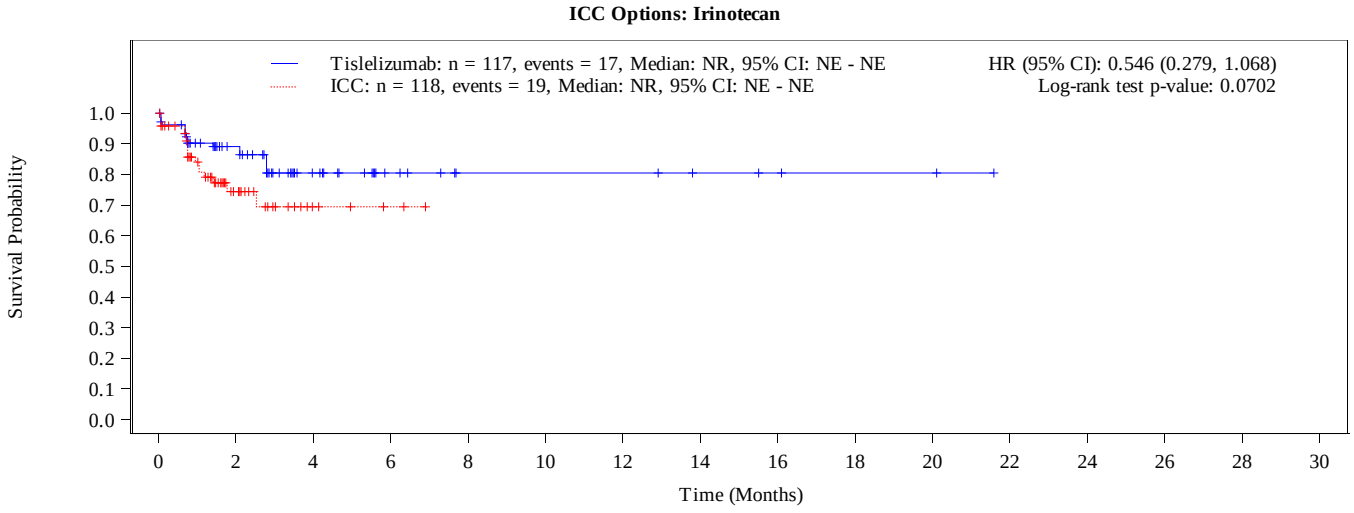
Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	56	27	11	8	7	5	2	2	2	1	1	0	0	0	0	0
ICC	53	18	5	3	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 16MAY2024 03:40 f-14-02-07-02-02-s-km-tteqs-subgrp-o18-itt-fa.rtf

Figure 14.2.7.2.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Pain



Number of Patients at Risk:

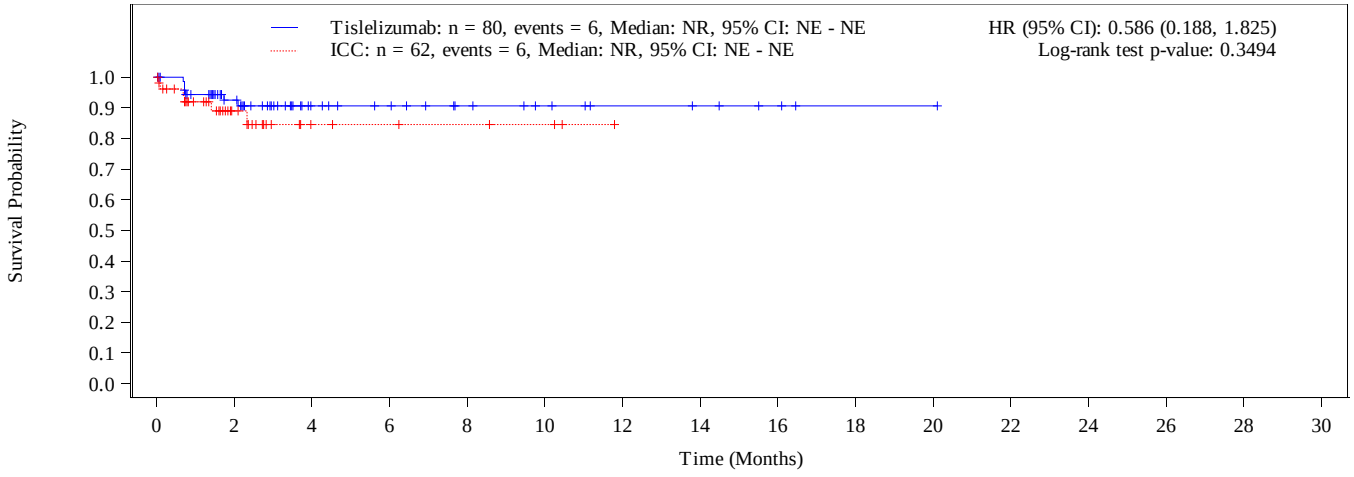
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	117	67	23	12	6	6	6	4	3	2	2	0	0	0	0	0
ICC	118	24	5	2	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 16MAY2024 03:40 f-14-02-07-02-02-s-km-tteqs-subgrp-o18-itt-fa.rtf

Figure 14.2.7.2.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Choked When Swallowing

Baseline PD-L1 Status: vCPS >= 10%

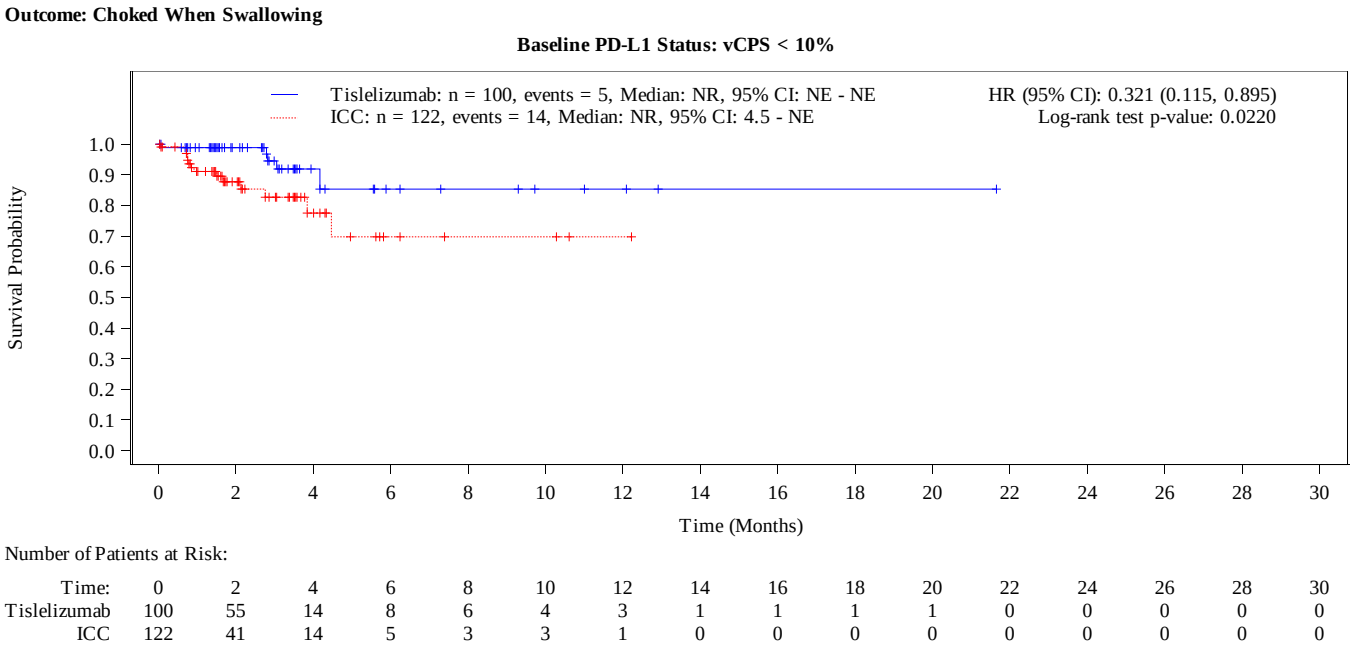


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	80	50	22	18	12	9	6	5	3	1	1	0	0	0	0	0
ICC	62	21	6	5	4	3	0	0	0	0	0	0	0	0	0	0

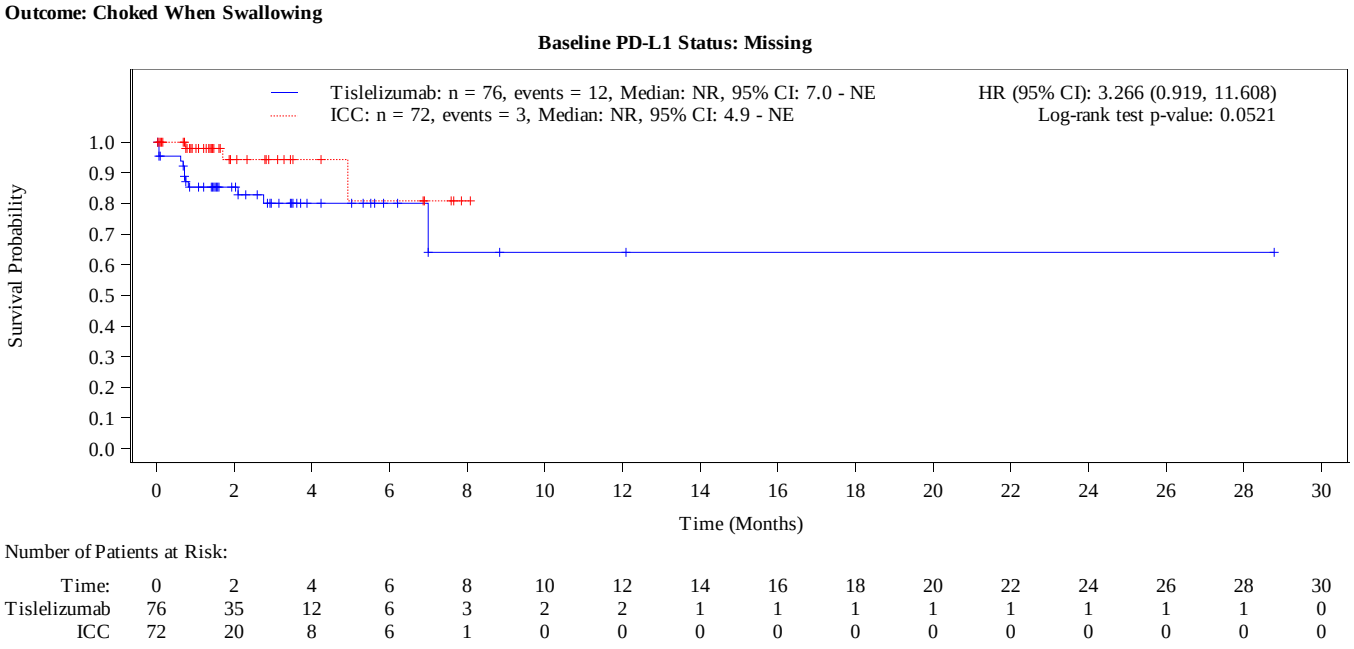
Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 16MAY2024 03:40 f-14-02-07-02-02-s-km-tteqs-subgrp-o18-itt-fa.rtf

Figure 14.2.7.2.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set



Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 16MAY2024 03:40 f-14-02-07-02-02-s-km-tteqs-subgrp-o18-itt-fa.rtf

Figure 14.2.7.2.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set



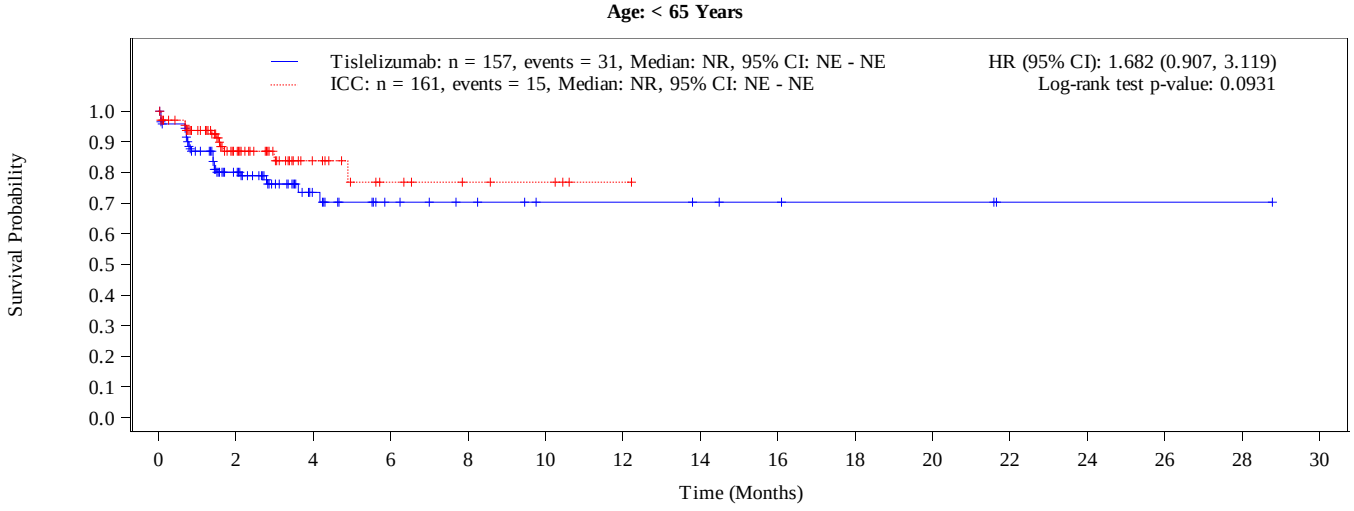
Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	76	35	12	6	3	2	2	1	1	1	1	1	1	1	1	0
ICC	72	20	8	6	1	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 16MAY2024 03:40 f-14-02-07-02-02-s-km-tteqs-subgrp-o18-itt-fa.rtf

Figure 14.2.7.2.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Dry Mouth



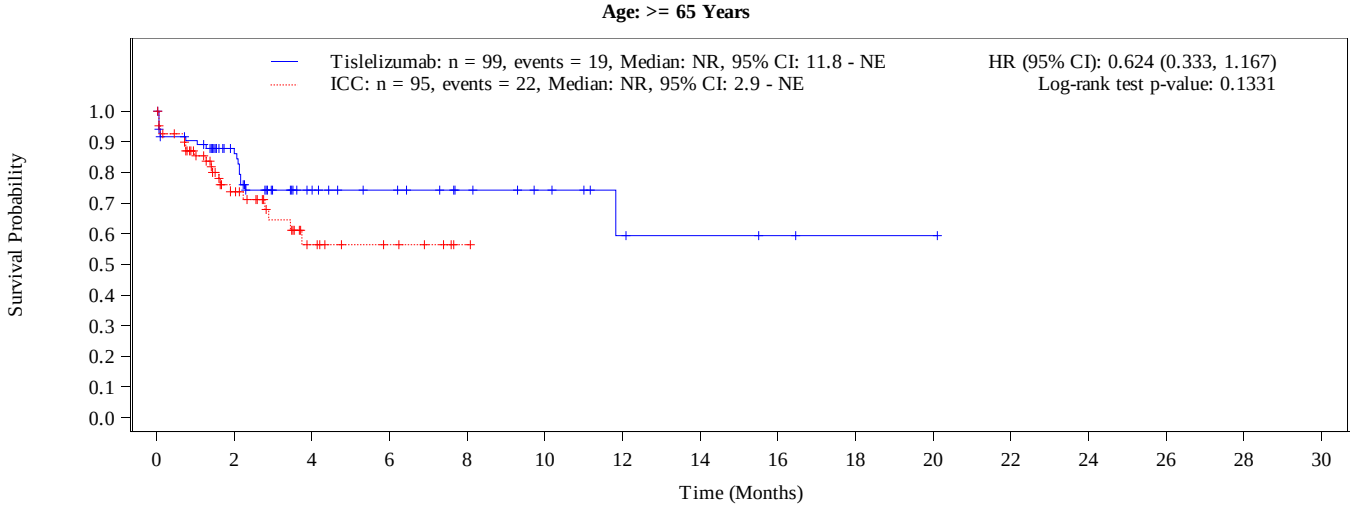
Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	157	74	23	12	9	6	6	5	4	3	3	1	1	1	1	0
ICC	161	44	16	8	5	4	1	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 16MAY2024 03:40 f-14-02-07-02-02-s-km-tteqs-subgrp-o18-itt-fa.rtf

Figure 14.2.7.2.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Dry Mouth

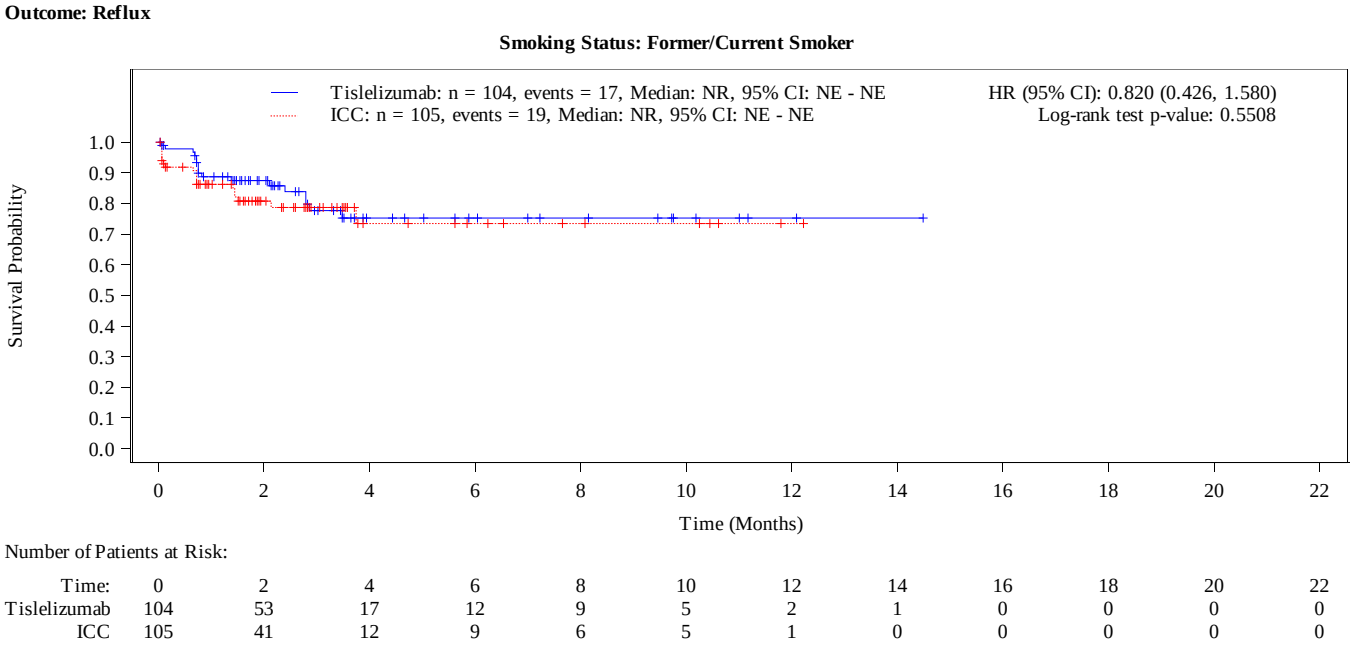


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	99	52	21	16	11	8	4	3	2	1	1	0	0	0	0	0
ICC	95	31	11	6	1	0	0	0	0	0	0	0	0	0	0	0

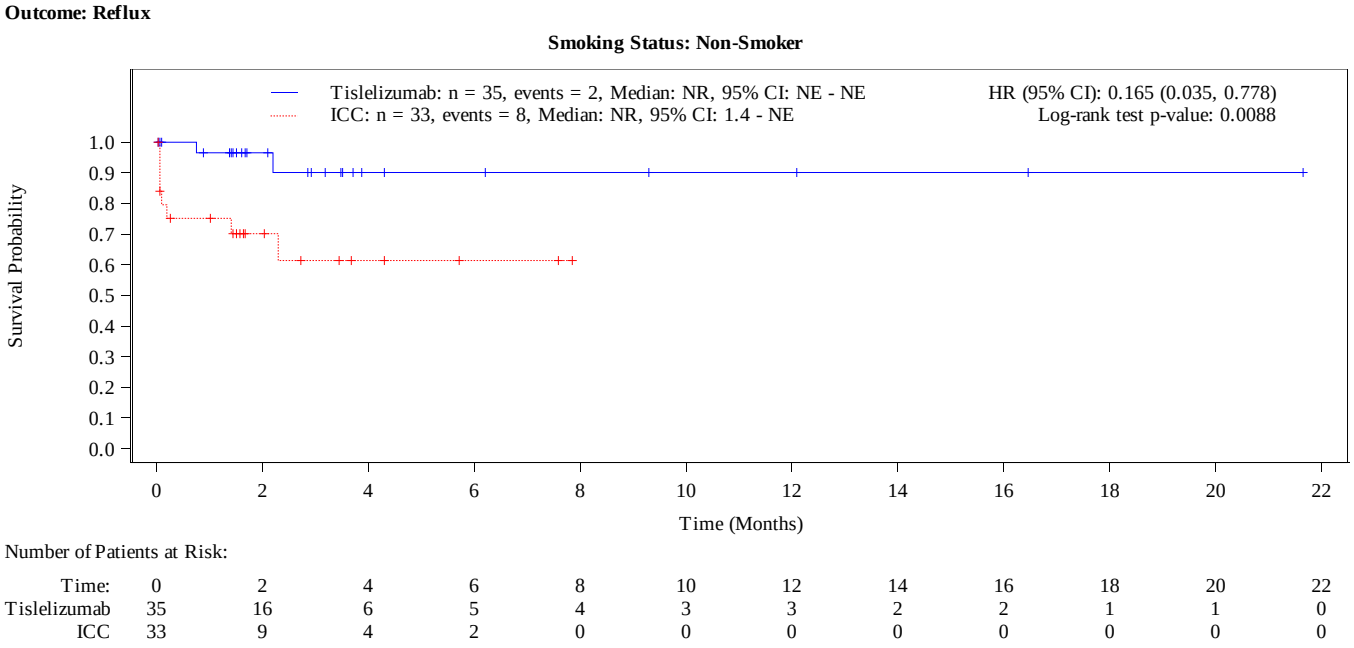
Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 16MAY2024 03:40 f-14-02-07-02-02-s-km-tteqs-subgrp-o18-itt-fa.rtf

Figure 14.2.7.2.2.b.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 16MAY2024 03:40 f-14-02-07-02-02-b-s-km-tteqs-subgrp-o18-itts-fa.rtf

Figure 14.2.7.2.2.b.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan



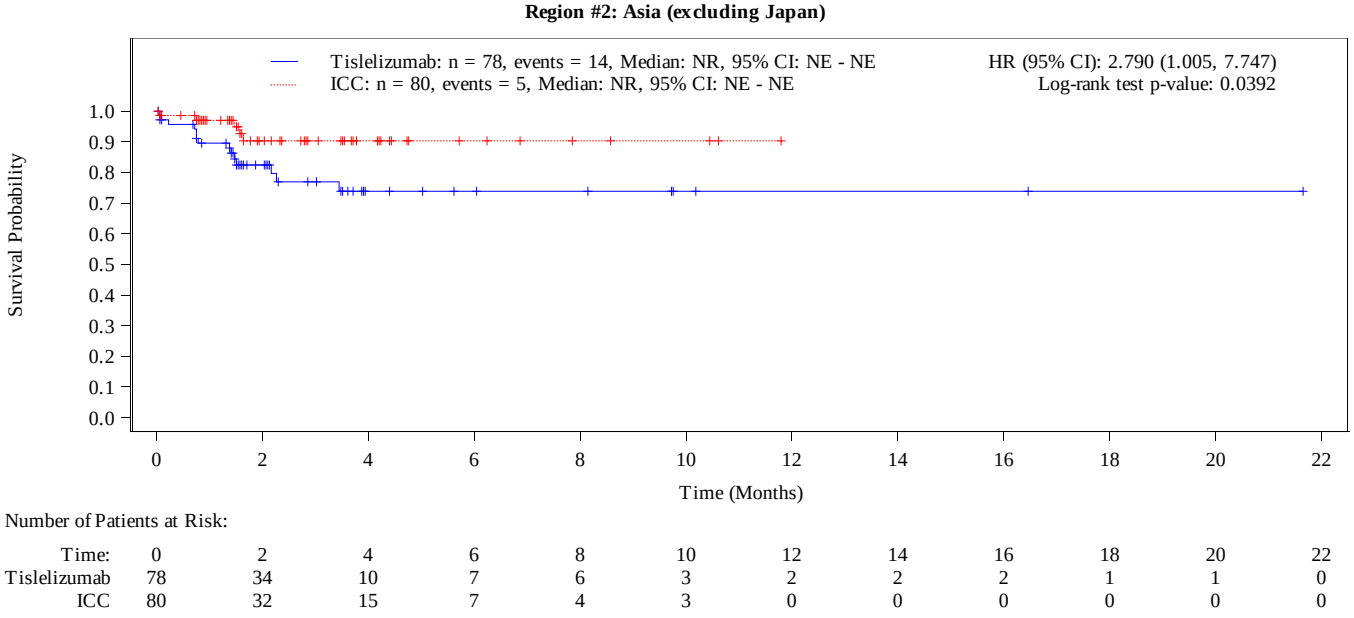
Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	35	16	6	5	4	3	3	2	2	1	1	0
ICC	33	9	4	2	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 16MAY2024 03:40 f-14-02-07-02-02-b-s-km-tteqs-subgrp-o18-itts-fa.rtf

Figure 14.2.7.2.2.b.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble With Taste

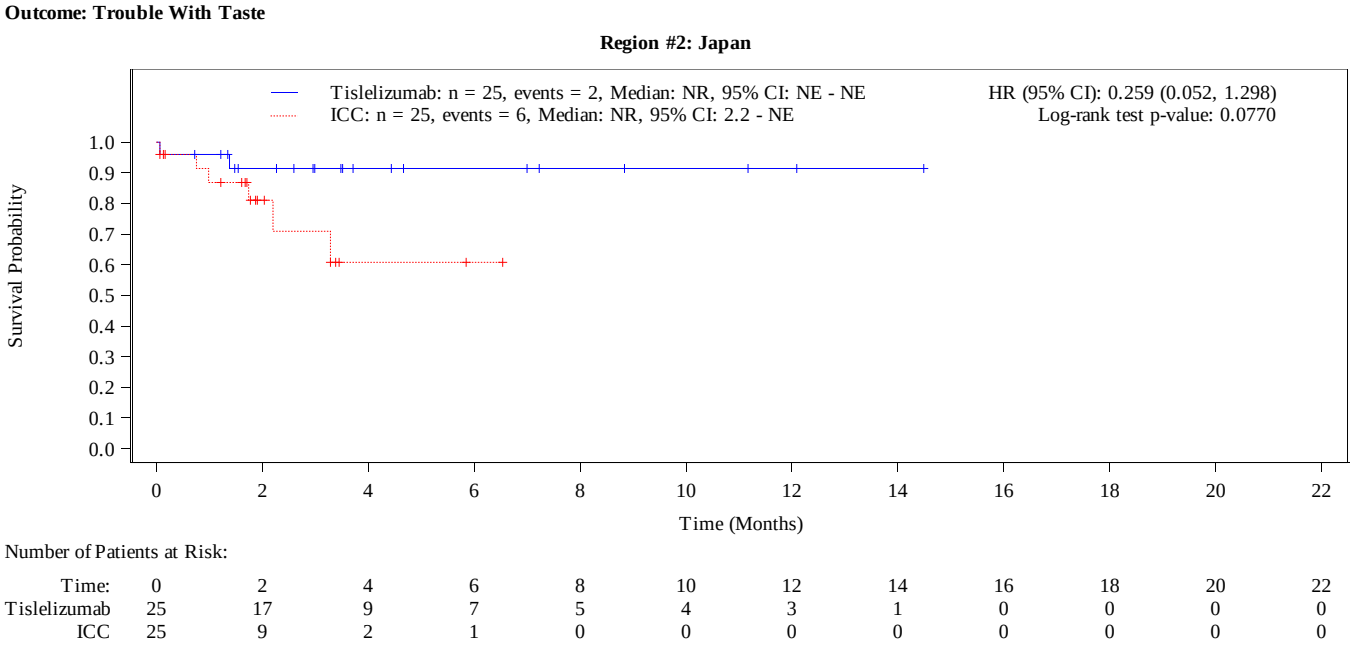


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	78	34	10	7	6	3	2	2	2	1	1	0
ICC	80	32	15	7	4	3	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 16MAY2024 03:40 f-14-02-07-02-02-b-s-km-tteqs-subgrp-o18-itts-fa.rtf

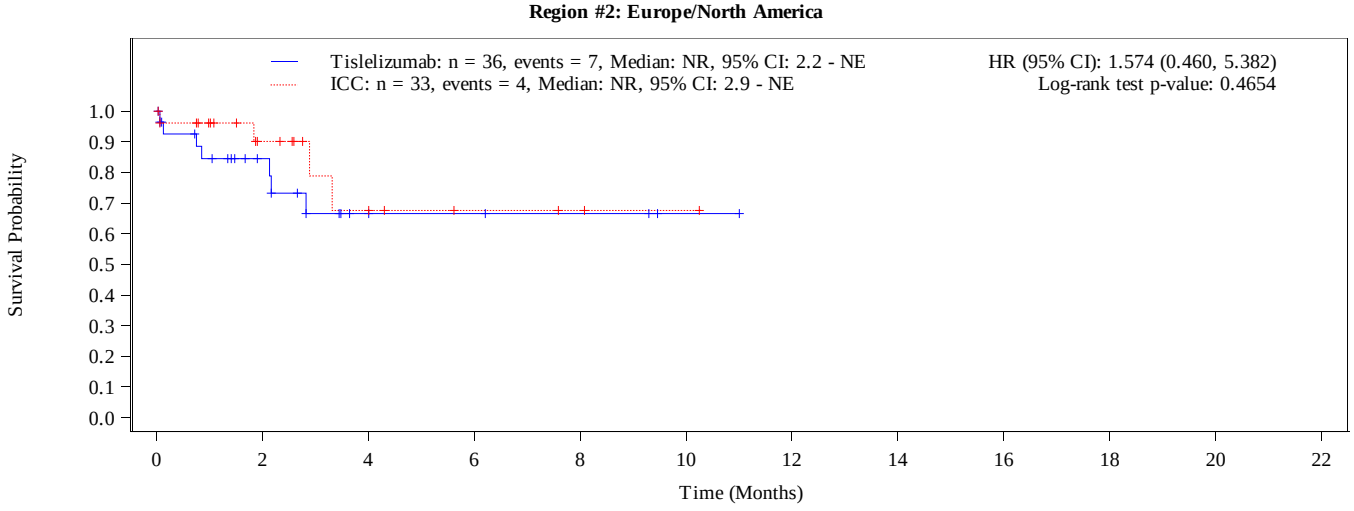
Figure 14.2.7.2.2.b.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 16MAY2024 03:40 f-14-02-07-02-02-b-s-km-tteqs-subgrp-o18-itts-fa.rtf

Figure 14.2.7.2.2.b.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble With Taste



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	36	15	5	4	3	1	0	0	0	0	0	0
ICC	33	13	6	3	2	1	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 16MAY2024 03:40 f-14-02-07-02-02-b-s-km-tteqs-subgrp-o18-itts-fa.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: EQ-5D-5L VAS Score

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	242		247	
	Mean (SD)	73.7 (17.05)		72.5 (18.13)	
	Median	80.0		75.0	
	Min, Max	10, 100		10, 100	
Cycle 1	n	140	133	134	130
	Mean (SD)	73.4 (17.90)	0.1 (11.59)	72.9 (17.68)	-0.3 (10.87)
	Median	79.0	0.0	75.0	0.0
	Min, Max	10, 100	-43, 35	10, 100	-30, 42
Cycle 2	n	223	212	173	169
	Mean (SD)	74.0 (18.22)	-1.2 (14.73)	70.3 (18.67)	-2.1 (14.76)
	Median	80.0	0.0	75.0	0.0
	Min, Max	5, 100	-65, 45	10, 100	-65, 49
Cycle 3	n	180	171	90	87
	Mean (SD)	74.5 (17.53)	-1.6 (13.26)	70.9 (18.15)	-1.9 (14.25)
	Median	80.0	0.0	75.0	0.0
	Min, Max	1, 100	-69, 31	0, 100	-49, 30

Source: Listing 16.2.6.6.3. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-05-01-qs-chg-eq5d-itt-fa.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: EQ-5D-5L VAS Score

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	147	139	77	74
	Mean (SD)	77.5 (14.77)	-0.2 (10.91)	70.8 (17.01)	-1.8 (14.17)
	Median	80.0	0.0	76.0	0.0
	Min, Max	19, 100	-28, 30	25, 100	-50, 25
Cycle 5	n	109	104	45	42
	Mean (SD)	78.7 (14.64)	0.3 (13.40)	73.3 (15.53)	-4.2 (17.64)
	Median	81.0	0.0	76.0	-0.5
	Min, Max	40, 100	-44, 34	39, 100	-50, 45
Cycle 6	n	99	94	36	33
	Mean (SD)	78.5 (16.03)	-0.6 (14.81)	73.8 (16.32)	-5.9 (16.34)
	Median	80.0	0.0	80.0	-3.0
	Min, Max	18, 100	-72, 34	40, 100	-50, 20
End of Treatment	n	73	71	83	81
	Mean (SD)	62.0 (22.10)	-11.2 (17.06)	63.8 (19.90)	-9.8 (15.68)
	Median	62.0	-10.0	62.0	-10.0
	Min, Max	10, 100	-60, 20	3, 100	-50, 31

Source: Listing 16.2.6.6.3. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-05-01-qs-chg-eq5d-itt-fa.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: EQ-5D-5L VAS Score

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	106	102	96	94
	Mean (SD)	65.2 (21.95)	-10.0 (18.19)	65.6 (21.21)	-8.2 (16.72)
	Median	70.0	-7.5	70.0	-9.5
	Min, Max	1, 100	-69, 35	0, 100	-59, 30
Worst Post-Baseline Value	n	245	231	228	221
	Mean (SD)	62.5 (21.49)	-11.6 (16.53)	61.5 (20.35)	-10.8 (16.47)
	Median	69.0	-10.0	64.5	-10.0
	Min, Max	1, 100	-72, 28	0, 100	-65, 32

Source: Listing 16.2.6.6.3. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-05-01-qs-chg-eq5d-itt-fa.rtf

Table 14.2.6.5.1.b:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: EQ-5D-5L VAS Score

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		134	
	Mean (SD)	72.3 (17.25)		72.0 (18.80)	
	Median	76.5		75.0	
	Min, Max	10, 100		10, 100	
Cycle 1	n	83	78	83	82
	Mean (SD)	72.3 (19.36)	0.3 (12.13)	71.5 (18.96)	-0.7 (11.18)
	Median	75.0	0.0	75.0	0.0
	Min, Max	10, 100	-43, 35	10, 100	-30, 32
Cycle 2	n	124	114	96	95
	Mean (SD)	72.6 (18.85)	-1.1 (16.70)	69.2 (20.14)	-2.9 (15.29)
	Median	80.0	0.0	75.0	0.0
	Min, Max	5, 100	-65, 45	10, 100	-65, 30
Cycle 3	n	98	89	57	56
	Mean (SD)	71.9 (19.34)	-2.0 (15.22)	68.4 (19.48)	-4.1 (15.28)
	Median	76.5	0.0	70.0	-5.0
	Min, Max	1, 100	-69, 30	0, 100	-49, 30

Source: Listing 16.2.6.6.3. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-05-01-b-qs-chg-eq5d-itts-fa.rtf

Table 14.2.6.5.1.b:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: EQ-5D-5L VAS Score

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	77	69	52	51
	Mean (SD)	75.6 (16.27)	0.6 (11.85)	68.4 (18.00)	-3.9 (15.45)
	Median	80.0	0.0	71.5	0.0
	Min, Max	19, 100	-28, 29	25, 100	-50, 25
Cycle 5	n	57	52	32	31
	Mean (SD)	75.9 (15.56)	-0.7 (15.52)	71.1 (16.41)	-4.5 (19.59)
	Median	80.0	0.0	74.0	0.0
	Min, Max	40, 100	-44, 34	39, 100	-50, 45
Cycle 6	n	55	50	25	24
	Mean (SD)	76.9 (18.49)	-0.9 (18.22)	72.9 (17.83)	-6.9 (18.83)
	Median	83.0	0.5	80.0	-2.5
	Min, Max	18, 100	-72, 34	40, 100	-50, 20
End of Treatment	n	38	36	46	45
	Mean (SD)	58.6 (21.76)	-13.5 (18.33)	63.1 (20.70)	-10.4 (16.44)
	Median	60.0	-10.0	62.0	-9.0
	Min, Max	20, 97	-60, 20	3, 100	-50, 31

Source: Listing 16.2.6.6.3. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-05-01-b-qs-chg-eq5d-itts-fa.rtf

Table 14.2.6.5.1.b:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: EQ-5D-5L VAS Score

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	62	58	61	60
	Mean (SD)	60.4 (22.95)	-12.0 (20.72)	64.8 (22.38)	-8.8 (17.11)
	Median	65.0	-9.5	70.0	-10.0
	Min, Max	1, 100	-69, 35	0, 100	-59, 25
Worst Post-Baseline Value	n	136	125	129	126
	Mean (SD)	59.2 (21.93)	-13.6 (18.11)	59.4 (21.89)	-12.4 (17.75)
	Median	62.5	-10.0	60.0	-10.0
	Min, Max	1, 100	-72, 28	0, 100	-65, 32

Source: Listing 16.2.6.6.3. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 22APR2024 22:41 t-14-02-06-05-01-b-qs-chg-eq5d-itts-fa.rtf

Table 14.2.6.5.1.1:
EQ-5D VAS: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
EQ-5D VAS									
Cycle 4	139		-0.15 (0.97)	74		-2.88 (1.25)	2.73 (-0.28, 5.75)	0.24 (-0.02, 0.50)	0.0755
Cycle 6	94		-1.86 (1.31)	33		-6.31 (1.95)	4.46 (-0.09, 9.01)	0.31 (-0.01, 0.63)	0.0549
Overall Treatment Effect	228	73.73 (17.05)	-0.70 (0.81)	208	72.50 (18.13)	-3.33 (0.97)	2.63 (0.29, 4.97)	0.26 (0.03, 0.49)	0.0278

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Only patients with baseline and postbaseline value are included in analysis.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Positive changes are favorable.

[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Positive changes are favorable.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-05-01-01-eff-mmrmqs-eq5-itt-fa.rtf

Table 14.2.6.5.1.1.b:
EQ-5D VAS: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
EQ-5D VAS									
Cycle 4	69		0.04 (1.48)	51		-5.05 (1.70)	5.09 (0.73, 9.44)	0.38 (0.05, 0.71)	0.0225
Cycle 6	50		-2.26 (2.11)	24		-8.57 (2.75)	6.31 (-0.50, 13.13)	0.35 (-0.03, 0.74)	0.0691
Overall Treatment Effect	123	72.27 (17.25)	-0.81 (1.24)	120	71.99 (18.80)	-4.76 (1.39)	3.96 (0.39, 7.52)	0.33 (0.03, 0.63)	0.0298

Source: ADSL, ADQS. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

Only patients with baseline and postbaseline value are included in analysis.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Positive changes are favorable.

[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Positive changes are favorable.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 16MAY2024 03:33 t-14-02-06-05-01-01-b-eff-mmrmqs-eq5-itts-fa.rtf

Table 14.2.6.5.1.2:
Analyses of Time to Deterioration of EQ-5D-VAS
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
EQ-5D VAS Score	256	31 (12.1)	NR (NE, NE)	256	27 (10.5)	NR (NE, NE)	0.928 (0.551, 1.564)	0.7795

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-tte-qlq.sas 16MAY2024 03:12 t-14-02-06-05-01-02-eff-tte-qlq-eq5-itt-fa.rtf

Table 14.2.6.5.1.2.b:
Analysis of Time to Deterioration of EQ-5D-VAS
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
EQ-5D VAS Score	139	17 (12.2)	NR (NE, NE)	138	20 (14.5)	NR (NE, NE)	0.774 (0.405, 1.481)	0.4368

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.

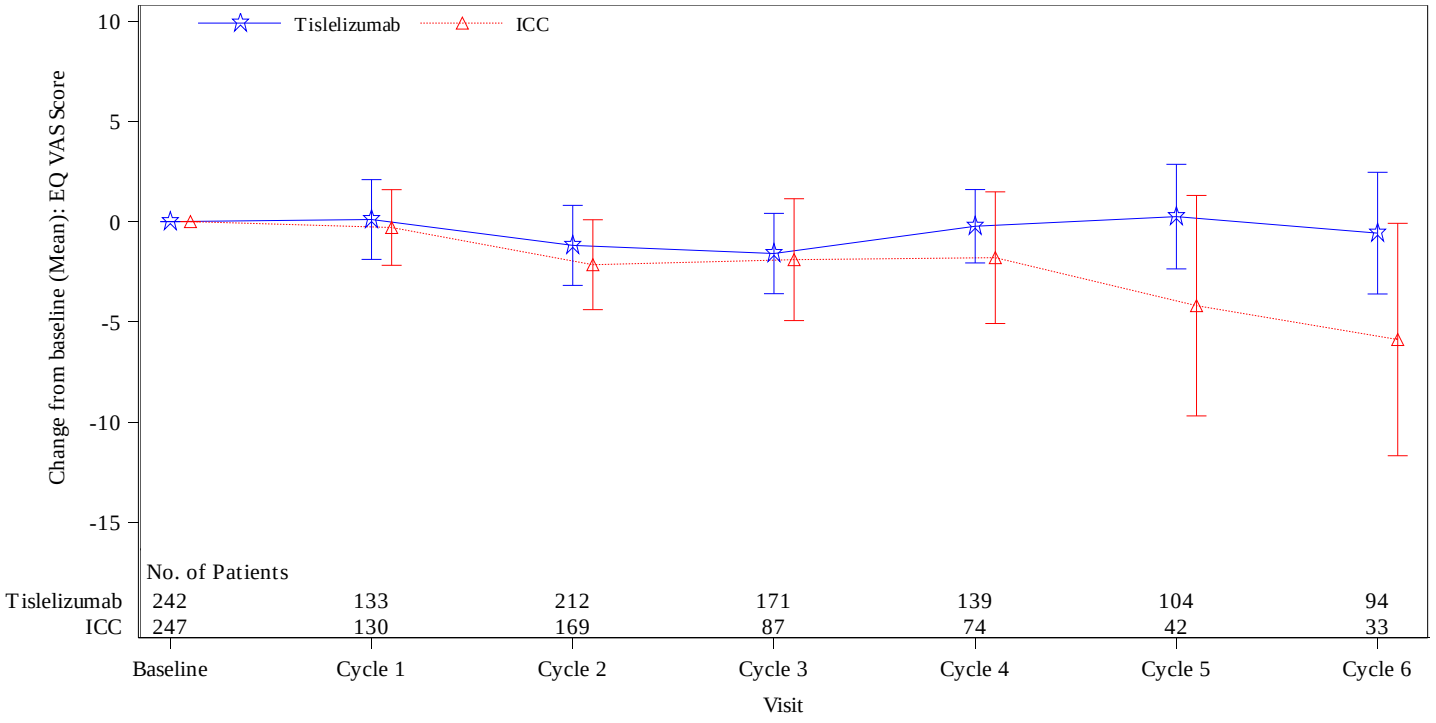
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

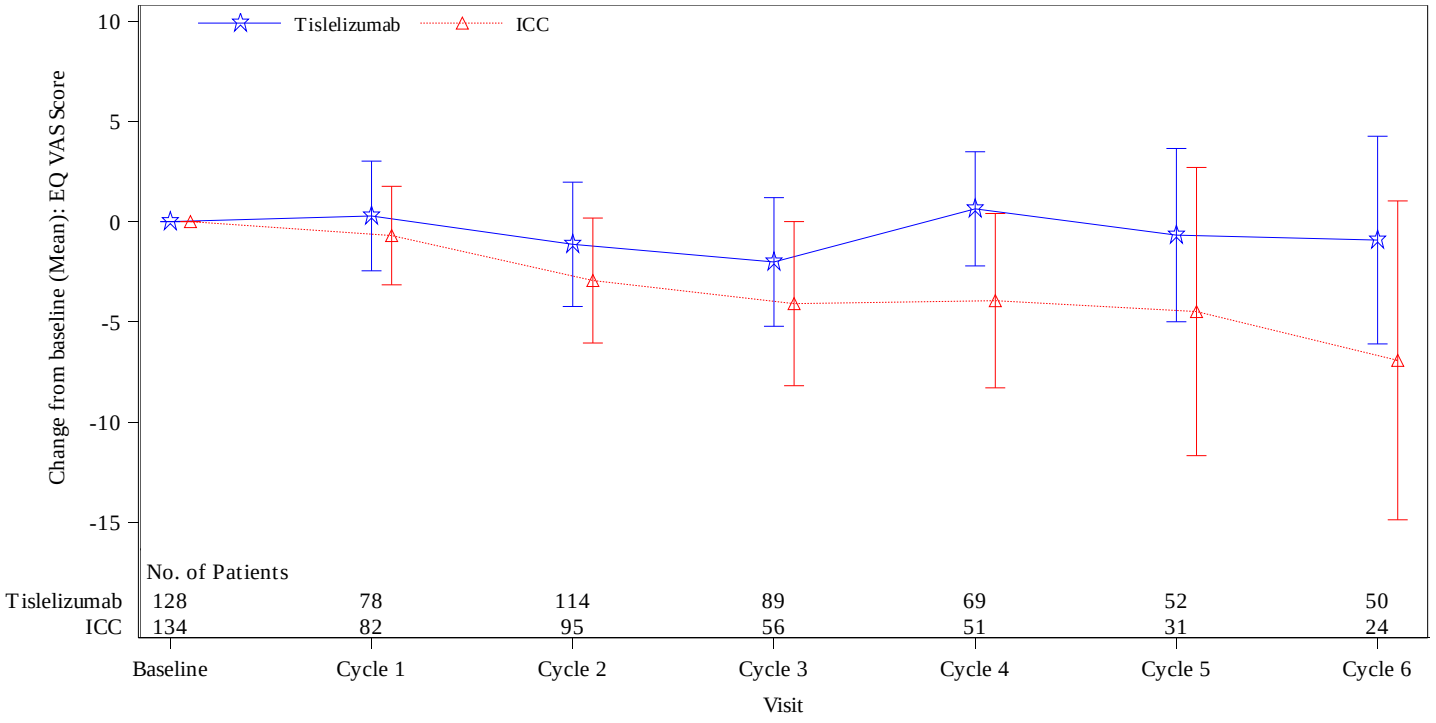
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-tte-qlq.sas 16MAY2024 03:12 t-14-02-06-05-01-02-b-eff-tte-qlq-eq5-itts-fa.rtf

Figure 14.2.7.4:
Summary of EQ-5D-VAS Scores by Visit
ITT Analysis Set



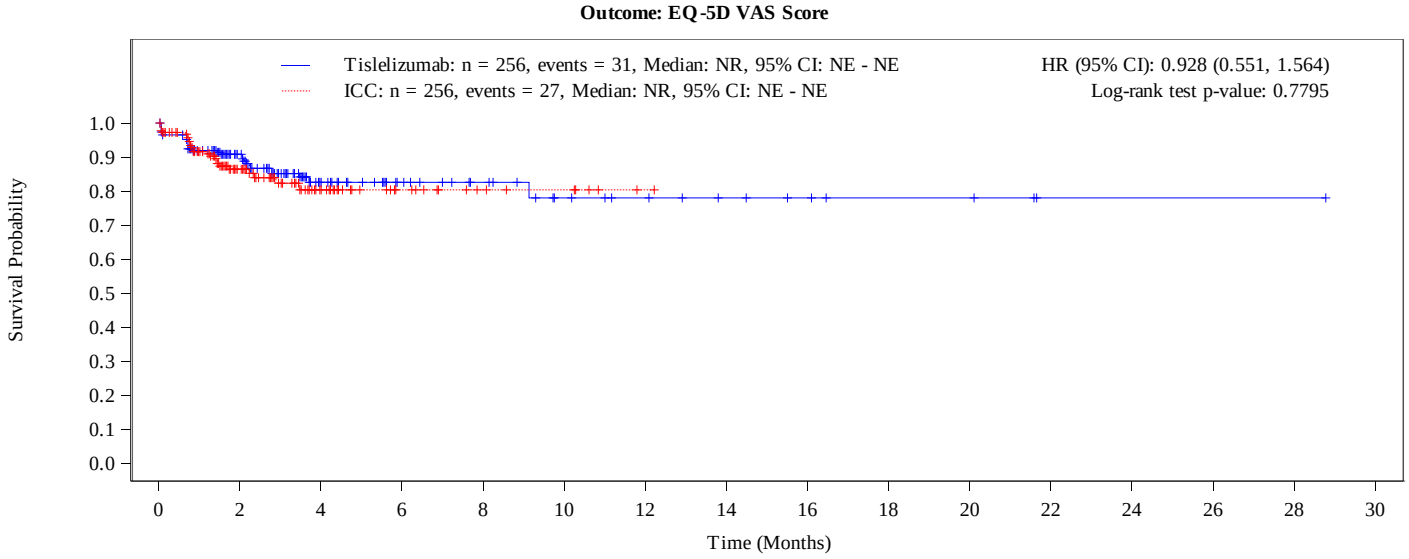
Source: Listing 16.2.6.6.3. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Datapoints represent means and 95% CI.
Increases in scores are improvements.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-series.sas 15MAY2024 20:01 f-14-02-07-04-series-eq5d-itt-fa.rtf

Figure 14.2.7.4.b:
Summary of EQ-5D-VAS Scores by Visit
ITT Analysis Set - Subpopulation without Irinotecan



Source: Listing 16.2.6.6.3. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Datapoints represent means and 95% CI.
Increases in scores are improvements.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-series.sas 15MAY2024 20:01 f-14-02-07-04-b-series-eq5d-itts-fa.rtf

Figure 14.2.7.4.2:
Kaplan-Meier Plot of Time to Deterioration of EQ-5D-VAS
ITT Analysis Set

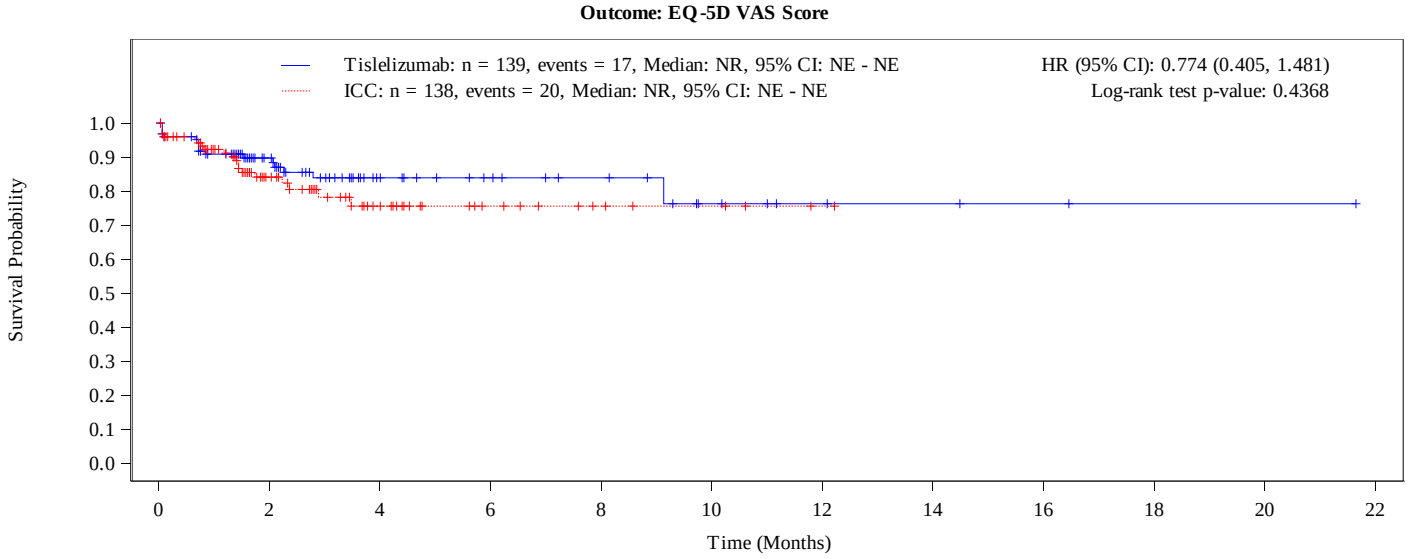


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	256	137	46	28	21	14	11	8	6	4	4	1	1	1	1	0
ICC	256	81	31	15	8	6	1	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 16MAY2024 03:34 f-14-02-07-04-02-km-qs-eq5-itt-fa.rtf

Figure 14.2.7.4.2.b:
Kaplan-Meier Plot of Time to Deterioration of EQ-5D-VAS
ITT Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	139	67	24	17	13	7	4	3	2	1	1	0
ICC	138	52	23	11	6	4	1	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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Table 14.2.6.5.1.2.s:
Analyses of Time to Deterioration of EQ-5D-VAS - Subgroup Analysis
ITT Analysis Set

Outcome: EQ-5D VAS Score

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	20 (12.7)	NR (9.1, NE)	161	14 (8.7)	NR (NE, NE)	1.145 (0.577, 2.275)	0.6967
>= 65 Years	99	11 (11.1)	NR (NE, NE)	95	13 (13.7)	NR (NE, NE)	0.605 (0.270, 1.358)	0.2176
Interaction								0.2904
Gender								
Male	217	27 (12.4)	NR (NE, NE)	215	24 (11.2)	NR (NE, NE)	0.881 (0.507, 1.532)	0.6519
Female	39	4 (10.3)	NR (NE, NE)	41	3 (7.3)	NR (3.5, NE)	0.784 (0.171, 3.604)	0.7530
Interaction								0.8165

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.5.1.2.s:
Analyses of Time to Deterioration of EQ-5D-VAS - Subgroup Analysis
ITT Analysis Set

Outcome: EQ-5D VAS Score

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	24 (12.8)	NR (NE, NE)	192	23 (12.0)	NR (NE, NE)	0.814 (0.458, 1.447)	0.4803
Non-Smoker	68	7 (10.3)	NR (NE, NE)	63	4 (6.3)	NR (NE, NE)	1.248 (0.362, 4.301)	0.7252
Interaction								0.5622
ICC Options								
Paclitaxel	83	9 (10.8)	NR (9.1, NE)	85	13 (15.3)	NR (NE, NE)	0.636 (0.272, 1.489)	0.2908
Docetaxel	56	8 (14.3)	NR (NE, NE)	53	7 (13.2)	NR (NE, NE)	0.967 (0.350, 2.674)	0.9489
Irinotecan	117	14 (12.0)	NR (NE, NE)	118	7 (5.9)	NR (NE, NE)	1.288 (0.513, 3.233)	0.5877
Interaction								0.5543

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.5.1.2.s:
Analyses of Time to Deterioration of EQ-5D-VAS - Subgroup Analysis
ITT Analysis Set

Outcome: EQ-5D VAS Score

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	9 (14.1)	NR (9.1, NE)	63	7 (11.1)	NR (NE, NE)	0.979 (0.362, 2.648)	0.9658
1	192	22 (11.5)	NR (NE, NE)	193	20 (10.4)	NR (NE, NE)	0.834 (0.454, 1.534)	0.5574
Interaction								0.7536
Region #1								
Asia	201	24 (11.9)	NR (NE, NE)	203	23 (11.3)	NR (NE, NE)	0.799 (0.449, 1.421)	0.4420
Europe/North America	55	7 (12.7)	NR (3.7, NE)	53	4 (7.5)	NR (NE, NE)	1.462 (0.426, 5.016)	0.5431
Interaction								0.3534

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.5.1.2.s:
Analyses of Time to Deterioration of EQ-5D-VAS - Subgroup Analysis
ITT Analysis Set

Outcome: EQ-5D VAS Score

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	20 (11.4)	NR (NE, NE)	178	15 (8.4)	NR (NE, NE)	1.033 (0.527, 2.027)	0.9231
Japan	25	4 (16.0)	NR (NE, NE)	25	8 (32.0)	NR (1.5, NE)	0.387 (0.115, 1.305)	0.1066
Europe/North America	55	7 (12.7)	NR (3.7, NE)	53	4 (7.5)	NR (NE, NE)	1.462 (0.426, 5.016)	0.5431
Interaction								0.2053
Race								
Asian and other	203	24 (11.8)	NR (NE, NE)	212	23 (10.8)	NR (NE, NE)	0.821 (0.462, 1.460)	0.4990
White	53	7 (13.2)	NR (3.7, NE)	44	4 (9.1)	NR (NE, NE)	1.340 (0.391, 4.600)	0.6398
Interaction								0.4622

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.5.1.2.s:
Analyses of Time to Deterioration of EQ-5D-VAS - Subgroup Analysis
ITT Analysis Set

Outcome: EQ-5D VAS Score

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	11 (13.8)	NR (NE, NE)	62	5 (8.1)	NR (NE, NE)	1.160 (0.398, 3.375)	0.7851
vCPS < 10%	100	13 (13.0)	NR (NE, NE)	122	11 (9.0)	NR (NE, NE)	1.190 (0.531, 2.664)	0.6704
Missing	76	7 (9.2)	NR (NE, NE)	72	11 (15.3)	NR (NE, NE)	0.462 (0.178, 1.199)	0.1013
Interaction								0.2267

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.5.1.2.b.s:
Analysis of Time to Deterioration of EQ-5D-VAS - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: EQ-5D VAS Score

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	11 (14.3)	NR (9.1, NE)	77	8 (10.4)	NR (NE, NE)	1.299 (0.522, 3.231)	0.5712
>= 65 Years	62	6 (9.7)	NR (NE, NE)	61	12 (19.7)	NR (2.9, NE)	0.400 (0.150, 1.069)	0.0577
Interaction								0.0828
Gender								
Male	118	16 (13.6)	NR (NE, NE)	111	17 (15.3)	NR (NE, NE)	0.789 (0.398, 1.566)	0.4955
Female	21	1 (4.8)	NR (NE, NE)	27	3 (11.1)	NR (2.4, NE)	0.267 (0.026, 2.735)	0.2380
Interaction								0.5259

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 16MAY2024 03:12 t-14-02-06-05-01-02-b-s-eff-tteqs-subgrp-eq5-itts-fa.rtf

Table 14.2.6.5.1.2.b.s:
Analysis of Time to Deterioration of EQ-5D-VAS - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: EQ-5D VAS Score

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	14 (13.5)	NR (9.1, NE)	105	18 (17.1)	NR (NE, NE)	0.711 (0.353, 1.433)	0.3360
Non-Smoker	35	3 (8.6)	NR (NE, NE)	33	2 (6.1)	NR (NE, NE)	1.149 (0.192, 6.882)	0.8786
Interaction								0.6987
ICC Options								
Paclitaxel	83	9 (10.8)	NR (9.1, NE)	85	13 (15.3)	NR (NE, NE)	0.636 (0.272, 1.489)	0.2908
Docetaxel	56	8 (14.3)	NR (NE, NE)	53	7 (13.2)	NR (NE, NE)	0.967 (0.350, 2.674)	0.9489
Interaction								0.5864

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.5.1.2.b.s:
Analysis of Time to Deterioration of EQ-5D-VAS - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: EQ-5D VAS Score

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	5 (11.6)	NR (9.1, NE)	42	5 (11.9)	NR (NE, NE)	0.814 (0.234, 2.830)	0.7442
1	96	12 (12.5)	NR (NE, NE)	96	15 (15.6)	NR (NE, NE)	0.740 (0.346, 1.582)	0.4339
Interaction								0.9188
Region #1								
Asia	103	14 (13.6)	NR (NE, NE)	105	17 (16.2)	NR (NE, NE)	0.743 (0.366, 1.509)	0.4064
Europe/North America	36	3 (8.3)	NR (9.1, NE)	33	3 (9.1)	NR (2.9, NE)	0.663 (0.131, 3.352)	0.6167
Interaction								0.8546

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 16MAY2024 03:12 t-14-02-06-05-01-02-b-s-eff-tteqs-subgrp-eq5-itts-fa.rtf

Table 14.2.6.5.1.2.b.s:
Analysis of Time to Deterioration of EQ-5D-VAS - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: EQ-5D VAS Score

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	10 (12.8)	NR (NE, NE)	80	9 (11.3)	NR (NE, NE)	1.079 (0.438, 2.655)	0.8684
Japan	25	4 (16.0)	NR (NE, NE)	25	8 (32.0)	NR (1.5, NE)	0.387 (0.115, 1.305)	0.1066
Europe/North America	36	3 (8.3)	NR (9.1, NE)	33	3 (9.1)	NR (2.9, NE)	0.663 (0.131, 3.352)	0.6167
Interaction								0.3493
Race								
Asian and other	105	14 (13.3)	NR (NE, NE)	114	17 (14.9)	NR (NE, NE)	0.777 (0.383, 1.578)	0.4805
White	34	3 (8.8)	NR (9.1, NE)	24	3 (12.5)	NR (2.4, NE)	0.588 (0.117, 2.955)	0.5145
Interaction								0.9583

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.5.1.2.b.s:
Analysis of Time to Deterioration of EQ-5D-VAS - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: EQ-5D VAS Score

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	5 (11.1)	NR (9.1, NE)	34	4 (11.8)	NR (3.5, NE)	0.806 (0.214, 3.035)	0.7488
vCPS < 10%	53	7 (13.2)	NR (NE, NE)	56	8 (14.3)	NR (NE, NE)	0.827 (0.300, 2.283)	0.7131
Missing	41	5 (12.2)	NR (NE, NE)	48	8 (16.7)	NR (2.2, NE)	0.671 (0.219, 2.054)	0.4776
Interaction								0.9427

Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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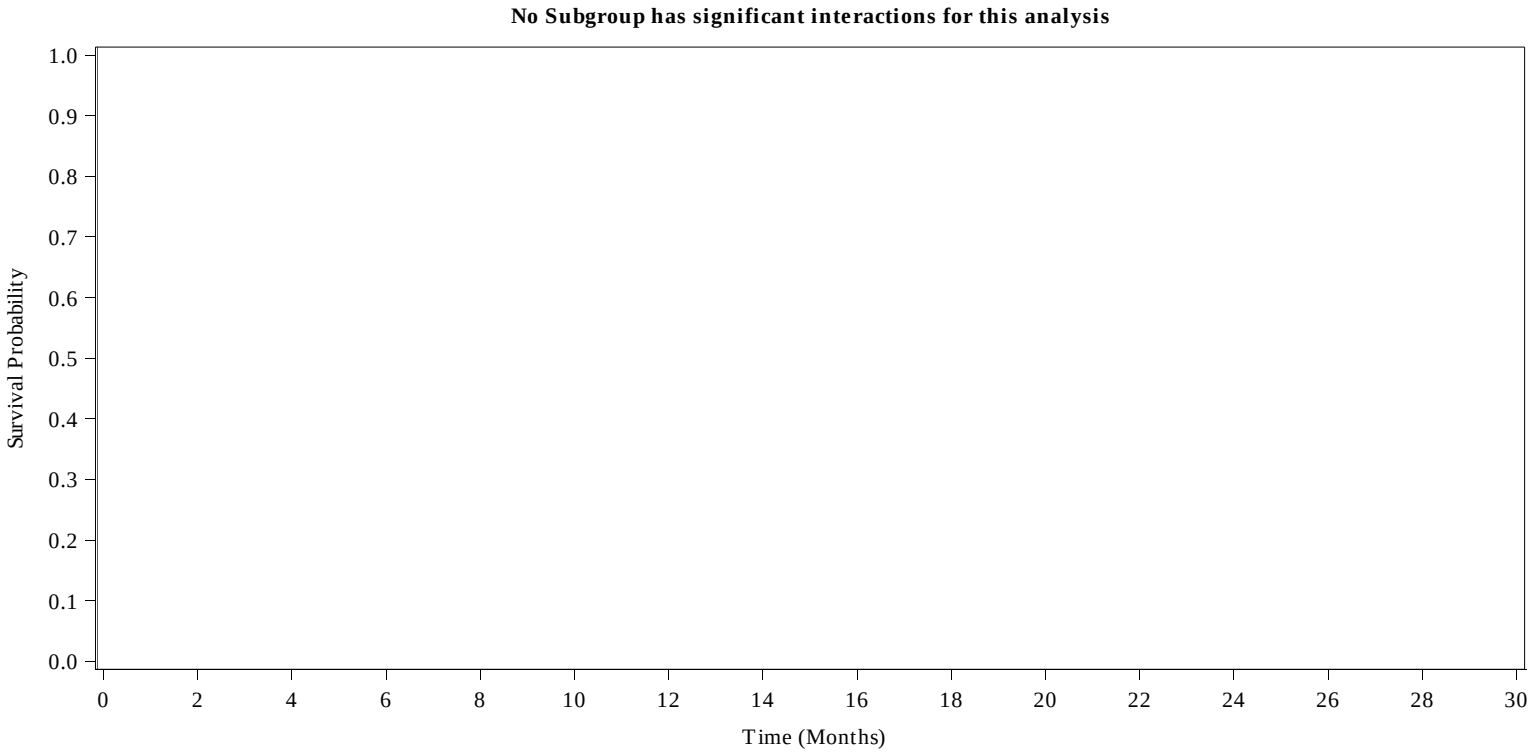
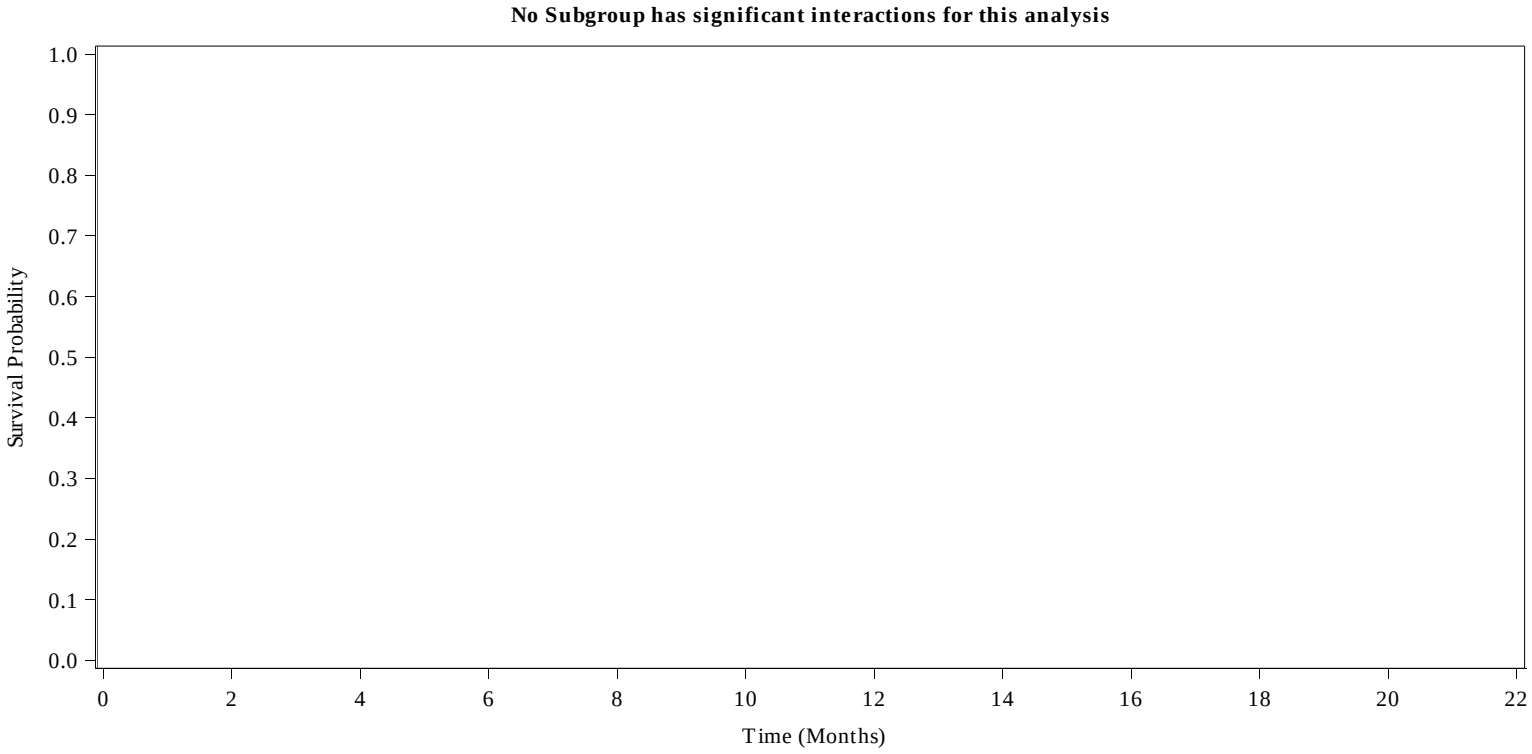
Figure 14.2.7.4.2.s:
Kaplan-Meier Plot of Time to Deterioration of EQ-5D-VAS - Subgroup Analysis
ITT Analysis Set



Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 16MAY2024 03:40 f-14-02-07-04-02-s-km-tteqs-subgrp-eq5-itt-fa.rtf

Figure 14.2.7.4.2.b.s:
Kaplan-Meier Plot of Time to Deterioration of EQ-5D-VAS - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEQS1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 16MAY2024 03:40 f-14-02-07-04-02-b-s-km-tteqs-subgrp-eq5-itts-fa.rtf

Table 14.2.8.1.b:
Post-Treatment Subsequent Anti-Cancer Therapies
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)	ICC (N = 138)
Patients With Any Subsequent Anti-Cancer Therapy, n (%)	75 (54.0)	84 (60.9)
Procedure, Radiotherapy or Surgery	27 (19.4)	28 (20.3)
Systemic Therapy	65 (46.8)	74 (53.6)
Immunotherapy	6 (4.3)	33 (23.9)
Time to First Post-Treatment Anti-Cancer Therapy (months)		
n	75	84
Mean (SD)	0.51 (0.857)	1.08 (1.861)
Median	0.26	0.53
Q1, Q3	0.10, 0.59	0.20, 0.99
Min, Max	-0.7, 6.0	-0.3, 12.6
Time to First Post-Treatment Immunotherapy (months)		
n	6	33
Mean (SD)	7.75 (4.876)	2.53 (3.139)
Median	6.93	0.85
Q1, Q3	3.42, 9.99	0.53, 4.17
Min, Max	3.1, 16.1	0.0, 12.6

Source: Listing 16.2.4.10,16.2.4.11. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

Percentages were based on N.

Time to first subsequent anti-cancer therapy is defined for patients with the use of subsequent anti-cancer therapy as the time from end of study treatment to first dose of subsequent anti-cancer therapy. There were 3 patients started new anti-cancer therapy before the treatment discontinuation without informing the investigator.

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Table 14.2.8.1.b:
Post-Treatment Subsequent Anti-Cancer Therapies
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)	ICC (N = 138)
Post-Treatment Systemic Therapy Duration (months)		
n	65	74
Mean (SD)	6.04 (6.007)	4.60 (6.080)
Median	4.04	1.97
Q1, Q3	2.10, 7.69	0.49, 6.60
Min, Max	0.0, 28.7	0.0, 30.1
Post-Treatment Immunotherapy Duration (months)		
n	6	33
Mean (SD)	0.64 (0.482)	4.65 (6.030)
Median	0.82	2.92
Q1, Q3	0.03, 1.02	0.53, 5.65
Min, Max	0.0, 1.1	0.0, 30.1

Source: Listing 16.2.4.10,16.2.4.11. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Time to first subsequent anti-cancer therapy is defined for patients with the use of subsequent anti-cancer therapy as the time from end of study treatment to first dose of subsequent anti-cancer therapy. There were 3 patients started new anti-cancer therapy before the treatment discontinuation without informing the investigator.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-subanti.sas 22APR2024 22:42 t-14-02-08-01-b-subanti-itts-fa.rtf

Table 14.3.1.1.1.b:
Study Medication Administration - Tislelizumab
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)
Duration of Exposure (Days)	
n	139
Mean (SD)	157.5 (165.99)
Median	84.0
Q1, Q3	43.0, 229.0
Min, Max	10, 779
Duration of Exposure, n (%)	
<1 month	12 (8.6)
>=1 to <3 month	69 (49.6)
>=3 to <6 month	18 (12.9)
>=6 to <12 month	25 (18.0)
>=12 to <18 month	7 (5.0)
>=18 to <24 month	7 (5.0)
>=24 month	1 (0.7)

Source: Listing 16.2.5.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Percentages were based on N.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/cycle) is defined as total dose (mg) / duration of exposure (day) * cycle length in days.

[c] RDI is defined as the ratio of the actual dose intensity (mg/cycle) and the planned dose intensity (mg/cycle) = dose intensity / (200 mg/cycle). The planned dose intensity is the total planned dose in a cycle. For a patient in the tislelizumab arm, the planned dose intensity is 200 mg once every three weeks.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.1.b:
Study Medication Administration - Tislelizumab
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)
Number of Cycles Received, n (%)	
1	12 (8.6)
2	28 (20.1)
3	22 (15.8)
4	19 (13.7)
5	4 (2.9)
6	11 (7.9)
7	2 (1.4)
8	1 (0.7)
9	1 (0.7)
10	4 (2.9)
>10	35 (25.2)

Source: Listing 16.2.5.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Percentages were based on N.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/cycle) is defined as total dose (mg) / duration of exposure (day) * cycle length in days.

[c] RDI is defined as the ratio of the actual dose intensity (mg/cycle) and the planned dose intensity (mg/cycle) = dose intensity / (200 mg/cycle). The planned dose intensity is the total planned dose in a cycle. For a patient in the tislelizumab arm, the planned dose intensity is 200 mg once every three weeks.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.1.b:
Study Medication Administration - Tislelizumab
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)
Number of Cycles Received, n (%)	
1-3	62 (44.6)
4-6	34 (24.5)
7-9	4 (2.9)
10-12	11 (7.9)
13-18	14 (10.1)
>18	14 (10.1)
Number of Treatment Cycles	
n	139
Mean (SD)	7.3 (7.68)
Median	4.0
Q1, Q3	2.0, 11.0
Min, Max	1, 38

Source: Listing 16.2.5.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Percentages were based on N.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/cycle) is defined as total dose (mg) / duration of exposure (day) * cycle length in days.

[c] RDI is defined as the ratio of the actual dose intensity (mg/cycle) and the planned dose intensity (mg/cycle) = dose intensity / (200 mg/cycle). The planned dose intensity is the total planned dose in a cycle. For a patient in the tislelizumab arm, the planned dose intensity is 200 mg once every three weeks.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.1.b:
Study Medication Administration - Tislelizumab
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)
Cumulative Total Dose (mg) per Patient [a]	
n	139
Mean (SD)	1464.75 (1536.836)
Median	800.00
Q1, Q3	400.00, 2200.00
Min, Max	200.0, 7600.0
Actual Dose Intensity (mg/cycle) per Patient [b]	
n	139
Mean (SD)	198.22 (21.812)
Median	200.00
Q1, Q3	195.35, 200.00
Min, Max	133.3, 420.0

Source: Listing 16.2.5.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Percentages were based on N.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/cycle) is defined as total dose (mg) / duration of exposure (day) * cycle length in days.

[c] RDI is defined as the ratio of the actual dose intensity (mg/cycle) and the planned dose intensity (mg/cycle) = dose intensity / (200 mg/cycle). The planned dose intensity is the total planned dose in a cycle. For a patient in the tislelizumab arm, the planned dose intensity is 200 mg once every three weeks.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.1.b:
Study Medication Administration - Tislelizumab
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)
Relative Dose Intensity (%) per Patient [c]	
n	139
Mean (SD)	99.11 (10.906)
Median	100.00
Q1, Q3	97.67, 100.00
Min, Max	66.7, 210.0
Patients with Any Dose Modification, n (%) [d]	41 (29.5)
Dose Delay	41 (29.5)
Adverse Event	23 (16.5)
Other	23 (16.5)
COVID-19	6 (4.3)

Source: Listing 16.2.5.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Percentages were based on N.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/cycle) is defined as total dose (mg) / duration of exposure (day) * cycle length in days.

[c] RDI is defined as the ratio of the actual dose intensity (mg/cycle) and the planned dose intensity (mg/cycle) = dose intensity / (200 mg/cycle). The planned dose intensity is the total planned dose in a cycle. For a patient in the tislelizumab arm, the planned dose intensity is 200 mg once every three weeks.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.1.b:
Study Medication Administration - Tislelizumab
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)
Infusion Interrupted	0 (0.0)
Adverse Event	0 (0.0)
Other	0 (0.0)
COVID-19	0 (0.0)

Source: Listing 16.2.5.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Percentages were based on N.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/cycle) is defined as total dose (mg) / duration of exposure (day) * cycle length in days.

[c] RDI is defined as the ratio of the actual dose intensity (mg/cycle) and the planned dose intensity (mg/cycle) = dose intensity / (200 mg/cycle). The planned dose intensity is the total planned dose in a cycle. For a patient in the tislelizumab arm, the planned dose intensity is 200 mg once every three weeks.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.2.b:
Study Medication Administration - Investigator Chosen Chemotherapy (ICC)
Safety Analysis Set - Subpopulation without Irinotecan

	Paclitaxel			Docetaxel			
	Paclitaxel Grp1 (N = 62)	Paclitaxel Grp2 (N = 17)	Overall (N = 79)	Docetaxel Grp1 (N = 44)	Docetaxel Grp2 (N = 6)	Overall (N = 50)	Overall (N = 129)
Duration of Exposure (Days)							
n	62	17	79	44	6	50	129
Mean (SD)	94.9 (80.28)	89.9 (89.70)	93.8 (81.83)	87.7 (99.70)	69.8 (26.81)	85.6 (93.97)	90.6 (86.47)
Median	63.0	49.0	59.0	45.0	66.5	47.5	50.0
Q1, Q3	42.0, 126.0	37.0, 91.0	42.0, 126.0	41.5, 95.0	49.0, 87.0	42.0, 92.0	42.0, 108.0
Min, Max	7, 357	21, 357	7, 357	7, 584	42, 108	7, 584	7, 584

Source: Listing 16.2.5.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Percentages were based on N. Paclitaxel Grp1: 135-175mg/m^2 IV on Day 1, given every 21 days. Paclitaxel may also be given in doses of 80-100mg/m^2 IV on a weekly schedule; Paclitaxel Grp2--Paclitaxel (Japan): 100 mg/m^2 IV on Day 1, 8, 15, 22, 29, and 36, followed by one week of rest. Docetaxel Grp1: 75 mg/m^2 IV on Day 1, given every 21 days; Docetaxel Grp2--70 mg/m^2 IV on Day 1, given every 21 days for Japan patients.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/ m^2/cycle) = (total dose received / BSA) / Duration of Treatment in cycle * cycle length in days. Baseline weights are used to derive BSA, unless the change of the BSA at the visit are at least 10% or greater than the baseline (increased or decreased).

[c] Relative dose intensity (RDI) is defined as the ratio of the actual dose intensity (mg/ m^2/cycle) and the planned dose intensity (mg/ m^2/cycle). The planned dose intensity is the total planned dose in a cycle.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.2.b:
Study Medication Administration - Investigator Chosen Chemotherapy (ICC)
Safety Analysis Set - Subpopulation without Irinotecan

	Paclitaxel			Docetaxel			
	Paclitaxel Grp1 (N = 62)	Paclitaxel Grp2 (N = 17)	Overall (N = 79)	Docetaxel Grp1 (N = 44)	Docetaxel Grp2 (N = 6)	Overall (N = 50)	Overall (N = 129)
Duration of Exposure, n (%)							
<1 month	9 (14.5)	1 (5.9)	10 (12.7)	9 (20.5)	0 (0.0)	9 (18.0)	19 (14.7)
>=1 to <3 month	30 (48.4)	12 (70.6)	42 (53.2)	23 (52.3)	5 (83.3)	28 (56.0)	70 (54.3)
>=3 to <6 month	14 (22.6)	2 (11.8)	16 (20.3)	6 (13.6)	1 (16.7)	7 (14.0)	23 (17.8)
>=6 to <12 month	9 (14.5)	2 (11.8)	11 (13.9)	5 (11.4)	0 (0.0)	5 (10.0)	16 (12.4)
>=12 to <18 month	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
>=18 to <24 month	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (2.0)	1 (0.8)
>=24 month	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Source: Listing 16.2.5.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Percentages were based on N. Paclitaxel Grp1: 135-175mg/m^2 IV on Day 1, given every 21 days. Paclitaxel may also be given in doses of 80-100mg/m^2 IV on a weekly schedule; Paclitaxel Grp2--Paclitaxel (Japan): 100 mg/m^2 IV on Day 1, 8, 15, 22, 29, and 36, followed by one week of rest. Docetaxel Grp1: 75 mg/m^2 IV on Day 1, given every 21 days; Docetaxel Grp2--70 mg/m^2 IV on Day 1, given every 21 days for Japan patients.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/ m^2/cycle) = (total dose received / BSA) / Duration of Treatment in cycle * cycle length in days. Baseline weights are used to derive BSA, unless the change of the BSA at the visit are at least 10% or greater than the baseline (increased or decreased).

[c] Relative dose intensity (RDI) is defined as the ratio of the actual dose intensity (mg/ m^2/cycle) and the planned dose intensity (mg/ m^2/cycle). The planned dose intensity is the total planned dose in a cycle.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.2.b:
Study Medication Administration - Investigator Chosen Chemotherapy (ICC)
Safety Analysis Set - Subpopulation without Irinotecan

	Paclitaxel			Docetaxel			
	Paclitaxel Grp1 (N = 62)	Paclitaxel Grp2 (N = 17)	Overall (N = 79)	Docetaxel Grp1 (N = 44)	Docetaxel Grp2 (N = 6)	Overall (N = 50)	Overall (N = 129)
Number of Cycles Received							
n	62	17	79	44	6	50	129
Mean (SD)	4.0 (3.20)	2.1 (1.82)	3.6 (3.06)	4.2 (4.69)	3.2 (1.33)	4.0 (4.43)	3.8 (3.64)
Median	3.0	1.0	2.0	2.0	3.0	2.0	2.0
Q1, Q3	2.0, 5.0	1.0, 2.0	1.0, 4.0	2.0, 4.5	2.0, 4.0	2.0, 4.0	2.0, 4.0
Min, Max	1, 14	1, 7	1, 14	1, 28	2, 5	1, 28	1, 28

Source: Listing 16.2.5.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Percentages were based on N. Paclitaxel Grp1: 135-175mg/m^2 IV on Day 1, given every 21 days. Paclitaxel may also be given in doses of 80-100mg/m^2 IV on a weekly schedule; Paclitaxel Grp2--Paclitaxel (Japan): 100 mg/m^2 IV on Day 1, 8, 15, 22, 29, and 36, followed by one week of rest. Docetaxel Grp1: 75 mg/m^2 IV on Day 1, given every 21 days; Docetaxel Grp2--70 mg/m^2 IV on Day 1, given every 21 days for Japan patients.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/ m^2/cycle) = (total dose received / BSA) / Duration of Treatment in cycle * cycle length in days. Baseline weights are used to derive BSA, unless the change of the BSA at the visit are at least 10% or greater than the baseline (increased or decreased).

[c] Relative dose intensity (RDI) is defined as the ratio of the actual dose intensity (mg/ m^2/cycle) and the planned dose intensity (mg/ m^2/cycle). The planned dose intensity is the total planned dose in a cycle.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.2.b:
Study Medication Administration - Investigator Chosen Chemotherapy (ICC)
Safety Analysis Set - Subpopulation without Irinotecan

	Paclitaxel			Docetaxel			
	Paclitaxel Grp1 (N = 62)	Paclitaxel Grp2 (N = 17)	Overall (N = 79)	Docetaxel Grp1 (N = 44)	Docetaxel Grp2 (N = 6)	Overall (N = 50)	Overall (N = 129)
Number of Cycles Received, n (%)							
1	9 (14.5)	11 (64.7)	20 (25.3)	7 (15.9)	0 (0.0)	7 (14.0)	27 (20.9)
2	19 (30.6)	2 (11.8)	21 (26.6)	18 (40.9)	3 (50.0)	21 (42.0)	42 (32.6)
3	6 (9.7)	0 (0.0)	6 (7.6)	3 (6.8)	0 (0.0)	3 (6.0)	9 (7.0)
4	11 (17.7)	2 (11.8)	13 (16.5)	5 (11.4)	2 (33.3)	7 (14.0)	20 (15.5)
5	2 (3.2)	1 (5.9)	3 (3.8)	2 (4.5)	1 (16.7)	3 (6.0)	6 (4.7)
6	5 (8.1)	0 (0.0)	5 (6.3)	1 (2.3)	0 (0.0)	1 (2.0)	6 (4.7)
7	2 (3.2)	1 (5.9)	3 (3.8)	0 (0.0)	0 (0.0)	0 (0.0)	3 (2.3)

Source: Listing 16.2.5.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Percentages were based on N. Paclitaxel Grp1: 135-175mg/m^2 IV on Day 1, given every 21 days. Paclitaxel may also be given in doses of 80-100mg/m^2 IV on a weekly schedule; Paclitaxel Grp2--Paclitaxel (Japan): 100 mg/m^2 IV on Day 1, 8, 15, 22, 29, and 36, followed by one week of rest. Docetaxel Grp1: 75 mg/m^2 IV on Day 1, given every 21 days; Docetaxel Grp2--70 mg/m^2 IV on Day 1, given every 21 days for Japan patients.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/ m^2/cycle) = (total dose received / BSA) / Duration of Treatment in cycle * cycle length in days. Baseline weights are used to derive BSA, unless the change of the BSA at the visit are at least 10% or greater than the baseline (increased or decreased).

[c] Relative dose intensity (RDI) is defined as the ratio of the actual dose intensity (mg/ m^2/cycle) and the planned dose intensity (mg/ m^2/cycle). The planned dose intensity is the total planned dose in a cycle.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.2.b:
Study Medication Administration - Investigator Chosen Chemotherapy (ICC)
Safety Analysis Set - Subpopulation without Irinotecan

	Paclitaxel			Docetaxel			
	Paclitaxel Grp1 (N = 62)	Paclitaxel Grp2 (N = 17)	Overall (N = 79)	Docetaxel Grp1 (N = 44)	Docetaxel Grp2 (N = 6)	Overall (N = 50)	Overall (N = 129)
8	2 (3.2)	0 (0.0)	2 (2.5)	2 (4.5)	0 (0.0)	2 (4.0)	4 (3.1)
9	1 (1.6)	0 (0.0)	1 (1.3)	1 (2.3)	0 (0.0)	1 (2.0)	2 (1.6)
10	1 (1.6)	0 (0.0)	1 (1.3)	2 (4.5)	0 (0.0)	2 (4.0)	3 (2.3)
>10	4 (6.5)	0 (0.0)	4 (5.1)	3 (6.8)	0 (0.0)	3 (6.0)	7 (5.4)

Source: Listing 16.2.5.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Percentages were based on N. Paclitaxel Grp1: 135-175mg/m^2 IV on Day 1, given every 21 days. Paclitaxel may also be given in doses of 80-100mg/m^2 IV on a weekly schedule; Paclitaxel Grp2--Paclitaxel (Japan): 100 mg/m^2 IV on Day 1, 8, 15, 22, 29, and 36, followed by one week of rest. Docetaxel Grp1: 75 mg/m^2 IV on Day 1, given every 21 days; Docetaxel Grp2--70 mg/m^2 IV on Day 1, given every 21 days for Japan patients.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/ m^2/cycle) = (total dose received / BSA) / Duration of Treatment in cycle * cycle length in days. Baseline weights are used to derive BSA, unless the change of the BSA at the visit are at least 10% or greater than the baseline (increased or decreased).

[c] Relative dose intensity (RDI) is defined as the ratio of the actual dose intensity (mg/ m^2/cycle) and the planned dose intensity (mg/ m^2/cycle). The planned dose intensity is the total planned dose in a cycle.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.2.b:
Study Medication Administration - Investigator Chosen Chemotherapy (ICC)
Safety Analysis Set - Subpopulation without Irinotecan

	Paclitaxel			Docetaxel			
	Paclitaxel Grp1 (N = 62)	Paclitaxel Grp2 (N = 17)	Overall (N = 79)	Docetaxel Grp1 (N = 44)	Docetaxel Grp2 (N = 6)	Overall (N = 50)	Overall (N = 129)
Number of Cycles Received, n (%)							
1-3	34 (54.8)	13 (76.5)	47 (59.5)	28 (63.6)	3 (50.0)	31 (62.0)	78 (60.5)
4-6	18 (29.0)	3 (17.6)	21 (26.6)	8 (18.2)	3 (50.0)	11 (22.0)	32 (24.8)
7-9	5 (8.1)	1 (5.9)	6 (7.6)	3 (6.8)	0 (0.0)	3 (6.0)	9 (7.0)
10-12	3 (4.8)	0 (0.0)	3 (3.8)	4 (9.1)	0 (0.0)	4 (8.0)	7 (5.4)
13-18	2 (3.2)	0 (0.0)	2 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)
>18	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (2.0)	1 (0.8)

Source: Listing 16.2.5.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Percentages were based on N. Paclitaxel Grp1: 135-175mg/m^2 IV on Day 1, given every 21 days. Paclitaxel may also be given in doses of 80-100mg/m^2 IV on a weekly schedule; Paclitaxel Grp2--Paclitaxel (Japan): 100 mg/m^2 IV on Day 1, 8, 15, 22, 29, and 36, followed by one week of rest. Docetaxel Grp1: 75 mg/m^2 IV on Day 1, given every 21 days; Docetaxel Grp2--70 mg/m^2 IV on Day 1, given every 21 days for Japan patients.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/ m^2/cycle) = (total dose received / BSA) / Duration of Treatment in cycle * cycle length in days. Baseline weights are used to derive BSA, unless the change of the BSA at the visit are at least 10% or greater than the baseline (increased or decreased).

[c] Relative dose intensity (RDI) is defined as the ratio of the actual dose intensity (mg/ m^2/cycle) and the planned dose intensity (mg/ m^2/cycle). The planned dose intensity is the total planned dose in a cycle.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.2.b:
Study Medication Administration - Investigator Chosen Chemotherapy (ICC)
Safety Analysis Set - Subpopulation without Irinotecan

	Paclitaxel			Docetaxel			
	Paclitaxel Grp1 (N = 62)	Paclitaxel Grp2 (N = 17)	Overall (N = 79)	Docetaxel Grp1 (N = 44)	Docetaxel Grp2 (N = 6)	Overall (N = 50)	Overall (N = 129)
Cumulative Total Dose (mg/m^2) per Patient [a]							
n	62	17	79	44	6	50	
Mean (SD)	699.36 (540.257)	713.20 (668.246)	702.34 (565.594)	296.22 (301.360)	208.37 (85.386)	285.68 (285.084)	
Median	549.64	415.83	525.93	150.96	198.53	150.96	
Q1, Q3	322.55, 865.74	314.83, 731.13	314.83, 865.74	143.55, 333.20	133.93, 258.37	141.99, 299.22	
Min, Max	79.7, 2175.3	210.4, 2675.2	79.7, 2675.2	72.7, 1661.0	128.3, 332.5	72.7, 1661.0	

Source: Listing 16.2.5.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Percentages were based on N. Paclitaxel Grp1: 135-175mg/m^2 IV on Day 1, given every 21 days. Paclitaxel may also be given in doses of 80-100mg/m^2 IV on a weekly schedule; Paclitaxel Grp2--Paclitaxel (Japan): 100 mg/m^2 IV on Day 1, 8, 15, 22, 29, and 36, followed by one week of rest. Docetaxel Grp1: 75 mg/m^2 IV on Day 1, given every 21 days; Docetaxel Grp2--70 mg/m^2 IV on Day 1, given every 21 days for Japan patients.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/ m^2/cycle) = (total dose received / BSA) / Duration of Treatment in cycle * cycle length in days. Baseline weights are used to derive BSA, unless the change of the BSA at the visit are at least 10% or greater than the baseline (increased or decreased).

[c] Relative dose intensity (RDI) is defined as the ratio of the actual dose intensity (mg/ m^2/cycle) and the planned dose intensity (mg/ m^2/cycle). The planned dose intensity is the total planned dose in a cycle.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.2.b:
Study Medication Administration - Investigator Chosen Chemotherapy (ICC)
Safety Analysis Set - Subpopulation without Irinotecan

	Paclitaxel			Docetaxel			
	Paclitaxel Grp1 (N = 62)	Paclitaxel Grp2 (N = 17)	Overall (N = 79)	Docetaxel Grp1 (N = 44)	Docetaxel Grp2 (N = 6)	Overall (N = 50)	Overall (N = 129)
Actual Dose Intensity (mg/m^2/cycle) per Patient [b]							
n	62	17		44	6		
Mean (SD)	168.76 (44.155)	417.24 (79.515)		78.12 (25.864)	62.37 (5.732)		
Median	164.71	421.48		73.69	63.08		
Q1, Q3	137.35, 194.95	367.18, 447.24		70.26, 75.40	57.40, 64.66		
Min, Max	66.4, 289.8	264.2, 572.1		50.0, 219.3	55.0, 71.0		

Source: Listing 16.2.5.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Percentages were based on N. Paclitaxel Grp1: 135-175mg/m^2 IV on Day 1, given every 21 days. Paclitaxel may also be given in doses of 80-100mg/m^2 IV on a weekly schedule; Paclitaxel Grp2--Paclitaxel (Japan): 100 mg/m^2 IV on Day 1, 8, 15, 22, 29, and 36, followed by one week of rest. Docetaxel Grp1: 75 mg/m^2 IV on Day 1, given every 21 days; Docetaxel Grp2--70 mg/m^2 IV on Day 1, given every 21 days for Japan patients.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/ m^2/cycle) = (total dose received / BSA) / Duration of Treatment in cycle * cycle length in days. Baseline weights are used to derive BSA, unless the change of the BSA at the visit are at least 10% or greater than the baseline (increased or decreased).

[c] Relative dose intensity (RDI) is defined as the ratio of the actual dose intensity (mg/ m^2/cycle) and the planned dose intensity (mg/ m^2/cycle). The planned dose intensity is the total planned dose in a cycle.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.2.b:
Study Medication Administration - Investigator Chosen Chemotherapy (ICC)
Safety Analysis Set - Subpopulation without Irinotecan

	Paclitaxel			Docetaxel			
	Paclitaxel Grp1 (N = 62)	Paclitaxel Grp2 (N = 17)	Overall (N = 79)	Docetaxel Grp1 (N = 44)	Docetaxel Grp2 (N = 6)	Overall (N = 50)	Overall (N = 129)
Relative Dose Intensity (%) per Patient [c]							
n	62	17	79	44	6	50	129
Mean (SD)	85.09 (17.618)	69.54 (13.252)	81.74 (17.892)	104.16 (34.485)	89.10 (8.189)	102.35 (32.785)	89.73 (26.611)
Median	87.31	70.25	82.83	98.25	90.12	97.65	92.54
Q1, Q3	71.71, 100.00	61.20, 74.54	67.51, 100.00	93.68, 100.53	82.00, 92.37	92.27, 100.51	77.78, 100.00
Min, Max	37.6, 126.0	44.0, 95.4	37.6, 126.0	66.7, 292.4	78.6, 101.4	66.7, 292.4	37.6, 292.4

Source: Listing 16.2.5.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Percentages were based on N. Paclitaxel Grp1: 135-175mg/m^2 IV on Day 1, given every 21 days. Paclitaxel may also be given in doses of 80-100mg/m^2 IV on a weekly schedule; Paclitaxel Grp2--Paclitaxel (Japan): 100 mg/m^2 IV on Day 1, 8, 15, 22, 29, and 36, followed by one week of rest. Docetaxel Grp1: 75 mg/m^2 IV on Day 1, given every 21 days; Docetaxel Grp2--70 mg/m^2 IV on Day 1, given every 21 days for Japan patients.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/ m^2/cycle) = (total dose received / BSA) / Duration of Treatment in cycle * cycle length in days. Baseline weights are used to derive BSA, unless the change of the BSA at the visit are at least 10% or greater than the baseline (increased or decreased).

[c] Relative dose intensity (RDI) is defined as the ratio of the actual dose intensity (mg/ m^2/cycle) and the planned dose intensity (mg/ m^2/cycle). The planned dose intensity is the total planned dose in a cycle.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.2.b:
Study Medication Administration - Investigator Chosen Chemotherapy (ICC)
Safety Analysis Set - Subpopulation without Irinotecan

	Paclitaxel			Docetaxel			
	Paclitaxel Grp1 (N = 62)	Paclitaxel Grp2 (N = 17)	Overall (N = 79)	Docetaxel Grp1 (N = 44)	Docetaxel Grp2 (N = 6)	Overall (N = 50)	Overall (N = 129)
Patients with Any Dose Modification, n (%) [d]	38 (61.3)	15 (88.2)	53 (67.1)	17 (38.6)	4 (66.7)	21 (42.0)	74 (57.4)
Dose Reduction	19 (30.6)	10 (58.8)	29 (36.7)	8 (18.2)	4 (66.7)	12 (24.0)	41 (31.8)
Adverse Event	18 (29.0)	5 (29.4)	23 (29.1)	8 (18.2)	4 (66.7)	12 (24.0)	35 (27.1)

Source: Listing 16.2.5.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Percentages were based on N. Paclitaxel Grp1: 135-175mg/m^2 IV on Day 1, given every 21 days. Paclitaxel may also be given in doses of 80-100mg/m^2 IV on a weekly schedule; Paclitaxel Grp2--Paclitaxel (Japan): 100 mg/m^2 IV on Day 1, 8, 15, 22, 29, and 36, followed by one week of rest. Docetaxel Grp1: 75 mg/m^2 IV on Day 1, given every 21 days; Docetaxel Grp2--70 mg/m^2 IV on Day 1, given every 21 days for Japan patients.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/ m^2/cycle) = (total dose received / BSA) / Duration of Treatment in cycle * cycle length in days. Baseline weights are used to derive BSA, unless the change of the BSA at the visit are at least 10% or greater than the baseline (increased or decreased).

[c] Relative dose intensity (RDI) is defined as the ratio of the actual dose intensity (mg/ m^2/cycle) and the planned dose intensity (mg/ m^2/cycle). The planned dose intensity is the total planned dose in a cycle.

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Table 14.3.1.1.2.b:
Study Medication Administration - Investigator Chosen Chemotherapy (ICC)
Safety Analysis Set - Subpopulation without Irinotecan

	Paclitaxel			Docetaxel			
	Paclitaxel Grp1 (N = 62)	Paclitaxel Grp2 (N = 17)	Overall (N = 79)	Docetaxel Grp1 (N = 44)	Docetaxel Grp2 (N = 6)	Overall (N = 50)	Overall (N = 129)
Dose Delay	26 (41.9)	15 (88.2)	41 (51.9)	15 (34.1)	2 (33.3)	17 (34.0)	58 (45.0)
Adverse Event	21 (33.9)	14 (82.4)	35 (44.3)	8 (18.2)	2 (33.3)	10 (20.0)	45 (34.9)
Other	10 (16.1)	3 (17.6)	13 (16.5)	4 (9.1)	0 (0.0)	4 (8.0)	17 (13.2)
COVID-19	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (2.0)	1 (0.8)

Source: Listing 16.2.5.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Percentages were based on N. Paclitaxel Grp1: 135-175mg/m^2 IV on Day 1, given every 21 days. Paclitaxel may also be given in doses of 80-100mg/m^2 IV on a weekly schedule; Paclitaxel Grp2--Paclitaxel (Japan): 100 mg/m^2 IV on Day 1, 8, 15, 22, 29, and 36, followed by one week of rest. Docetaxel Grp1: 75 mg/m^2 IV on Day 1, given every 21 days; Docetaxel Grp2--70 mg/m^2 IV on Day 1, given every 21 days for Japan patients.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/ m^2/cycle) = (total dose received / BSA) / Duration of Treatment in cycle * cycle length in days. Baseline weights are used to derive BSA, unless the change of the BSA at the visit are at least 10% or greater than the baseline (increased or decreased).

[c] Relative dose intensity (RDI) is defined as the ratio of the actual dose intensity (mg/ m^2/cycle) and the planned dose intensity (mg/ m^2/cycle). The planned dose intensity is the total planned dose in a cycle.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.2.b:
Study Medication Administration - Investigator Chosen Chemotherapy (ICC)
Safety Analysis Set - Subpopulation without Irinotecan

	Paclitaxel			Docetaxel			
	Paclitaxel Grp1 (N = 62)	Paclitaxel Grp2 (N = 17)	Overall (N = 79)	Docetaxel Grp1 (N = 44)	Docetaxel Grp2 (N = 6)	Overall (N = 50)	Overall (N = 129)
Infusion Interrupted	7 (11.3)	0 (0.0)	7 (8.9)	1 (2.3)	0 (0.0)	1 (2.0)	8 (6.2)
Adverse Event	4 (6.5)	0 (0.0)	4 (5.1)	1 (2.3)	0 (0.0)	1 (2.0)	5 (3.9)
Other	3 (4.8)	0 (0.0)	3 (3.8)	0 (0.0)	0 (0.0)	0 (0.0)	3 (2.3)
COVID-19	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Source: Listing 16.2.5.2. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Percentages were based on N. Paclitaxel Grp1: 135-175mg/m^2 IV on Day 1, given every 21 days. Paclitaxel may also be given in doses of 80-100mg/m^2 IV on a weekly schedule; Paclitaxel Grp2--Paclitaxel (Japan): 100 mg/m^2 IV on Day 1, 8, 15, 22, 29, and 36, followed by one week of rest. Docetaxel Grp1: 75 mg/m^2 IV on Day 1, given every 21 days; Docetaxel Grp2--70 mg/m^2 IV on Day 1, given every 21 days for Japan patients.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/ m^2/cycle) = (total dose received / BSA) / Duration of Treatment in cycle * cycle length in days. Baseline weights are used to derive BSA, unless the change of the BSA at the visit are at least 10% or greater than the baseline (increased or decreased).

[c] Relative dose intensity (RDI) is defined as the ratio of the actual dose intensity (mg/ m^2/cycle) and the planned dose intensity (mg/ m^2/cycle). The planned dose intensity is the total planned dose in a cycle.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.2.1.1:
Time to Treatment-Emergent Adverse Events
Safety Analysis Set

	Tislelizumab (N = 255)			ICC (N = 240)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Any TEAE	255	244 (95.7)	0.3 (0.3, 0.5)	240	236 (98.3)	0.1 (0.1, 0.1)	0.441 (0.362, 0.536)	<0.0001
TEAE >= Grade 3	255	118 (46.3)	6.2 (3.6, 10.1)	240	163 (67.9)	0.9 (0.5, 1.0)	0.360 (0.280, 0.463)	<0.0001
Serious TEAE	255	105 (41.2)	9.0 (6.3, 13.9)	240	105 (43.8)	4.2 (2.8, 8.6)	0.623 (0.469, 0.828)	0.0010
TEAE Leading to Treatment Discontinuation	255	49 (19.2)	NR (14.0, NE)	240	64 (26.7)	7.9 (6.1, NE)	0.435 (0.292, 0.647)	<0.0001

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.1.1.b:
Time to Treatment-Emergent Adverse Events
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 129)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Any TEAE	139	135 (97.1)	0.3 (0.3, 0.5)	129	126 (97.7)	0.1 (0.1, 0.2)	0.513 (0.395, 0.667)	<0.0001
TEAE >= Grade 3	139	65 (46.8)	6.9 (3.1, 10.8)	129	88 (68.2)	0.9 (0.5, 1.2)	0.379 (0.269, 0.532)	<0.0001
Serious TEAE	139	60 (43.2)	9.7 (4.4, 14.0)	129	54 (41.9)	6.1 (3.0, 8.6)	0.712 (0.483, 1.048)	0.0822
TEAE Leading to Treatment Discontinuation	139	25 (18.0)	NR (13.9, NE)	129	28 (21.7)	NR (6.5, NE)	0.551 (0.311, 0.979)	0.0391

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.
Adverse events were graded for severity using CTCAE v4.03.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.
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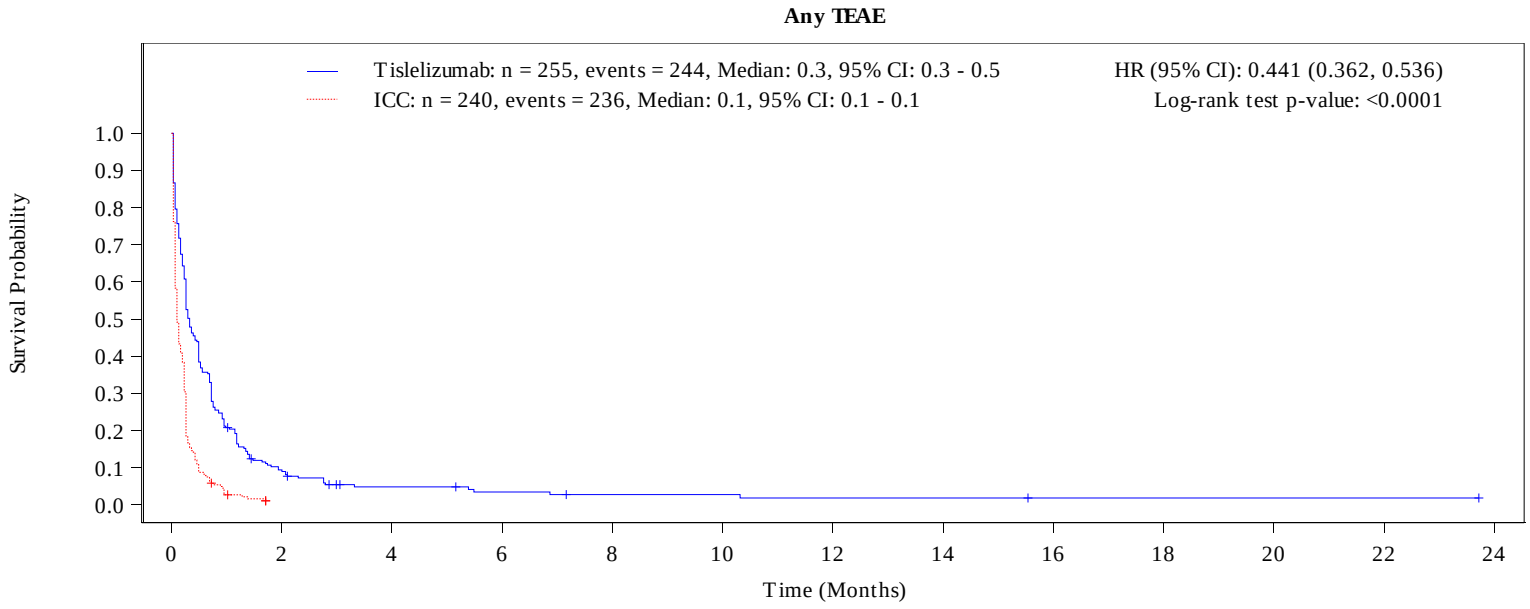
Figure 14.3.1.1:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24
Tislelizumab	255	22	8	5	3	3	2	2	1	1	1	1	0
ICC	240	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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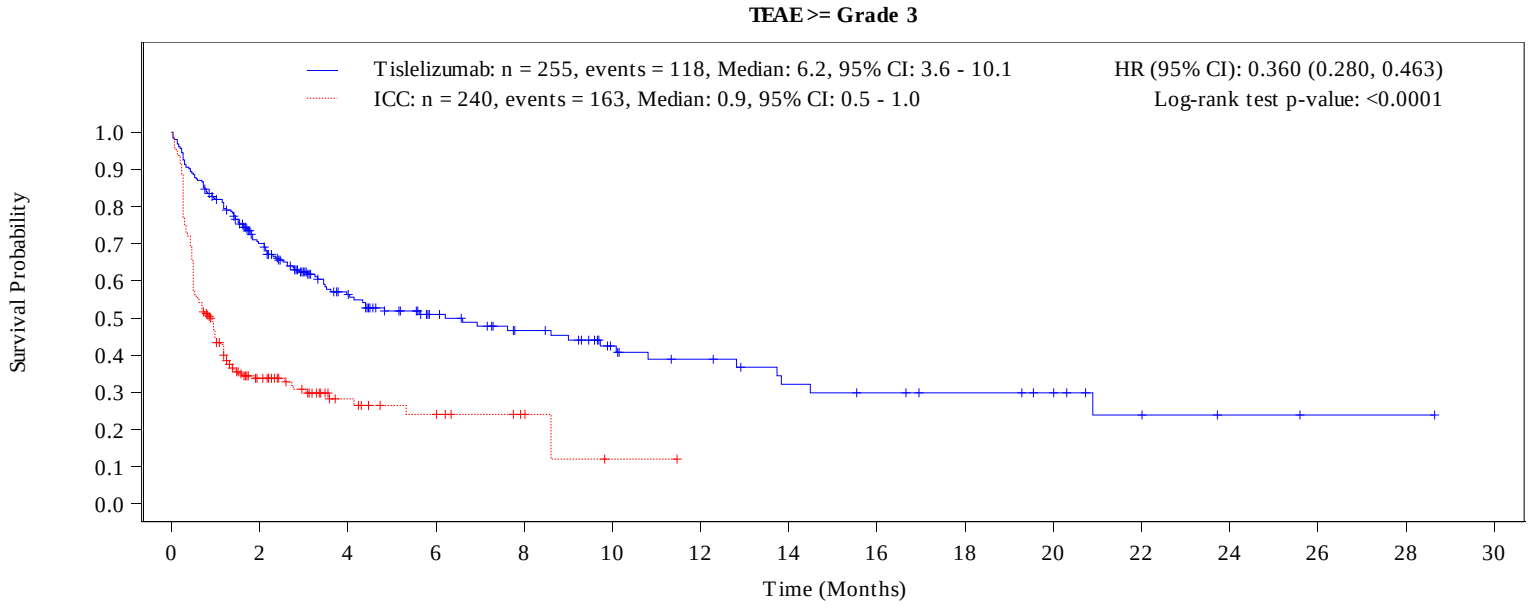
Figure 14.3.1.1:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events
Safety Analysis Set

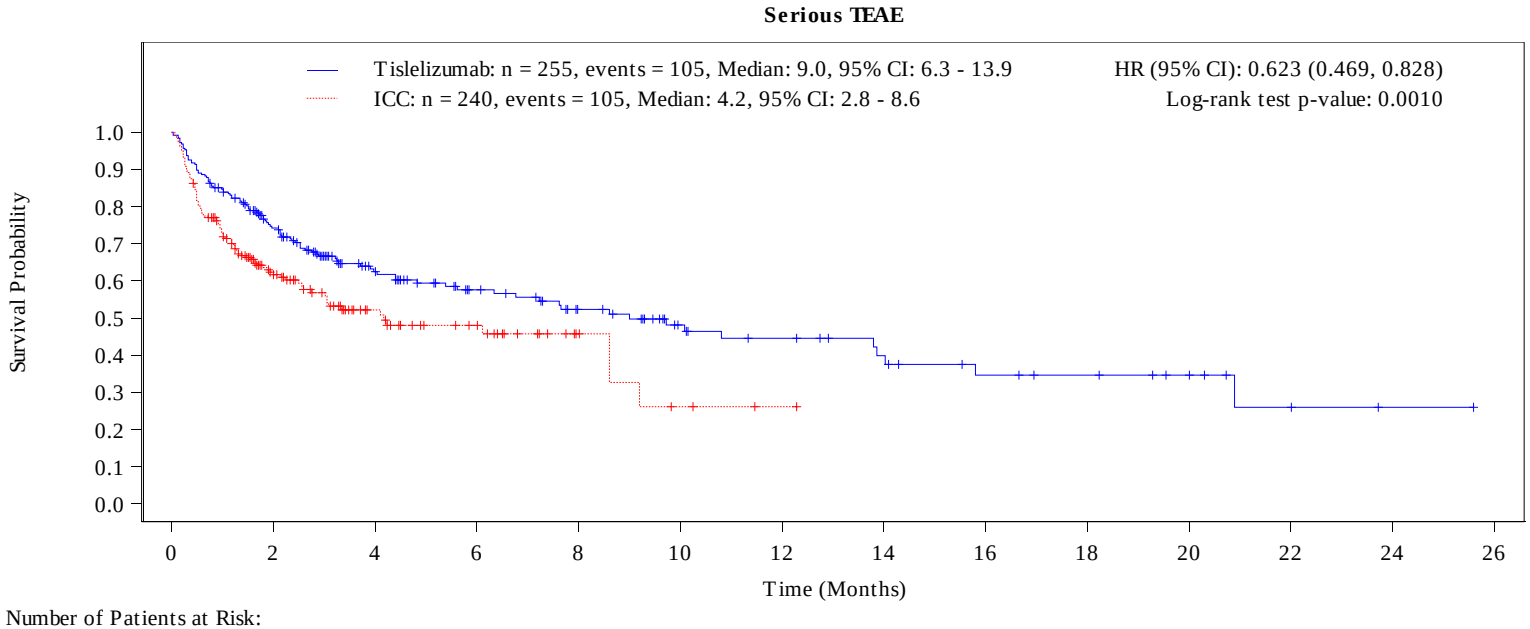


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	143	79	50	38	25	19	14	12	10	8	4	2	1	1	0
ICC	240	49	16	10	5	1	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteae.sas 19AUG2024 22:10 f-14-03-01-01-km-tteae-safety-fa.rtf

Figure 14.3.1.1:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	255	154	85	59	43	28	22	17	12	10	7	3	1	0
ICC	240	92	38	22	8	3	1	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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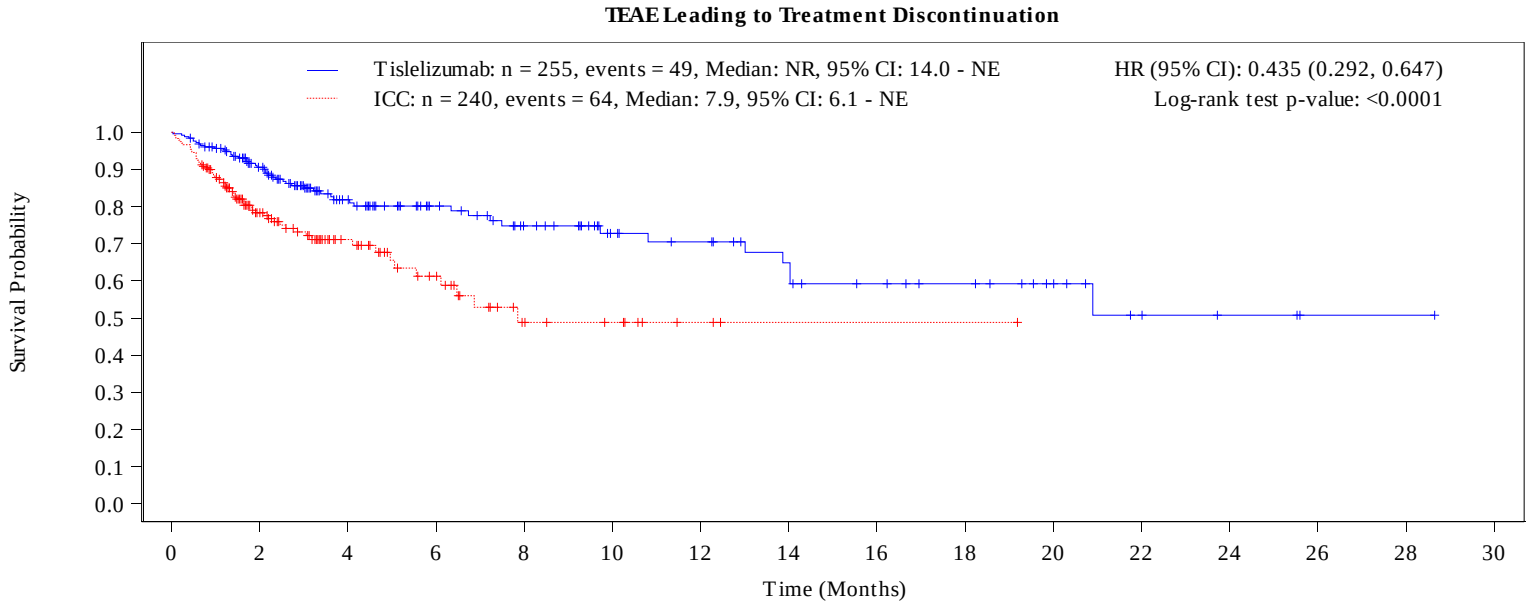
Figure 14.3.1.1:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	172	97	64	49	34	29	23	18	15	10	5	3	1	1	0
ICC	240	106	45	26	11	8	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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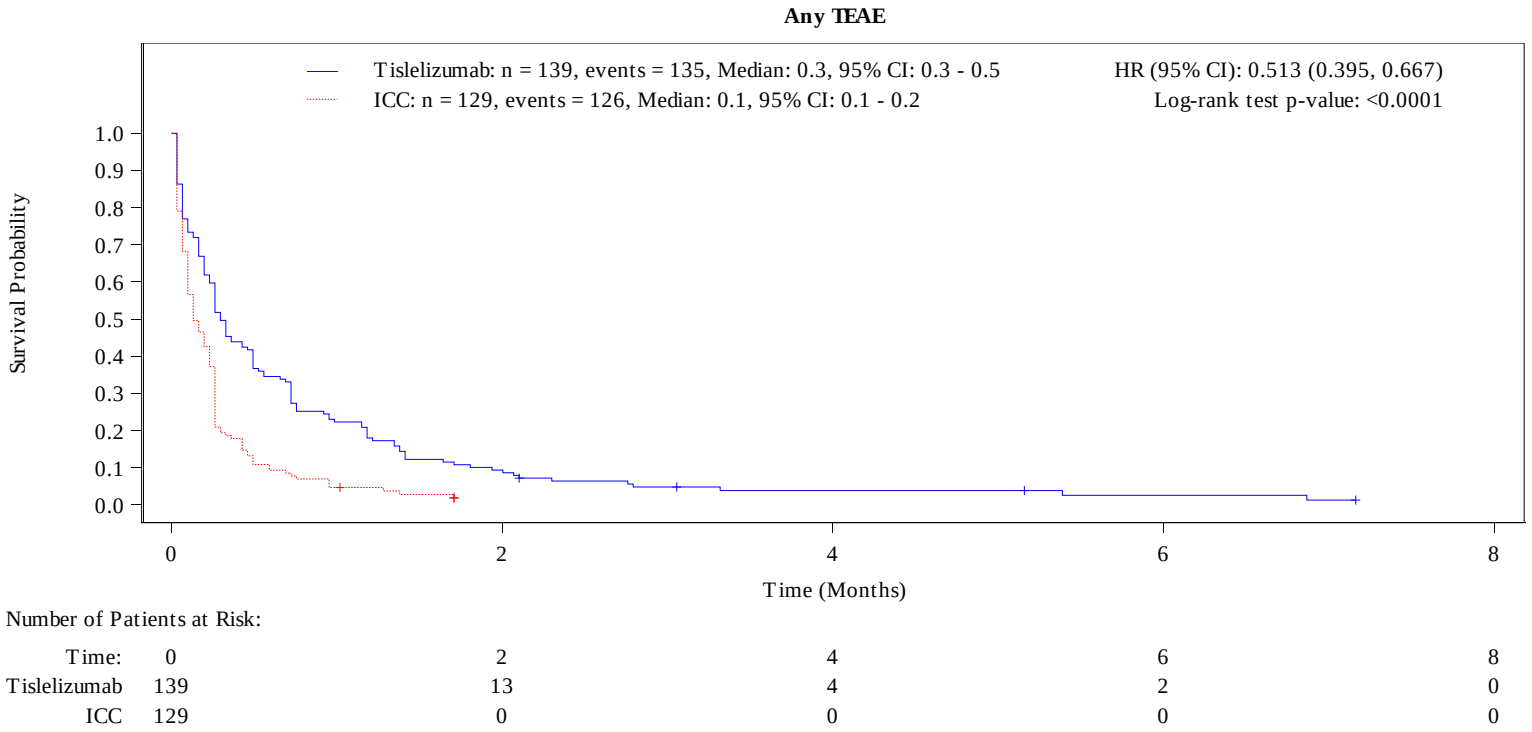
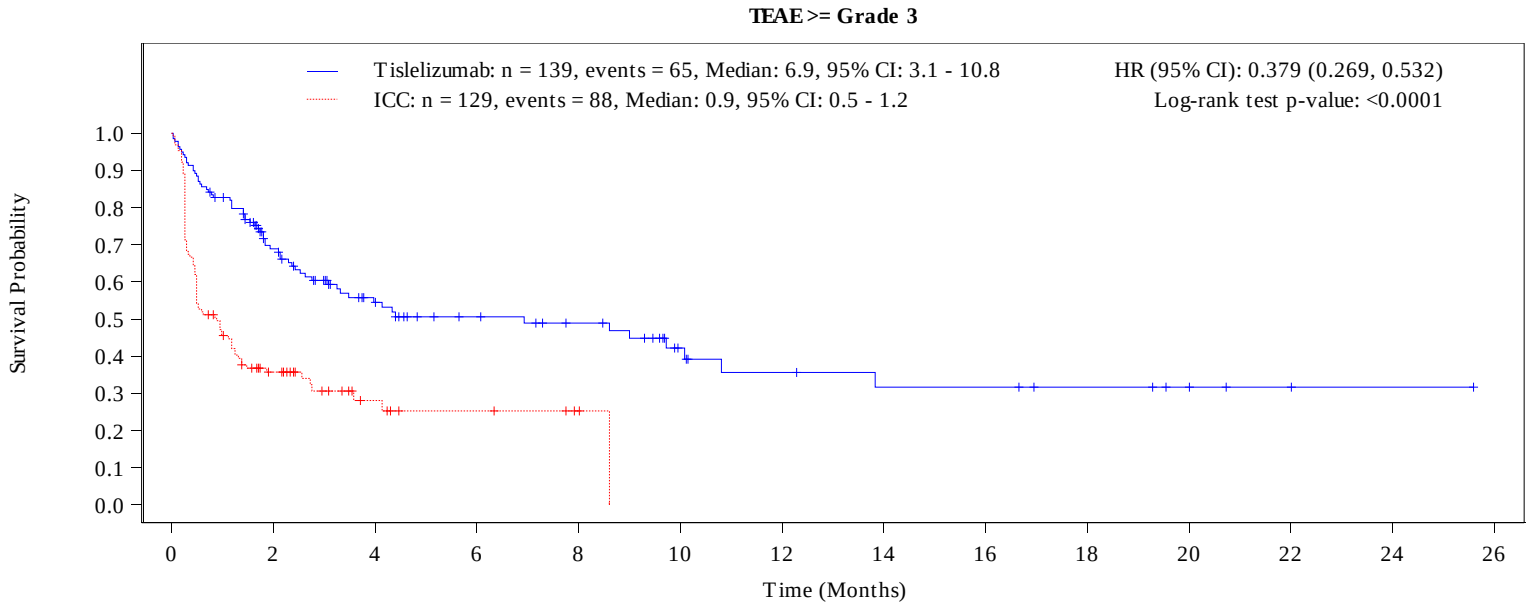
Figure 14.3.1.1.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteae.sas 19AUG2024 22:10 f-14-03-01-01-b-km-tteae-safetys-fa.rtf

Figure 14.3.1.1.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events
Safety Analysis Set - Subpopulation without Irinotecan

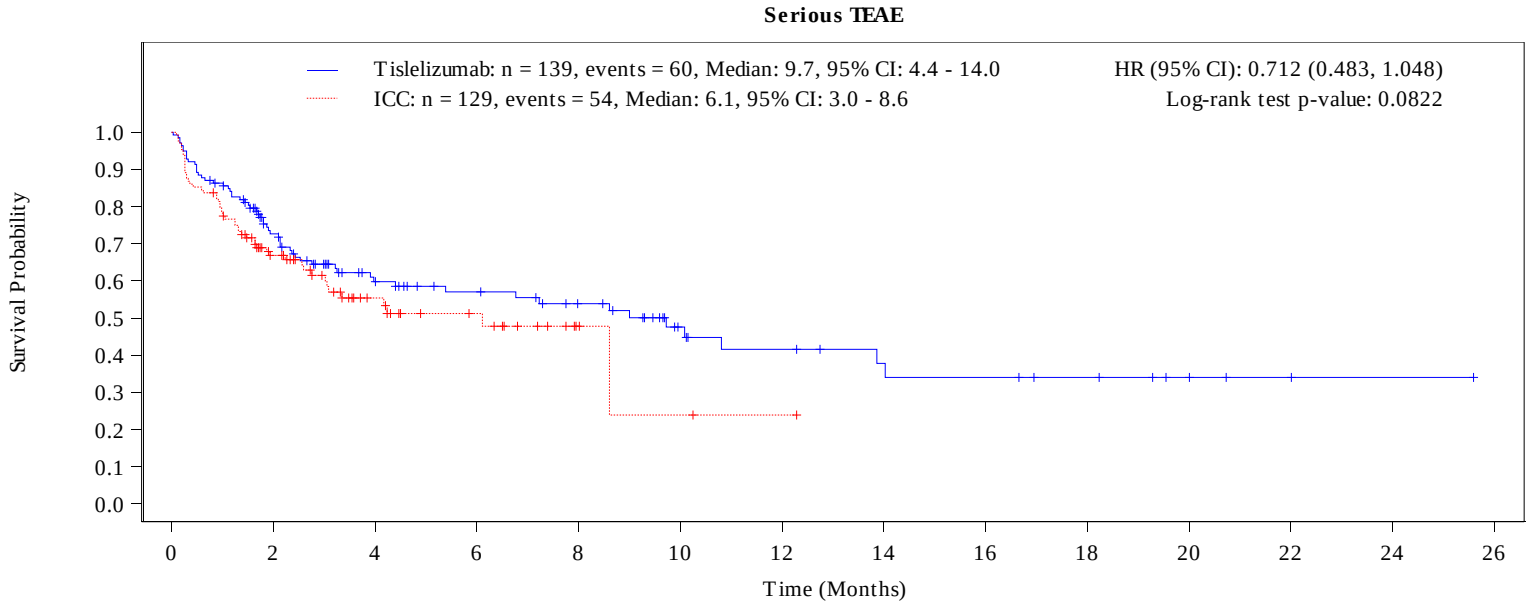


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	75	43	31	25	14	10	8	8	6	4	2	1	0
ICC	129	33	10	6	3	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteae.sas 19AUG2024 22:10 f-14-03-01-01-b-km-tteae-safetys-fa.rtf

Figure 14.3.1.1.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events
Safety Analysis Set - Subpopulation without Irinotecan

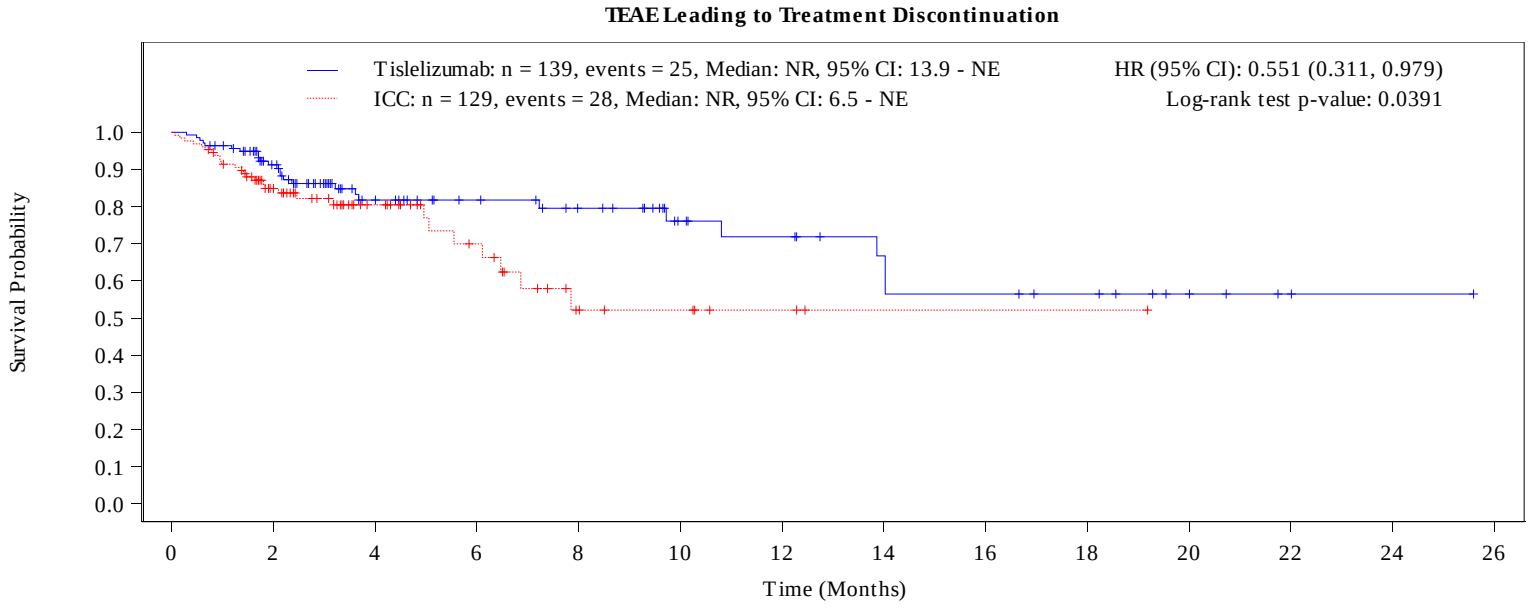


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	82	49	38	30	17	13	10	9	7	4	2	1	0
ICC	129	62	27	15	5	2	1	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteae.sas 19AUG2024 22:10 f-14-03-01-01-b-km-tteae-safetys-fa.rtf

Figure 14.3.1.1.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	93	52	40	32	20	17	13	11	9	5	2	1	0
ICC	129	71	33	19	8	6	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteae.sas 19AUG2024 22:10 f-14-03-01-01-b-km-tteae-safetys-fa.rtf

Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Any TEAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	154 (98.1)	0.3 (0.3, 0.4)	149	146 (98.0)	0.1 (0.1, 0.1)	0.476 (0.374, 0.605)	<0.0001
>= 65 Years	98	90 (91.8)	0.4 (0.3, 0.5)	91	90 (98.9)	0.1 (0.1, 0.2)	0.427 (0.311, 0.585)	<0.0001
Interaction								0.5244
Gender								
Male	216	206 (95.4)	0.3 (0.3, 0.5)	204	201 (98.5)	0.1 (0.1, 0.2)	0.444 (0.360, 0.547)	<0.0001
Female	39	38 (97.4)	0.2 (0.2, 0.4)	36	35 (97.2)	0.1 (0.1, 0.2)	0.525 (0.323, 0.852)	0.0046
Interaction								0.5658

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Any TEAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	178 (95.2)	0.3 (0.3, 0.5)	183	179 (97.8)	0.1 (0.1, 0.1)	0.480 (0.385, 0.599)	<0.0001
Non-Smoker	68	66 (97.1)	0.4 (0.2, 0.6)	57	57 (100.0)	0.1 (0.1, 0.2)	0.346 (0.229, 0.523)	<0.0001
Interaction								0.8992
ICC Options								
Paclitaxel	83	80 (96.4)	0.3 (0.2, 0.5)	79	78 (98.7)	0.2 (0.1, 0.3)	0.560 (0.403, 0.778)	0.0002
Docetaxel	56	55 (98.2)	0.3 (0.2, 0.5)	50	48 (96.0)	0.1 (0.1, 0.2)	0.483 (0.319, 0.733)	0.0002
Irinotecan	116	109 (94.0)	0.4 (0.3, 0.5)	111	110 (99.1)	0.1 (0.1, 0.1)	0.365 (0.272, 0.490)	<0.0001
Interaction								0.1070

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Any TEAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	60 (95.2)	0.5 (0.3, 0.7)	57	55 (96.5)	0.2 (0.1, 0.3)	0.549 (0.374, 0.806)	0.0010
1	192	184 (95.8)	0.3 (0.3, 0.4)	183	181 (98.9)	0.1 (0.1, 0.1)	0.422 (0.337, 0.528)	<0.0001
Interaction								0.1940
Region #1								
Asia	201	192 (95.5)	0.4 (0.3, 0.5)	191	189 (99.0)	0.1 (0.1, 0.1)	0.375 (0.301, 0.466)	<0.0001
Europe/North America	54	52 (96.3)	0.1 (0.1, 0.2)	49	47 (95.9)	0.2 (0.1, 0.3)	0.889 (0.593, 1.333)	0.5348
Interaction								0.0018

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Any TEAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	168 (95.5)	0.3 (0.3, 0.5)	168	167 (99.4)	0.1 (0.1, 0.1)	0.355 (0.280, 0.450)	<0.0001
Japan	25	24 (96.0)	0.6 (0.4, 1.1)	23	22 (95.7)	0.2 (0.1, 0.3)	0.452 (0.246, 0.832)	0.0074
Europe/North America	54	52 (96.3)	0.1 (0.1, 0.2)	49	47 (95.9)	0.2 (0.1, 0.3)	0.889 (0.593, 1.333)	0.5348
Interaction								0.0032
Race								
Asian and other	203	194 (95.6)	0.4 (0.3, 0.5)	198	195 (98.5)	0.1 (0.1, 0.1)	0.400 (0.323, 0.496)	<0.0001
White	52	50 (96.2)	0.1 (0.1, 0.2)	42	41 (97.6)	0.1 (0.1, 0.3)	0.774 (0.505, 1.186)	0.1931
Interaction								0.0413

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Any TEAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	76 (95.0)	0.3 (0.3, 0.5)	60	58 (96.7)	0.1 (0.1, 0.2)	0.459 (0.319, 0.661)	<0.0001
vCPS < 10%	100	95 (95.0)	0.2 (0.2, 0.3)	119	117 (98.3)	0.1 (0.1, 0.2)	0.573 (0.431, 0.760)	<0.0001
Missing	75	73 (97.3)	0.5 (0.3, 0.7)	61	61 (100.0)	0.1 (0.1, 0.2)	0.335 (0.229, 0.489)	<0.0001
Interaction								0.2741

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	74 (47.1)	5.6 (3.3, 12.8)	149	97 (65.1)	1.0 (0.6, 1.2)	0.392 (0.285, 0.538)	<0.0001
>= 65 Years	98	44 (44.9)	6.6 (3.5, 13.7)	91	66 (72.5)	0.7 (0.5, 1.2)	0.330 (0.220, 0.494)	<0.0001
Interaction								0.4148
Gender								
Male	216	101 (46.8)	6.6 (4.0, 10.1)	204	138 (67.6)	0.9 (0.5, 1.0)	0.366 (0.280, 0.480)	<0.0001
Female	39	17 (43.6)	3.5 (2.0, NE)	36	25 (69.4)	0.9 (0.5, 1.4)	0.365 (0.194, 0.690)	0.0012
Interaction								0.9751

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	87 (46.5)	6.6 (3.6, 10.8)	183	124 (67.8)	0.9 (0.5, 1.2)	0.359 (0.269, 0.478)	<0.0001
Non-Smoker	68	31 (45.6)	6.2 (2.5, 20.9)	57	39 (68.4)	1.0 (0.5, 1.3)	0.386 (0.234, 0.636)	<0.0001
Interaction								0.7929
ICC Options								
Paclitaxel	83	37 (44.6)	10.8 (2.5, NE)	79	53 (67.1)	1.2 (0.5, 1.9)	0.418 (0.271, 0.646)	<0.0001
Docetaxel	56	28 (50.0)	6.9 (2.4, 9.7)	50	35 (70.0)	0.3 (0.3, 1.0)	0.313 (0.181, 0.541)	<0.0001
Irinotecan	116	53 (45.7)	6.2 (3.5, 13.7)	111	75 (67.6)	0.9 (0.6, 1.0)	0.345 (0.237, 0.502)	<0.0001
Interaction								0.7777

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	21 (33.3)	13.8 (6.9, NE)	57	33 (57.9)	1.2 (0.5, NE)	0.299 (0.166, 0.539)	<0.0001
1	192	97 (50.5)	3.6 (2.8, 7.6)	183	130 (71.0)	0.7 (0.5, 1.0)	0.377 (0.286, 0.497)	<0.0001
Interaction								0.4866
Region #1								
Asia	201	88 (43.8)	7.6 (4.3, 12.8)	191	128 (67.0)	0.7 (0.5, 1.0)	0.318 (0.238, 0.426)	<0.0001
Europe/North America	54	30 (55.6)	2.5 (1.7, NE)	49	35 (71.4)	1.2 (0.5, 2.6)	0.567 (0.346, 0.929)	0.0216
Interaction								0.0390

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	77 (43.8)	6.9 (4.0, 10.8)	168	112 (66.7)	0.8 (0.5, 1.0)	0.322 (0.236, 0.438)	<0.0001
Japan	25	11 (44.0)	10.1 (1.9, NE)	23	16 (69.6)	0.5 (0.3, 1.3)	0.298 (0.129, 0.688)	0.0023
Europe/North America	54	30 (55.6)	2.5 (1.7, NE)	49	35 (71.4)	1.2 (0.5, 2.6)	0.567 (0.346, 0.929)	0.0216
Interaction								0.1016
Race								
Asian and other	203	89 (43.8)	7.6 (4.3, 10.8)	198	132 (66.7)	0.7 (0.5, 1.0)	0.326 (0.245, 0.435)	<0.0001
White	52	29 (55.8)	2.5 (1.7, NE)	42	31 (73.8)	1.2 (0.5, 2.6)	0.538 (0.322, 0.897)	0.0152
Interaction								0.0780

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	36 (45.0)	6.6 (3.4, 14.5)	60	44 (73.3)	1.0 (0.5, 1.3)	0.259 (0.161, 0.417)	<0.0001
vCPS < 10%	100	52 (52.0)	4.0 (2.2, 10.8)	119	84 (70.6)	0.7 (0.5, 1.0)	0.417 (0.291, 0.596)	<0.0001
Missing	75	30 (40.0)	13.7 (3.5, NE)	61	35 (57.4)	1.2 (0.5, 5.3)	0.426 (0.255, 0.711)	0.0006
Interaction								0.4449

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Serious TEAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	72 (45.9)	7.2 (3.7, 13.9)	149	63 (42.3)	4.2 (2.2, NE)	0.743 (0.525, 1.052)	0.0919
>= 65 Years	98	33 (33.7)	13.8 (8.6, NE)	91	42 (46.2)	4.1 (2.5, NE)	0.495 (0.306, 0.800)	0.0034
Interaction								0.1410
Gender								
Male	216	92 (42.6)	8.6 (5.4, 13.9)	204	91 (44.6)	4.1 (2.6, 9.2)	0.649 (0.481, 0.876)	0.0043
Female	39	13 (33.3)	NR (4.4, NE)	36	14 (38.9)	8.6 (1.9, NE)	0.652 (0.301, 1.412)	0.2732
Interaction								0.8324

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Serious TEAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	80 (42.8)	8.6 (4.4, 13.9)	183	81 (44.3)	4.2 (2.8, 8.6)	0.656 (0.476, 0.902)	0.0089
Non-Smoker	68	25 (36.8)	20.9 (6.3, NE)	57	24 (42.1)	NR (1.8, NE)	0.636 (0.358, 1.130)	0.1183
Interaction								0.6285
ICC Options								
Paclitaxel	83	29 (34.9)	NR (7.2, NE)	79	30 (38.0)	8.6 (3.4, NE)	0.771 (0.456, 1.302)	0.3288
Docetaxel	56	31 (55.4)	4.4 (2.1, 9.0)	50	24 (48.0)	3.1 (1.3, NE)	0.680 (0.388, 1.191)	0.1716
Irinotecan	116	45 (38.8)	7.7 (4.8, 20.9)	111	51 (45.9)	3.1 (1.6, NE)	0.533 (0.351, 0.810)	0.0027
Interaction								0.4774

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Serious TEAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	22 (34.9)	13.9 (7.2, NE)	57	17 (29.8)	9.2 (4.2, NE)	0.726 (0.373, 1.412)	0.3429
1	192	83 (43.2)	7.6 (4.4, 13.8)	183	88 (48.1)	3.0 (1.9, 6.1)	0.622 (0.457, 0.847)	0.0023
Interaction								0.3845
Region #1								
Asia	201	84 (41.8)	9.0 (5.6, 13.9)	191	82 (42.9)	4.2 (2.2, NE)	0.628 (0.458, 0.861)	0.0035
Europe/North America	54	21 (38.9)	NR (2.6, NE)	49	23 (46.9)	6.1 (2.5, 9.2)	0.714 (0.393, 1.297)	0.2645
Interaction								0.6511

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Serious TEAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	75 (42.6)	7.7 (4.0, 13.8)	168	72 (42.9)	4.2 (2.2, NE)	0.644 (0.460, 0.900)	0.0093
Japan	25	9 (36.0)	13.9 (6.8, NE)	23	10 (43.5)	NR (1.1, NE)	0.511 (0.197, 1.327)	0.1596
Europe/North America	54	21 (38.9)	NR (2.6, NE)	49	23 (46.9)	6.1 (2.5, 9.2)	0.714 (0.393, 1.297)	0.2645
Interaction								0.7975
Race								
Asian and other	203	85 (41.9)	9.0 (5.6, 13.9)	198	84 (42.4)	4.2 (2.6, NE)	0.650 (0.475, 0.889)	0.0064
White	52	20 (38.5)	NR (4.4, NE)	42	21 (50.0)	6.1 (2.5, 9.2)	0.648 (0.349, 1.203)	0.1642
Interaction								0.9433

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Serious TEAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	29 (36.3)	13.9 (6.3, NE)	60	27 (45.0)	3.1 (1.9, NE)	0.432 (0.246, 0.757)	0.0026
vCPS < 10%	100	47 (47.0)	6.8 (3.7, 10.8)	119	53 (44.5)	4.2 (2.5, NE)	0.825 (0.554, 1.230)	0.3433
Missing	75	29 (38.7)	13.8 (3.3, NE)	61	25 (41.0)	NR (1.6, NE)	0.660 (0.380, 1.146)	0.1358
Interaction								0.2465

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

TEAE Leading to Treatment Discontinuation

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	31 (19.7)	20.9 (13.0, NE)	149	34 (22.8)	7.9 (5.0, NE)	0.505 (0.302, 0.843)	0.0078
>= 65 Years	98	18 (18.4)	NR (14.0, NE)	91	30 (33.0)	6.9 (5.1, NE)	0.397 (0.217, 0.727)	0.0020
Interaction								0.3008
Gender								
Male	216	42 (19.4)	20.9 (14.0, NE)	204	55 (27.0)	7.9 (5.6, NE)	0.443 (0.289, 0.677)	0.0001
Female	39	7 (17.9)	NR (7.2, NE)	36	9 (25.0)	NR (2.6, NE)	0.563 (0.207, 1.534)	0.2548
Interaction								0.7659

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

TEAE Leading to Treatment Discontinuation

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	35 (18.7)	NR (14.0, NE)	183	48 (26.2)	NR (6.1, NE)	0.458 (0.291, 0.723)	0.0006
Non-Smoker	68	14 (20.6)	20.9 (7.5, NE)	57	16 (28.1)	6.9 (4.6, NE)	0.464 (0.219, 0.983)	0.0404
Interaction								0.8729
ICC Options								
Paclitaxel	83	11 (13.3)	NR (14.0, NE)	79	19 (24.1)	NR (5.1, NE)	0.365 (0.163, 0.815)	0.0105
Docetaxel	56	14 (25.0)	14.0 (9.7, NE)	50	9 (18.0)	6.9 (5.6, NE)	0.944 (0.400, 2.224)	0.8952
Irinotecan	116	24 (20.7)	20.9 (13.0, NE)	111	36 (32.4)	4.6 (2.9, NE)	0.359 (0.208, 0.619)	0.0001
Interaction								0.0856

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

TEAE Leading to Treatment Discontinuation

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	9 (14.3)	NR (13.9, NE)	57	14 (24.6)	NR (5.0, NE)	0.283 (0.112, 0.715)	0.0046
1	192	40 (20.8)	20.9 (13.0, NE)	183	50 (27.3)	7.9 (6.1, NE)	0.513 (0.334, 0.788)	0.0019
Interaction								0.5949
Region #1								
Asia	201	41 (20.4)	20.9 (13.9, NE)	191	49 (25.7)	NR (6.5, NE)	0.489 (0.316, 0.756)	0.0010
Europe/North America	54	8 (14.8)	NR (NE, NE)	49	15 (30.6)	6.9 (5.0, NE)	0.392 (0.165, 0.929)	0.0275
Interaction								0.6837

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

TEAE Leading to Treatment Discontinuation

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	39 (22.2)	20.9 (14.0, NE)	168	45 (26.8)	NR (6.5, NE)	0.525 (0.336, 0.821)	0.0040
Japan	25	2 (8.0)	NR (10.8, NE)	23	4 (17.4)	NR (5.1, NE)	0.114 (0.011, 1.160)	0.0366
Europe/North America	54	8 (14.8)	NR (NE, NE)	49	15 (30.6)	6.9 (5.0, NE)	0.392 (0.165, 0.929)	0.0275
Interaction								0.7419
Race								
Asian and other	203	42 (20.7)	20.9 (13.9, NE)	198	50 (25.3)	NR (6.5, NE)	0.509 (0.331, 0.783)	0.0018
White	52	7 (13.5)	NR (NE, NE)	42	14 (33.3)	6.1 (5.0, NE)	0.325 (0.131, 0.810)	0.0110
Interaction								0.4010

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

TEAE Leading to Treatment Discontinuation

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	15 (18.8)	NR (10.8, NE)	60	19 (31.7)	7.9 (4.6, NE)	0.349 (0.174, 0.702)	0.0021
vCPS < 10%	100	20 (20.0)	14.0 (13.0, NE)	119	28 (23.5)	NR (5.6, NE)	0.558 (0.304, 1.024)	0.0560
Missing	75	14 (18.7)	NR (20.9, NE)	61	17 (27.9)	6.9 (5.1, NE)	0.499 (0.241, 1.035)	0.0568
Interaction								0.4533

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	77 (100.0)	0.3 (0.2, 0.4)	70	68 (97.1)	0.1 (0.1, 0.2)	0.569 (0.404, 0.802)	0.0005
>= 65 Years	62	58 (93.5)	0.4 (0.2, 0.6)	59	58 (98.3)	0.2 (0.1, 0.2)	0.487 (0.330, 0.718)	<0.0001
Interaction								0.4541
Gender								
Male	118	115 (97.5)	0.3 (0.3, 0.5)	106	104 (98.1)	0.1 (0.1, 0.2)	0.530 (0.400, 0.702)	<0.0001
Female	21	20 (95.2)	0.3 (0.2, 0.5)	23	22 (95.7)	0.1 (0.1, 0.2)	0.539 (0.285, 1.018)	0.0423
Interaction								0.9361

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	102 (98.1)	0.3 (0.2, 0.4)	101	98 (97.0)	0.1 (0.1, 0.2)	0.562 (0.420, 0.753)	<0.0001
Non-Smoker	35	33 (94.3)	0.4 (0.2, 0.7)	28	28 (100.0)	0.2 (0.1, 0.3)	0.370 (0.206, 0.667)	0.0003
Interaction								0.7055
ICC Options								
Paclitaxel	83	80 (96.4)	0.3 (0.2, 0.5)	79	78 (98.7)	0.2 (0.1, 0.3)	0.560 (0.403, 0.778)	0.0002
Docetaxel	56	55 (98.2)	0.3 (0.2, 0.5)	50	48 (96.0)	0.1 (0.1, 0.2)	0.483 (0.319, 0.733)	0.0002
Interaction								0.4758

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	40 (93.0)	0.4 (0.3, 0.7)	37	35 (94.6)	0.3 (0.1, 0.3)	0.567 (0.352, 0.915)	0.0119
1	96	95 (99.0)	0.3 (0.2, 0.4)	92	91 (98.9)	0.1 (0.1, 0.2)	0.501 (0.367, 0.683)	<0.0001
Interaction								0.8389
Region #1								
Asia	103	101 (98.1)	0.4 (0.3, 0.5)	99	98 (99.0)	0.1 (0.1, 0.2)	0.435 (0.323, 0.586)	<0.0001
Europe/North America	36	34 (94.4)	0.2 (0.1, 0.2)	30	28 (93.3)	0.2 (0.1, 0.3)	0.943 (0.564, 1.577)	0.8102
Interaction								0.0751

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	77 (98.7)	0.3 (0.3, 0.5)	76	76 (100.0)	0.1 (0.1, 0.2)	0.418 (0.296, 0.591)	<0.0001
Japan	25	24 (96.0)	0.6 (0.4, 1.1)	23	22 (95.7)	0.2 (0.1, 0.3)	0.452 (0.246, 0.832)	0.0074
Europe/North America	36	34 (94.4)	0.2 (0.1, 0.2)	30	28 (93.3)	0.2 (0.1, 0.3)	0.943 (0.564, 1.577)	0.8102
Interaction								0.1632
Race								
Asian and other	105	103 (98.1)	0.4 (0.3, 0.5)	106	104 (98.1)	0.1 (0.1, 0.2)	0.477 (0.357, 0.637)	<0.0001
White	34	32 (94.1)	0.2 (0.1, 0.3)	23	22 (95.7)	0.2 (0.0, 0.3)	0.783 (0.448, 1.369)	0.3484
Interaction								0.5525

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	45 (100.0)	0.3 (0.2, 0.5)	34	33 (97.1)	0.1 (0.1, 0.2)	0.541 (0.337, 0.867)	0.0062
vCPS < 10%	53	50 (94.3)	0.2 (0.1, 0.3)	54	52 (96.3)	0.2 (0.1, 0.3)	0.746 (0.501, 1.112)	0.1240
Missing	41	40 (97.6)	0.5 (0.3, 1.2)	41	41 (100.0)	0.1 (0.1, 0.3)	0.338 (0.208, 0.549)	<0.0001
Interaction								0.1685

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	37 (48.1)	6.9 (2.4, 13.8)	70	49 (70.0)	0.9 (0.5, 1.2)	0.352 (0.224, 0.553)	<0.0001
>= 65 Years	62	28 (45.2)	8.6 (3.1, NE)	59	39 (66.1)	0.9 (0.4, 2.7)	0.406 (0.244, 0.674)	0.0003
Interaction								0.9974
Gender								
Male	118	55 (46.6)	8.6 (3.3, 10.8)	106	74 (69.8)	0.6 (0.5, 1.2)	0.344 (0.238, 0.498)	<0.0001
Female	21	10 (47.6)	3.1 (1.5, NE)	23	14 (60.9)	1.4 (0.5, NE)	0.599 (0.264, 1.356)	0.2110
Interaction								0.2372

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	52 (50.0)	4.4 (2.8, 10.8)	101	71 (70.3)	0.9 (0.5, 1.2)	0.378 (0.260, 0.551)	<0.0001
Non-Smoker	35	13 (37.1)	9.0 (2.1, NE)	28	17 (60.7)	1.0 (0.5, 3.6)	0.393 (0.184, 0.839)	0.0116
Interaction								0.9862
ICC Options								
Paclitaxel	83	37 (44.6)	10.8 (2.5, NE)	79	53 (67.1)	1.2 (0.5, 1.9)	0.418 (0.271, 0.646)	<0.0001
Docetaxel	56	28 (50.0)	6.9 (2.4, 9.7)	50	35 (70.0)	0.3 (0.3, 1.0)	0.313 (0.181, 0.541)	<0.0001
Interaction								0.4579

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	15 (34.9)	13.8 (6.9, NE)	37	23 (62.2)	1.1 (0.5, NE)	0.290 (0.143, 0.588)	0.0002
1	96	50 (52.1)	3.1 (2.1, 9.7)	92	65 (70.7)	0.7 (0.5, 1.2)	0.410 (0.279, 0.601)	<0.0001
Interaction								0.4342
Region #1								
Asia	103	46 (44.7)	8.6 (3.3, 13.8)	99	68 (68.7)	0.5 (0.4, 1.2)	0.312 (0.208, 0.467)	<0.0001
Europe/North America	36	19 (52.8)	2.5 (1.5, NE)	30	20 (66.7)	1.5 (0.5, 3.6)	0.640 (0.340, 1.204)	0.1607
Interaction								0.0536

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	35 (44.9)	6.9 (2.8, 10.8)	76	52 (68.4)	0.7 (0.3, 1.2)	0.321 (0.203, 0.508)	<0.0001
Japan	25	11 (44.0)	10.1 (1.9, NE)	23	16 (69.6)	0.5 (0.3, 1.3)	0.298 (0.129, 0.688)	0.0023
Europe/North America	36	19 (52.8)	2.5 (1.5, NE)	30	20 (66.7)	1.5 (0.5, 3.6)	0.640 (0.340, 1.204)	0.1607
Interaction								0.1393
Race								
Asian and other	105	47 (44.8)	8.6 (3.3, 10.8)	106	72 (67.9)	0.6 (0.5, 1.2)	0.327 (0.220, 0.486)	<0.0001
White	34	18 (52.9)	3.1 (1.5, NE)	23	16 (69.6)	1.9 (0.5, 3.6)	0.613 (0.311, 1.207)	0.1512
Interaction								0.1081

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	21 (46.7)	9.7 (3.1, 13.8)	34	25 (73.5)	1.0 (0.5, 2.8)	0.340 (0.183, 0.630)	0.0003
vCPS < 10%	53	29 (54.7)	4.1 (2.1, 10.8)	54	39 (72.2)	0.5 (0.4, 1.0)	0.340 (0.202, 0.571)	<0.0001
Missing	41	15 (36.6)	8.6 (2.5, NE)	41	24 (58.5)	1.2 (0.3, NE)	0.430 (0.221, 0.836)	0.0090
Interaction								0.9825

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious TEAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	37 (48.1)	7.2 (2.8, 13.9)	70	31 (44.3)	4.2 (1.9, 8.6)	0.776 (0.476, 1.266)	0.3076
>= 65 Years	62	23 (37.1)	10.8 (6.8, NE)	59	23 (39.0)	6.1 (2.8, NE)	0.729 (0.398, 1.335)	0.3033
Interaction								0.7256
Gender								
Male	118	52 (44.1)	9.0 (4.0, 14.0)	106	46 (43.4)	4.2 (2.8, NE)	0.729 (0.484, 1.097)	0.1272
Female	21	8 (38.1)	NR (1.7, NE)	23	8 (34.8)	8.6 (1.9, NE)	0.988 (0.361, 2.705)	0.9819
Interaction								0.6592

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious TEAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	48 (46.2)	8.6 (3.9, 13.9)	101	45 (44.6)	4.2 (2.8, 8.6)	0.739 (0.485, 1.124)	0.1548
Non-Smoker	35	12 (34.3)	NR (2.5, NE)	28	9 (32.1)	NR (1.9, NE)	0.913 (0.378, 2.205)	0.8386
Interaction								0.8114
ICC Options								
Paclitaxel	83	29 (34.9)	NR (7.2, NE)	79	30 (38.0)	8.6 (3.4, NE)	0.771 (0.456, 1.302)	0.3288
Docetaxel	56	31 (55.4)	4.4 (2.1, 9.0)	50	24 (48.0)	3.1 (1.3, NE)	0.680 (0.388, 1.191)	0.1716
Interaction								0.9066

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious TEAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	14 (32.6)	13.9 (7.2, NE)	37	10 (27.0)	8.6 (4.2, NE)	0.774 (0.328, 1.829)	0.5576
1	96	46 (47.9)	4.4 (2.3, 10.8)	92	44 (47.8)	3.1 (2.2, NE)	0.750 (0.491, 1.147)	0.1822
Interaction								0.6485
Region #1								
Asia	103	45 (43.7)	9.0 (3.9, 14.0)	99	43 (43.4)	4.2 (2.6, NE)	0.675 (0.437, 1.041)	0.0726
Europe/North America	36	15 (41.7)	7.2 (2.4, NE)	30	11 (36.7)	8.6 (2.8, NE)	1.121 (0.510, 2.462)	0.7764
Interaction								0.2400

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious TEAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	36 (46.2)	8.6 (2.8, 14.0)	76	33 (43.4)	4.2 (2.2, NE)	0.727 (0.446, 1.186)	0.1977
Japan	25	9 (36.0)	13.9 (6.8, NE)	23	10 (43.5)	NR (1.1, NE)	0.511 (0.197, 1.327)	0.1596
Europe/North America	36	15 (41.7)	7.2 (2.4, NE)	30	11 (36.7)	8.6 (2.8, NE)	1.121 (0.510, 2.462)	0.7764
Interaction								0.4038
Race								
Asian and other	105	46 (43.8)	9.0 (3.9, 14.0)	106	45 (42.5)	4.2 (2.6, NE)	0.714 (0.466, 1.094)	0.1192
White	34	14 (41.2)	NR (2.4, NE)	23	9 (39.1)	8.6 (2.8, NE)	1.039 (0.446, 2.421)	0.9284
Interaction								0.4014

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious TEAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	17 (37.8)	10.1 (3.3, NE)	34	16 (47.1)	4.2 (1.9, NE)	0.481 (0.231, 1.001)	0.0449
vCPS < 10%	53	26 (49.1)	7.2 (2.4, 14.0)	54	23 (42.6)	6.1 (2.6, NE)	0.860 (0.483, 1.531)	0.6066
Missing	41	17 (41.5)	8.6 (2.3, NE)	41	15 (36.6)	NR (1.7, NE)	0.951 (0.470, 1.925)	0.8886
Interaction								0.5144

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE Leading to Treatment Discontinuation

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	14 (18.2)	14.0 (9.7, NE)	70	13 (18.6)	NR (5.6, NE)	0.638 (0.290, 1.405)	0.2608
>= 65 Years	62	11 (17.7)	NR (14.0, NE)	59	15 (25.4)	NR (5.1, NE)	0.518 (0.230, 1.162)	0.1047
Interaction								0.4434
Gender								
Male	118	20 (16.9)	NR (13.9, NE)	106	24 (22.6)	7.9 (6.1, NE)	0.468 (0.248, 0.882)	0.0163
Female	21	5 (23.8)	NR (2.1, NE)	23	4 (17.4)	NR (NE, NE)	1.463 (0.387, 5.528)	0.5725
Interaction								0.2265

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE Leading to Treatment Discontinuation

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	20 (19.2)	NR (13.9, NE)	101	22 (21.8)	NR (6.1, NE)	0.556 (0.291, 1.062)	0.0714
Non-Smoker	35	5 (14.3)	NR (3.7, NE)	28	6 (21.4)	6.9 (5.0, NE)	0.601 (0.182, 1.983)	0.3984
Interaction								0.8978
ICC Options								
Paclitaxel	83	11 (13.3)	NR (14.0, NE)	79	19 (24.1)	NR (5.1, NE)	0.365 (0.163, 0.815)	0.0105
Docetaxel	56	14 (25.0)	14.0 (9.7, NE)	50	9 (18.0)	6.9 (5.6, NE)	0.944 (0.400, 2.224)	0.8952
Interaction								0.0950

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE Leading to Treatment Discontinuation

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	6 (14.0)	NR (10.8, NE)	37	7 (18.9)	NR (5.6, NE)	0.301 (0.083, 1.093)	0.0553
1	96	19 (19.8)	NR (14.0, NE)	92	21 (22.8)	7.9 (6.1, NE)	0.673 (0.358, 1.264)	0.2149
Interaction								0.7167
Region #1								
Asia	103	18 (17.5)	NR (13.9, NE)	99	19 (19.2)	NR (6.5, NE)	0.592 (0.301, 1.163)	0.1238
Europe/North America	36	7 (19.4)	NR (7.2, NE)	30	9 (30.0)	6.9 (5.0, NE)	0.570 (0.209, 1.551)	0.2651
Interaction								0.9617

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE Leading to Treatment Discontinuation

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	16 (20.5)	NR (14.0, NE)	76	15 (19.7)	NR (6.5, NE)	0.765 (0.371, 1.577)	0.4660
Japan	25	2 (8.0)	NR (10.8, NE)	23	4 (17.4)	NR (5.1, NE)	0.114 (0.011, 1.160)	0.0366
Europe/North America	36	7 (19.4)	NR (7.2, NE)	30	9 (30.0)	6.9 (5.0, NE)	0.570 (0.209, 1.551)	0.2651
Interaction								0.5757
Race								
Asian and other	105	19 (18.1)	NR (13.9, NE)	106	20 (18.9)	NR (7.9, NE)	0.635 (0.329, 1.225)	0.1714
White	34	6 (17.6)	NR (7.2, NE)	23	8 (34.8)	6.1 (5.0, NE)	0.452 (0.155, 1.316)	0.1353
Interaction								0.6734

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE Leading to Treatment Discontinuation

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	9 (20.0)	13.9 (9.7, NE)	34	9 (26.5)	NR (7.9, NE)	0.574 (0.225, 1.461)	0.2380
vCPS < 10%	53	9 (17.0)	NR (14.0, NE)	54	8 (14.8)	NR (5.0, NE)	0.657 (0.234, 1.844)	0.4224
Missing	41	7 (17.1)	NR (NE, NE)	41	11 (26.8)	6.9 (5.1, NE)	0.549 (0.212, 1.425)	0.2114
Interaction								0.7529

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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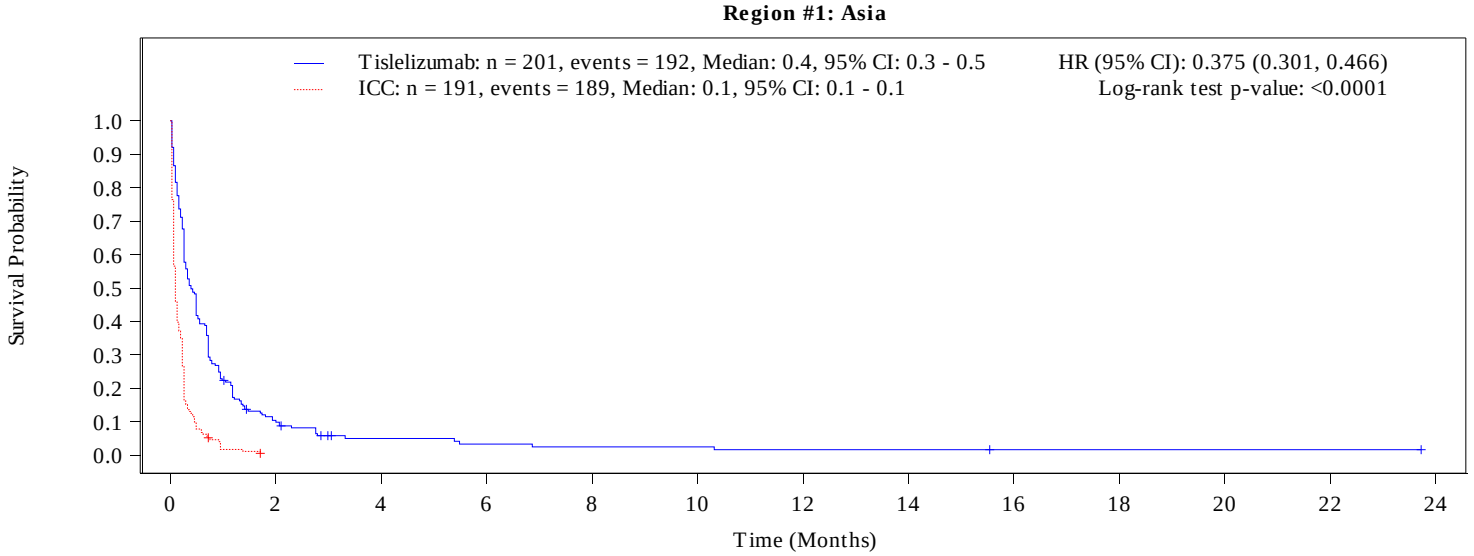
Figure 14.3.1.1.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Any TEAE



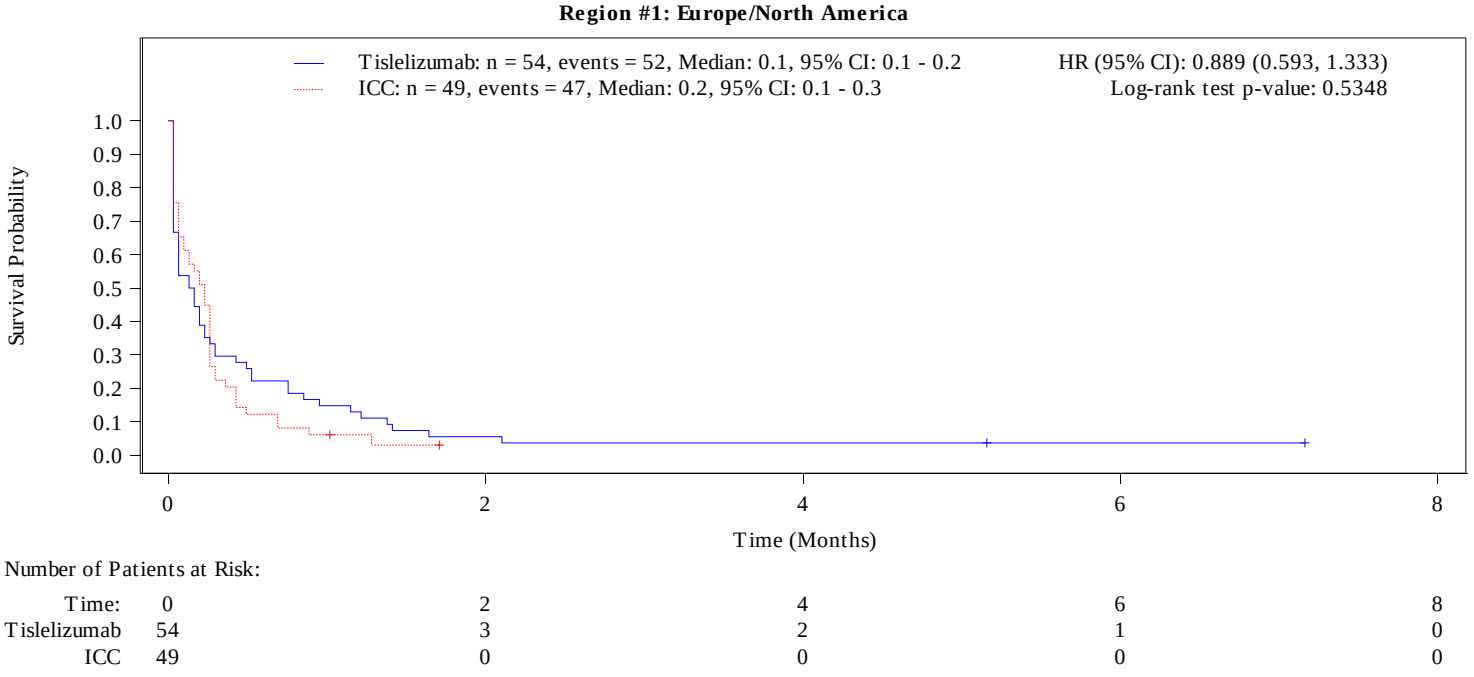
Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24
Tislelizumab	201	19	6	4	3	3	2	2	1	1	1	1	0
ICC	191	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteae-subgrp.sas 19AUG2024 22:16 f-14-03-01-01-s-km-tteae-subgrp-safety-fa.rtf

Figure 14.3.1.1.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Any TEAE



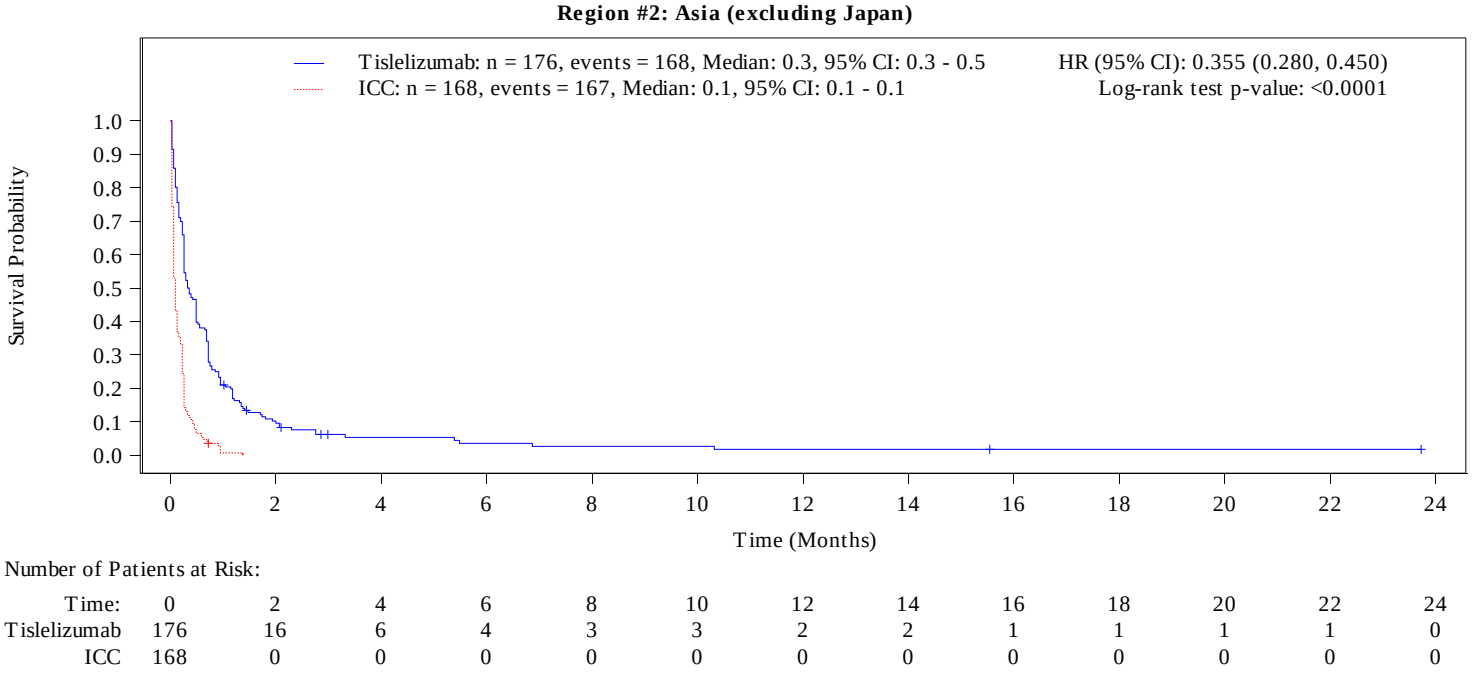
Number of Patients at Risk:

Time:	0	2	4	6	8
Tislelizumab	54	3	2	1	0
ICC	49	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteae-subgrp.sas 19AUG2024 22:16 f-14-03-01-01-s-km-tteae-subgrp-safety-fa.rtf

Figure 14.3.1.1.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Any TEAE



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24
Tislelizumab	176	16	6	4	3	3	2	2	1	1	1	1	0
ICC	168	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
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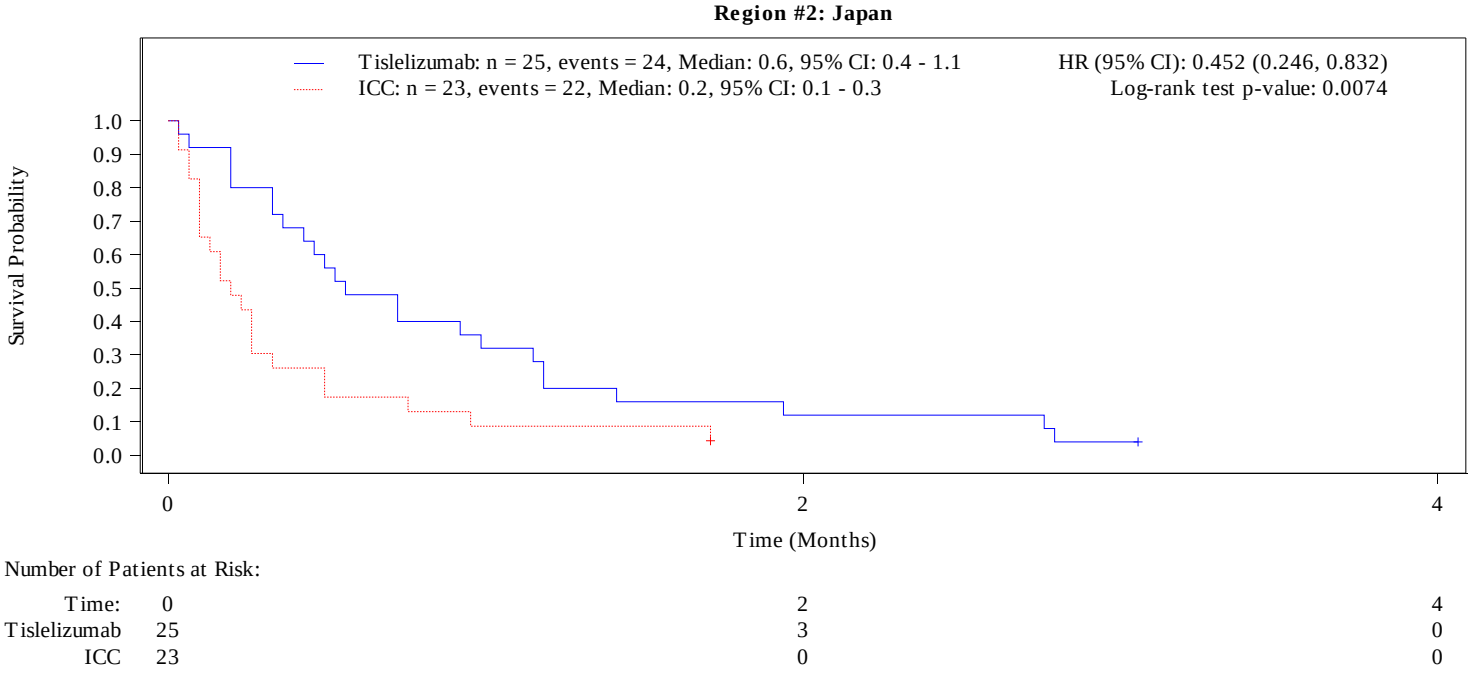
Figure 14.3.1.1.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Any TEAE



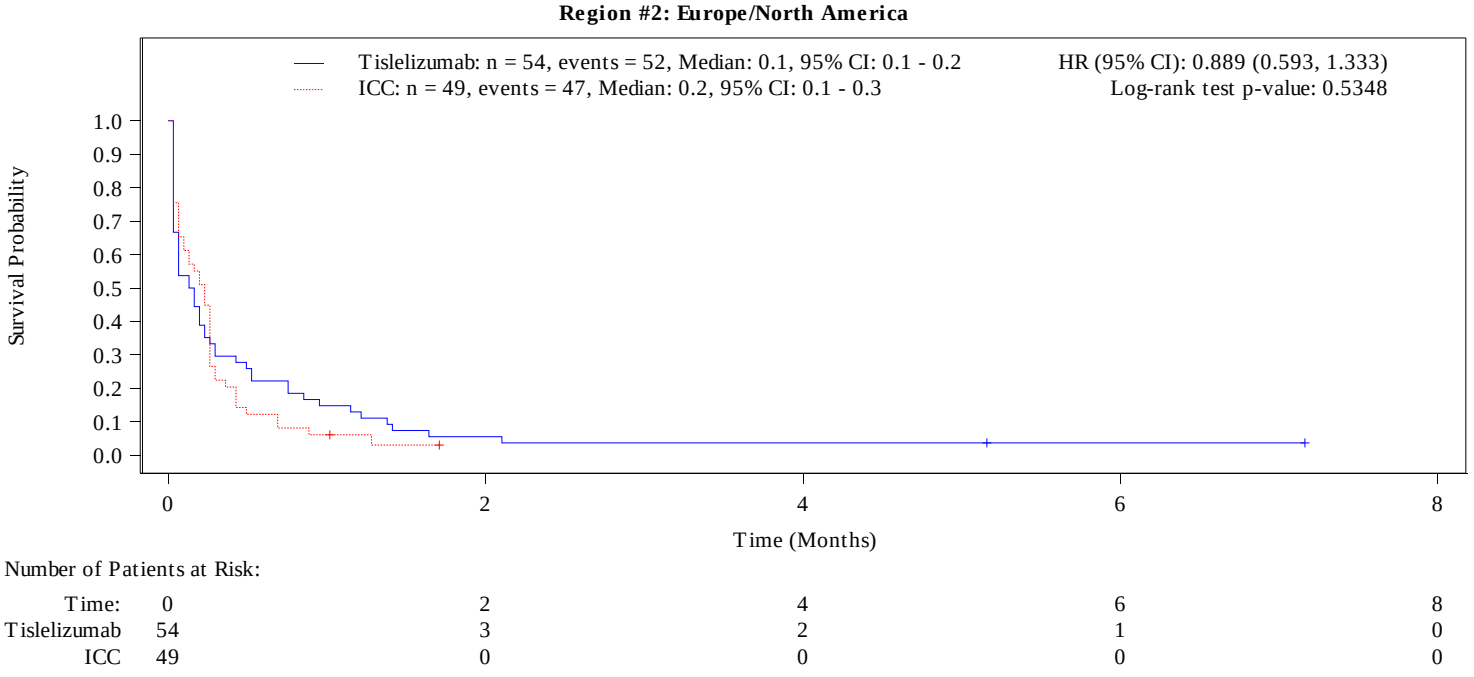
Number of Patients at Risk:

Time:	0	2	4
Tislelizumab	25	3	0
ICC	23	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteae-subgrp.sas 19AUG2024 22:16 f-14-03-01-01-s-km-tteae-subgrp-safety-fa.rtf

Figure 14.3.1.1.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Any TEAE

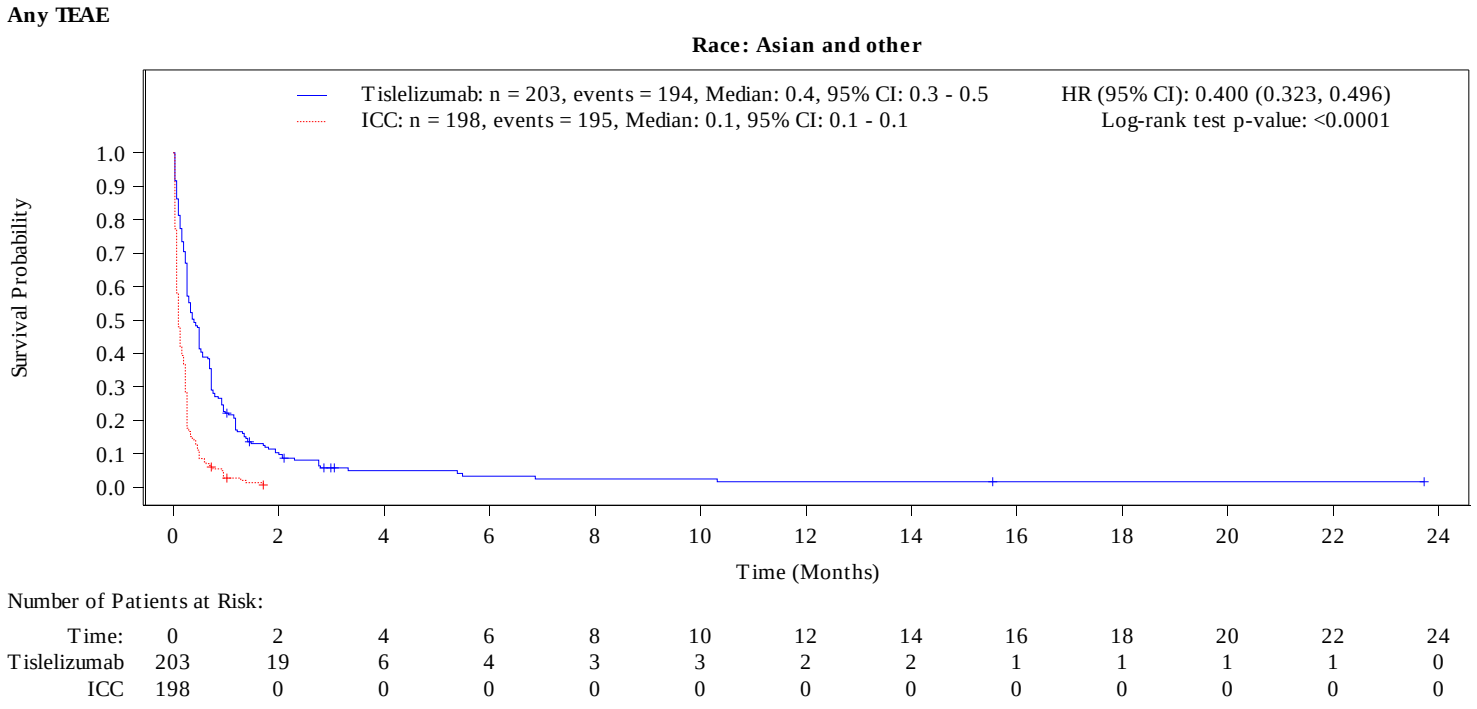


Number of Patients at Risk:

Time:	0	2	4	6	8
Tislelizumab	54	3	2	1	0
ICC	49	0	0	0	0

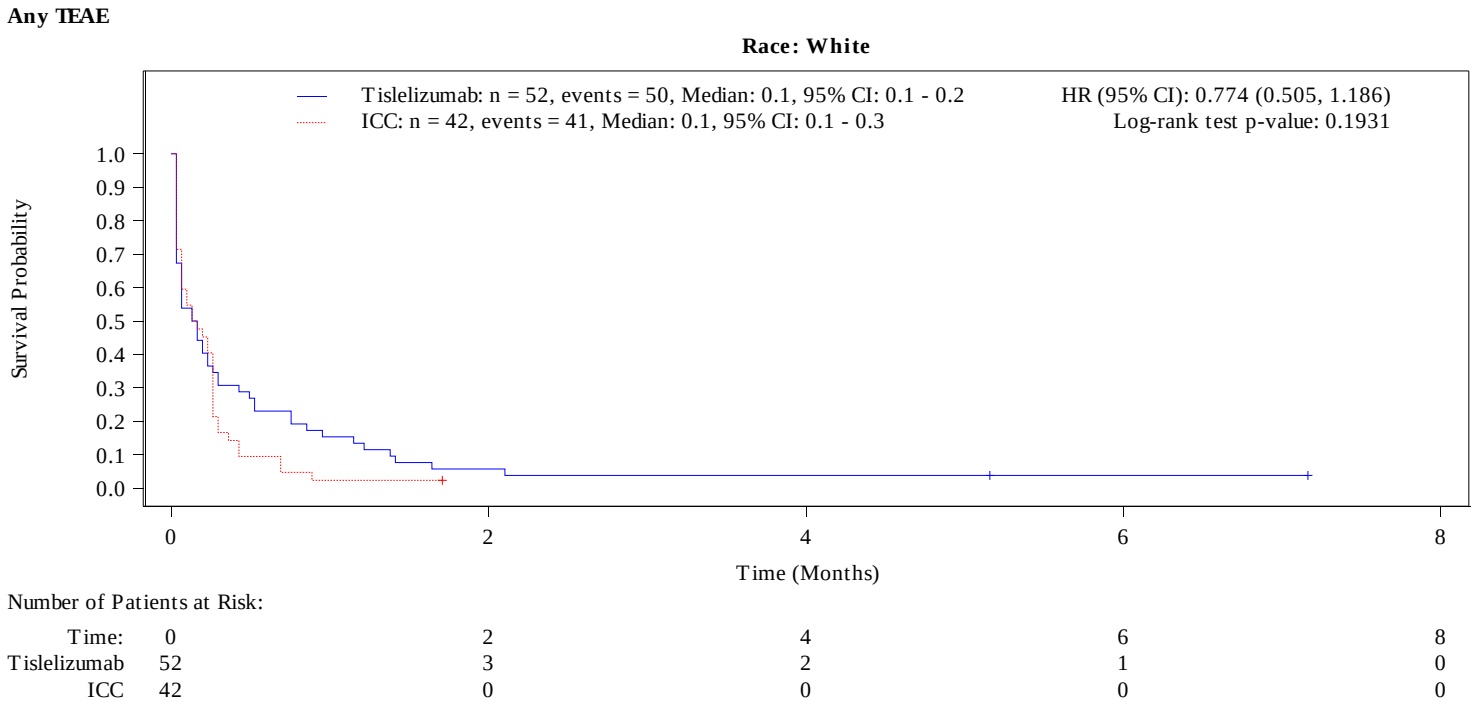
Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteae-subgrp.sas 19AUG2024 22:16 f-14-03-01-01-s-km-tteae-subgrp-safety-fa.rtf

Figure 14.3.1.1.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteae-subgrp.sas 19AUG2024 22:16 f-14-03-01-01-s-km-tteae-subgrp-safety-fa.rtf

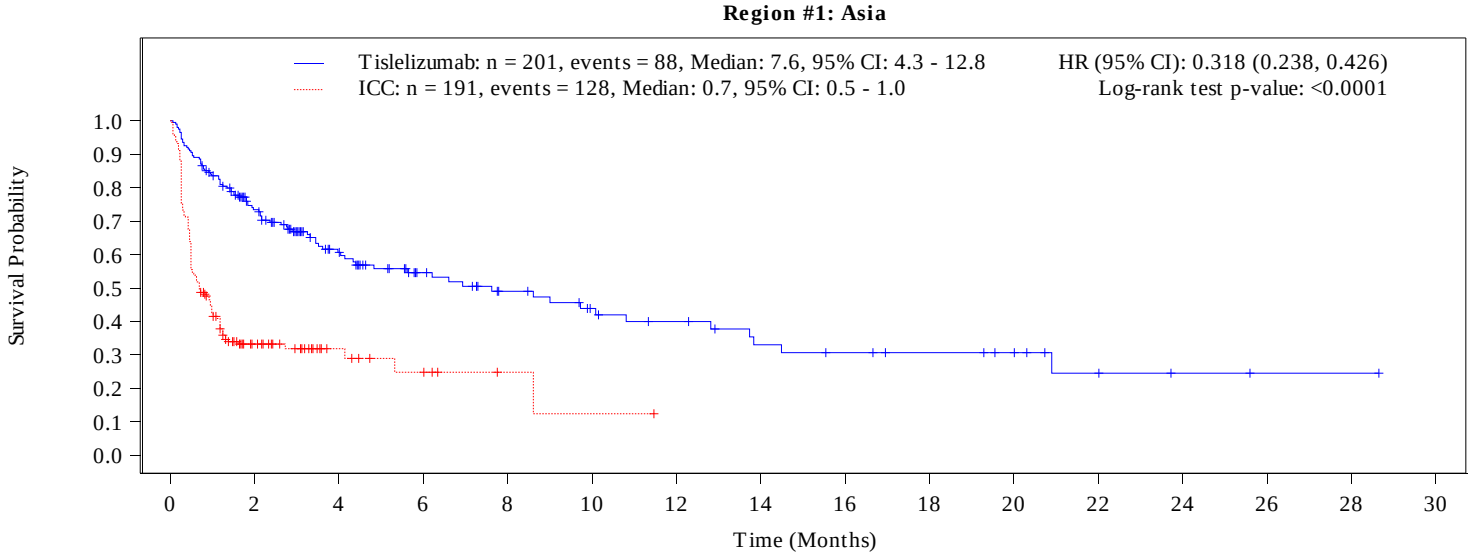
Figure 14.3.1.1.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteae-subgrp.sas 19AUG2024 22:16 f-14-03-01-01-s-km-tteae-subgrp-safety-fa.rtf

Figure 14.3.1.1.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3



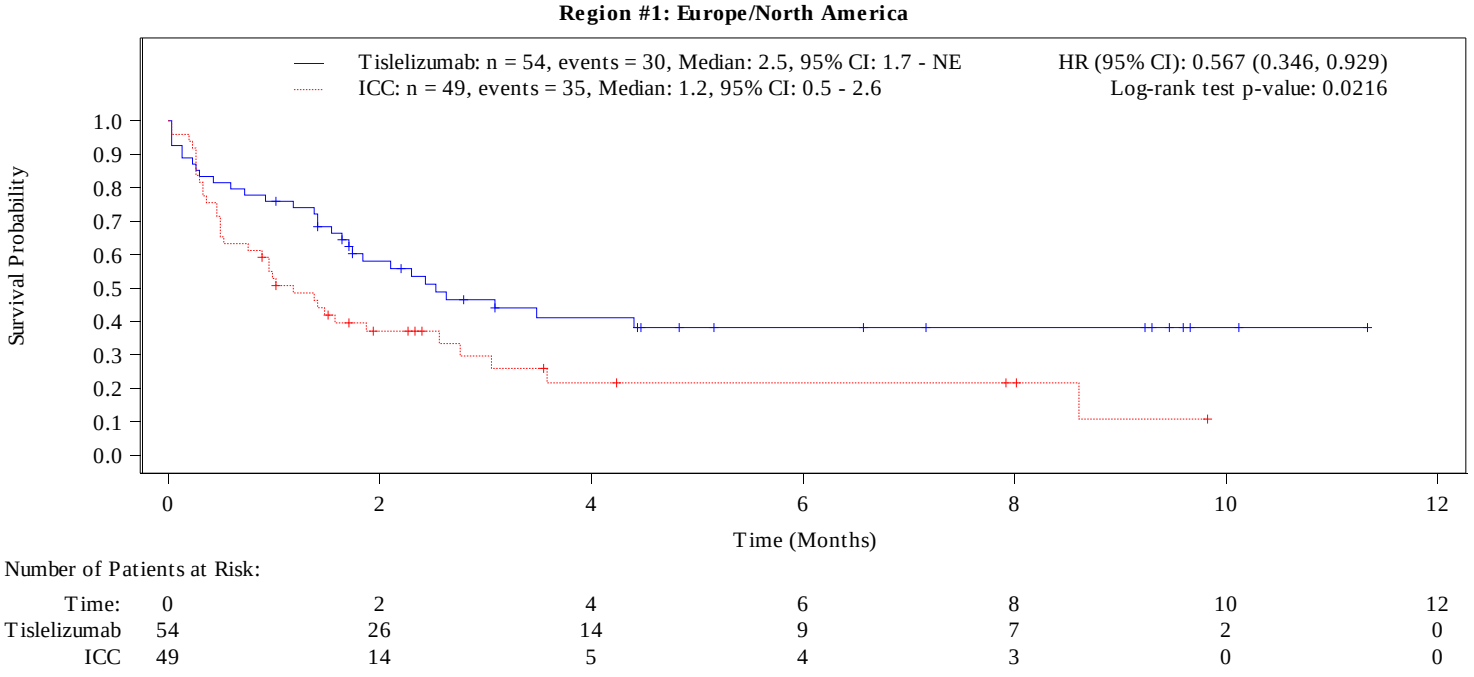
Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	201	117	65	41	31	23	19	14	12	10	8	4	2	1	1	0
ICC	191	35	11	6	2	1	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteae-subgrp.sas 19AUG2024 22:16 f-14-03-01-01-s-km-tteae-subgrp-safety-fa.rtf

Figure 14.3.1.1.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3

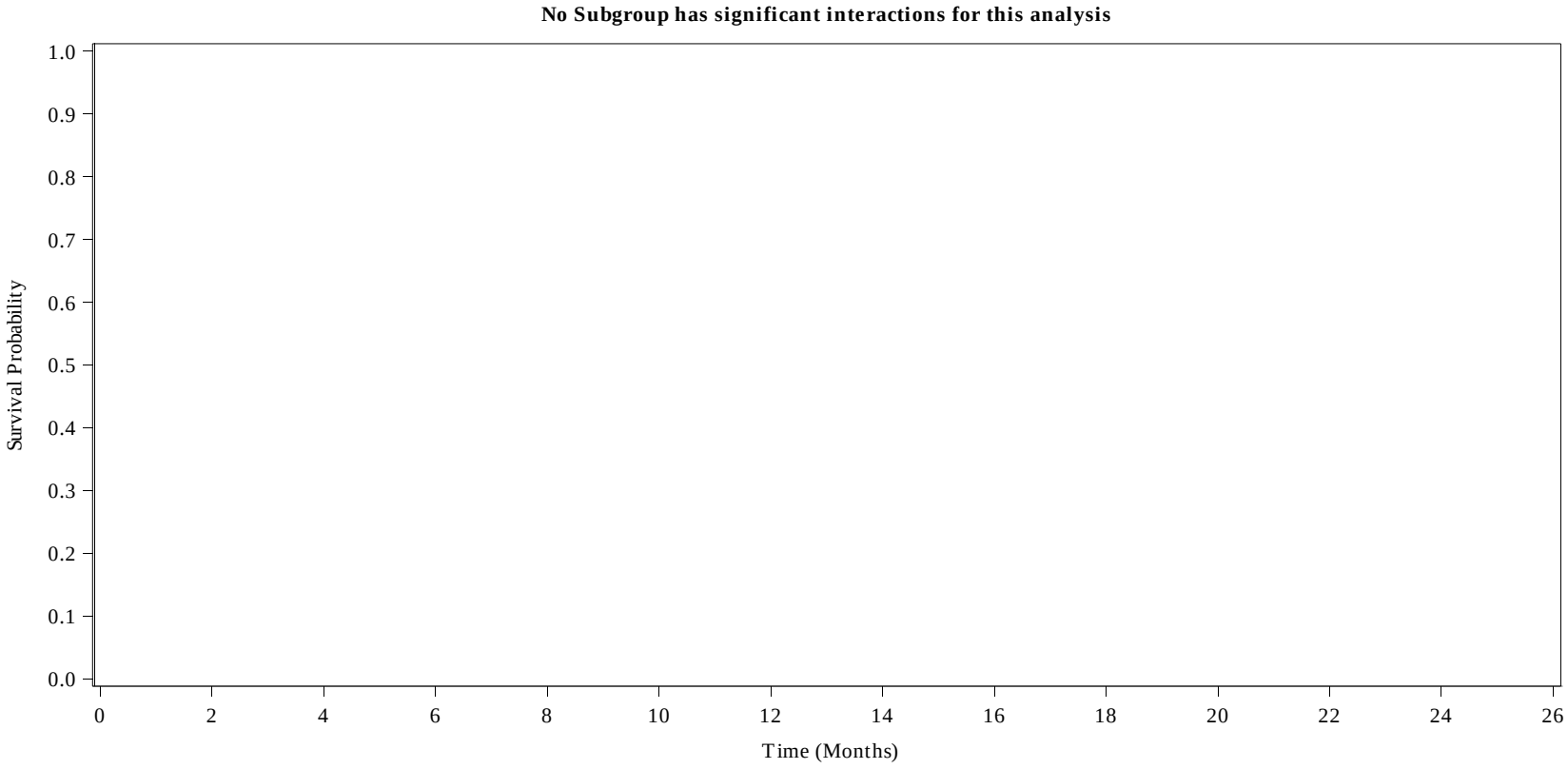


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12
Tislelizumab	54	26	14	9	7	2	0
ICC	49	14	5	4	3	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteae-subgrp.sas 19AUG2024 22:16 f-14-03-01-01-s-km-tteae-subgrp-safety-fa.rtf

Figure 14.3.1.1.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteae-subgrp.sas 19AUG2024 22:16 f-14-03-01-01-b-s-km-tteae-subgrp-safetys-fa.rtf

Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

	Tislelizumab (N = 255)			ICC (N = 240)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Blood and lymphatic system disorders	255	92 (36.1)	12.4 (8.9, NE)	240	139 (57.9)	1.1 (0.9, 2.0)	0.384 (0.291, 0.507)	<0.0001
Anaemia	255	78 (30.6)	19.4 (11.0, NE)	240	107 (44.6)	4.1 (2.0, NE)	0.457 (0.336, 0.621)	<0.0001
Febrile neutropenia	255	0 (0.0)	NR (NE, NE)	240	12 (5.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0002
Leukopenia	255	8 (3.1)	NR (NE, NE)	240	30 (12.5)	NR (NE, NE)	0.168 (0.072, 0.390)	<0.0001
Neutropenia	255	2 (0.8)	NR (NE, NE)	240	31 (12.9)	NR (NE, NE)	0.055 (0.013, 0.231)	<0.0001
Thrombocytopenia	255	5 (2.0)	NR (NE, NE)	240	10 (4.2)	NR (NE, NE)	0.338 (0.105, 1.083)	0.0555
Cardiac disorders	255	28 (11.0)	NR (NE, NE)	240	22 (9.2)	NR (NE, NE)	0.859 (0.479, 1.539)	0.6086

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.
Adverse events were classified based on MedDRA v23.0.
System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.
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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

	Tislelizumab (N = 255)			ICC (N = 240)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Endocrine disorders	255	39 (15.3)	NR (16.1, NE)	240	2 (0.8)	NR (NE, NE)	12.291 (2.944, 51.311)	<0.0001
Hypothyroidism	255	29 (11.4)	NR (16.5, NE)	240	1 (0.4)	NR (NE, NE)	17.093 (2.309, 126.546)	0.0002
Eye disorders	255	18 (7.1)	NR (NE, NE)	240	8 (3.3)	NR (NE, NE)	1.516 (0.642, 3.580)	0.3393

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.
Adverse events were classified based on MedDRA v23.0.
System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.
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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

System Organ Class Preferred Term	Tislelizumab (N = 255) Total No. of Patients	Tislelizumab (N = 255) Patients with events n (%)	Tislelizumab (N = 255) Median time to event (95% CI) [a]	ICC (N = 240) Total No. of Patients	ICC (N = 240) Patients with events n (%)	ICC (N = 240) Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Gastrointestinal disorders	255	149 (58.4)	2.9 (1.8, 4.1)	240	171 (71.3)	0.4 (0.3, 0.7)	0.447 (0.354, 0.564)	<0.0001
Abdominal pain	255	17 (6.7)	NR (NE, NE)	240	22 (9.2)	NR (10.8, NE)	0.558 (0.290, 1.075)	0.0773
Abdominal pain upper	255	9 (3.5)	NR (NE, NE)	240	16 (6.7)	NR (NE, NE)	0.421 (0.183, 0.968)	0.0360
Constipation	255	39 (15.3)	NR (NE, NE)	240	45 (18.8)	NR (NE, NE)	0.653 (0.420, 1.018)	0.0573
Diarrhoea	255	32 (12.5)	NR (NE, NE)	240	77 (32.1)	NR (NE, NE)	0.281 (0.184, 0.430)	<0.0001
Dysphagia	255	28 (11.0)	NR (NE, NE)	240	20 (8.3)	NR (NE, NE)	0.950 (0.525, 1.721)	0.8671
Gastrooesophageal reflux disease	255	14 (5.5)	NR (NE, NE)	240	12 (5.0)	NR (NE, NE)	0.760 (0.339, 1.705)	0.5041
Nausea	255	36 (14.1)	NR (NE, NE)	240	72 (30.0)	NR (5.1, NE)	0.345 (0.229, 0.521)	<0.0001
Stomatitis	255	9 (3.5)	NR (NE, NE)	240	14 (5.8)	NR (NE, NE)	0.505 (0.217, 1.177)	0.1051
Vomiting	255	27 (10.6)	NR (NE, NE)	240	48 (20.0)	NR (NE, NE)	0.392 (0.241, 0.638)	<0.0001

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

System Organ Class Preferred Term	Tislelizumab (N = 255) Total No. of Patients	Tislelizumab (N = 255) Patients with events n (%)	Tislelizumab (N = 255) Median time to event (95% CI) [a]	ICC (N = 240) Total No. of Patients	ICC (N = 240) Patients with events n (%)	ICC (N = 240) Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
General disorders and administration site conditions	255	116 (45.5)	7.0 (3.5, 9.9)	240	147 (61.3)	1.0 (0.8, 1.7)	0.484 (0.374, 0.626)	<0.0001
Asthenia	255	26 (10.2)	NR (NE, NE)	240	35 (14.6)	NR (9.0, NE)	0.553 (0.329, 0.930)	0.0234
Fatigue	255	33 (12.9)	NR (NE, NE)	240	42 (17.5)	NR (NE, NE)	0.633 (0.398, 1.009)	0.0521
Malaise	255	16 (6.3)	NR (NE, NE)	240	36 (15.0)	NR (NE, NE)	0.308 (0.166, 0.569)	<0.0001
Oedema peripheral	255	10 (3.9)	NR (NE, NE)	240	11 (4.6)	NR (10.2, NE)	0.642 (0.262, 1.576)	0.3296
Pyrexia	255	41 (16.1)	NR (NE, NE)	240	34 (14.2)	NR (NE, NE)	0.830 (0.518, 1.330)	0.4372
Hepatobiliary disorders	255	12 (4.7)	NR (NE, NE)	240	7 (2.9)	NR (NE, NE)	1.183 (0.451, 3.101)	0.7318

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

	Tislelizumab (N = 255)			ICC (N = 240)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Infections and infestations	255	75 (29.4)	13.7 (9.5, NE)	240	75 (31.3)	8.0 (4.9, NE)	0.682 (0.489, 0.951)	0.0233
Pneumonia	255	36 (14.1)	NR (15.8, NE)	240	27 (11.3)	NR (NE, NE)	0.837 (0.497, 1.409)	0.5028
Upper respiratory tract infection	255	8 (3.1)	NR (NE, NE)	240	11 (4.6)	NR (NE, NE)	0.542 (0.210, 1.401)	0.1993
Injury, poisoning and procedural complications	255	16 (6.3)	NR (NE, NE)	240	7 (2.9)	NR (NE, NE)	1.205 (0.462, 3.146)	0.7023

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

	Tislelizumab (N = 255)			ICC (N = 240)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Investigations	255	128 (50.2)	3.4 (2.1, 7.0)	240	166 (69.2)	0.5 (0.5, 0.7)	0.412 (0.324, 0.525)	<0.0001
Alanine aminotransferase increased	255	33 (12.9)	NR (NE, NE)	240	18 (7.5)	NR (NE, NE)	1.330 (0.740, 2.390)	0.3378
Aspartate aminotransferase increased	255	37 (14.5)	NR (NE, NE)	240	11 (4.6)	NR (NE, NE)	2.356 (1.188, 4.673)	0.0115
Blood alkaline phosphatase increased	255	17 (6.7)	NR (NE, NE)	240	5 (2.1)	NR (NE, NE)	2.779 (1.019, 7.577)	0.0369
Blood creatine phosphokinase MB increased	255	11 (4.3)	NR (NE, NE)	240	1 (0.4)	NR (NE, NE)	7.277 (0.922, 57.448)	0.0286
Blood creatine phosphokinase increased	255	10 (3.9)	NR (NE, NE)	240	0 (0.0)	NR (NE, NE)	26494210.892 (0.000, NE)	0.0056
Gamma-glutamyltransferase increased	255	14 (5.5)	NR (NE, NE)	240	8 (3.3)	NR (NE, NE)	1.439 (0.599, 3.454)	0.4125
Lymphocyte count decreased	255	12 (4.7)	NR (NE, NE)	240	22 (9.2)	NR (NE, NE)	0.391 (0.188, 0.814)	0.0092
Neutrophil count decreased	255	6 (2.4)	NR (NE, NE)	240	94 (39.2)	NR (2.8, NE)	0.047 (0.020, 0.107)	<0.0001
Platelet count decreased	255	14 (5.5)	NR (NE, NE)	240	15 (6.3)	NR (NE, NE)	0.634 (0.292, 1.376)	0.2447
Weight decreased	255	59 (23.1)	NR (NE, NE)	240	45 (18.8)	NR (NE, NE)	0.947 (0.636, 1.410)	0.7884
White blood cell count decreased	255	9 (3.5)	NR (NE, NE)	240	98 (40.8)	NR (NE, NE)	0.064 (0.032, 0.126)	<0.0001
White blood cell count increased	255	11 (4.3)	NR (NE, NE)	240	6 (2.5)	NR (NE, NE)	1.383 (0.505, 3.789)	0.5266

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

System Organ Class Preferred Term	Tislelizumab (N = 255) Total No. of Patients	Tislelizumab (N = 255) Patients with events n (%)	Tislelizumab (N = 255) Median time to event (95% CI) [a]	ICC (N = 240) Total No. of Patients	ICC (N = 240) Patients with events n (%)	ICC (N = 240) Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Metabolism and nutrition disorders	255	116 (45.5)	7.7 (3.4, 10.2)	240	141 (58.8)	1.2 (0.8, 2.2)	0.491 (0.380, 0.635)	<0.0001
Decreased appetite	255	40 (15.7)	NR (NE, NE)	240	84 (35.0)	6.6 (3.7, NE)	0.316 (0.214, 0.467)	<0.0001
Hyperglycaemia	255	16 (6.3)	NR (NE, NE)	240	7 (2.9)	NR (NE, NE)	1.758 (0.714, 4.332)	0.2124
Hyperuricaemia	255	6 (2.4)	NR (NE, NE)	240	11 (4.6)	NR (NE, NE)	0.407 (0.148, 1.121)	0.0726
Hypoalbuminaemia	255	34 (13.3)	NR (NE, NE)	240	30 (12.5)	NR (NE, NE)	0.883 (0.536, 1.456)	0.6253
Hypocalcaemia	255	8 (3.1)	NR (NE, NE)	240	11 (4.6)	NR (NE, NE)	0.500 (0.192, 1.303)	0.1485
Hypochloraemia	255	6 (2.4)	NR (NE, NE)	240	10 (4.2)	NR (NE, NE)	0.379 (0.128, 1.129)	0.0702
Hypokalaemia	255	20 (7.8)	NR (NE, NE)	240	22 (9.2)	NR (NE, NE)	0.622 (0.332, 1.168)	0.1362
Hyponatraemia	255	32 (12.5)	NR (17.2, NE)	240	33 (13.8)	NR (NE, NE)	0.593 (0.353, 0.995)	0.0437
Hypoproteinaemia	255	13 (5.1)	NR (NE, NE)	240	8 (3.3)	NR (NE, NE)	0.995 (0.396, 2.498)	0.9911

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

	Tislelizumab (N = 255)			ICC (N = 240)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Musculoskeletal and connective tissue disorders	255	66 (25.9)	NR (16.1, NE)	240	61 (25.4)	7.2 (6.2, NE)	0.763 (0.534, 1.091)	0.1355
Arthralgia	255	10 (3.9)	NR (NE, NE)	240	13 (5.4)	NR (NE, NE)	0.618 (0.267, 1.433)	0.2578
Back pain	255	26 (10.2)	NR (NE, NE)	240	18 (7.5)	NR (NE, NE)	0.999 (0.536, 1.860)	0.9964
Musculoskeletal pain	255	13 (5.1)	NR (NE, NE)	240	7 (2.9)	NR (NE, NE)	1.355 (0.531, 3.453)	0.5234
Myalgia	255	6 (2.4)	NR (NE, NE)	240	14 (5.8)	NR (NE, NE)	0.373 (0.142, 0.977)	0.0362
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	255	23 (9.0)	NR (NE, NE)	240	8 (3.3)	NR (NE, NE)	2.365 (1.049, 5.333)	0.0326
Cancer pain	255	10 (3.9)	NR (NE, NE)	240	4 (1.7)	NR (NE, NE)	2.014 (0.627, 6.472)	0.2307

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

	Tislelizumab (N = 255)			ICC (N = 240)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Nervous system disorders	255	31 (12.2)	NR (NE, NE)	240	63 (26.3)	9.7 (7.4, NE)	0.321 (0.206, 0.501)	<0.0001
Dizziness	255	11 (4.3)	NR (NE, NE)	240	19 (7.9)	NR (NE, NE)	0.426 (0.200, 0.908)	0.0231
Peripheral sensory neuropathy	255	2 (0.8)	NR (NE, NE)	240	23 (9.6)	NR (9.7, NE)	0.061 (0.014, 0.264)	<0.0001
Psychiatric disorders	255	26 (10.2)	NR (NE, NE)	240	26 (10.8)	NR (NE, NE)	0.736 (0.421, 1.286)	0.2791
Insomnia	255	20 (7.8)	NR (NE, NE)	240	17 (7.1)	NR (NE, NE)	0.916 (0.473, 1.772)	0.7940
Renal and urinary disorders	255	11 (4.3)	NR (NE, NE)	240	9 (3.8)	NR (NE, NE)	0.659 (0.253, 1.715)	0.3897

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

System Organ Class Preferred Term	Tislelizumab (N = 255) Total No. of Patients	Tislelizumab (N = 255) Patients with events n (%)	Tislelizumab (N = 255) Median time to event (95% CI) [a]	ICC (N = 240) Total No. of Patients	ICC (N = 240) Patients with events n (%)	ICC (N = 240) Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Respiratory, thoracic and mediastinal disorders	255	104 (40.8)	11.3 (4.4, 15.8)	240	81 (33.8)	5.7 (4.0, NE)	1.031 (0.766, 1.388)	0.8399
Cough	255	43 (16.9)	NR (NE, NE)	240	28 (11.7)	NR (NE, NE)	1.276 (0.786, 2.072)	0.3224
Dyspnoea	255	24 (9.4)	NR (NE, NE)	240	18 (7.5)	NR (NE, NE)	0.979 (0.522, 1.839)	0.9484
Haemoptysis	255	11 (4.3)	NR (NE, NE)	240	7 (2.9)	NR (NE, NE)	1.180 (0.449, 3.102)	0.7373
Pneumonitis	255	12 (4.7)	NR (NE, NE)	240	4 (1.7)	NR (NE, NE)	1.535 (0.464, 5.082)	0.4793
Productive cough	255	18 (7.1)	NR (NE, NE)	240	18 (7.5)	NR (NE, NE)	0.715 (0.363, 1.406)	0.3283

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

System Organ Class Preferred Term	Tislelizumab (N = 255) Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	ICC (N = 240) Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Skin and subcutaneous tissue disorders	255	59 (23.1)	NR (10.7, NE)	240	67 (27.9)	NR (5.3, NE)	0.670 (0.469, 0.957)	0.0263
Alopecia	255	0 (0.0)	NR (NE, NE)	240	42 (17.5)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Pruritus	255	23 (9.0)	NR (NE, NE)	240	11 (4.6)	NR (NE, NE)	1.462 (0.698, 3.061)	0.3105
Rash	255	21 (8.2)	NR (NE, NE)	240	10 (4.2)	NR (NE, NE)	1.796 (0.842, 3.830)	0.1234
Vascular disorders	255	26 (10.2)	NR (NE, NE)	240	17 (7.1)	NR (NE, NE)	1.179 (0.631, 2.205)	0.6042
Hypertension	255	12 (4.7)	NR (NE, NE)	240	6 (2.5)	NR (NE, NE)	1.539 (0.568, 4.171)	0.3918

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1.b:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 129)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Blood and lymphatic system disorders	139	44 (31.7)	NR (NE, NE)	129	72 (55.8)	1.5 (1.0, 4.7)	0.381 (0.257, 0.565)	<0.0001
Anaemia	139	37 (26.6)	NR (NE, NE)	129	52 (40.3)	5.6 (2.8, NE)	0.471 (0.303, 0.732)	0.0006
Leukopenia	139	4 (2.9)	NR (NE, NE)	129	12 (9.3)	NR (NE, NE)	0.250 (0.080, 0.780)	0.0098
Neutropenia	139	2 (1.4)	NR (NE, NE)	129	21 (16.3)	NR (NE, NE)	0.079 (0.018, 0.336)	<0.0001
Cardiac disorders	139	18 (12.9)	NR (NE, NE)	129	13 (10.1)	NR (NE, NE)	1.070 (0.517, 2.214)	0.8551
Endocrine disorders	139	24 (17.3)	NR (10.6, NE)	129	1 (0.8)	NR (NE, NE)	17.540 (2.356, 130.597)	0.0001
Hypothyroidism	139	17 (12.2)	NR (16.5, NE)	129	0 (0.0)	NR (NE, NE)	63725618.456 (0.000, NE)	0.0006
Eye disorders	139	10 (7.2)	NR (17.1, NE)	129	6 (4.7)	NR (NE, NE)	1.247 (0.442, 3.517)	0.6763

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1.b:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 129)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Gastrointestinal disorders	139	88 (63.3)	2.2 (1.4, 3.3)	129	79 (61.2)	1.1 (0.7, 2.1)	0.721 (0.528, 0.986)	0.0377
Abdominal pain upper	139	4 (2.9)	NR (NE, NE)	129	10 (7.8)	NR (NE, NE)	0.325 (0.101, 1.041)	0.0461
Constipation	139	24 (17.3)	NR (NE, NE)	129	20 (15.5)	NR (NE, NE)	0.931 (0.506, 1.712)	0.8172
Diarrhoea	139	19 (13.7)	NR (NE, NE)	129	23 (17.8)	NR (NE, NE)	0.664 (0.360, 1.223)	0.1850
Dysphagia	139	17 (12.2)	NR (NE, NE)	129	13 (10.1)	NR (NE, NE)	1.016 (0.487, 2.121)	0.9653
Nausea	139	22 (15.8)	NR (NE, NE)	129	19 (14.7)	NR (NE, NE)	0.980 (0.529, 1.818)	0.9500
Stomatitis	139	6 (4.3)	NR (NE, NE)	129	11 (8.5)	NR (NE, NE)	0.406 (0.149, 1.111)	0.0682
Vomiting	139	12 (8.6)	NR (NE, NE)	129	11 (8.5)	NR (NE, NE)	0.928 (0.408, 2.111)	0.8586

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1.b:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 129)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
General disorders and administration site conditions	139	73 (52.5)	6.9 (2.7, 8.5)	129	77 (59.7)	1.3 (0.9, 2.5)	0.570 (0.406, 0.801)	0.0009
Asthenia	139	18 (12.9)	NR (17.5, NE)	129	17 (13.2)	NR (9.0, NE)	0.804 (0.410, 1.578)	0.5253
Fatigue	139	22 (15.8)	NR (NE, NE)	129	25 (19.4)	NR (NE, NE)	0.702 (0.391, 1.261)	0.2321
Malaise	139	11 (7.9)	NR (NE, NE)	129	12 (9.3)	NR (NE, NE)	0.604 (0.255, 1.430)	0.2456
Pyrexia	139	23 (16.5)	NR (NE, NE)	129	20 (15.5)	NR (7.7, NE)	0.778 (0.418, 1.448)	0.4263
Infections and infestations	139	43 (30.9)	10.5 (5.6, NE)	129	47 (36.4)	5.3 (3.1, NE)	0.608 (0.395, 0.936)	0.0225
Pneumonia	139	20 (14.4)	NR (11.5, NE)	129	15 (11.6)	NR (NE, NE)	0.903 (0.453, 1.797)	0.7702
Injury, poisoning and procedural complications	139	13 (9.4)	NR (15.9, NE)	129	5 (3.9)	NR (NE, NE)	1.449 (0.482, 4.358)	0.5069

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.
Adverse events were classified based on MedDRA v23.0.
System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.
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Table 14.3.1.2.2.2.1.b:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

System Organ Class Preferred Term	Tislelizumab (N = 139) Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	ICC (N = 129) Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Investigations	139	58 (41.7)	7.7 (3.1, NE)	129	84 (65.1)	0.5 (0.5, 1.2)	0.348 (0.244, 0.495)	<0.0001
Alanine aminotransferase increased	139	11 (7.9)	NR (NE, NE)	129	4 (3.1)	NR (NE, NE)	2.297 (0.728, 7.244)	0.1438
Aspartate aminotransferase increased	139	13 (9.4)	NR (NE, NE)	129	3 (2.3)	NR (NE, NE)	3.593 (1.020, 12.657)	0.0331
Lymphocyte count decreased	139	3 (2.2)	NR (NE, NE)	129	10 (7.8)	NR (NE, NE)	0.255 (0.070, 0.931)	0.0251
Neutrophil count decreased	139	1 (0.7)	NR (NE, NE)	129	55 (42.6)	NR (1.4, NE)	0.013 (0.002, 0.094)	<0.0001
Weight decreased	139	30 (21.6)	NR (NE, NE)	129	16 (12.4)	NR (NE, NE)	1.537 (0.832, 2.840)	0.1650
White blood cell count decreased	139	4 (2.9)	NR (NE, NE)	129	48 (37.2)	NR (NE, NE)	0.059 (0.021, 0.163)	<0.0001

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1.b:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 129)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Metabolism and nutrition disorders	139	59 (42.4)	8.6 (3.7, NE)	129	67 (51.9)	2.8 (1.3, 5.7)	0.595 (0.413, 0.856)	0.0041
Decreased appetite	139	27 (19.4)	NR (NE, NE)	129	39 (30.2)	NR (5.7, NE)	0.508 (0.308, 0.840)	0.0068
Hypoalbuminaemia	139	18 (12.9)	NR (NE, NE)	129	13 (10.1)	NR (NE, NE)	1.002 (0.483, 2.078)	0.9953
Hypokalaemia	139	8 (5.8)	NR (NE, NE)	129	10 (7.8)	NR (NE, NE)	0.622 (0.244, 1.582)	0.3139
Hyponatraemia	139	12 (8.6)	NR (NE, NE)	129	8 (6.2)	NR (NE, NE)	0.952 (0.374, 2.424)	0.9176

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1.b:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 129)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Musculoskeletal and connective tissue disorders	139	38 (27.3)	18.0 (7.6, NE)	129	40 (31.0)	7.2 (6.2, NE)	0.661 (0.420, 1.041)	0.0712
Arthralgia	139	5 (3.6)	NR (NE, NE)	129	12 (9.3)	NR (NE, NE)	0.374 (0.132, 1.062)	0.0542
Back pain	139	12 (8.6)	NR (18.0, NE)	129	10 (7.8)	NR (8.6, NE)	0.800 (0.334, 1.917)	0.6154
Myalgia	139	4 (2.9)	NR (NE, NE)	129	14 (10.9)	NR (NE, NE)	0.244 (0.080, 0.748)	0.0074
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	139	14 (10.1)	NR (NE, NE)	129	4 (3.1)	NR (NE, NE)	3.279 (1.077, 9.981)	0.0266
Nervous system disorders	139	21 (15.1)	NR (17.8, NE)	129	43 (33.3)	9.7 (3.5, NE)	0.329 (0.194, 0.559)	<0.0001
Peripheral sensory neuropathy	139	1 (0.7)	NR (NE, NE)	129	22 (17.1)	NR (9.7, NE)	0.031 (0.004, 0.232)	<0.0001

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1.b:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 129)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Psychiatric disorders	139	18 (12.9)	NR (NE, NE)	129	15 (11.6)	NR (NE, NE)	0.948 (0.472, 1.903)	0.8806
Insomnia	139	14 (10.1)	NR (NE, NE)	129	9 (7.0)	NR (NE, NE)	1.243 (0.530, 2.917)	0.6161
Respiratory, thoracic and mediastinal disorders	139	58 (41.7)	8.6 (3.3, NE)	129	46 (35.7)	5.7 (3.1, NE)	1.014 (0.683, 1.507)	0.9436
Cough	139	22 (15.8)	NR (NE, NE)	129	14 (10.9)	NR (NE, NE)	1.237 (0.622, 2.460)	0.5427
Dyspnoea	139	12 (8.6)	NR (NE, NE)	129	13 (10.1)	NR (NE, NE)	0.706 (0.314, 1.589)	0.3981
Productive cough	139	8 (5.8)	NR (NE, NE)	129	10 (7.8)	NR (NE, NE)	0.671 (0.263, 1.713)	0.4011

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1.b:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 129)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Skin and subcutaneous tissue disorders	139	37 (26.6)	NR (9.6, NE)	129	49 (38.0)	NR (2.4, NE)	0.581 (0.376, 0.896)	0.0125
Alopecia	139	0 (0.0)	NR (NE, NE)	129	34 (26.4)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Pruritus	139	16 (11.5)	NR (11.8, NE)	129	5 (3.9)	NR (NE, NE)	2.299 (0.827, 6.392)	0.1012
Rash	139	14 (10.1)	NR (NE, NE)	129	7 (5.4)	NR (NE, NE)	1.748 (0.704, 4.341)	0.2216
Vascular disorders	139	20 (14.4)	NR (17.9, NE)	129	13 (10.1)	NR (NE, NE)	1.202 (0.591, 2.444)	0.6093
Hypertension	139	10 (7.2)	NR (NE, NE)	129	6 (4.7)	NR (NE, NE)	1.232 (0.437, 3.472)	0.6912

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

	Tislelizumab (N = 255)			ICC (N = 240)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Blood and lymphatic system disorders	255	18 (7.1)	NR (NE, NE)	240	56 (23.3)	NR (9.2, NE)	0.219 (0.127, 0.380)	<0.0001
Anaemia	255	15 (5.9)	NR (NE, NE)	240	26 (10.8)	NR (NE, NE)	0.414 (0.215, 0.799)	0.0066
Febrile neutropenia	255	0 (0.0)	NR (NE, NE)	240	11 (4.6)	NR (NE, NE)	0.000 (0.000, NE)	0.0003
Leukopenia	255	0 (0.0)	NR (NE, NE)	240	17 (7.1)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Neutropenia	255	1 (0.4)	NR (NE, NE)	240	16 (6.7)	NR (NE, NE)	0.049 (0.006, 0.378)	<0.0001
Gastrointestinal disorders	255	38 (14.9)	NR (20.9, NE)	240	45 (18.8)	NR (8.9, NE)	0.583 (0.374, 0.909)	0.0158
Diarrhoea	255	3 (1.2)	NR (NE, NE)	240	15 (6.3)	NR (NE, NE)	0.165 (0.047, 0.574)	0.0013
Dysphagia	255	16 (6.3)	NR (NE, NE)	240	7 (2.9)	NR (8.9, NE)	1.686 (0.683, 4.165)	0.2525

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

	Tislelizumab (N = 255)			ICC (N = 240)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
General disorders and administration site conditions	255	15 (5.9)	NR (NE, NE)	240	25 (10.4)	NR (NE, NE)	0.390 (0.197, 0.771)	0.0051
Infections and infestations	255	20 (7.8)	NR (NE, NE)	240	31 (12.9)	NR (9.2, NE)	0.437 (0.242, 0.790)	0.0049
Pneumonia	255	12 (4.7)	NR (NE, NE)	240	17 (7.1)	NR (NE, NE)	0.462 (0.213, 1.006)	0.0468
Investigations	255	25 (9.8)	NR (NE, NE)	240	90 (37.5)	NR (4.1, NE)	0.171 (0.107, 0.272)	<0.0001
Lymphocyte count decreased	255	6 (2.4)	NR (NE, NE)	240	18 (7.5)	NR (NE, NE)	0.260 (0.102, 0.664)	0.0025
Neutrophil count decreased	255	0 (0.0)	NR (NE, NE)	240	63 (26.3)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
White blood cell count decreased	255	1 (0.4)	NR (NE, NE)	240	48 (20.0)	NR (NE, NE)	0.017 (0.002, 0.120)	<0.0001

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

	Tislelizumab (N = 255)			ICC (N = 240)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Metabolism and nutrition disorders	255	26 (10.2)	NR (NE, NE)	240	31 (12.9)	NR (9.6, NE)	0.518 (0.296, 0.907)	0.0191
Decreased appetite	255	2 (0.8)	NR (NE, NE)	240	10 (4.2)	NR (NE, NE)	0.080 (0.010, 0.632)	0.0023
Hyponatraemia	255	14 (5.5)	NR (NE, NE)	240	10 (4.2)	NR (NE, NE)	0.881 (0.374, 2.075)	0.7722
Respiratory, thoracic and mediastinal disorders	255	25 (9.8)	NR (NE, NE)	240	18 (7.5)	NR (8.6, NE)	0.929 (0.496, 1.741)	0.8184

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.3.1.b:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

System Organ Class Preferred Term	Tislelizumab (N = 139) Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	ICC (N = 129) Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Blood and lymphatic system disorders	139	13 (9.4)	NR (NE, NE)	129	31 (24.0)	NR (NE, NE)	0.300 (0.155, 0.578)	0.0001
Anaemia	139	10 (7.2)	NR (NE, NE)	129	10 (7.8)	NR (NE, NE)	0.804 (0.333, 1.942)	0.6271
Febrile neutropenia	139	0 (0.0)	NR (NE, NE)	129	8 (6.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0014
Leukopenia	139	0 (0.0)	NR (NE, NE)	129	8 (6.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0019
Neutropenia	139	1 (0.7)	NR (NE, NE)	129	12 (9.3)	NR (NE, NE)	0.063 (0.008, 0.491)	0.0005
Gastrointestinal disorders	139	18 (12.9)	NR (NE, NE)	129	14 (10.9)	NR (8.9, NE)	0.993 (0.490, 2.013)	0.9847
Dysphagia	139	10 (7.2)	NR (NE, NE)	129	4 (3.1)	NR (8.9, NE)	2.016 (0.628, 6.472)	0.2298
General disorders and administration site conditions	139	11 (7.9)	NR (NE, NE)	129	11 (8.5)	NR (NE, NE)	0.673 (0.278, 1.633)	0.3786

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.3.1.b:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 129)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Infections and infestations	139	12 (8.6)	NR (NE, NE)	129	17 (13.2)	NR (NE, NE)	0.542 (0.256, 1.146)	0.1037
Pneumonia	139	7 (5.0)	NR (NE, NE)	129	11 (8.5)	NR (NE, NE)	0.476 (0.182, 1.247)	0.1228
Investigations	139	12 (8.6)	NR (NE, NE)	129	51 (39.5)	NR (2.4, NE)	0.143 (0.074, 0.276)	<0.0001
Lymphocyte count decreased	139	2 (1.4)	NR (NE, NE)	129	9 (7.0)	NR (NE, NE)	0.186 (0.040, 0.863)	0.0156
Neutrophil count decreased	139	0 (0.0)	NR (NE, NE)	129	38 (29.5)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
White blood cell count decreased	139	0 (0.0)	NR (NE, NE)	129	28 (21.7)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Metabolism and nutrition disorders	139	18 (12.9)	NR (13.8, NE)	129	13 (10.1)	NR (9.6, NE)	0.894 (0.423, 1.888)	0.7688
Hyponatraemia	139	7 (5.0)	NR (NE, NE)	129	4 (3.1)	NR (NE, NE)	1.158 (0.332, 4.045)	0.8177

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.3.1.b:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 129)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Respiratory, thoracic and mediastinal disorders	139	17 (12.2)	NR (NE, NE)	129	13 (10.1)	NR (8.6, NE)	1.035 (0.495, 2.162)	0.9276
Vascular disorders	139	8 (5.8)	NR (NE, NE)	129	0 (0.0)	NR (NE, NE)	69810561.547 (0.000, NE)	0.0091

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.4.1.1:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

System Organ Class Preferred Term	Tislelizumab (N = 255) Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	ICC (N = 240) Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Blood and lymphatic system disorders	255	1 (0.4)	NR (NE, NE)	240	19 (7.9)	NR (NE, NE)	0.046 (0.006, 0.343)	<0.0001
Gastrointestinal disorders	255	36 (14.1)	NR (20.9, NE)	240	30 (12.5)	NR (NE, NE)	0.874 (0.533, 1.433)	0.5930
Dysphagia	255	12 (4.7)	NR (NE, NE)	240	4 (1.7)	NR (NE, NE)	2.491 (0.800, 7.757)	0.1034
General disorders and administration site conditions	255	13 (5.1)	NR (NE, NE)	240	14 (5.8)	NR (NE, NE)	0.730 (0.336, 1.584)	0.4238
Infections and infestations	255	25 (9.8)	NR (NE, NE)	240	31 (12.9)	NR (9.2, NE)	0.510 (0.291, 0.894)	0.0166
Pneumonia	255	18 (7.1)	NR (NE, NE)	240	17 (7.1)	NR (NE, NE)	0.671 (0.335, 1.346)	0.2584
Investigations	255	1 (0.4)	NR (NE, NE)	240	13 (5.4)	NR (NE, NE)	0.069 (0.009, 0.529)	0.0006
Neutrophil count decreased	255	0 (0.0)	NR (NE, NE)	240	10 (4.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0008

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.4.1.1:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

	Tislelizumab (N = 255)			ICC (N = 240)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Respiratory, thoracic and mediastinal disorders	255	29 (11.4)	NR (NE, NE)	240	19 (7.9)	NR (NE, NE)	1.066 (0.587, 1.935)	0.8336

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.4.1.1.b:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

System Organ Class Preferred Term	Tislelizumab (N = 139) Total No. of Patients	Tislelizumab (N = 139) Patients with events n (%)	Tislelizumab (N = 139) Median time to event (95% CI) [a]	ICC (N = 129) Total No. of Patients	ICC (N = 129) Patients with events n (%)	ICC (N = 129) Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Blood and lymphatic system disorders	139	1 (0.7)	NR (NE, NE)	129	10 (7.8)	NR (NE, NE)	0.084 (0.011, 0.658)	0.0024
Gastrointestinal disorders	139	19 (13.7)	NR (NE, NE)	129	9 (7.0)	NR (NE, NE)	1.650 (0.741, 3.672)	0.2151
Dysphagia	139	9 (6.5)	NR (NE, NE)	129	2 (1.6)	NR (NE, NE)	3.836 (0.827, 17.799)	0.0647
General disorders and administration site conditions	139	9 (6.5)	NR (NE, NE)	129	9 (7.0)	NR (NE, NE)	0.765 (0.294, 1.990)	0.5821
Infections and infestations	139	14 (10.1)	NR (NE, NE)	129	18 (14.0)	NR (NE, NE)	0.545 (0.265, 1.118)	0.0927
Pneumonia	139	10 (7.2)	NR (NE, NE)	129	10 (7.8)	NR (NE, NE)	0.722 (0.297, 1.759)	0.4715
Metabolism and nutrition disorders	139	7 (5.0)	NR (NE, NE)	129	3 (2.3)	NR (NE, NE)	1.067 (0.246, 4.625)	0.9309
Respiratory, thoracic and mediastinal disorders	139	19 (13.7)	NR (NE, NE)	129	10 (7.8)	NR (8.6, NE)	1.423 (0.652, 3.103)	0.3728

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.5.1.b:
Treatment-Emergent Adverse Events (TEAEs) Leading to Treatment Discontinuation by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

System Organ Class Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)
Patients With at Least One TEAE Leading to Treatment Discontinuation	25 (18.0)	28 (21.7)
Respiratory, thoracic and mediastinal disorders	8 (5.8)	6 (4.7)
Immune-mediated pneumonitis	2 (1.4)	0 (0.0)
Pneumonitis	2 (1.4)	2 (1.6)
Dyspnoea	1 (0.7)	0 (0.0)
Lung disorder	1 (0.7)	0 (0.0)
Pulmonary arterial hypertension	1 (0.7)	0 (0.0)
Pulmonary haemorrhage	1 (0.7)	0 (0.0)
Acquired tracheo-oesophageal fistula	0 (0.0)	1 (0.8)
Haemoptysis	0 (0.0)	1 (0.8)
Pleural effusion	0 (0.0)	1 (0.8)
Pneumonia aspiration	0 (0.0)	1 (0.8)

Source: Listing 16.2.7.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = Treatment-Emergent Adverse Event.
Percentages were based on N.
Patients with multiple events for a given preferred term and system organ class were counted only once for the preferred term and system organ class, respectively.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 23.0.
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Table 14.3.1.5.1.b:
Treatment-Emergent Adverse Events (TEAEs) Leading to Treatment Discontinuation by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

System Organ Class Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)
Infections and infestations	6 (4.3)	4 (3.1)
Pneumonia	4 (2.9)	2 (1.6)
Bronchitis	1 (0.7)	0 (0.0)
Sepsis	1 (0.7)	0 (0.0)
Endocarditis	0 (0.0)	1 (0.8)
Septic shock	0 (0.0)	1 (0.8)
Gastrointestinal disorders	4 (2.9)	1 (0.8)
Dysphagia	1 (0.7)	0 (0.0)
Gastrointestinal haemorrhage	1 (0.7)	0 (0.0)
Oesophagomediastinal fistula	1 (0.7)	0 (0.0)
Upper gastrointestinal haemorrhage	1 (0.7)	1 (0.8)

Source: Listing 16.2.7.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = Treatment-Emergent Adverse Event.
Percentages were based on N.
Patients with multiple events for a given preferred term and system organ class were counted only once for the preferred term and system organ class, respectively.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 23.0.
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Table 14.3.1.5.1.b:
Treatment-Emergent Adverse Events (TEAEs) Leading to Treatment Discontinuation by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

System Organ Class Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)
General disorders and administration site conditions	4 (2.9)	6 (4.7)
General physical health deterioration	2 (1.4)	0 (0.0)
Death	1 (0.7)	2 (1.6)
Sudden death	1 (0.7)	1 (0.8)
Asthenia	0 (0.0)	2 (1.6)
Fatigue	0 (0.0)	1 (0.8)
Metabolism and nutrition disorders	2 (1.4)	1 (0.8)
Decreased appetite	1 (0.7)	1 (0.8)
Type 1 diabetes mellitus	1 (0.7)	0 (0.0)
Hepatobiliary disorders	1 (0.7)	0 (0.0)
Bile duct obstruction	1 (0.7)	0 (0.0)
Investigations	1 (0.7)	1 (0.8)
Platelet count decreased	1 (0.7)	0 (0.0)
Neutrophil count decreased	0 (0.0)	1 (0.8)

Source: Listing 16.2.7.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = Treatment-Emergent Adverse Event.
Percentages were based on N.
Patients with multiple events for a given preferred term and system organ class were counted only once for the preferred term and system organ class, respectively.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 23.0.
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Table 14.3.1.5.1.b:
Treatment-Emergent Adverse Events (TEAEs) Leading to Treatment Discontinuation by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

System Organ Class Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.7)	1 (0.8)
Tumour fistulisation	1 (0.7)	0 (0.0)
Tumour haemorrhage	0 (0.0)	1 (0.8)
Blood and lymphatic system disorders	0 (0.0)	4 (3.1)
Febrile neutropenia	0 (0.0)	3 (2.3)
Lymphadenopathy	0 (0.0)	1 (0.8)
Cardiac disorders	0 (0.0)	3 (2.3)
Acute left ventricular failure	0 (0.0)	1 (0.8)
Atrial flutter	0 (0.0)	1 (0.8)
Atrioventricular block	0 (0.0)	1 (0.8)
Cardiac arrest	0 (0.0)	1 (0.8)
Musculoskeletal and connective tissue disorders	0 (0.0)	1 (0.8)
Muscle spasms	0 (0.0)	1 (0.8)

Source: Listing 16.2.7.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = Treatment-Emergent Adverse Event.
Percentages were based on N.
Patients with multiple events for a given preferred term and system organ class were counted only once for the preferred term and system organ class, respectively.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 23.0.
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Table 14.3.1.5.1.b:
Treatment-Emergent Adverse Events (TEAEs) Leading to Treatment Discontinuation by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

System Organ Class Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)
Nervous system disorders	0 (0.0)	2 (1.6)
Hypoaesthesia	0 (0.0)	1 (0.8)
Peripheral sensory neuropathy	0 (0.0)	1 (0.8)

Source: Listing 16.2.7.1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = Treatment-Emergent Adverse Event.
Percentages were based on N.
Patients with multiple events for a given preferred term and system organ class were counted only once for the preferred term and system organ class, respectively.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 23.0.
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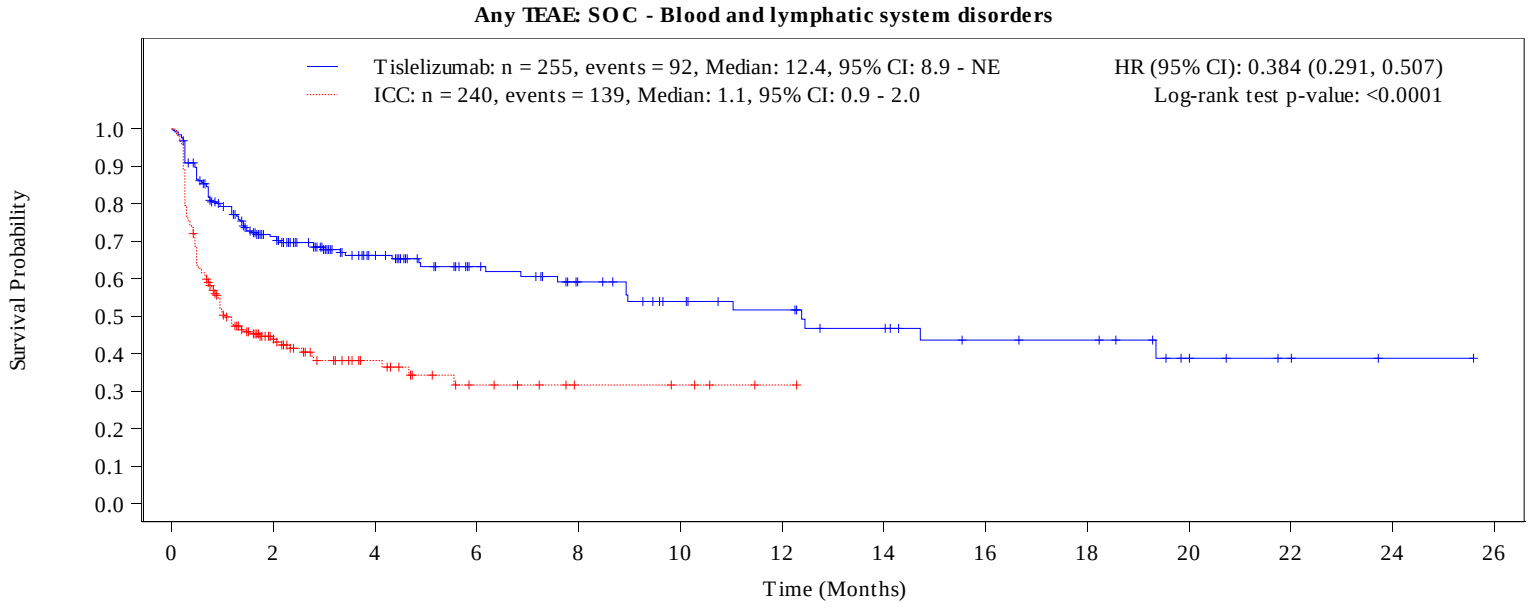
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	255	134	77	49	36	27	23	18	13	12	6	3	1	0
ICC	240	58	22	10	5	4	1	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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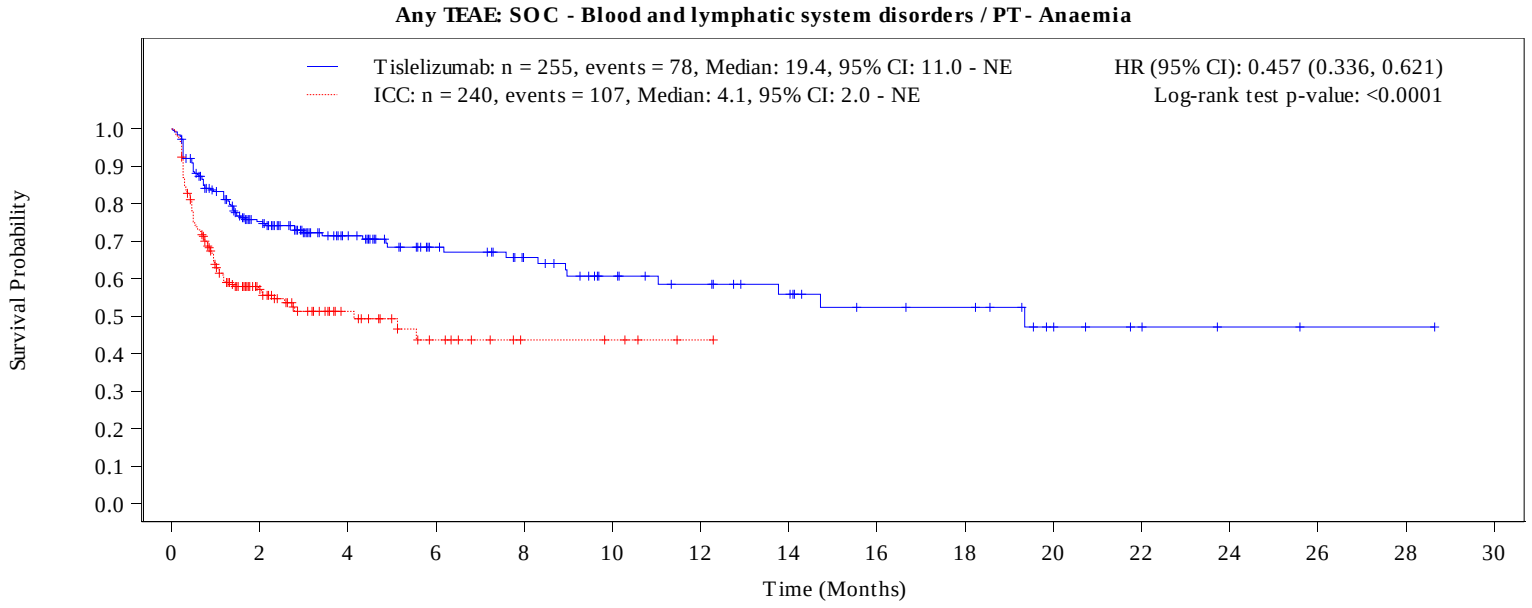
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	141	81	53	41	31	26	21	14	13	7	4	2	1	1	0
ICC	240	74	26	12	5	4	1	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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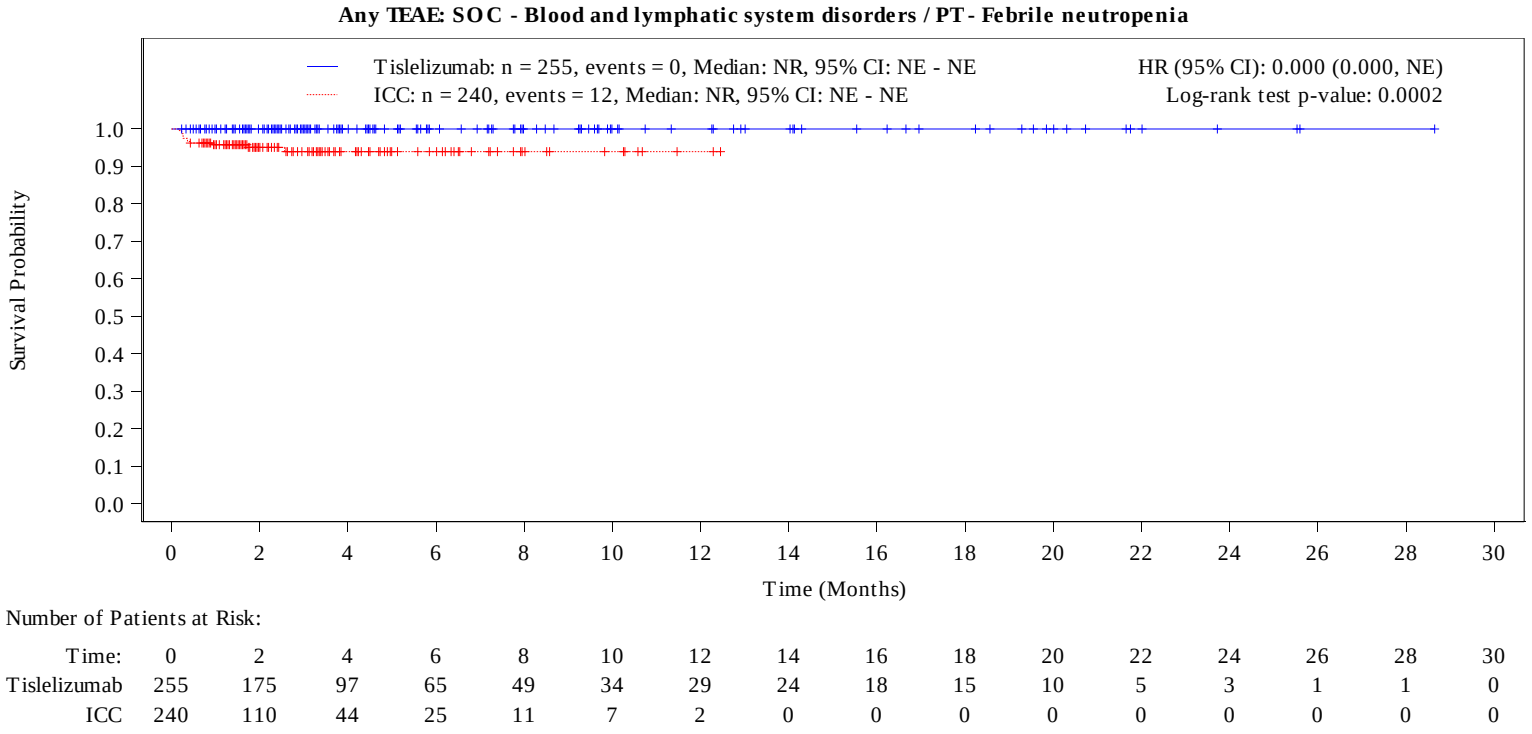
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	175	97	65	49	34	29	24	18	15	10	5	3	1	1	0
ICC	240	110	44	25	11	7	2	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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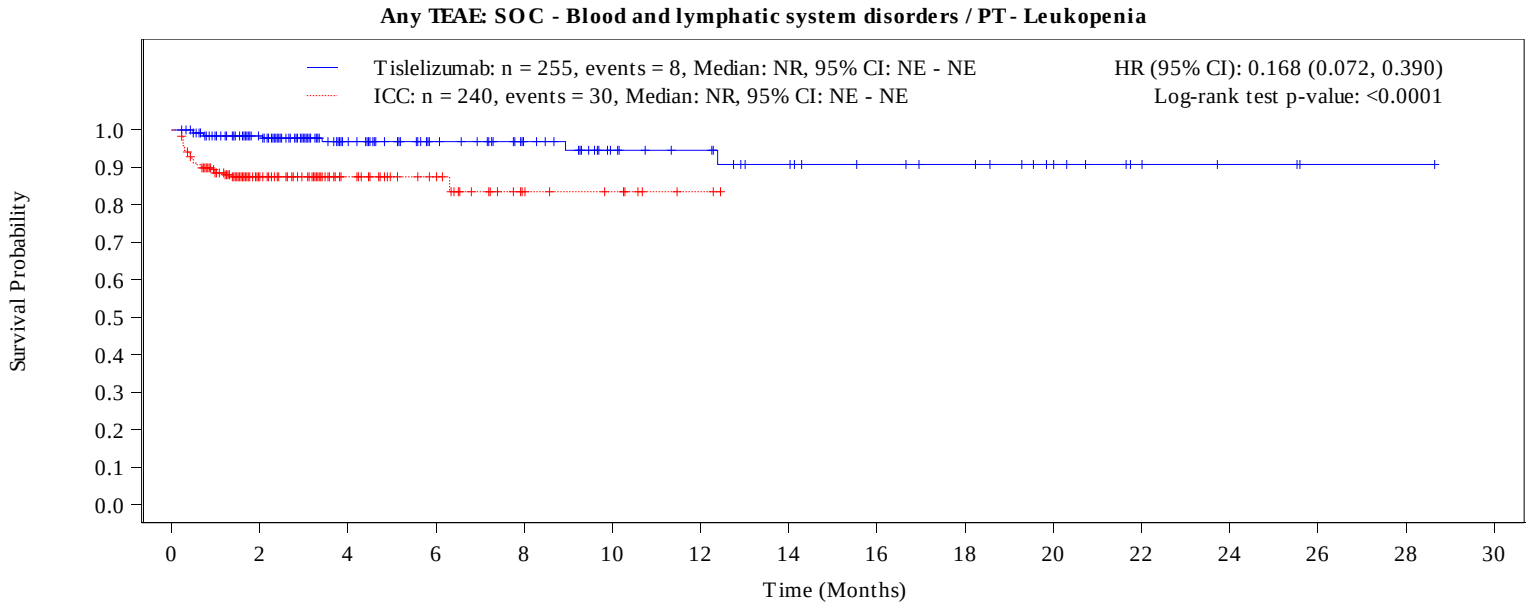
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

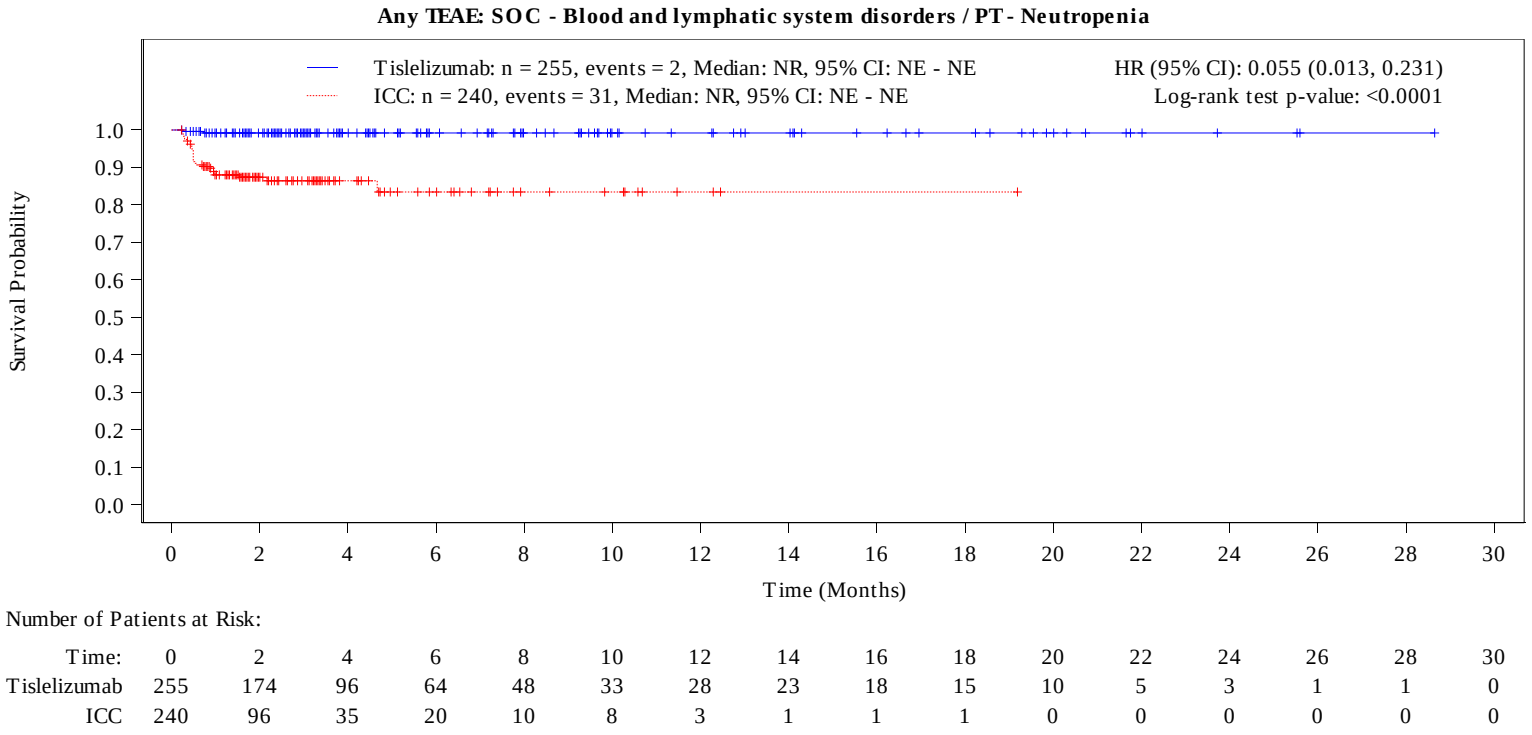


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	171	94	62	46	31	27	21	17	15	10	5	3	1	1	0
ICC	240	101	40	24	10	7	2	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

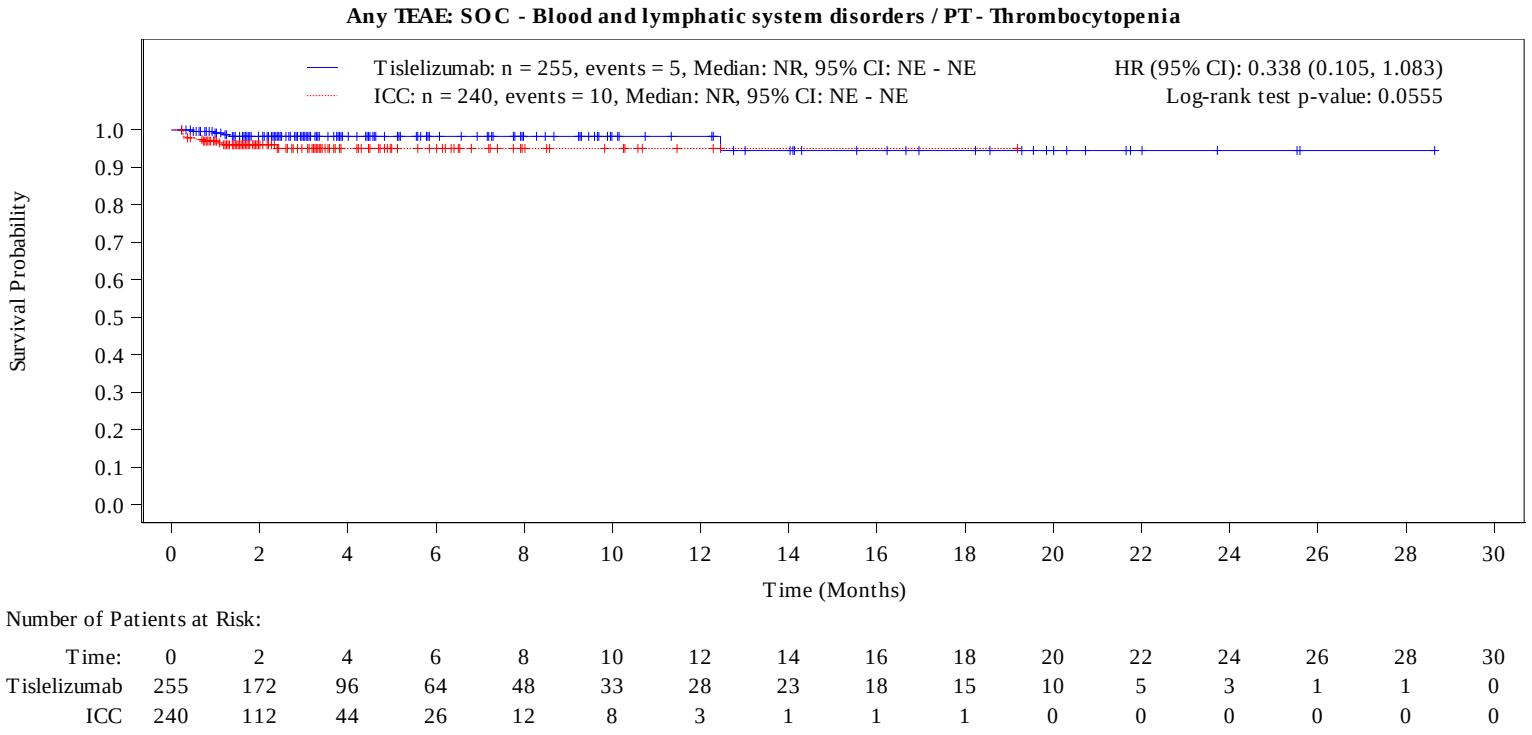


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	174	96	64	48	33	28	23	18	15	10	5	3	1	1	0
ICC	240	96	35	20	10	8	3	1	1	1	0	0	0	0	0	0

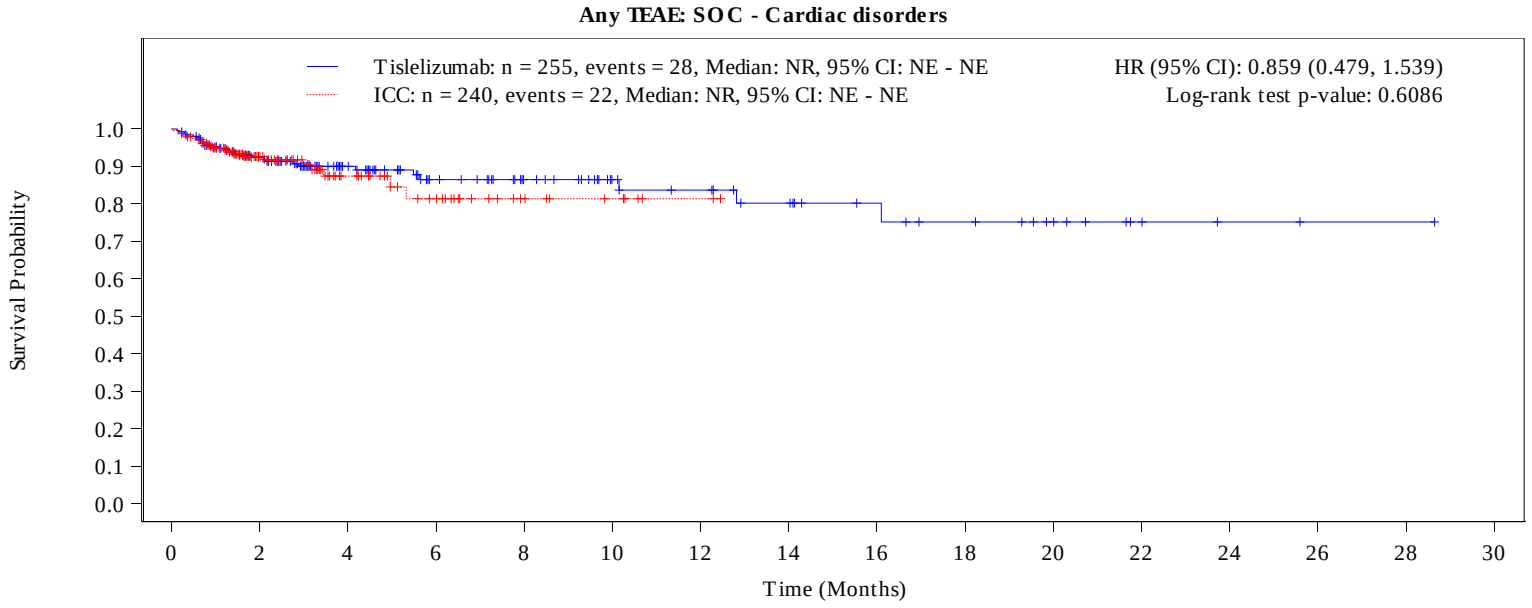
Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

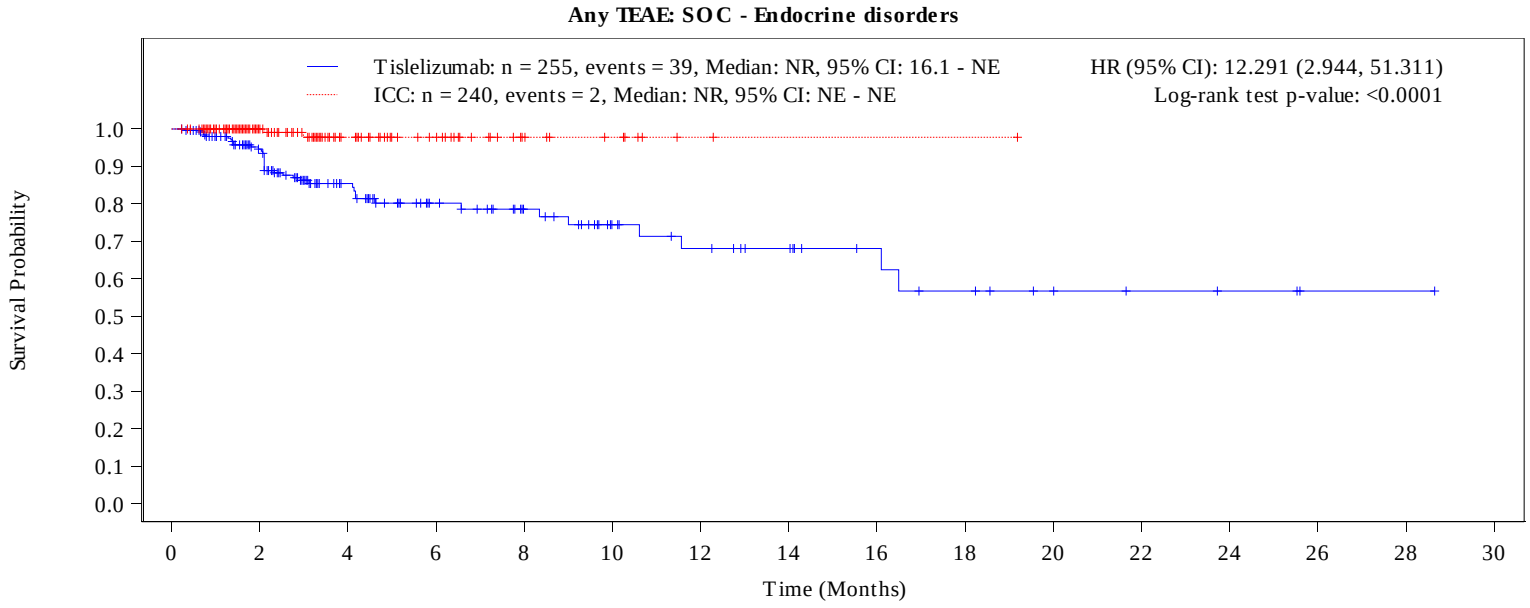


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	167	94	61	46	32	27	22	16	13	9	4	2	1	1	0
ICC	240	108	40	22	10	6	2	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

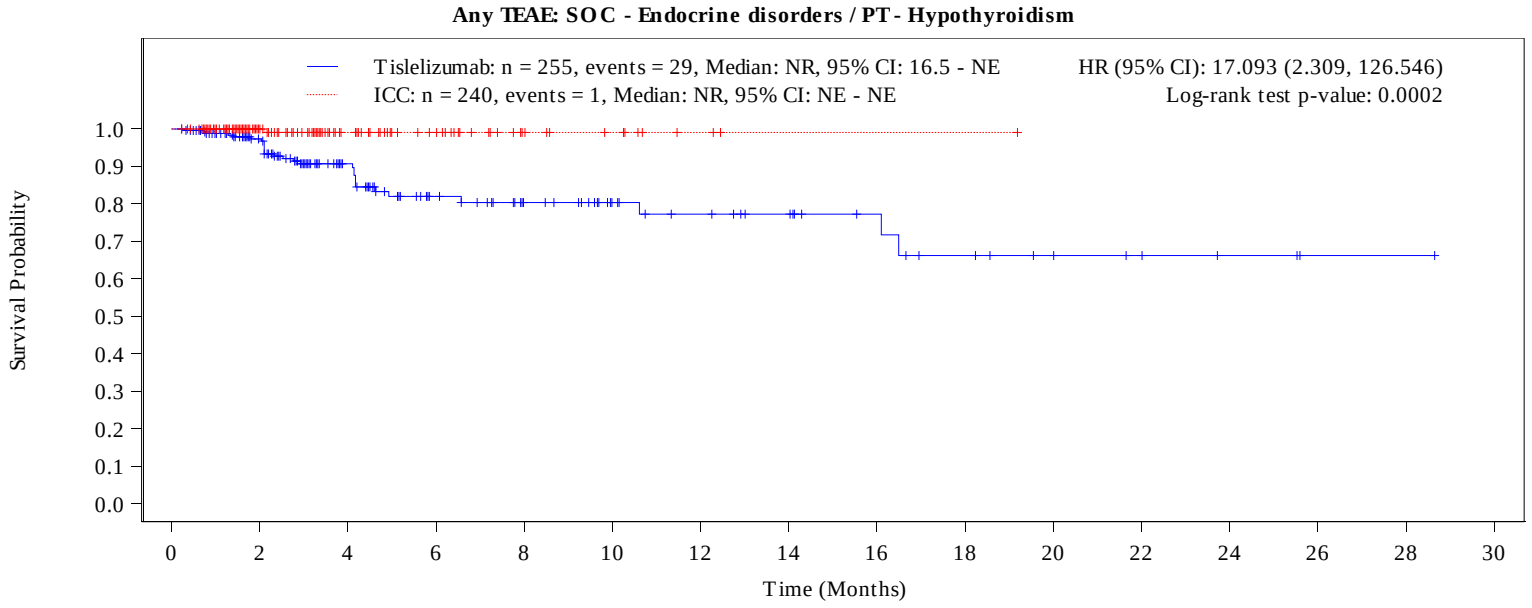


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	166	85	51	39	26	21	17	12	9	6	4	3	1	1	0
ICC	240	113	44	25	11	7	2	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

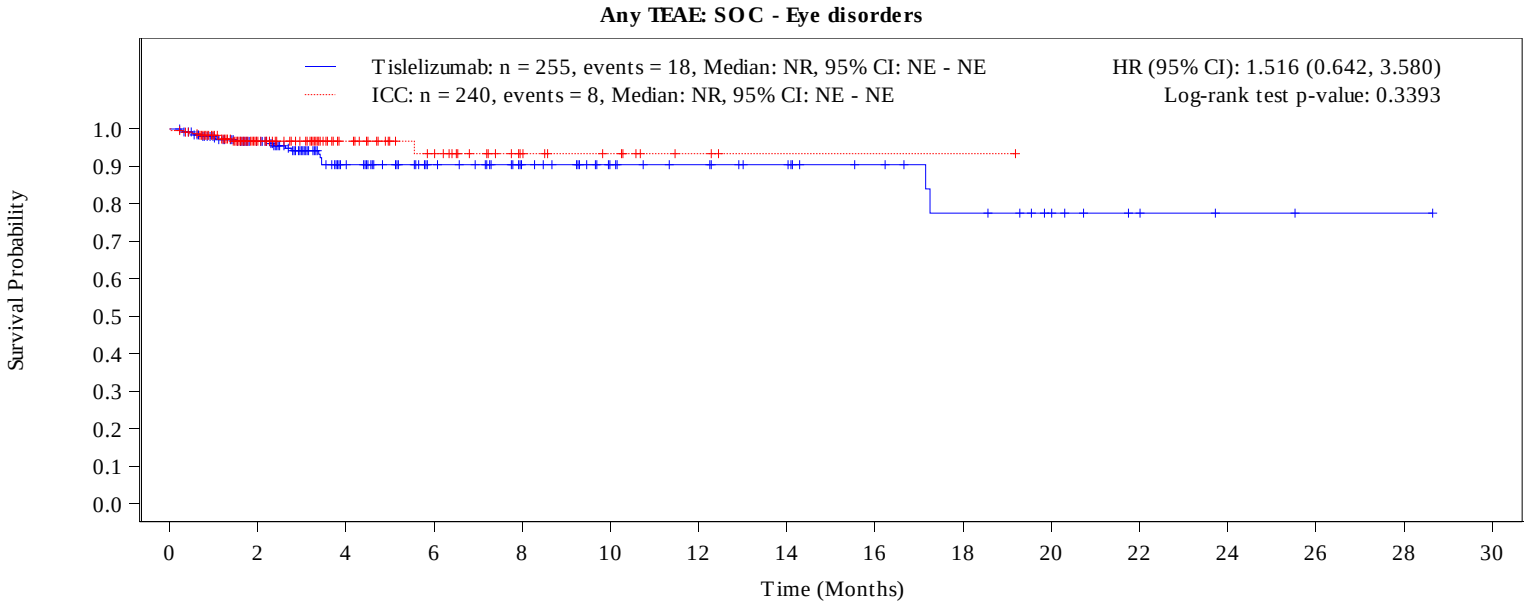


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	171	88	51	39	28	23	19	14	10	7	5	3	1	1	0
ICC	240	113	45	26	12	8	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

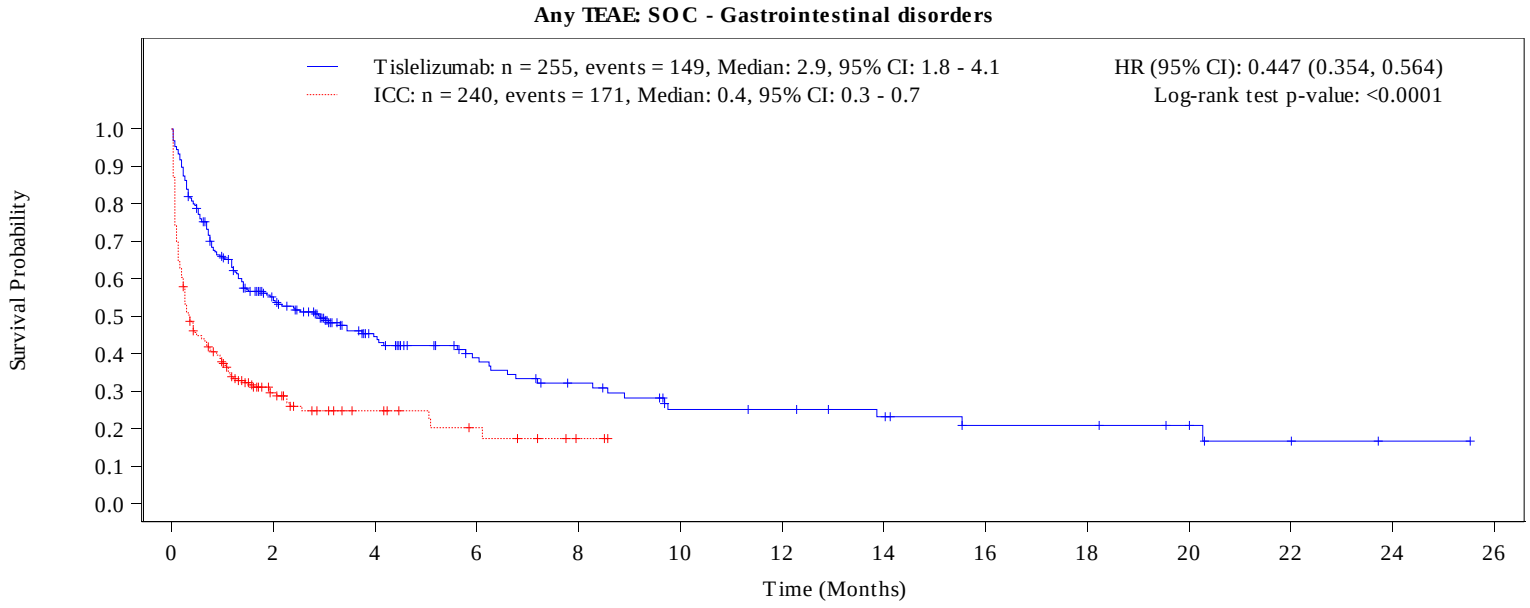


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	172	88	60	44	31	26	22	16	12	8	4	2	1	1	0
ICC	240	109	42	25	12	8	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	255	112	56	35	25	16	15	12	8	8	6	3	1	0
ICC	240	36	15	7	2	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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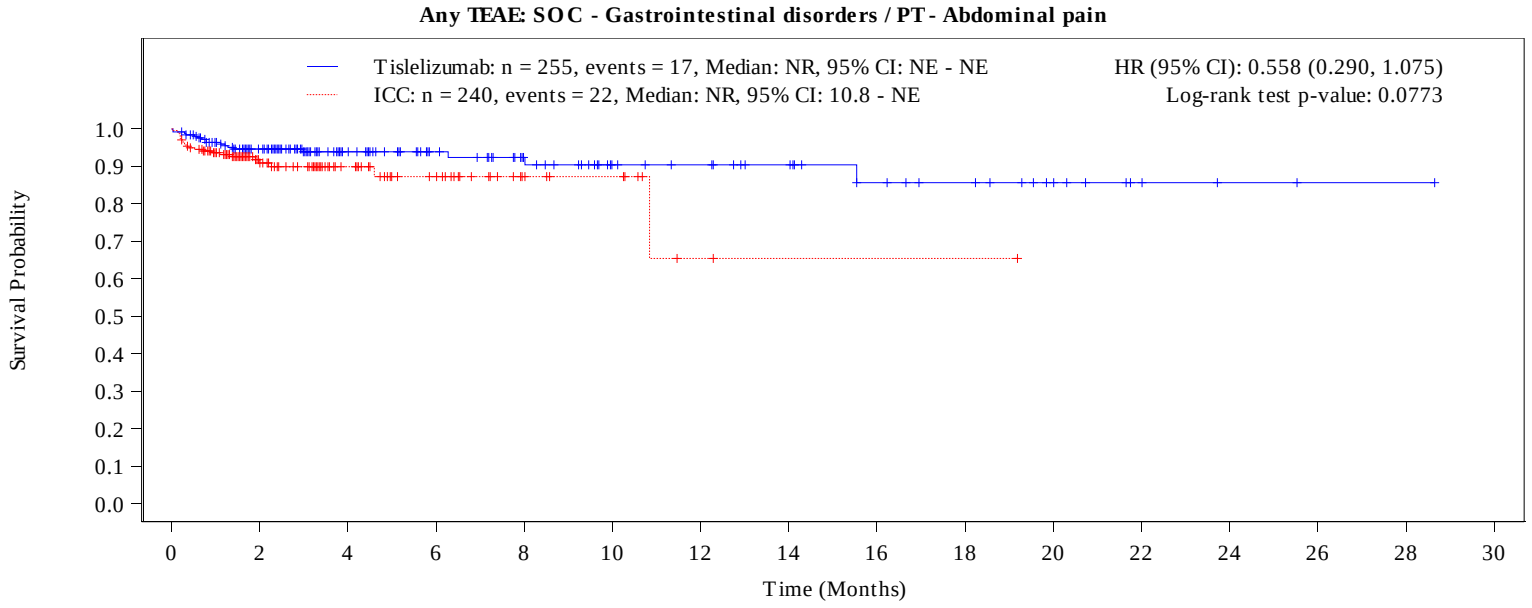
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	170	93	63	47	32	29	24	17	14	9	4	2	1	1	0
ICC	240	103	42	25	11	8	2	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

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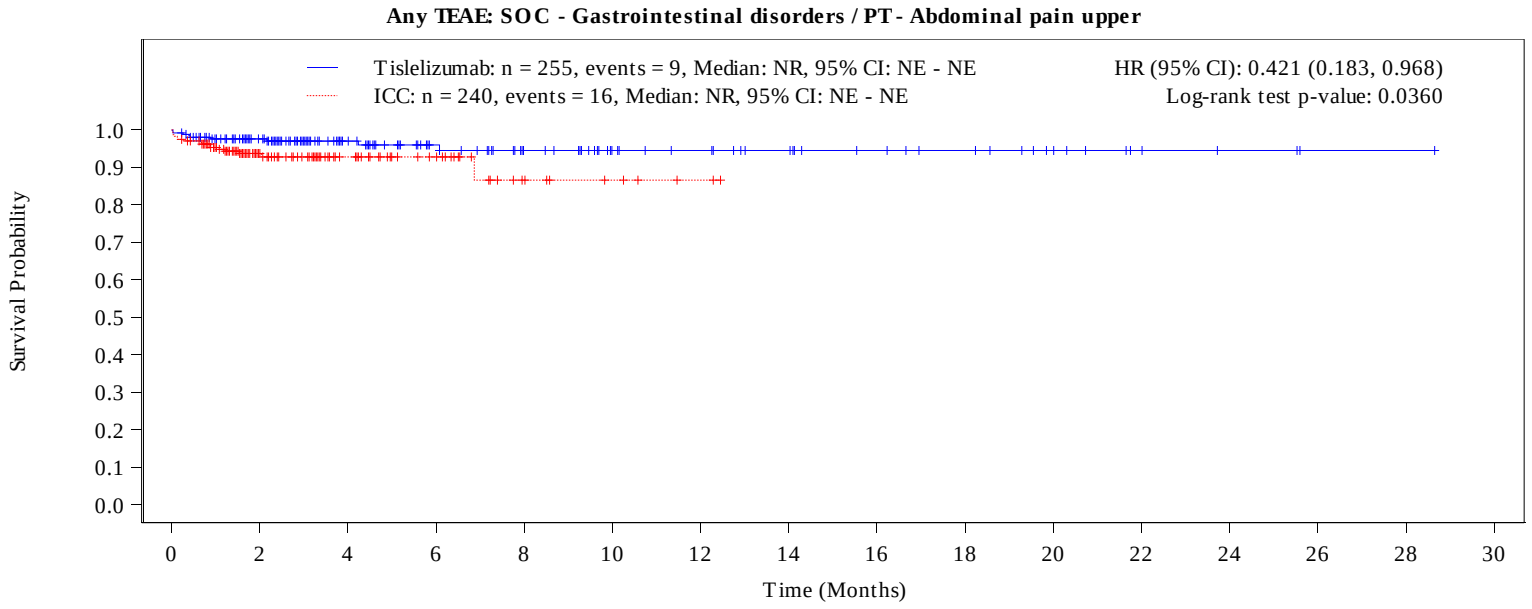
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	170	96	65	48	34	29	24	18	15	10	5	3	1	1	0
ICC	240	104	41	23	9	5	2	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

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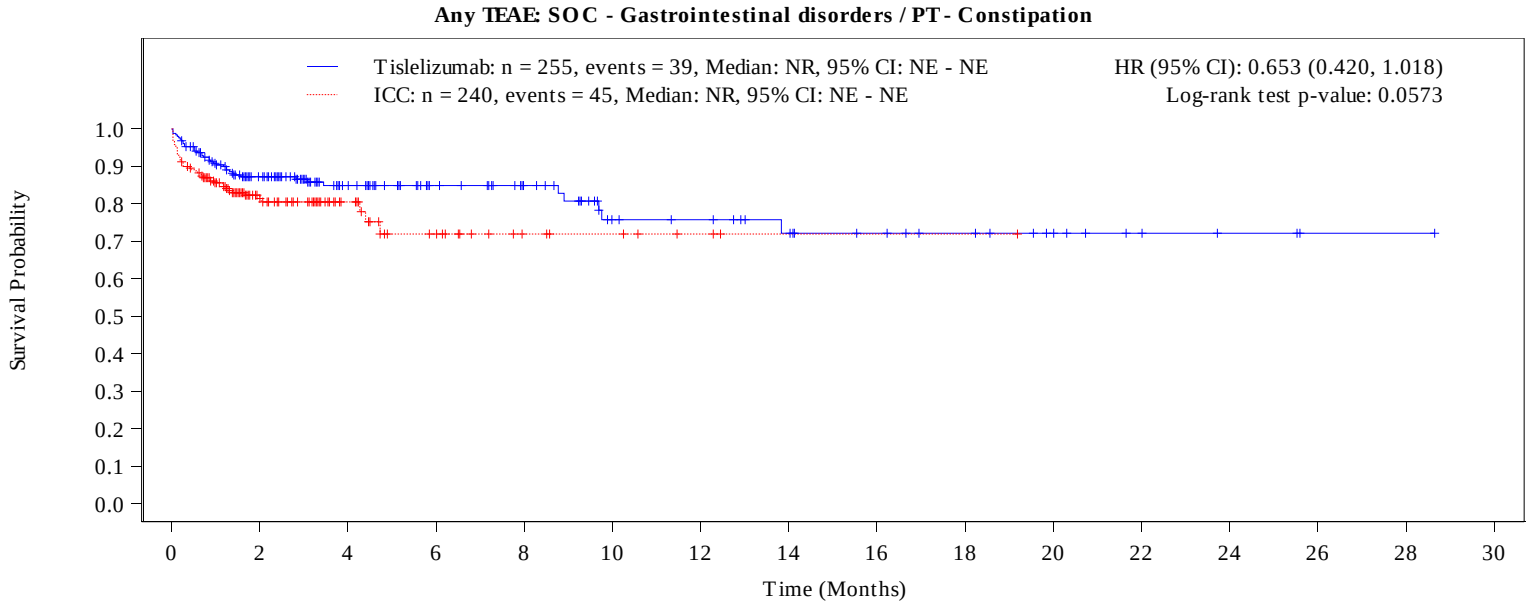
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	157	86	59	45	28	25	20	16	13	9	5	3	1	1	0
ICC	240	92	34	17	8	6	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

Figure 14.3.1.2:
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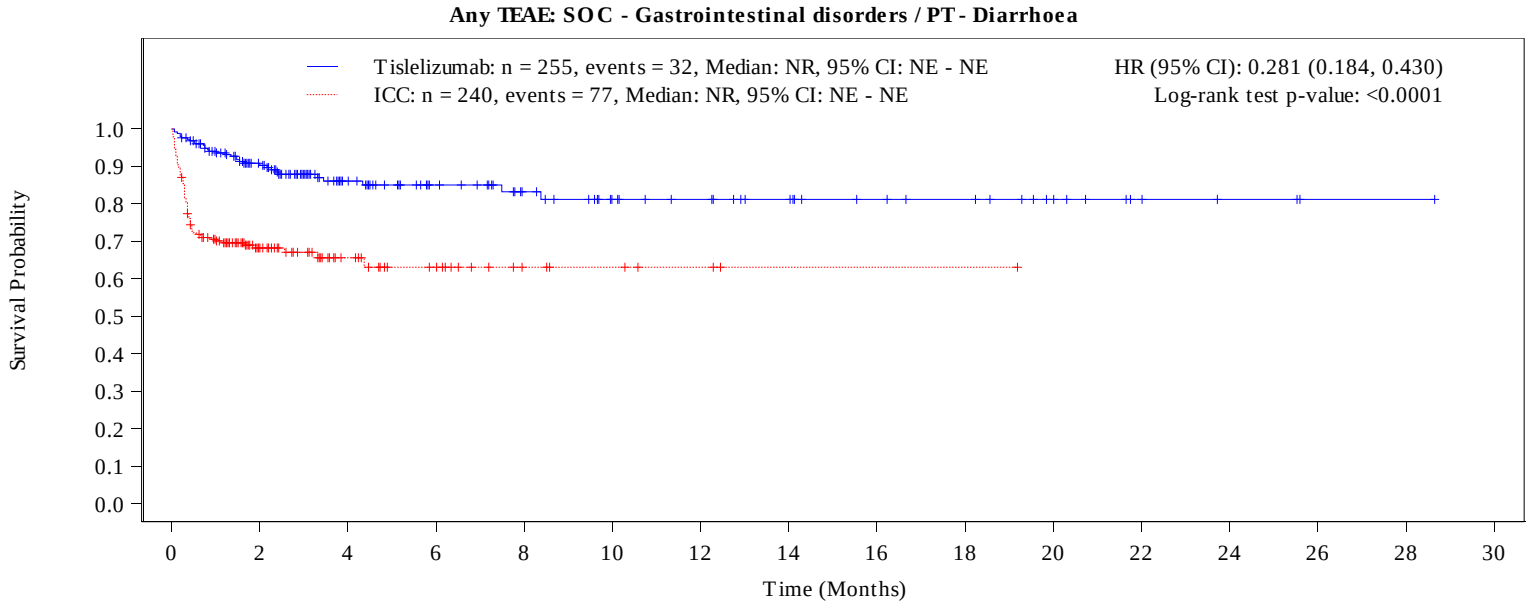
Safety Analysis Set

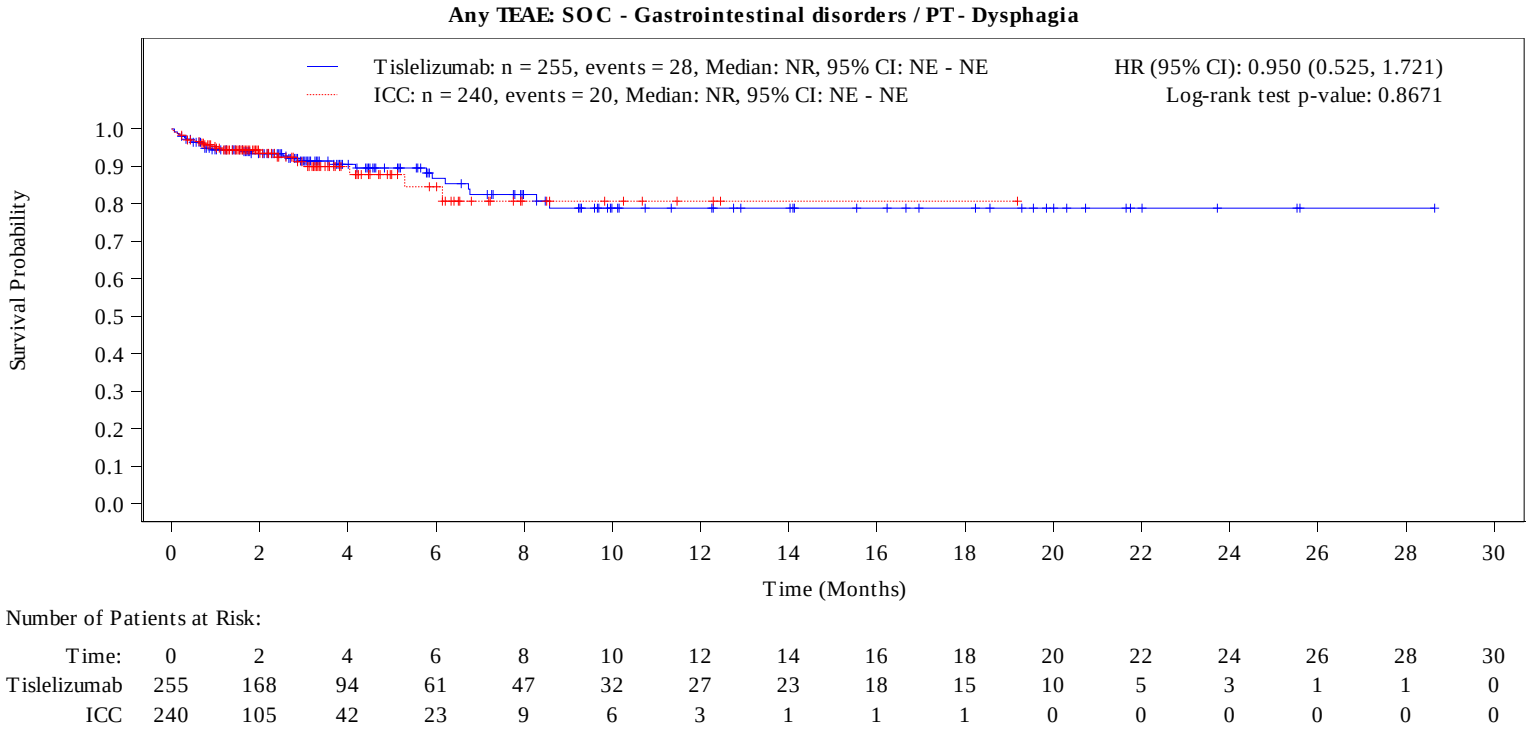


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	159	84	56	42	32	28	23	17	15	10	5	3	1	1	0
ICC	240	80	29	16	7	5	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	168	94	61	47	32	27	23	18	15	10	5	3	1	1	0
ICC	240	105	42	23	9	6	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

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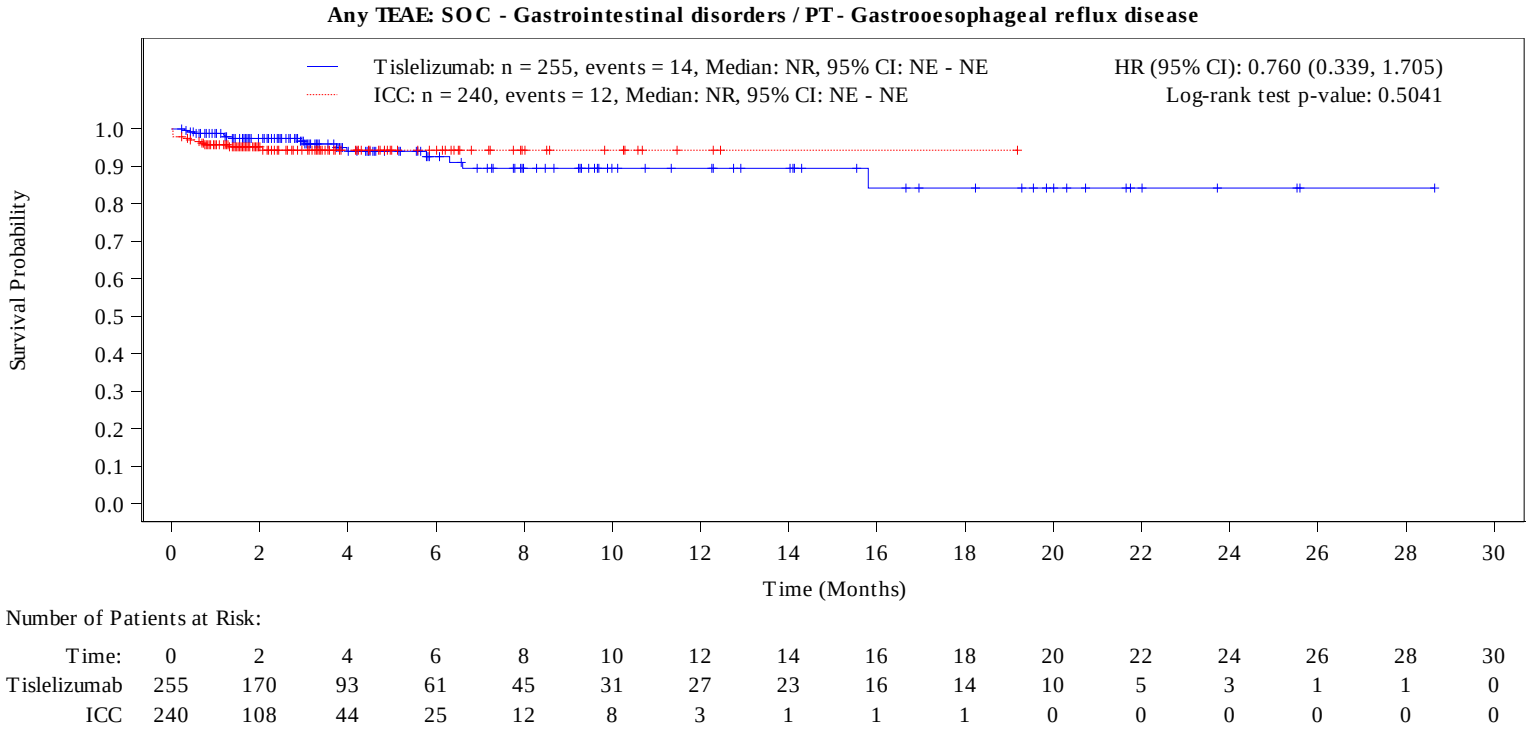
Safety Analysis Set



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

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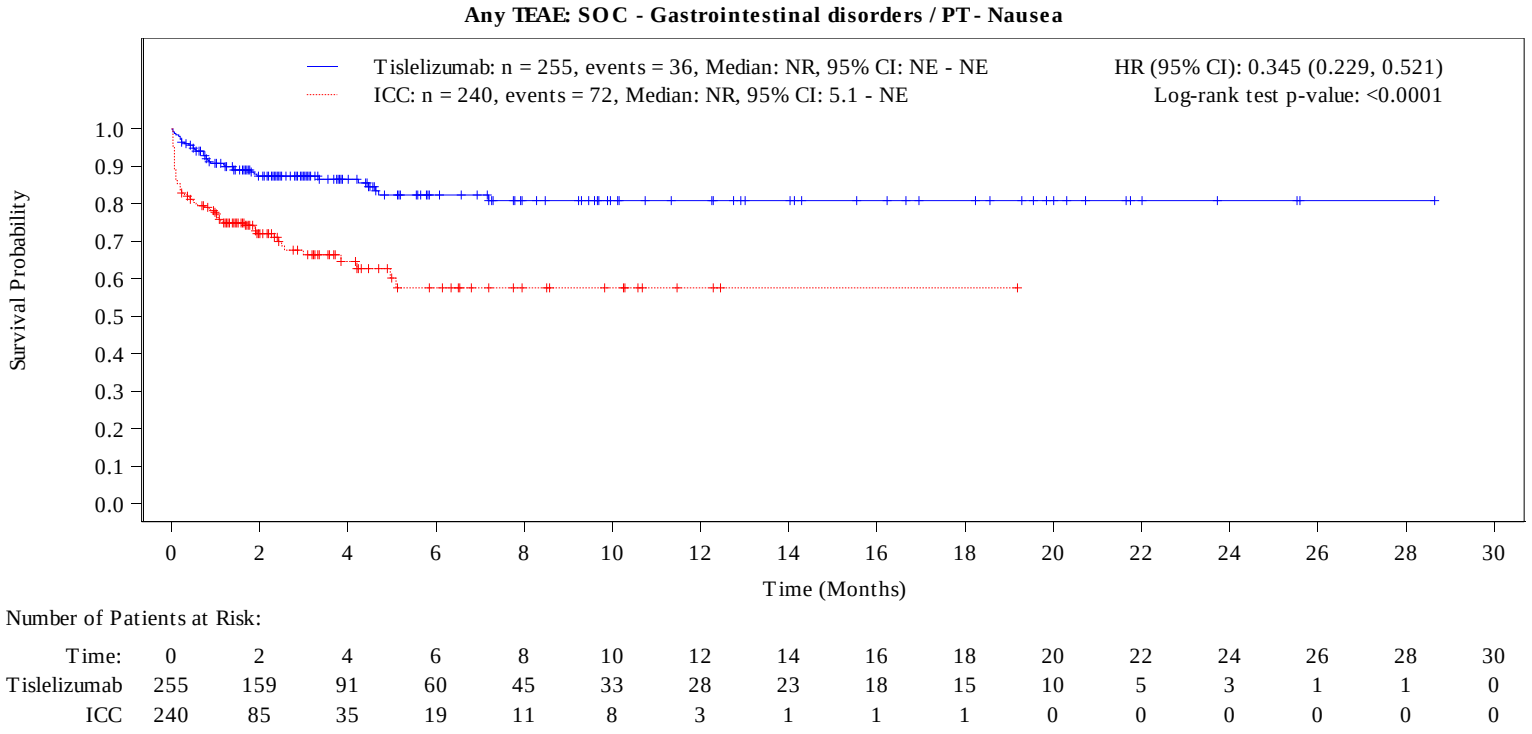

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	159	91	60	45	33	28	23	18	15	10	5	3	1	1	0
ICC	240	85	35	19	11	8	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

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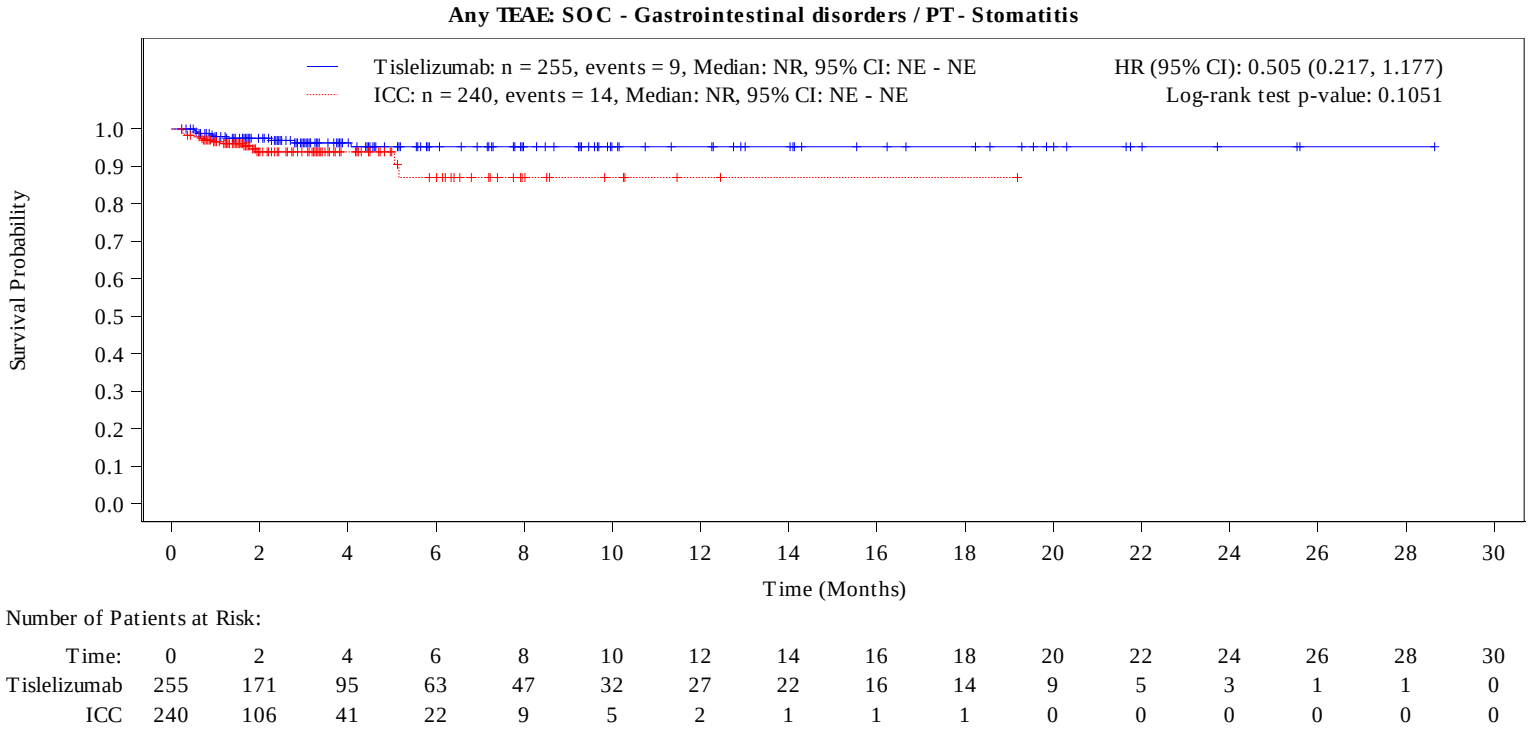
Safety Analysis Set



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

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Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
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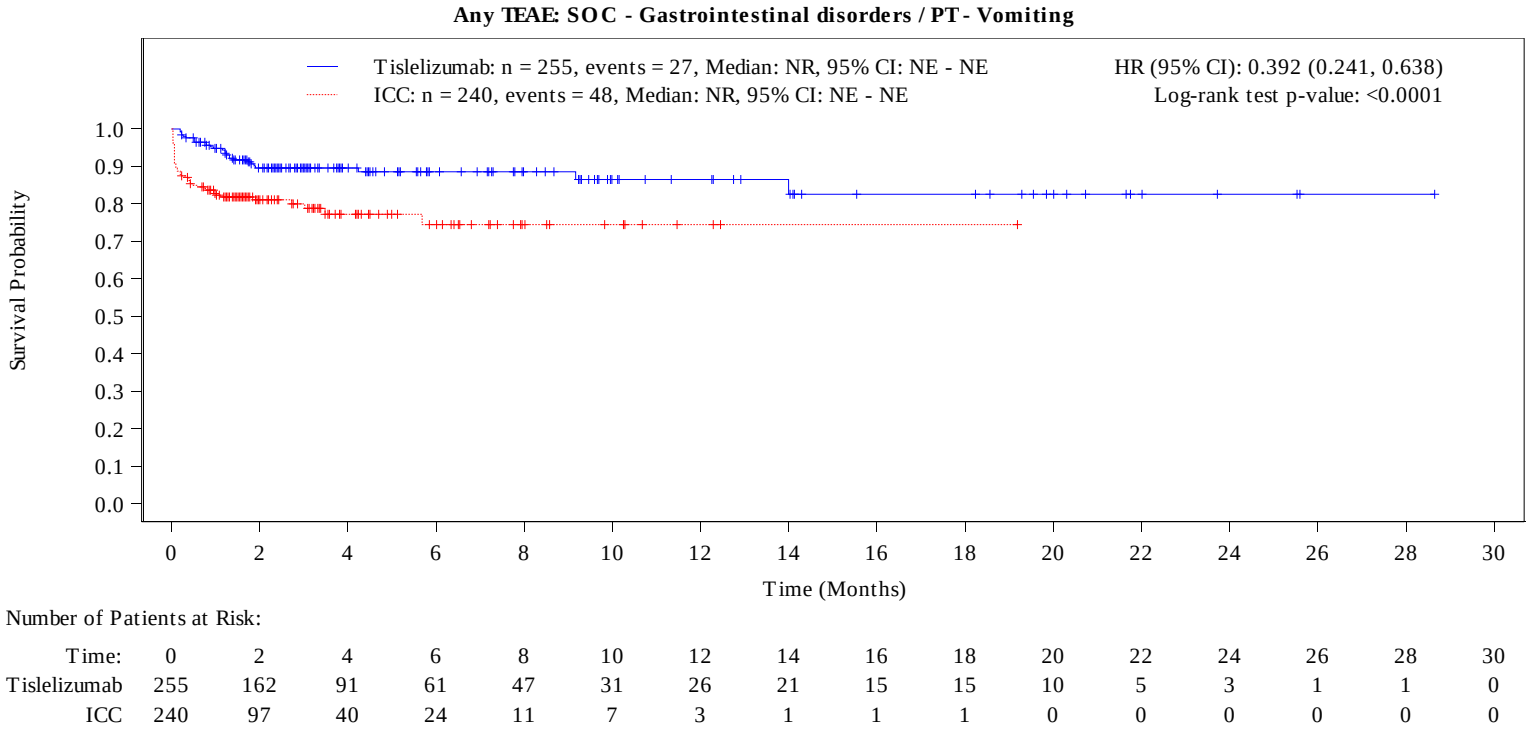

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

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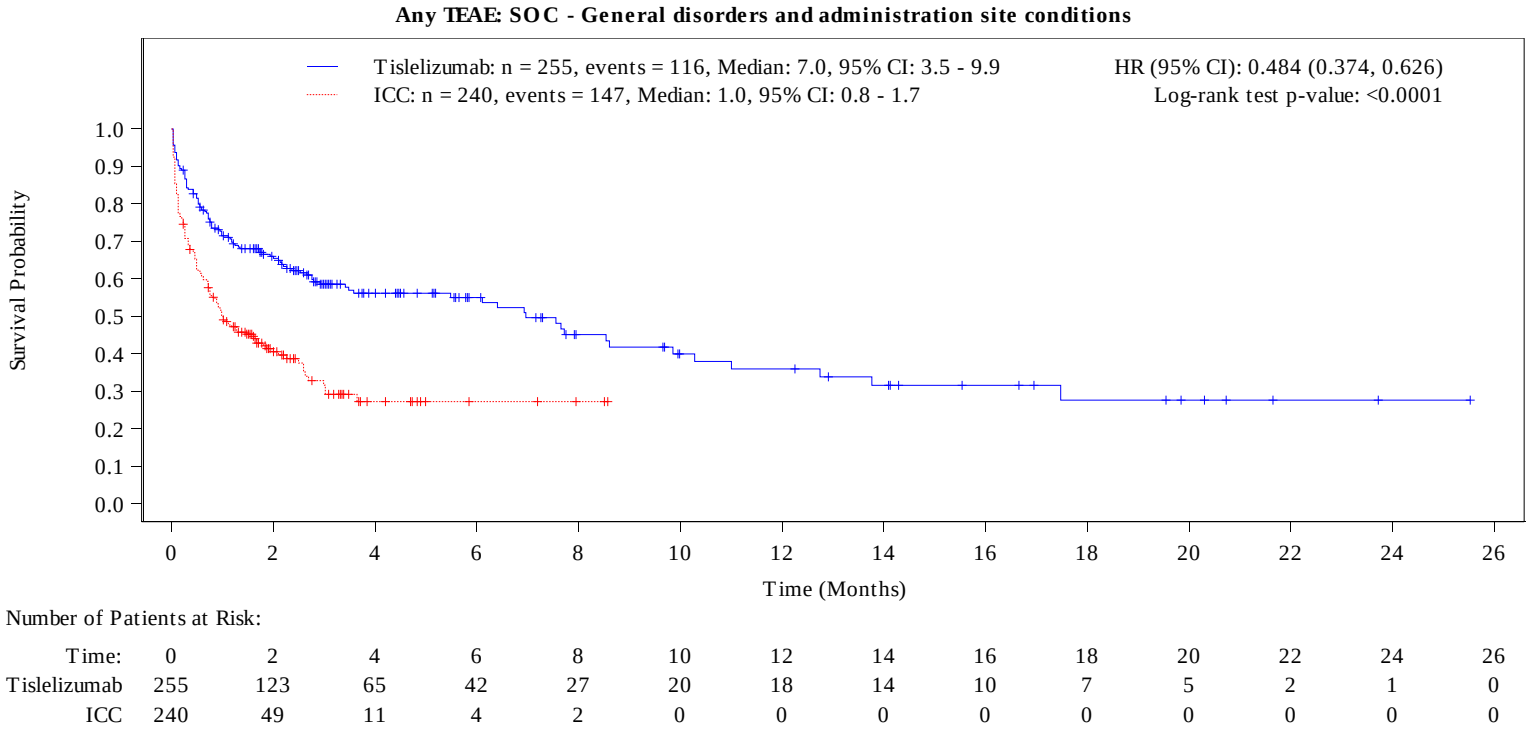

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	255	123	65	42	27	20	18	14	10	7	5	2	1	0
ICC	240	49	11	4	2	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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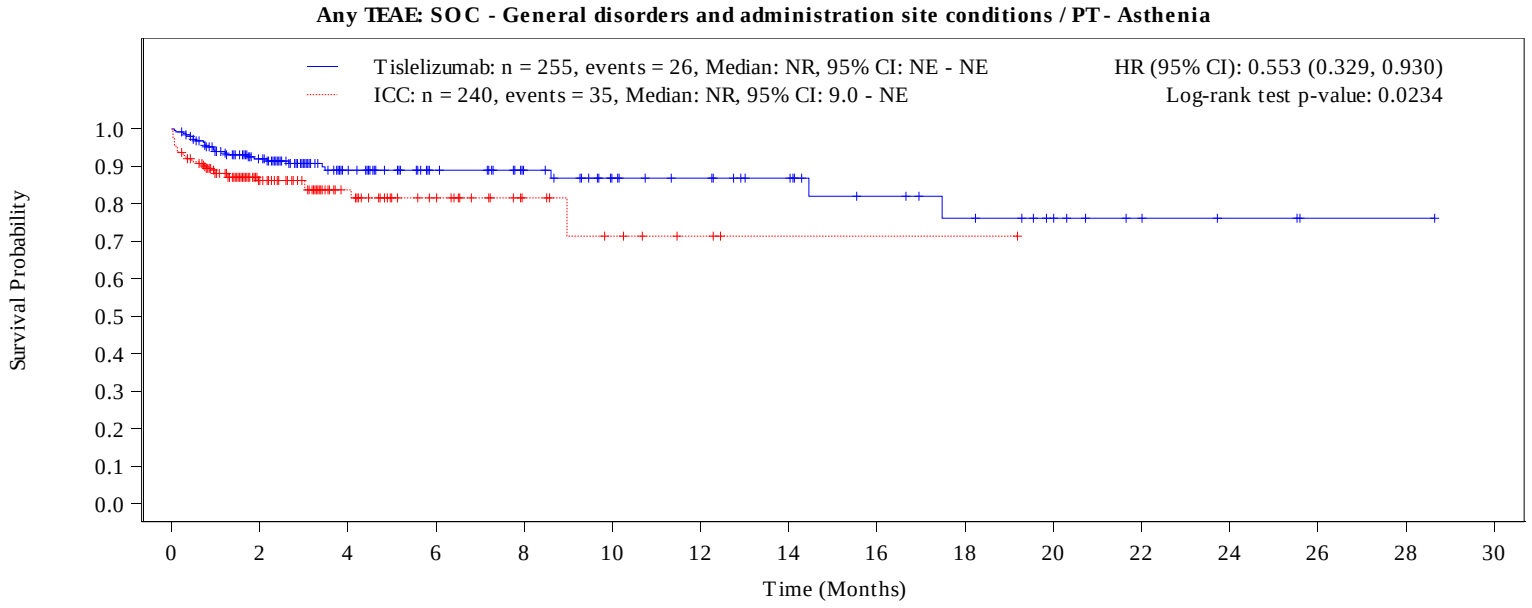
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	163	90	58	44	33	28	23	16	13	9	5	3	1	1	0
ICC	240	101	39	21	10	6	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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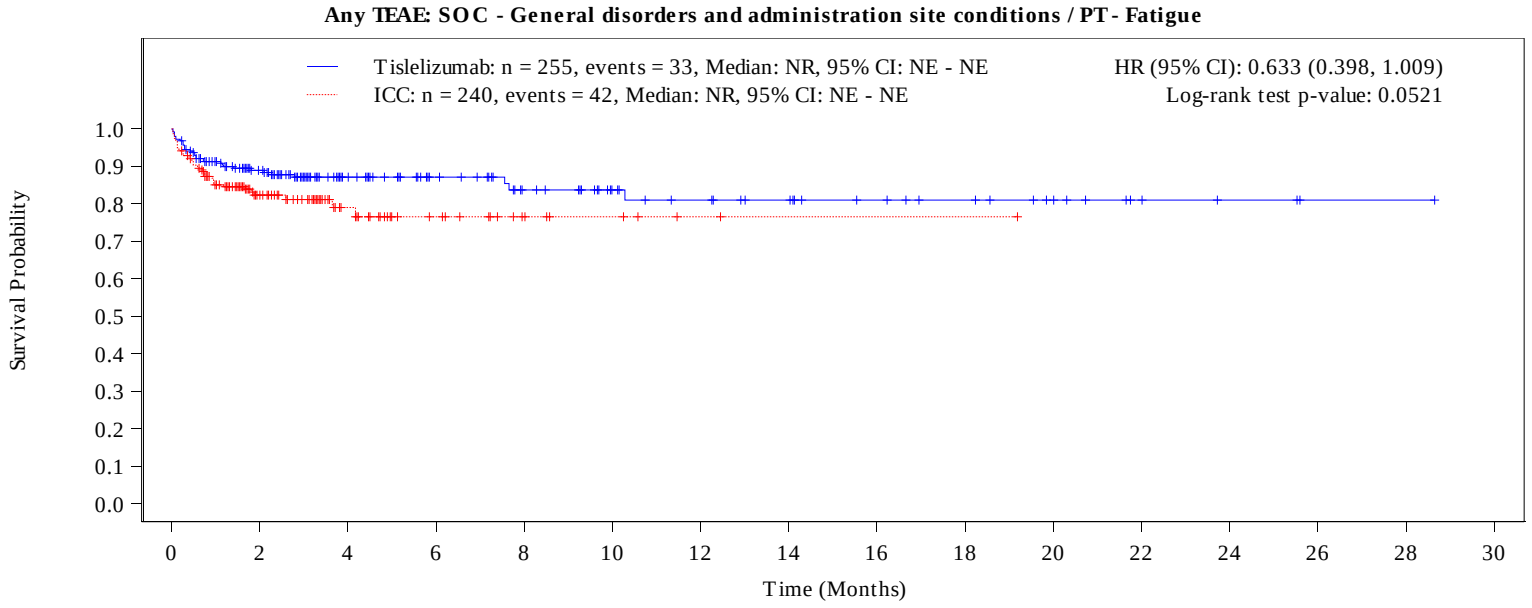
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	158	87	61	44	33	27	23	17	14	10	5	3	1	1	0
ICC	240	90	32	16	8	5	2	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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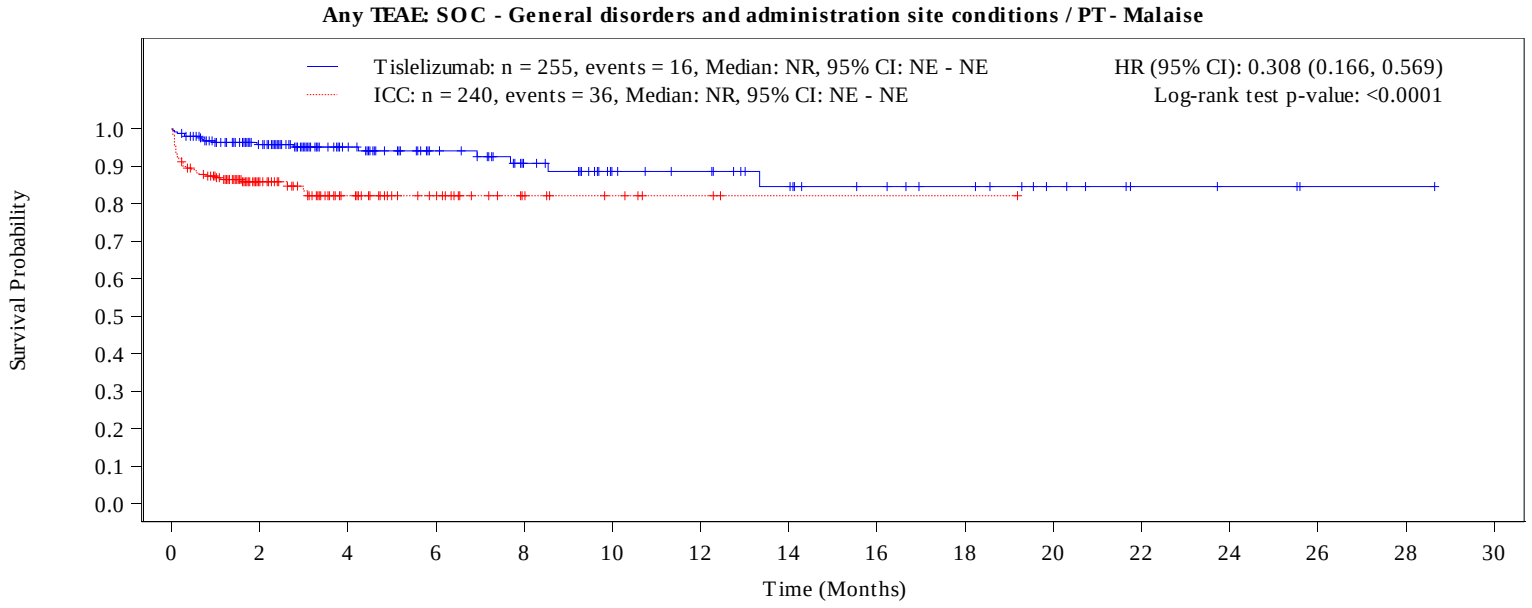

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	168	95	63	45	30	27	21	16	13	8	4	3	1	1	0
ICC	240	98	39	22	10	6	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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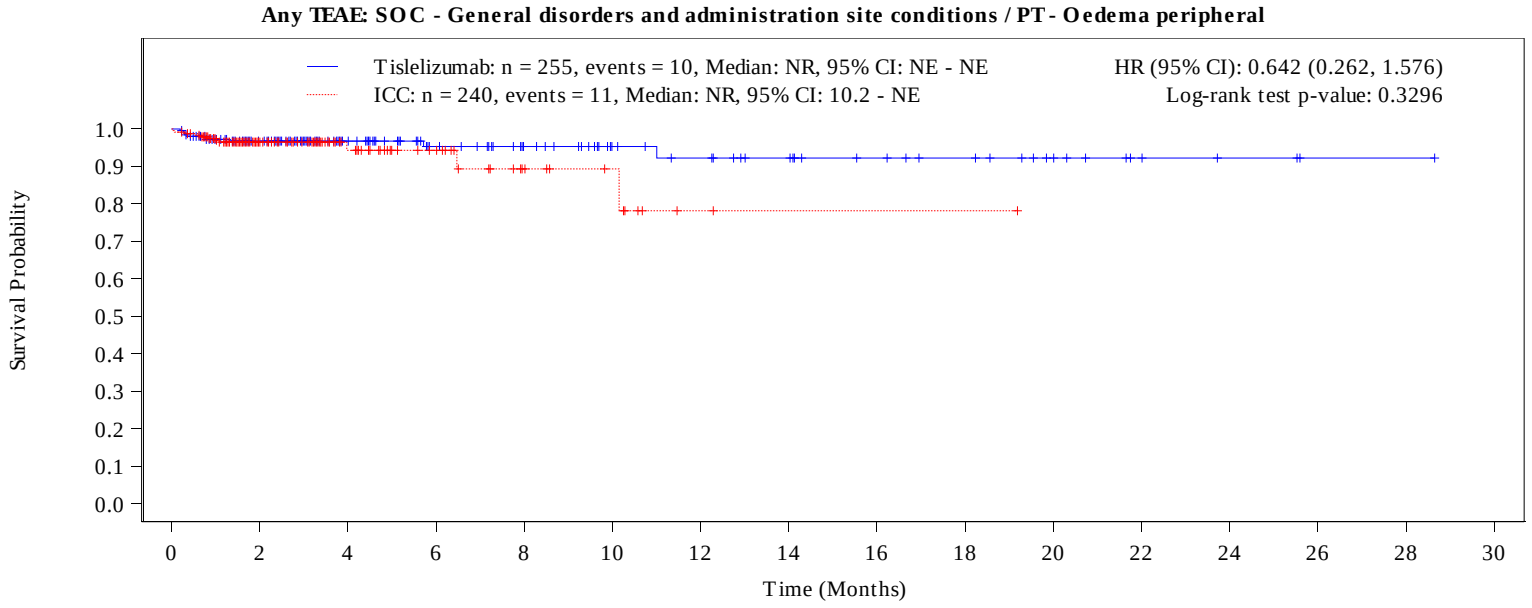

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	170	94	62	47	33	28	23	18	15	10	5	3	1	1	0
ICC	240	109	43	24	12	8	2	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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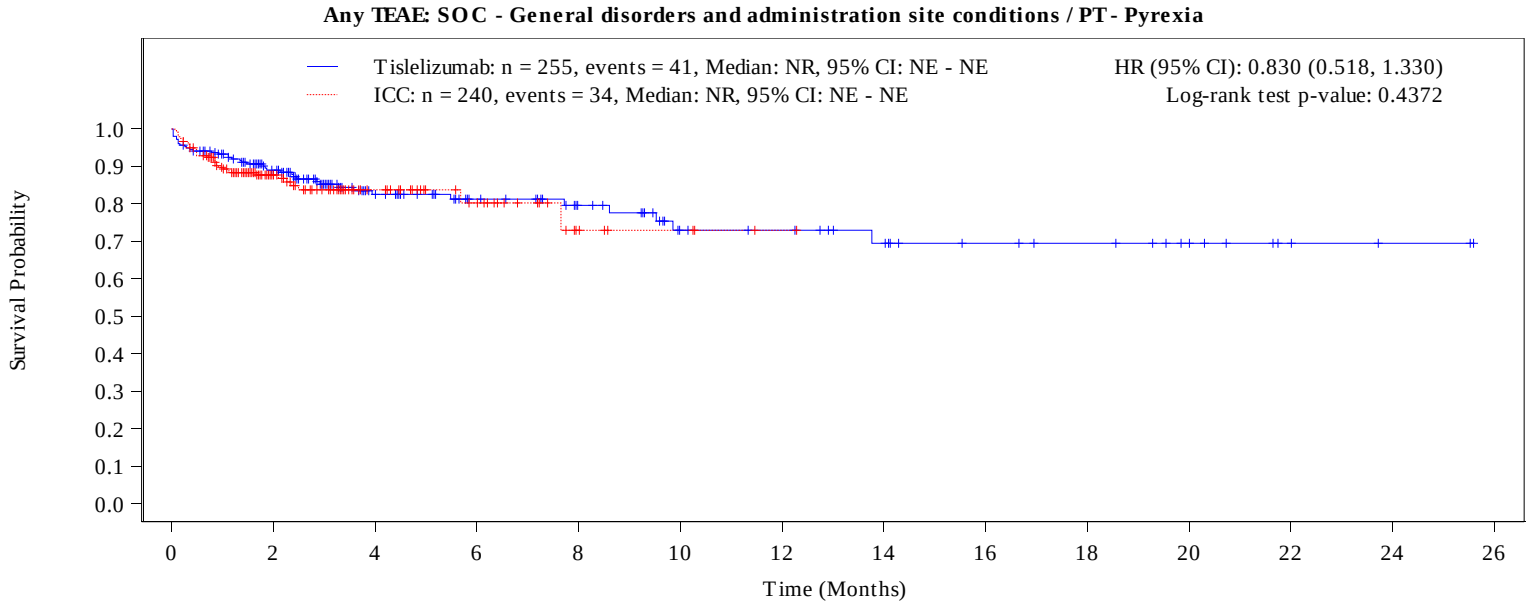
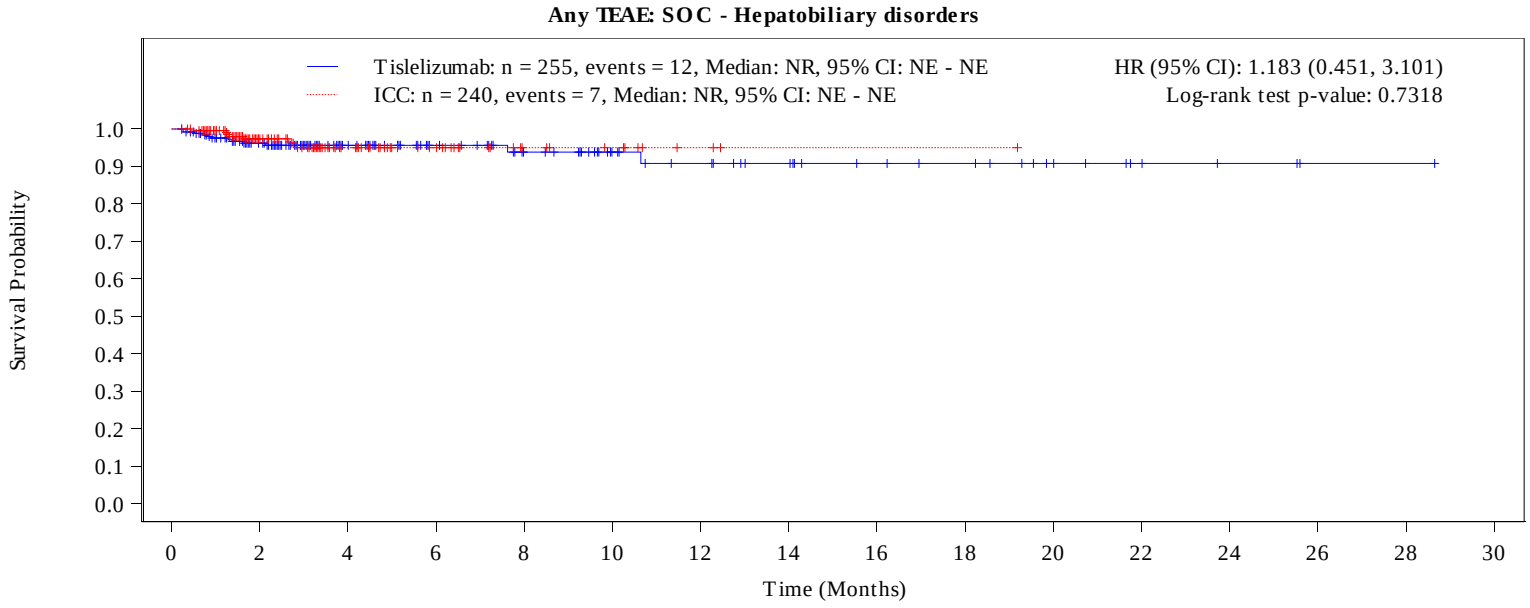


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	255	159	85	58	43	28	25	20	15	13	9	4	2	0
ICC	240	102	37	21	7	4	1	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	170	94	63	47	33	27	22	16	14	9	5	3	1	1	0
ICC	240	111	42	23	11	8	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

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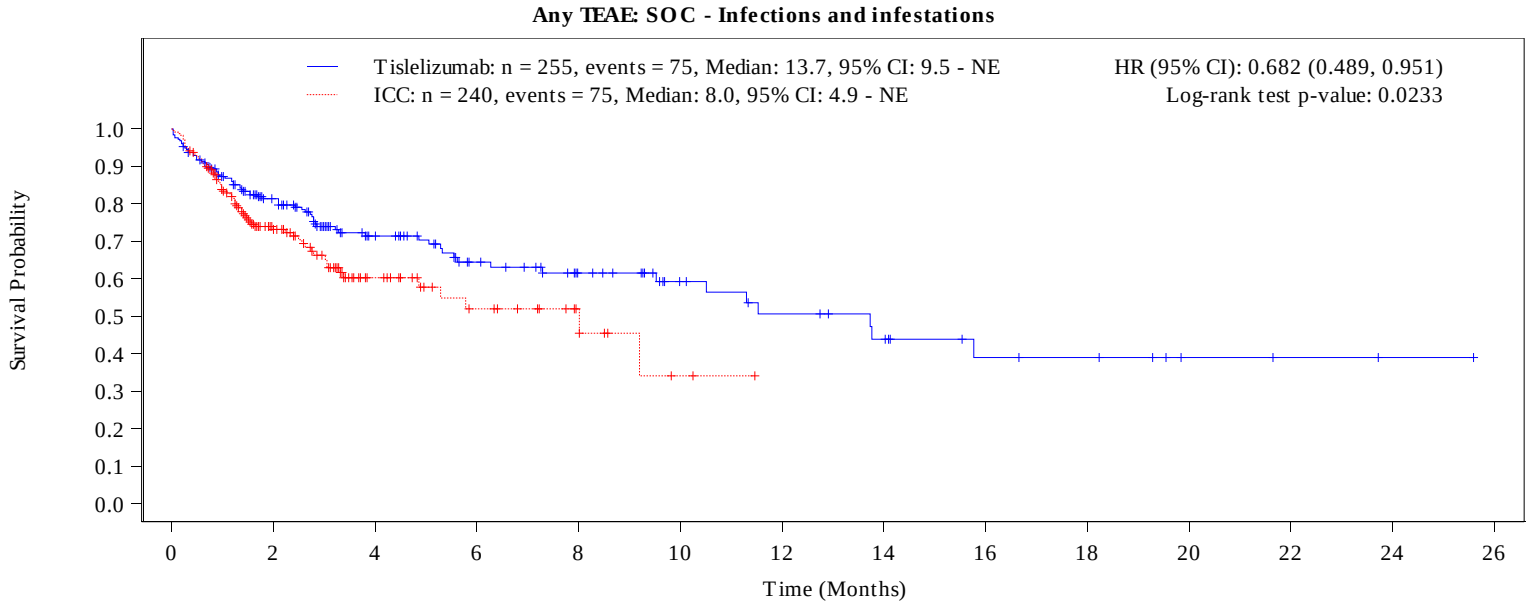
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	255	145	78	48	35	22	17	13	8	7	3	2	1	0
ICC	240	94	31	16	8	2	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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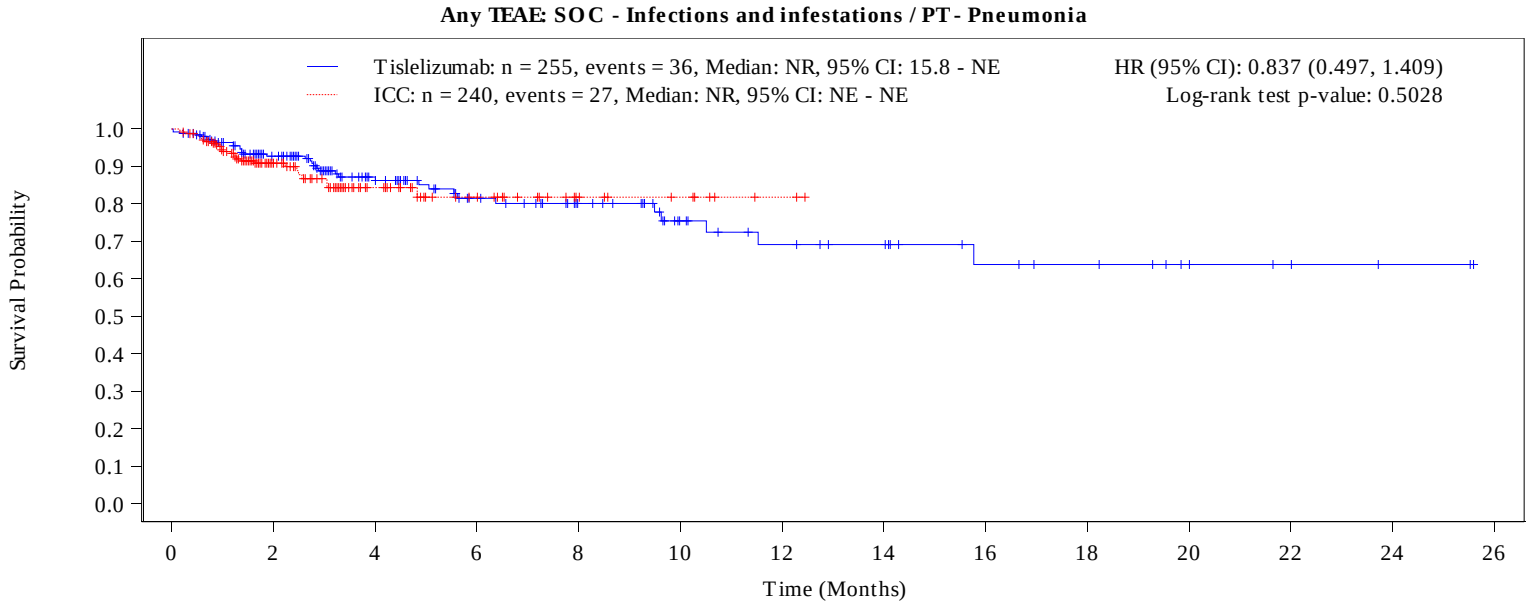
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

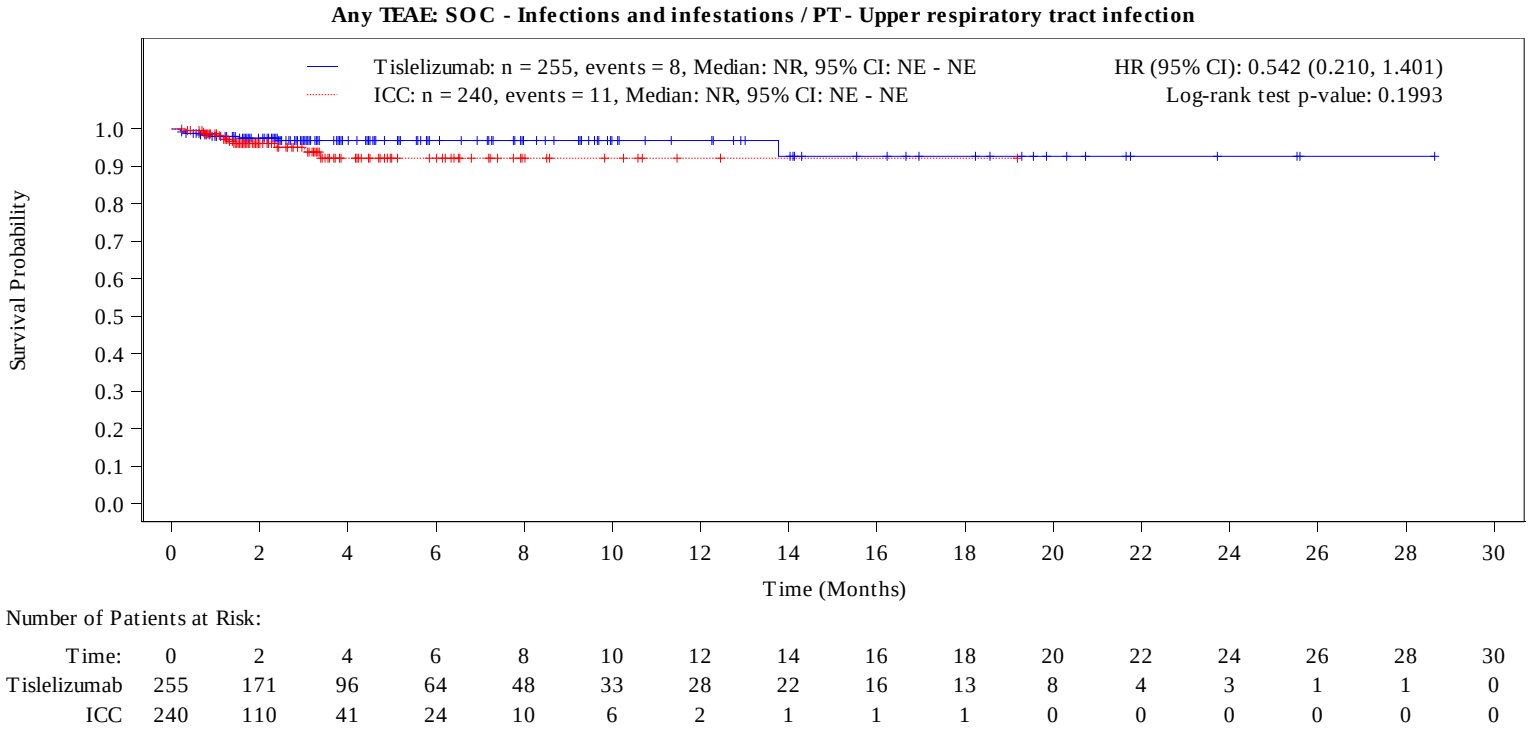


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	255	166	94	60	44	27	21	18	12	10	6	4	2	0
ICC	240	110	43	23	11	7	2	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

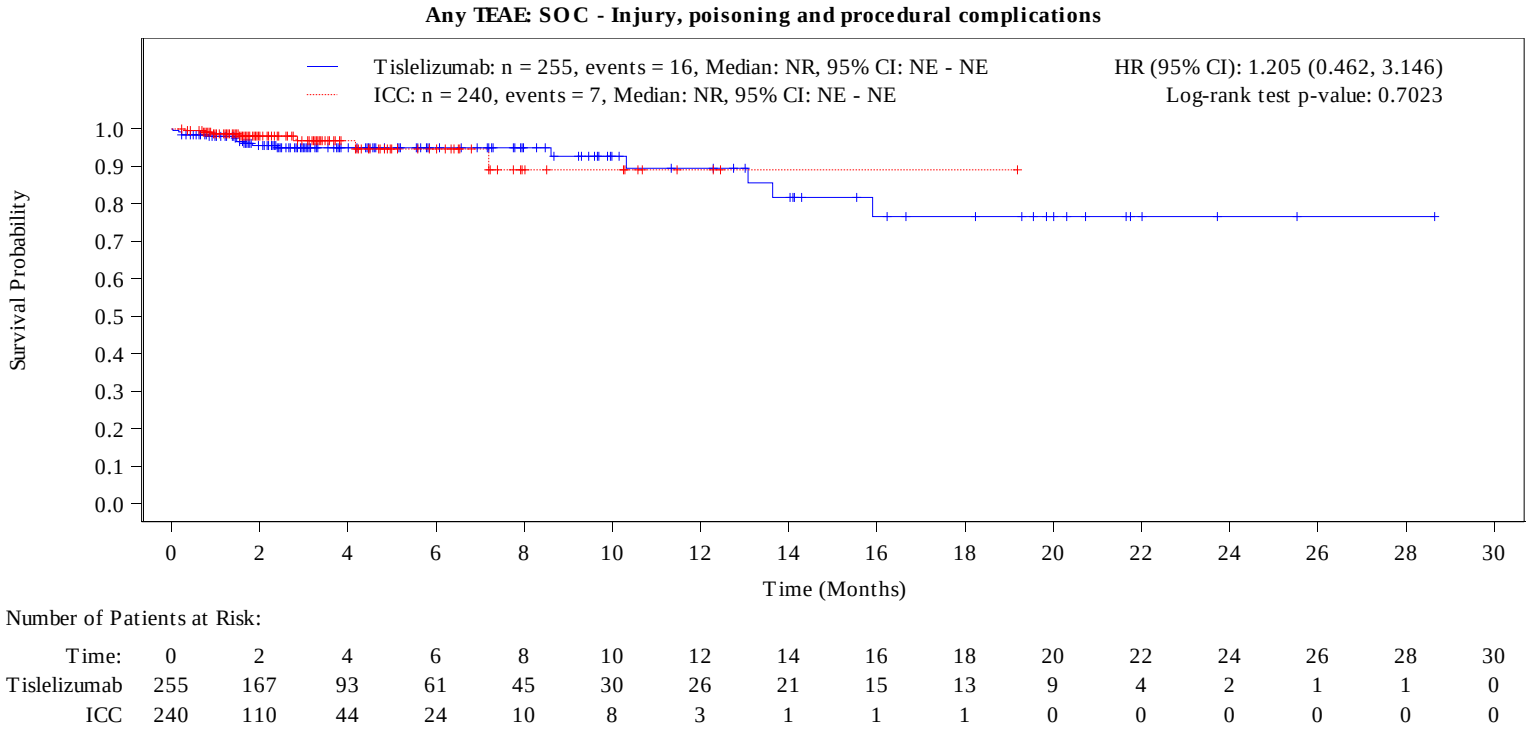


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	171	96	64	48	33	28	22	16	13	8	4	3	1	1	0
ICC	240	110	41	24	10	6	2	1	1	1	0	0	0	0	0	0

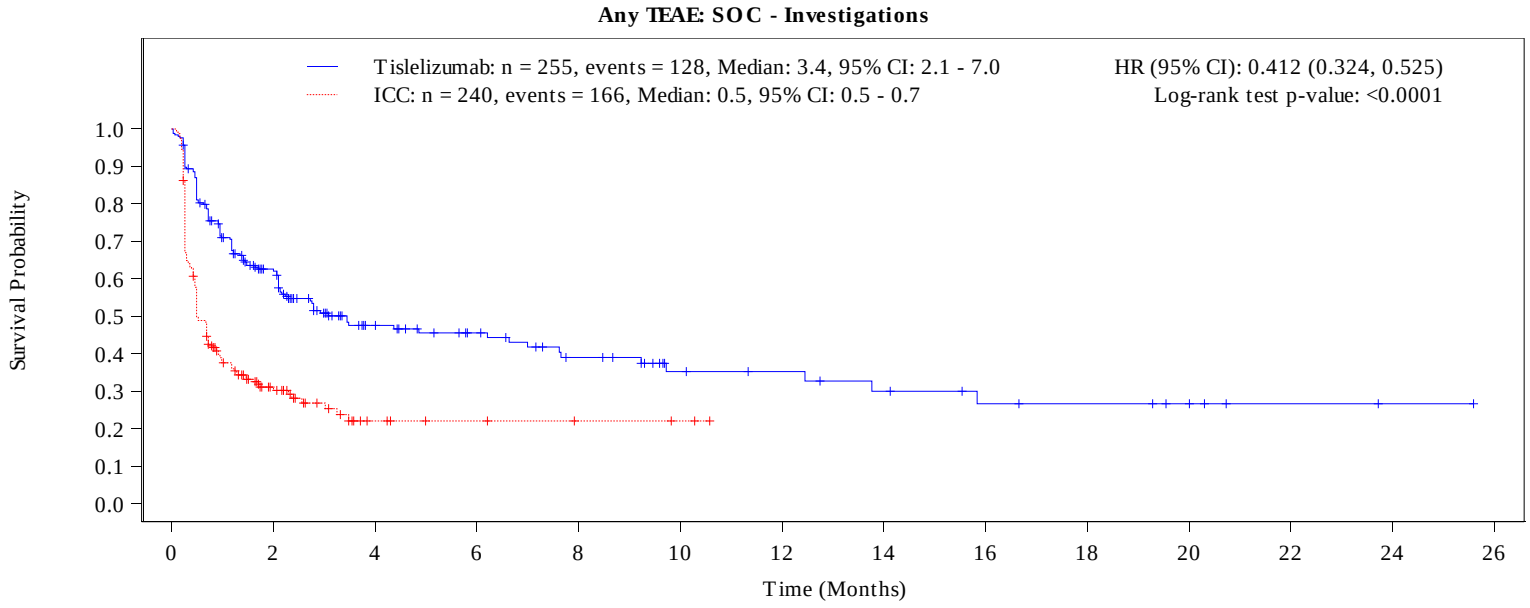
Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

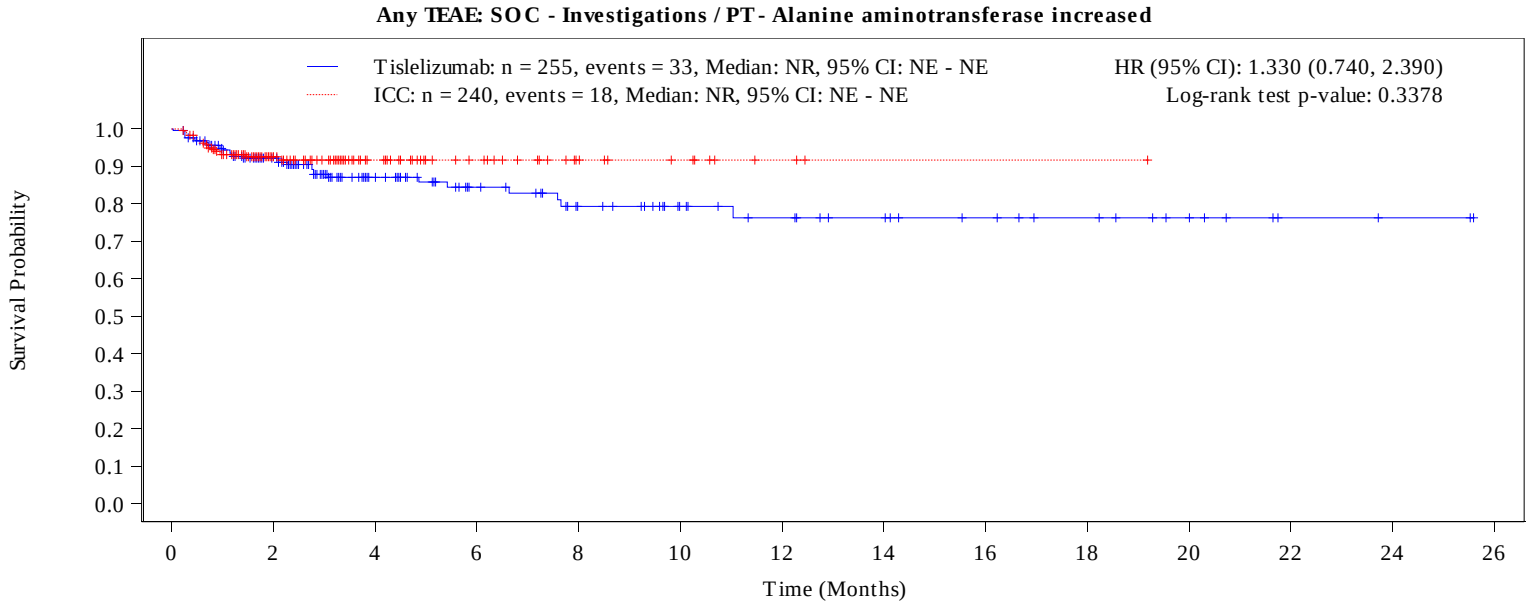


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	255	113	52	38	27	16	14	11	8	7	5	2	1	0
ICC	240	35	8	5	3	2	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

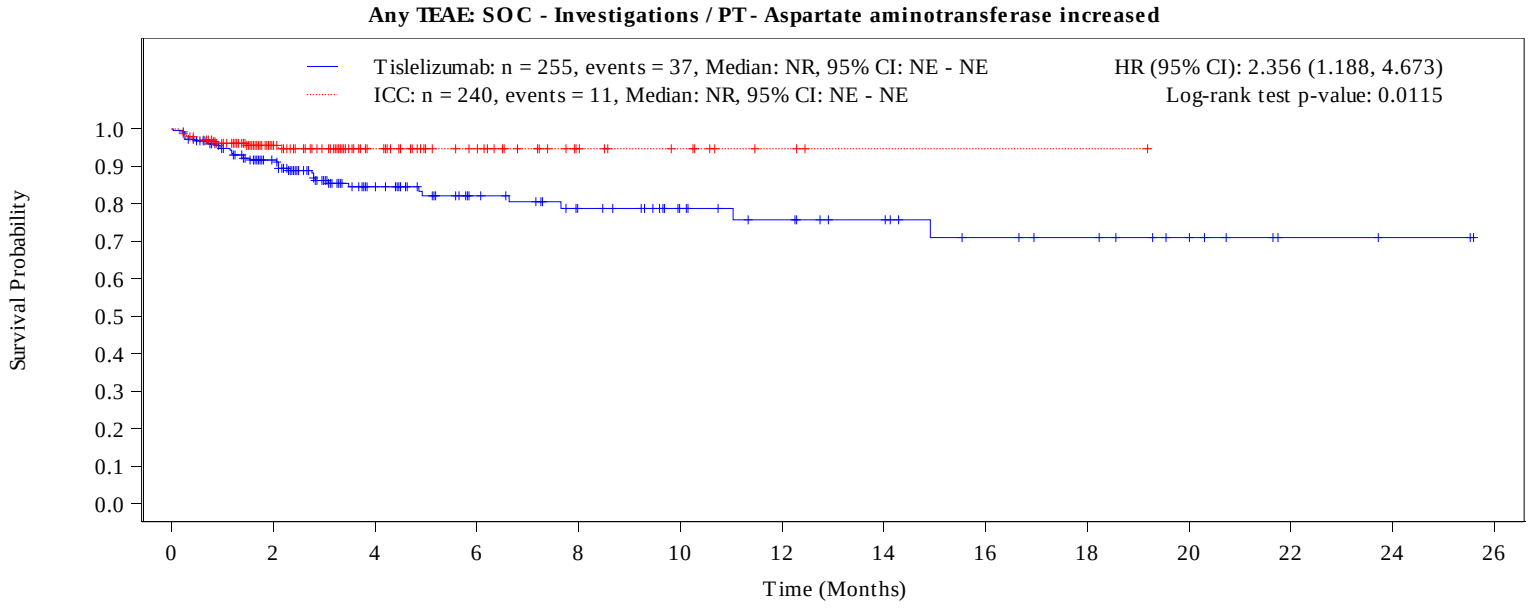


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	255	165	85	55	40	29	23	19	15	12	8	3	2	0
ICC	240	110	42	23	12	8	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	255	165	85	54	41	29	23	19	14	12	8	3	2	0
ICC	240	112	44	25	12	8	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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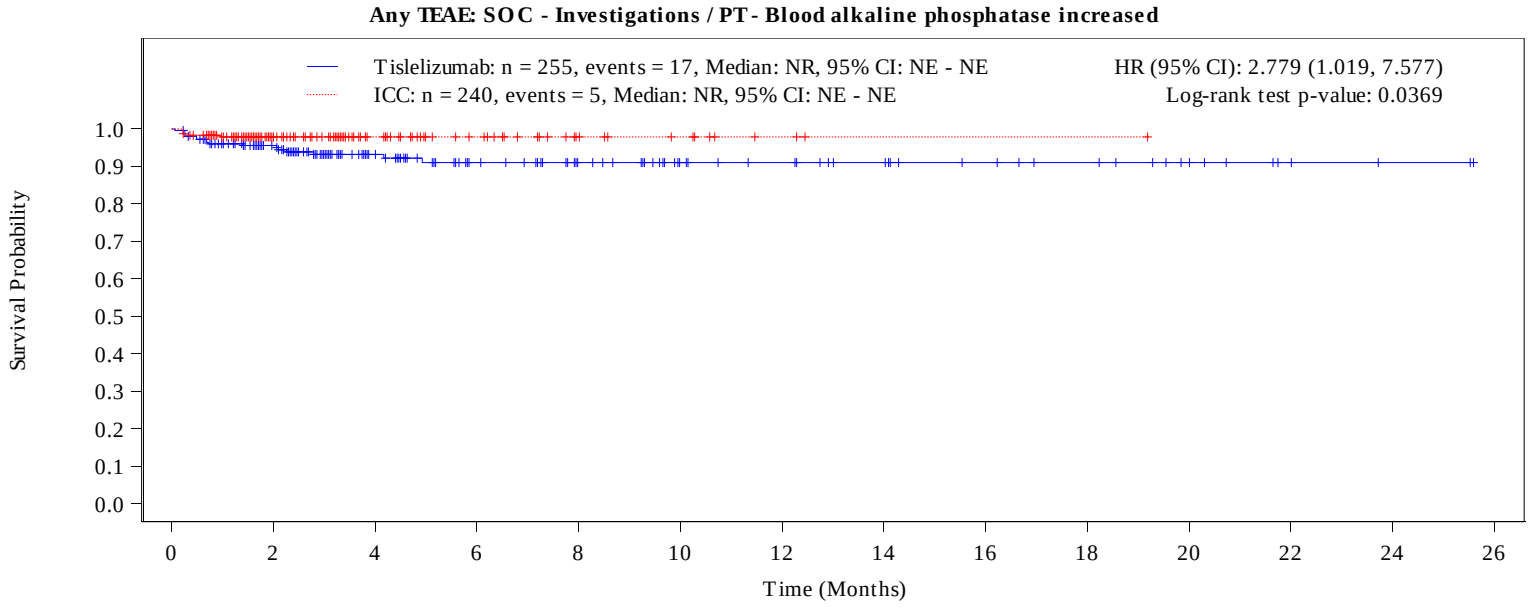
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	255	169	95	62	47	32	27	22	17	14	9	4	2	0
ICC	240	110	43	24	12	8	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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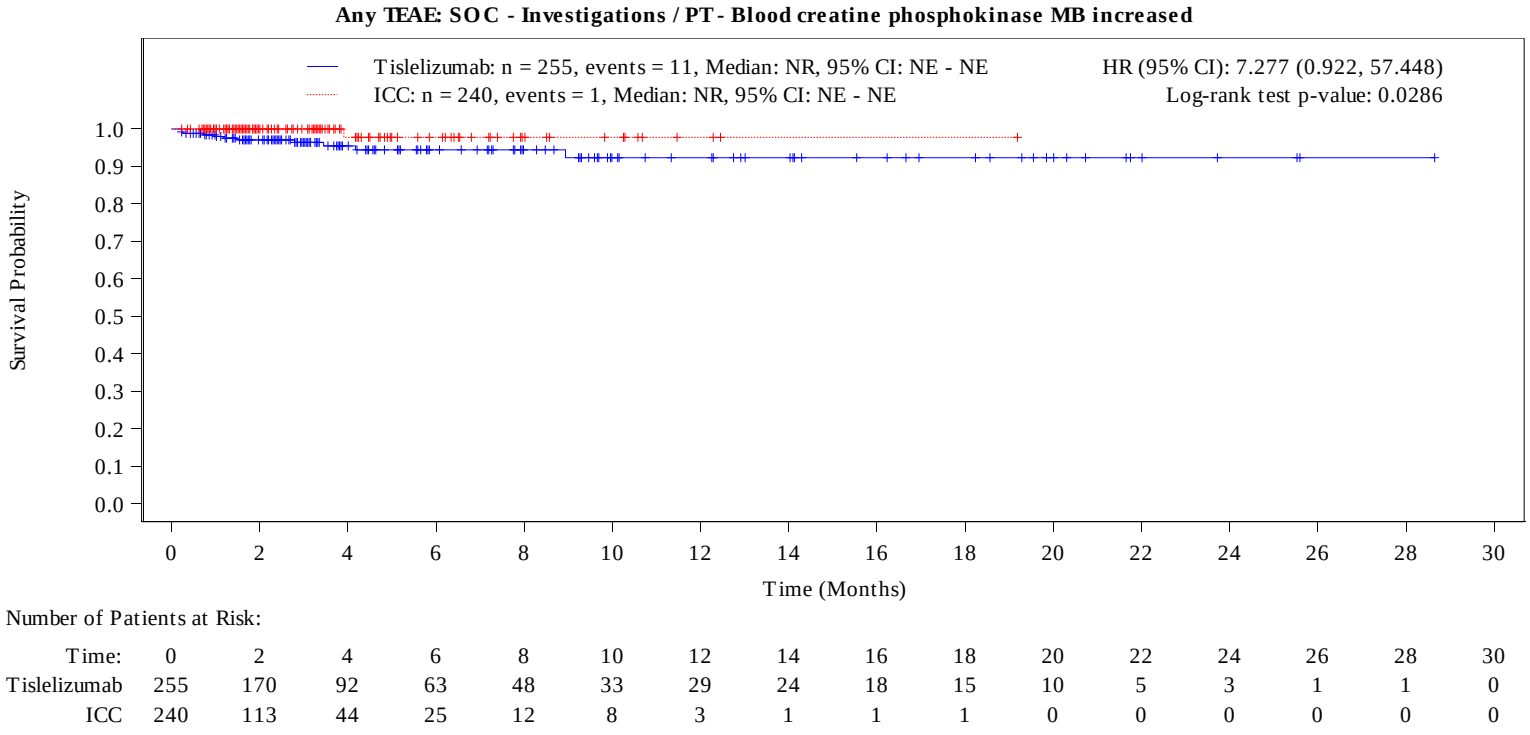
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	170	92	63	48	33	29	24	18	15	10	5	3	1	1	0
ICC	240	113	44	25	12	8	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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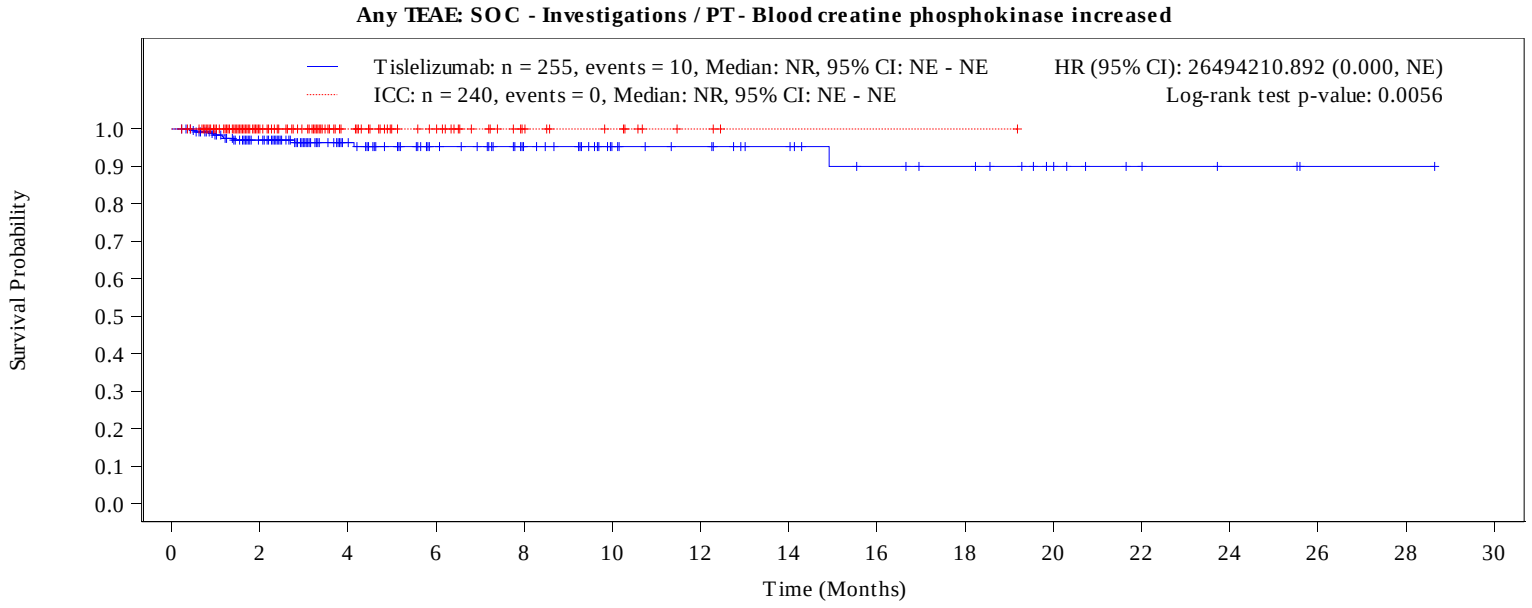
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	170	92	62	47	32	27	22	16	14	9	5	3	1	1	0
ICC	240	113	45	26	12	8	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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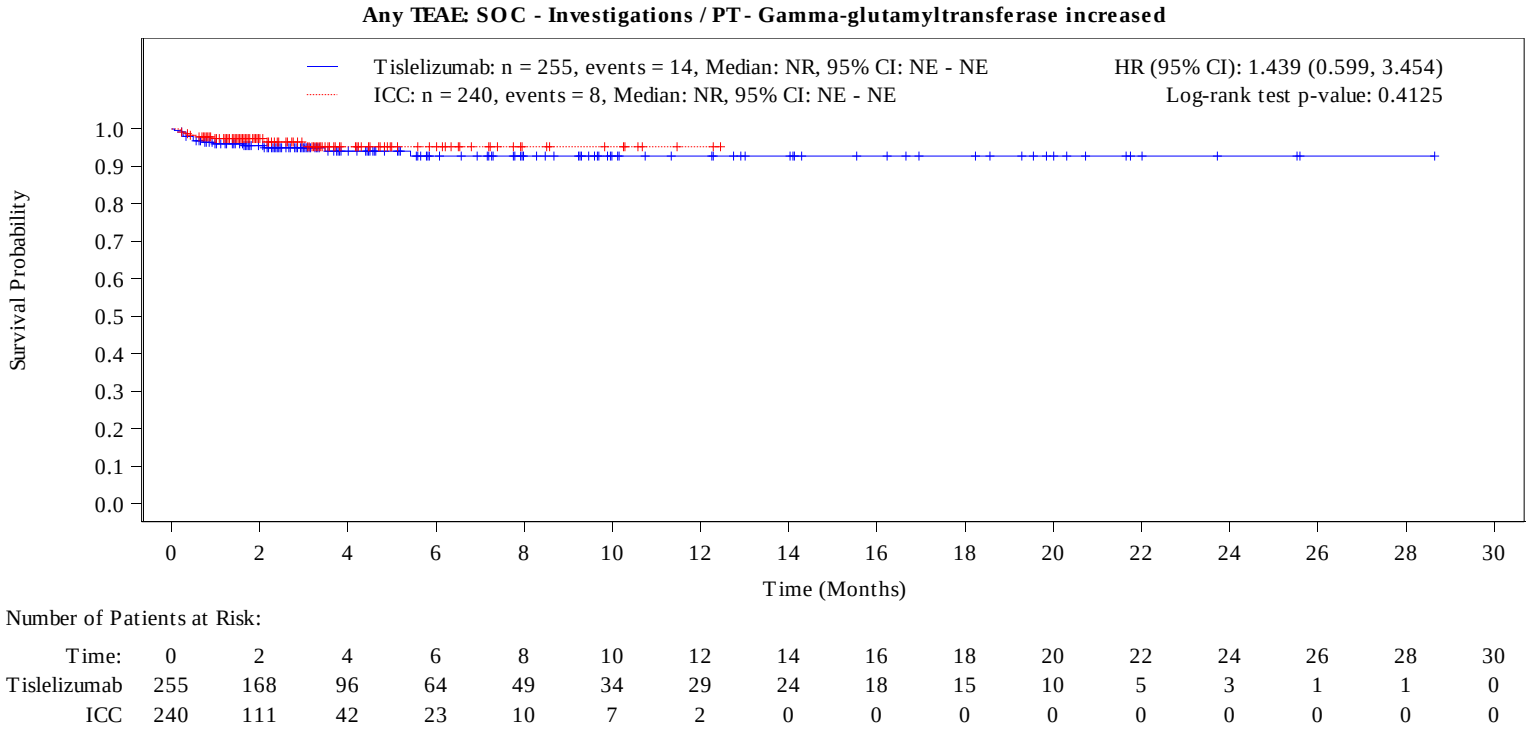
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	168	96	64	49	34	29	24	18	15	10	5	3	1	1	0
ICC	240	111	42	23	10	7	2	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

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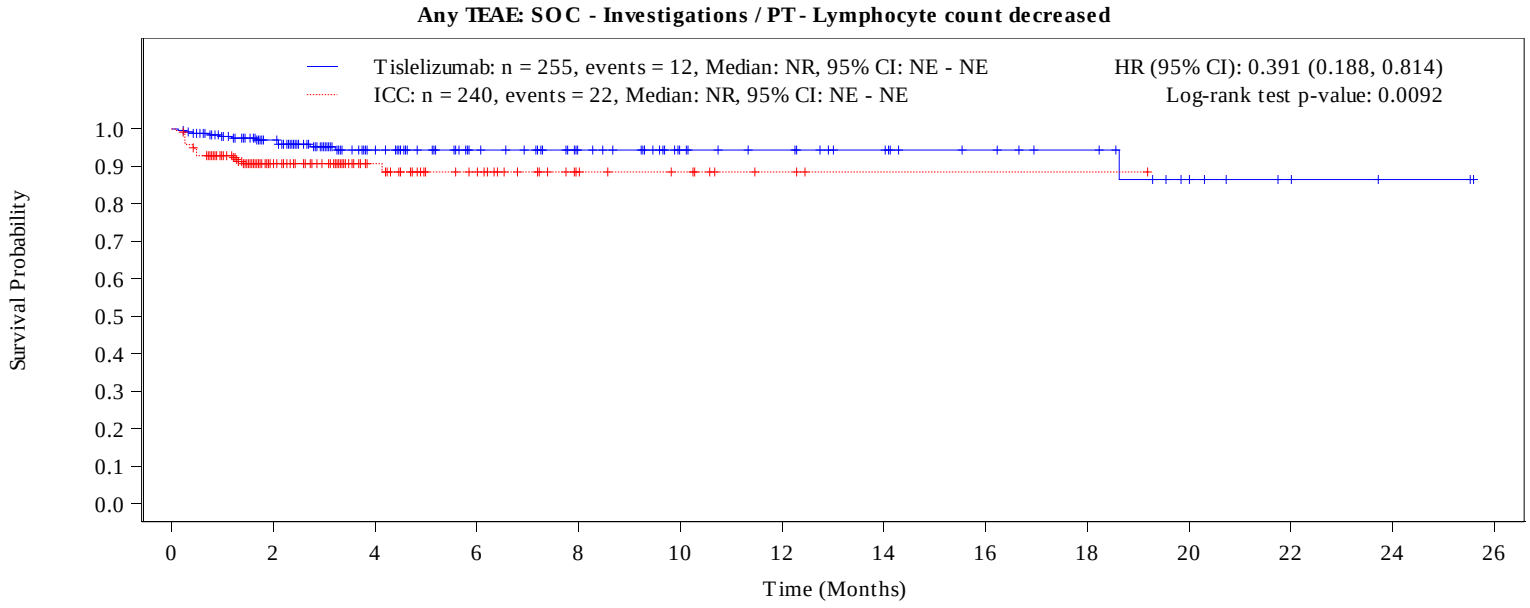
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	255	171	96	64	48	33	28	23	17	14	8	4	2	0
ICC	240	104	41	24	11	8	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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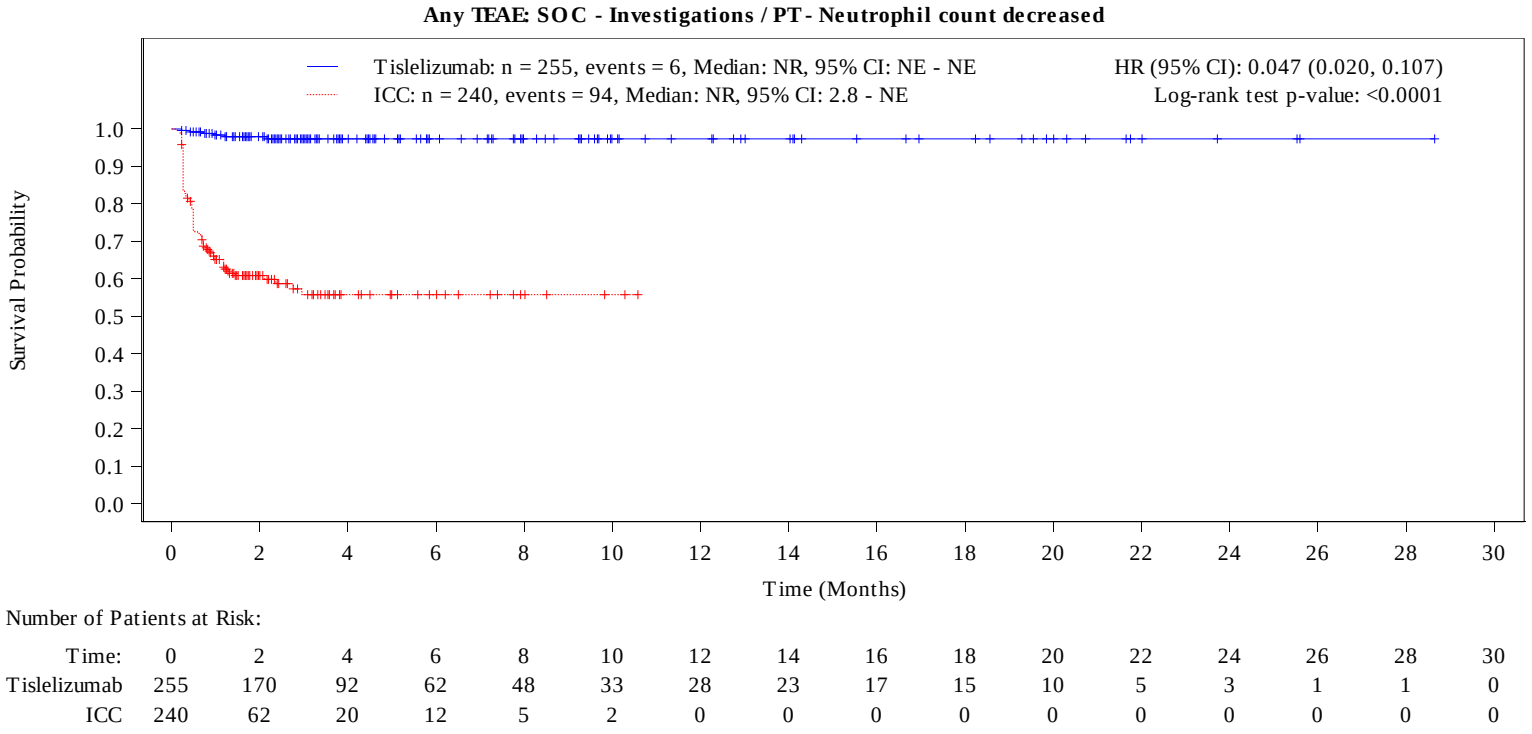

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	170	92	62	48	33	28	23	17	15	10	5	3	1	1	0
ICC	240	62	20	12	5	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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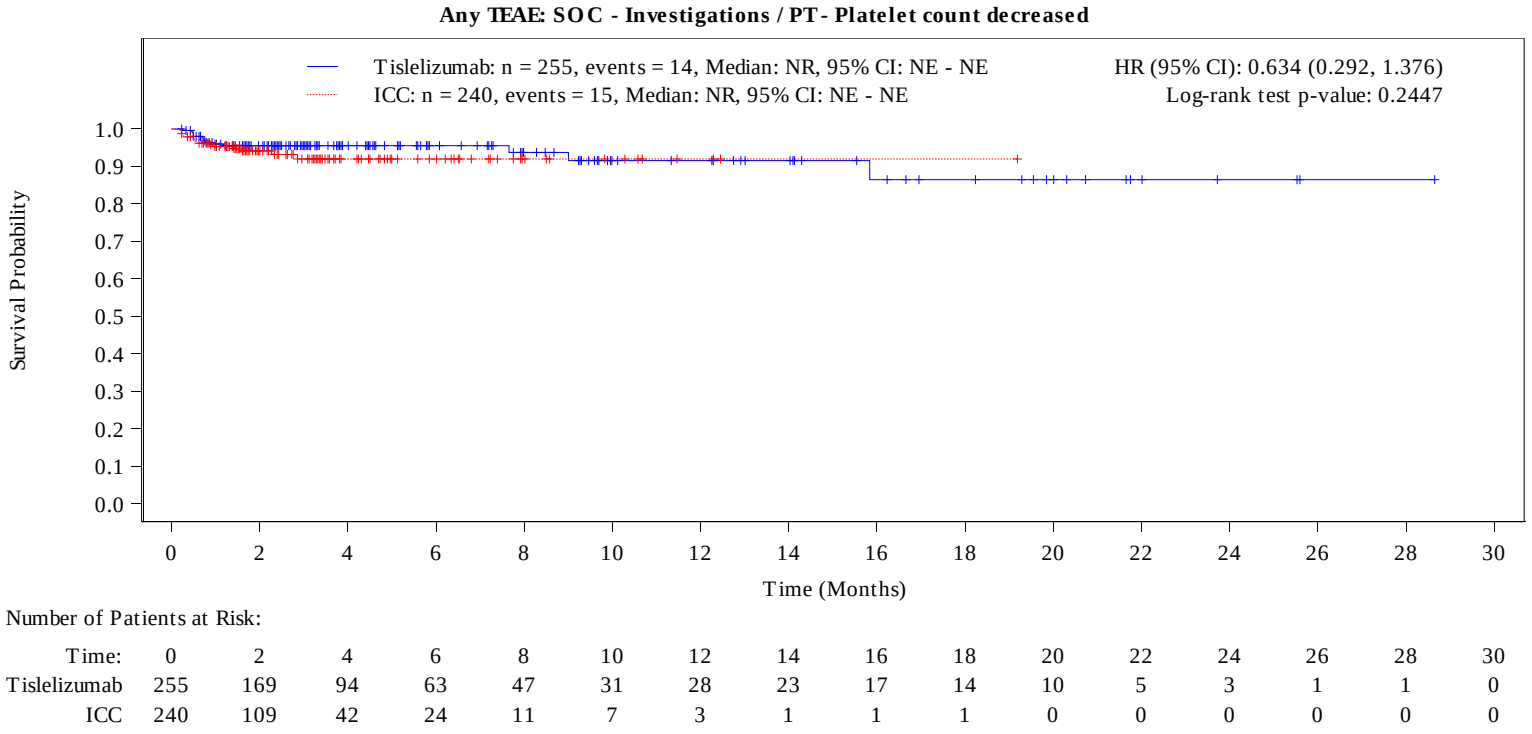

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	169	94	63	47	31	28	23	17	14	10	5	3	1	1	0
ICC	240	109	42	24	11	7	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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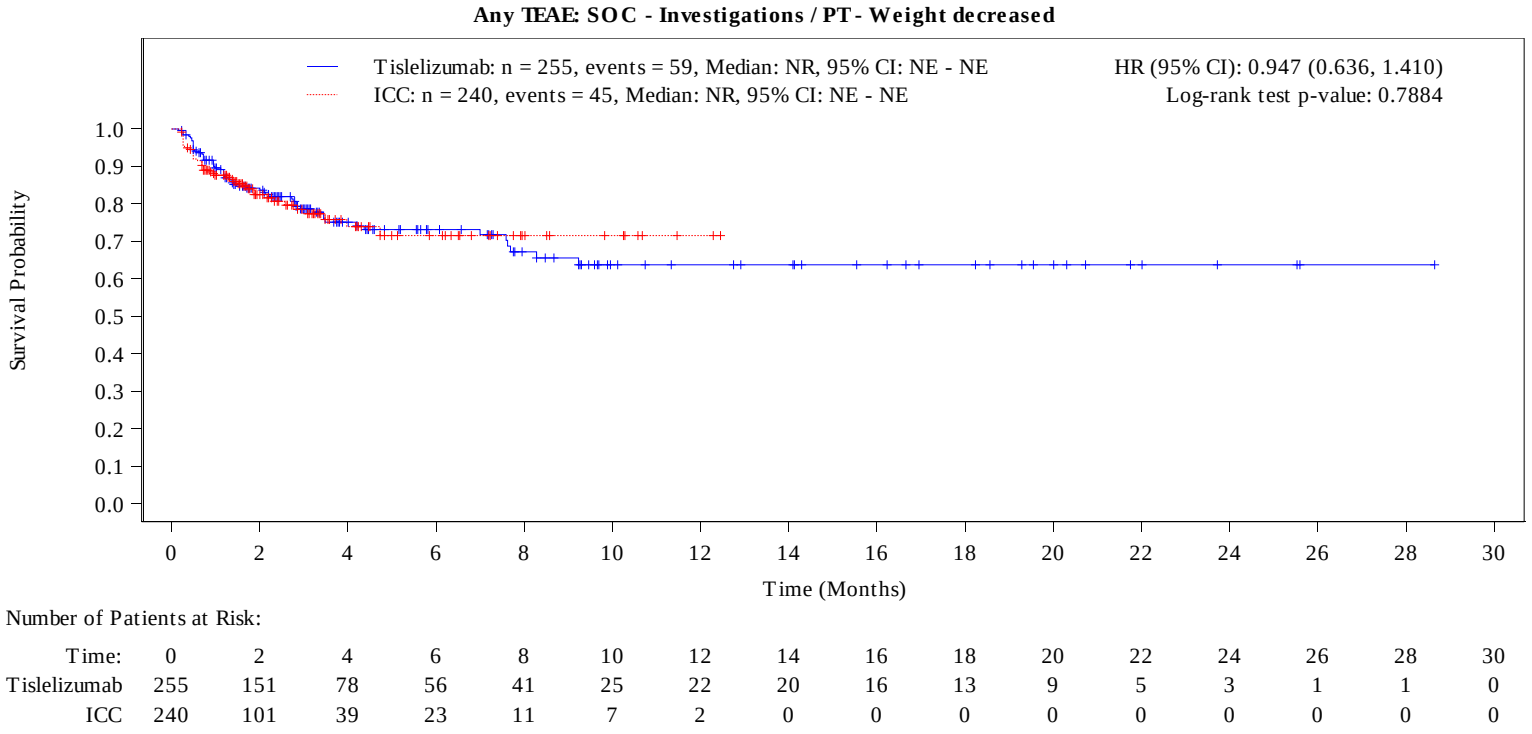

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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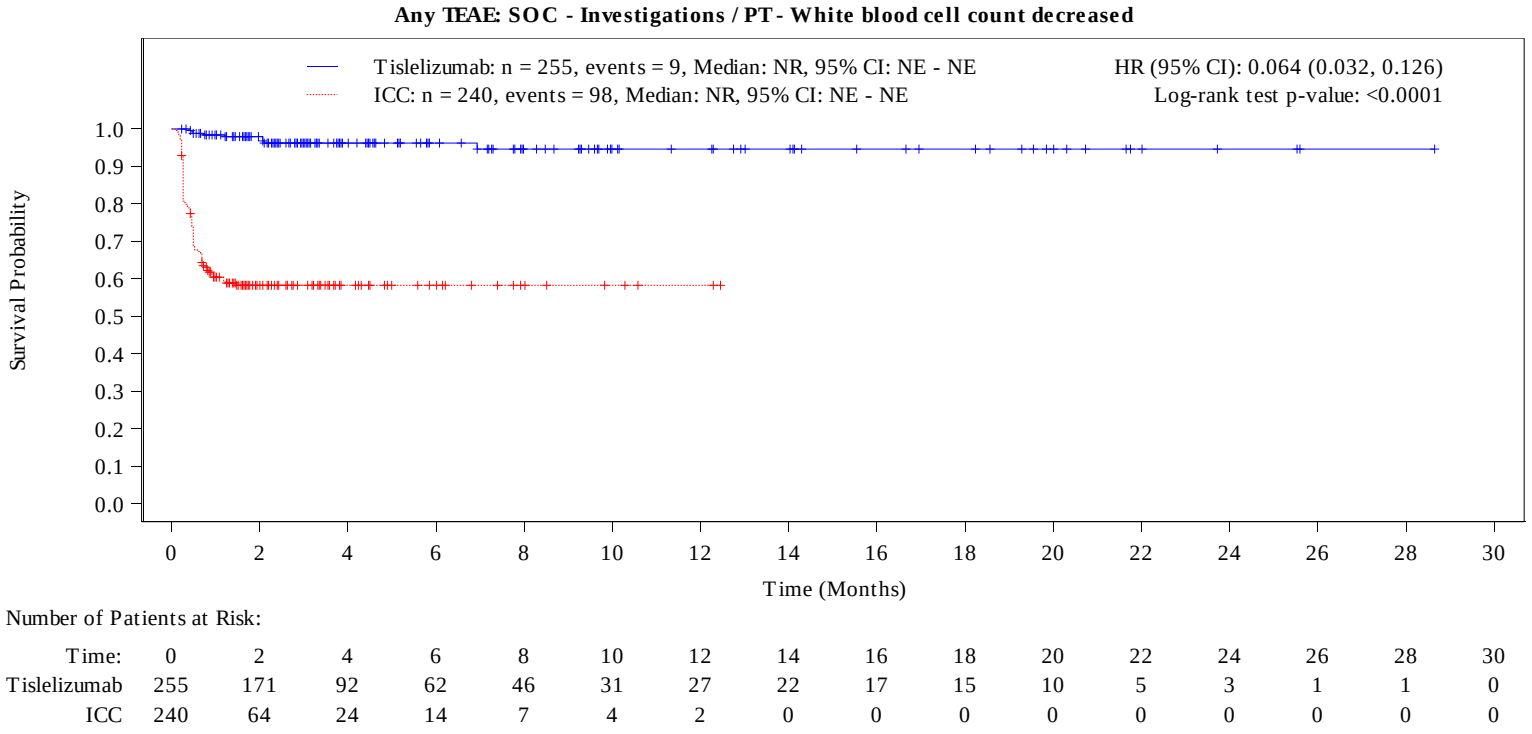

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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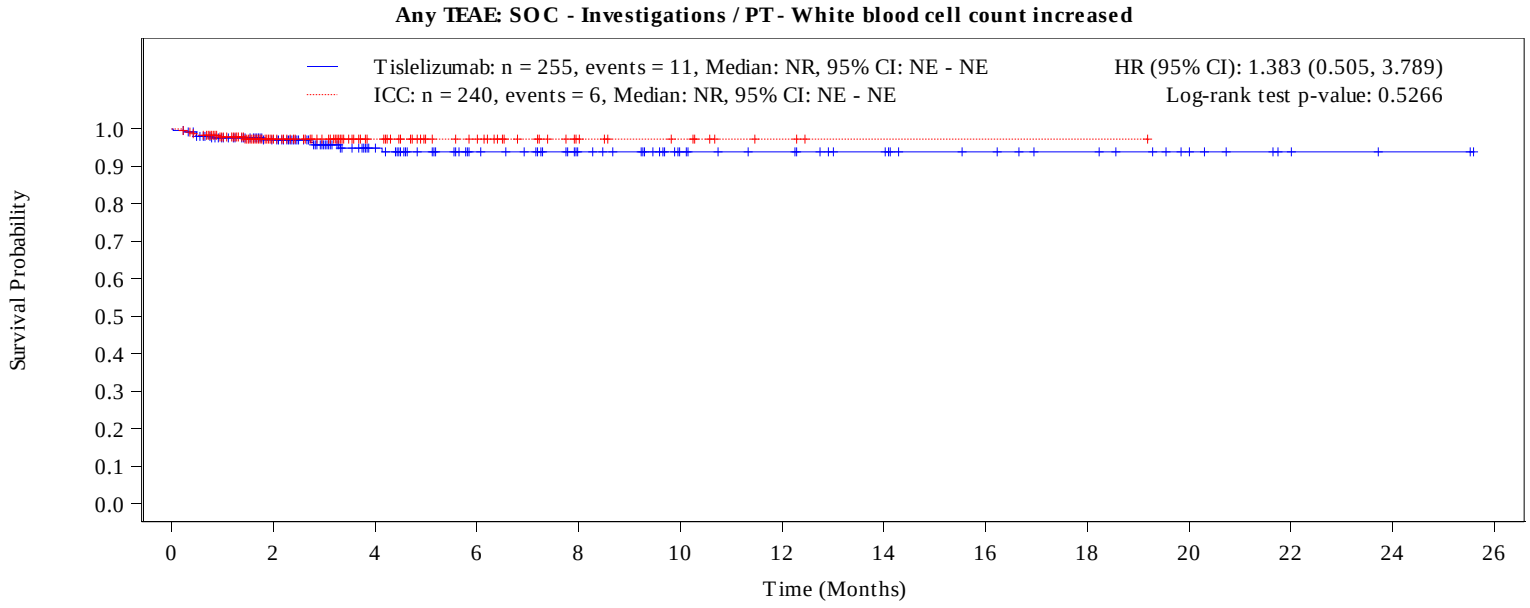
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

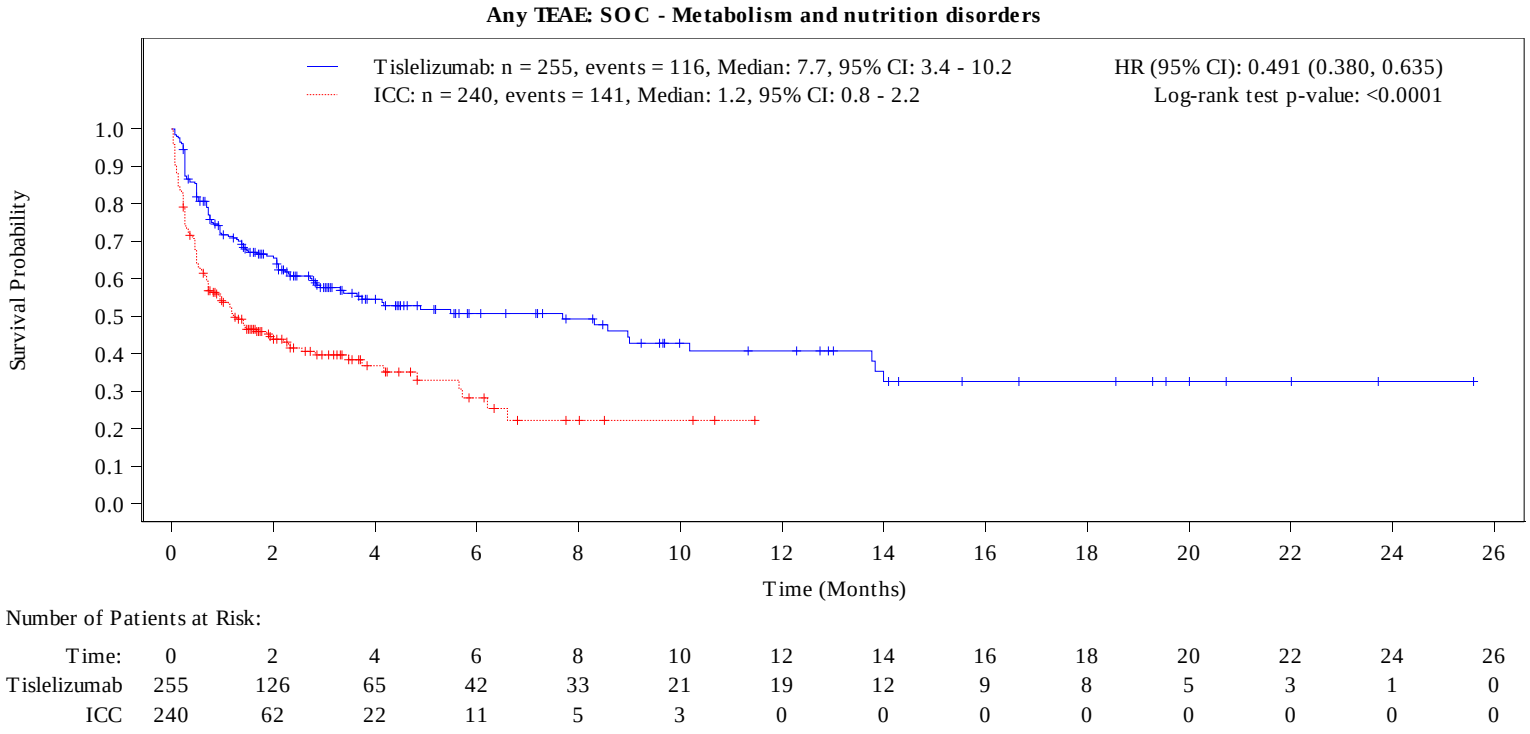


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	255	174	96	64	48	33	28	23	17	14	9	4	2	0
ICC	240	111	45	26	12	8	3	1	1	1	0	0	0	0

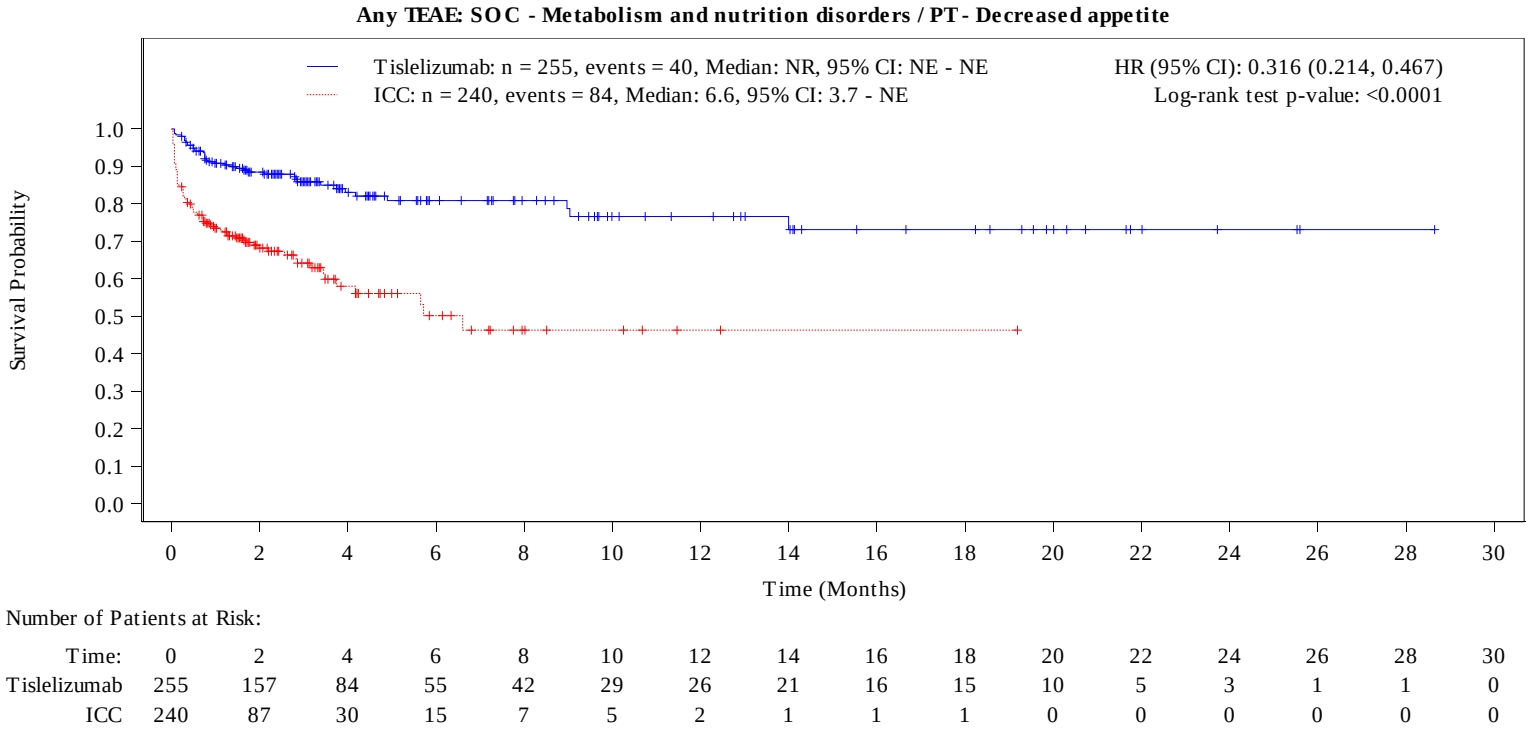
Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

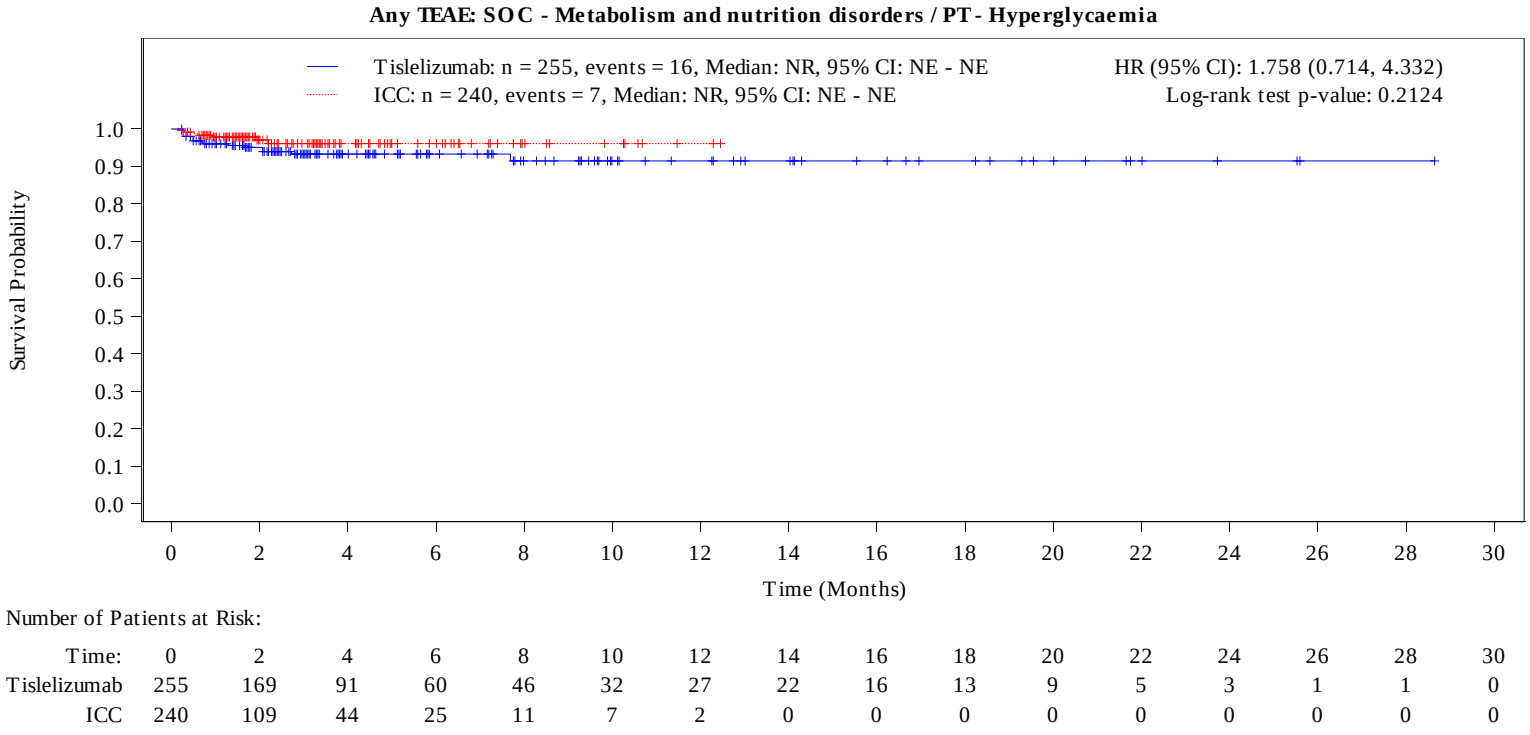


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	157	84	55	42	29	26	21	16	15	10	5	3	1	1	0
ICC	240	87	30	15	7	5	2	1	1	1	0	0	0	0	0	0

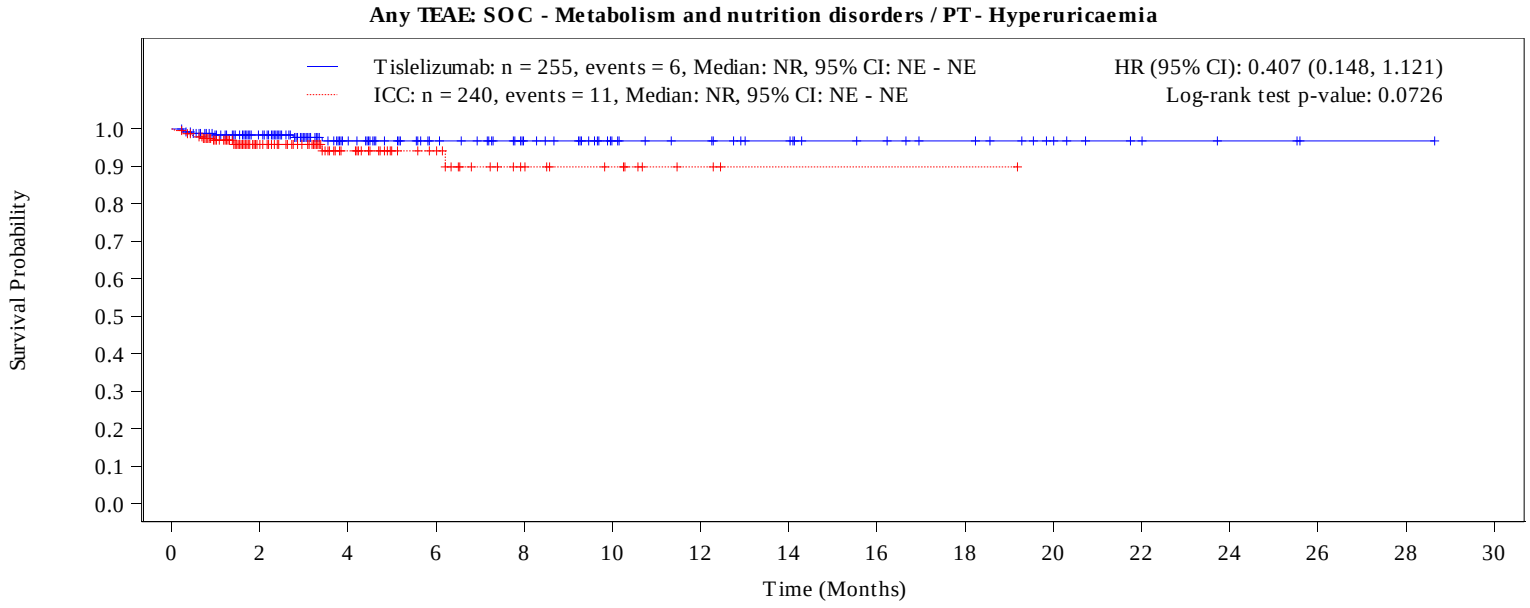
Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

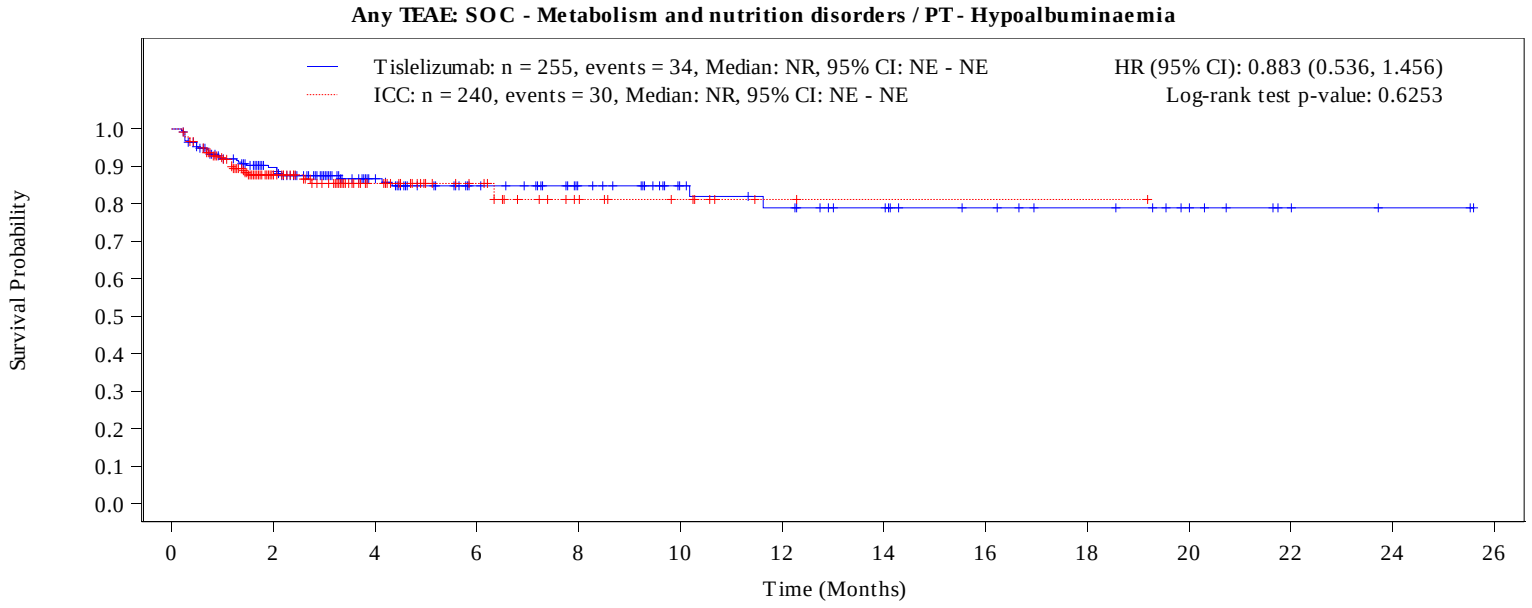


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	175	95	64	48	33	28	23	17	14	9	5	3	1	1	0
ICC	240	108	42	24	12	8	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	255	165	93	61	45	31	26	21	16	13	9	4	2	0
ICC	240	102	41	22	11	7	2	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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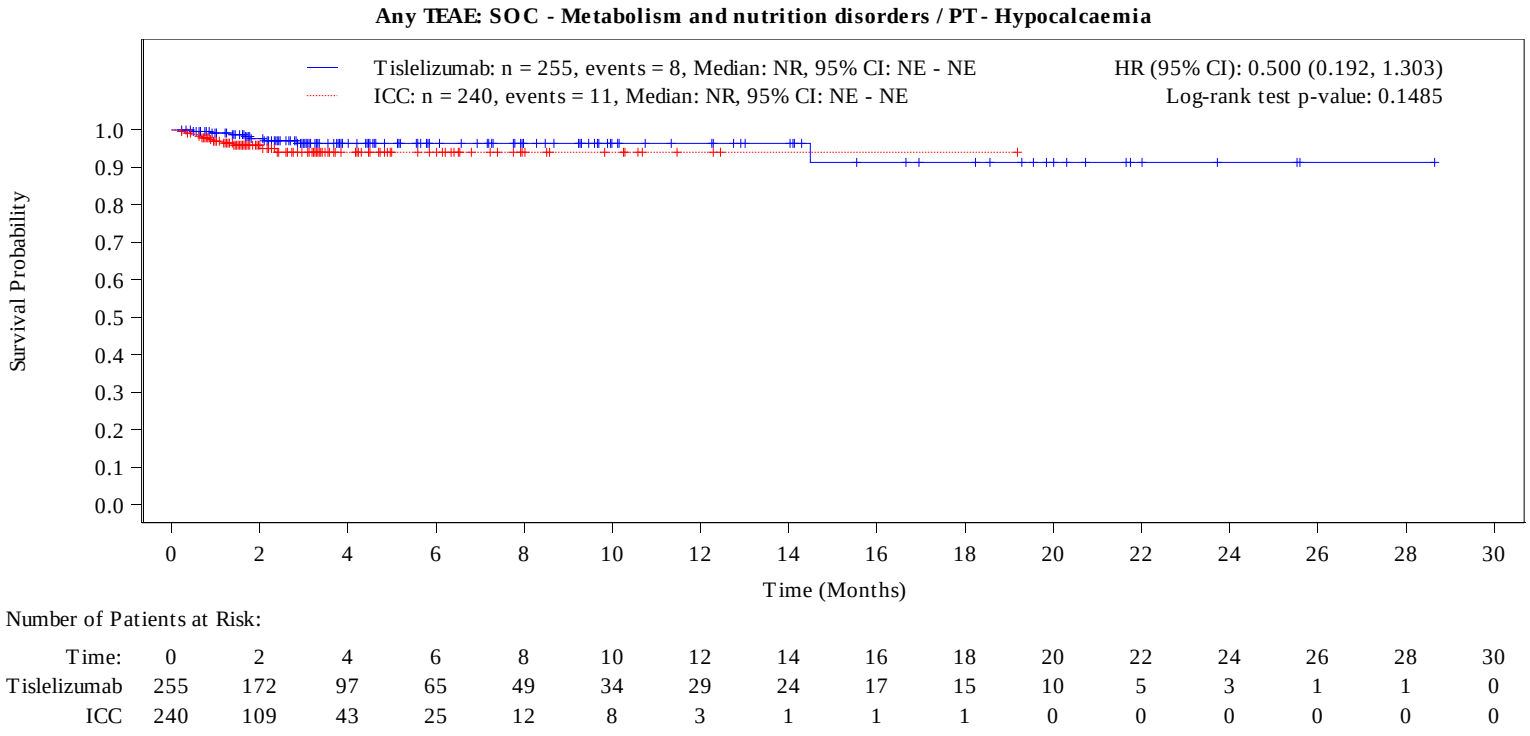
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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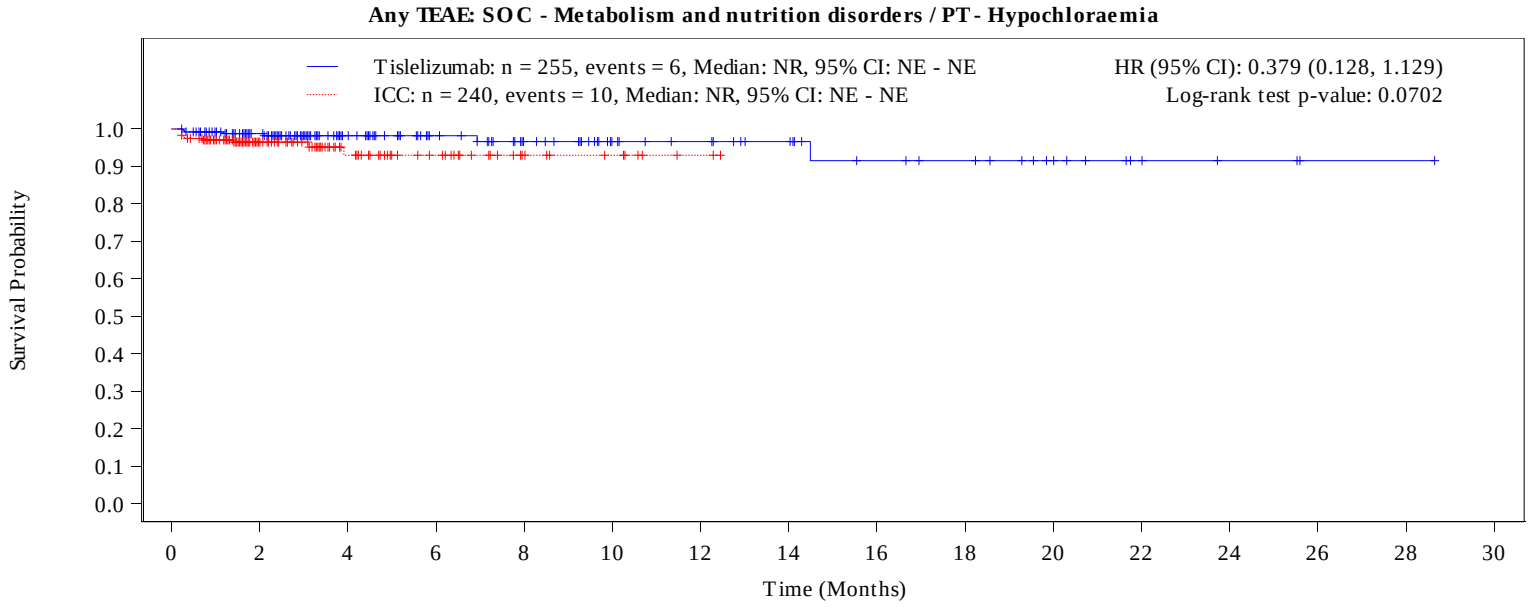

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	174	97	65	48	33	28	23	17	15	10	5	3	1	1	0
ICC	240	110	43	24	11	7	2	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

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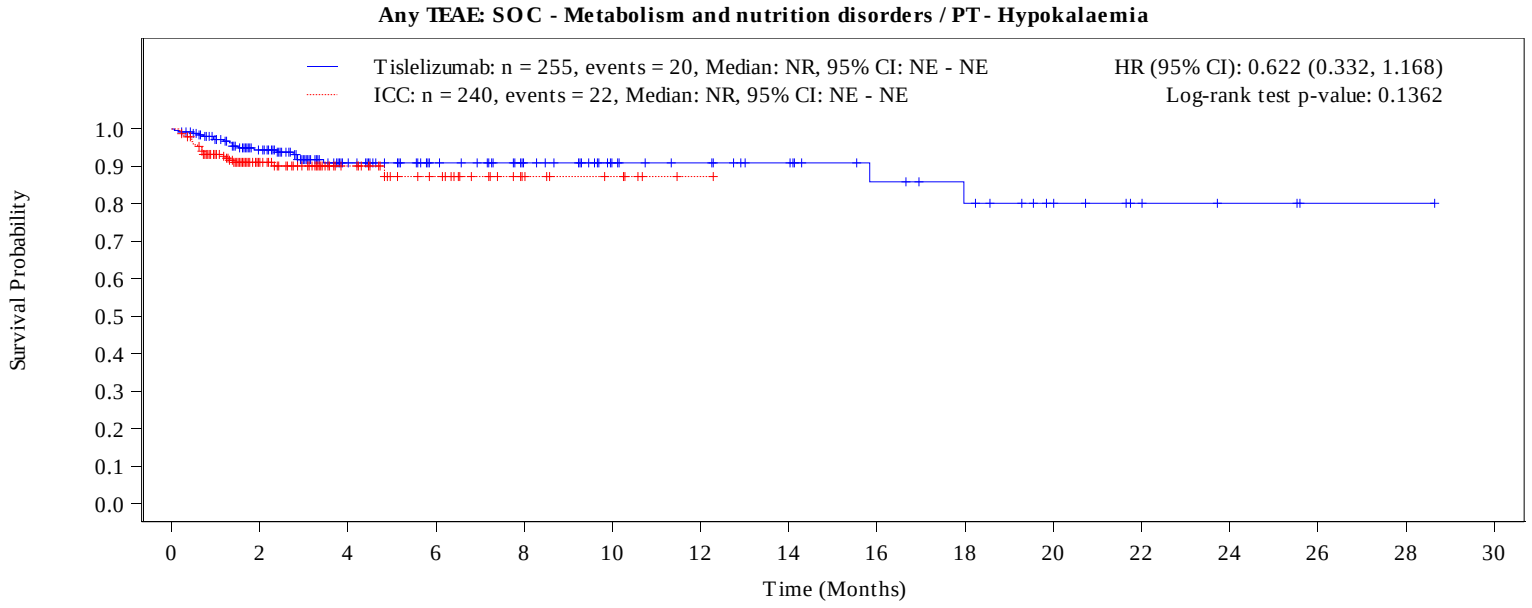
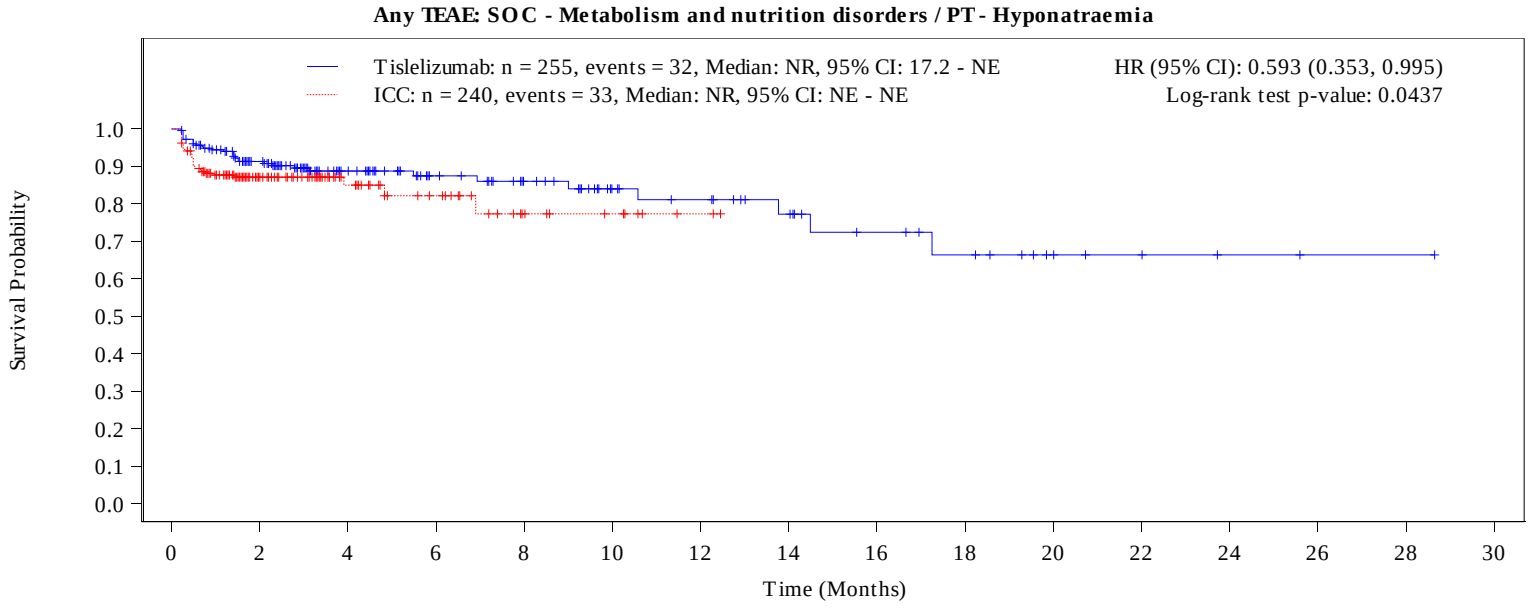


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	169	96	65	49	34	29	24	17	14	9	5	3	1	1	0
ICC	240	106	41	23	10	6	1	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

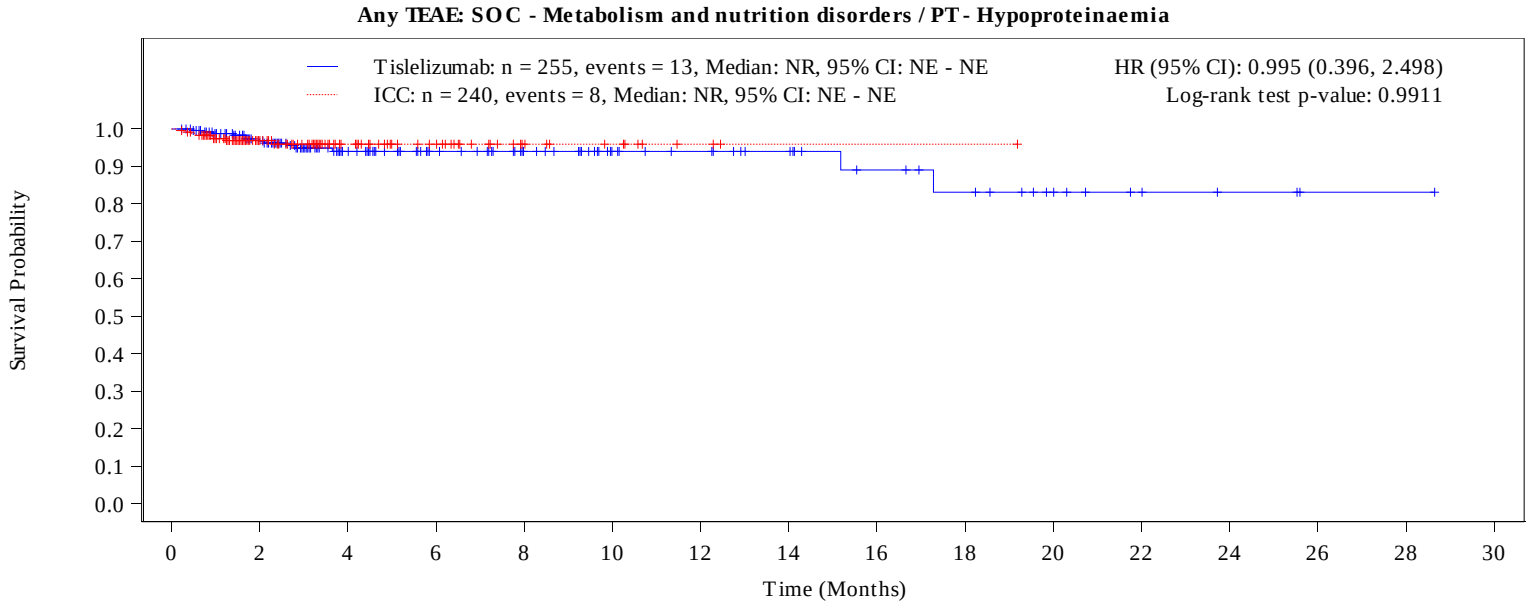


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	166	93	62	47	31	26	20	14	11	6	4	2	1	1	0
ICC	240	103	40	23	11	7	2	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

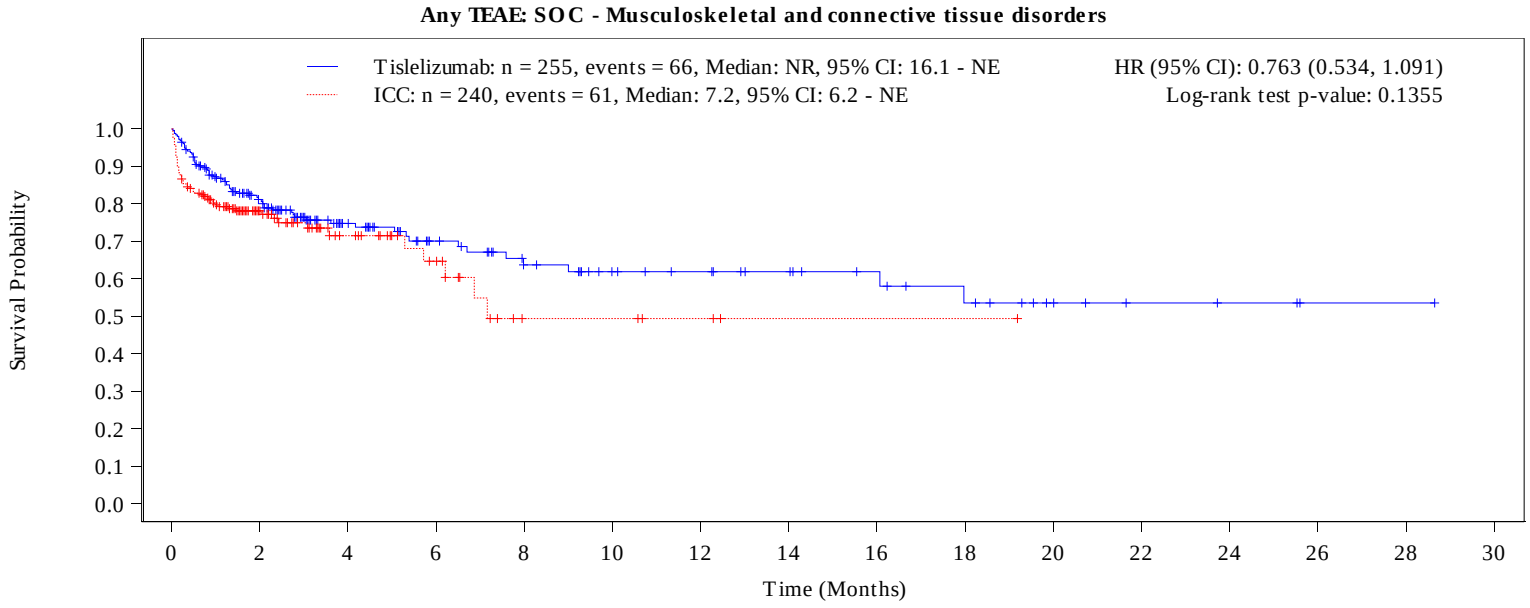


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	174	96	65	49	34	29	24	17	14	9	5	3	1	1	0
ICC	240	112	44	26	12	8	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	145	76	49	36	28	24	20	16	12	7	4	3	1	1	0
ICC	240	86	30	17	5	5	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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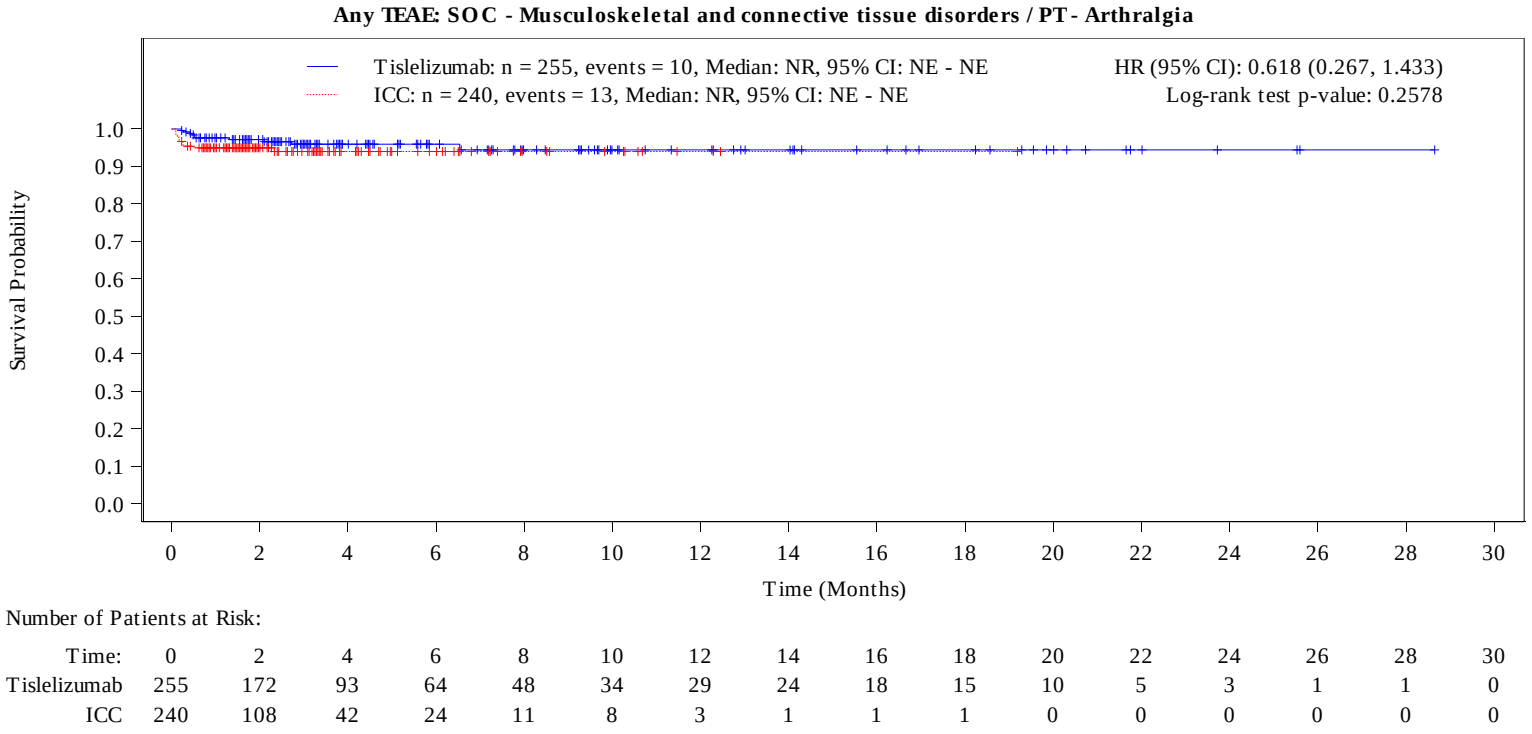
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	172	93	64	48	34	29	24	18	15	10	5	3	1	1	0
ICC	240	108	42	24	11	8	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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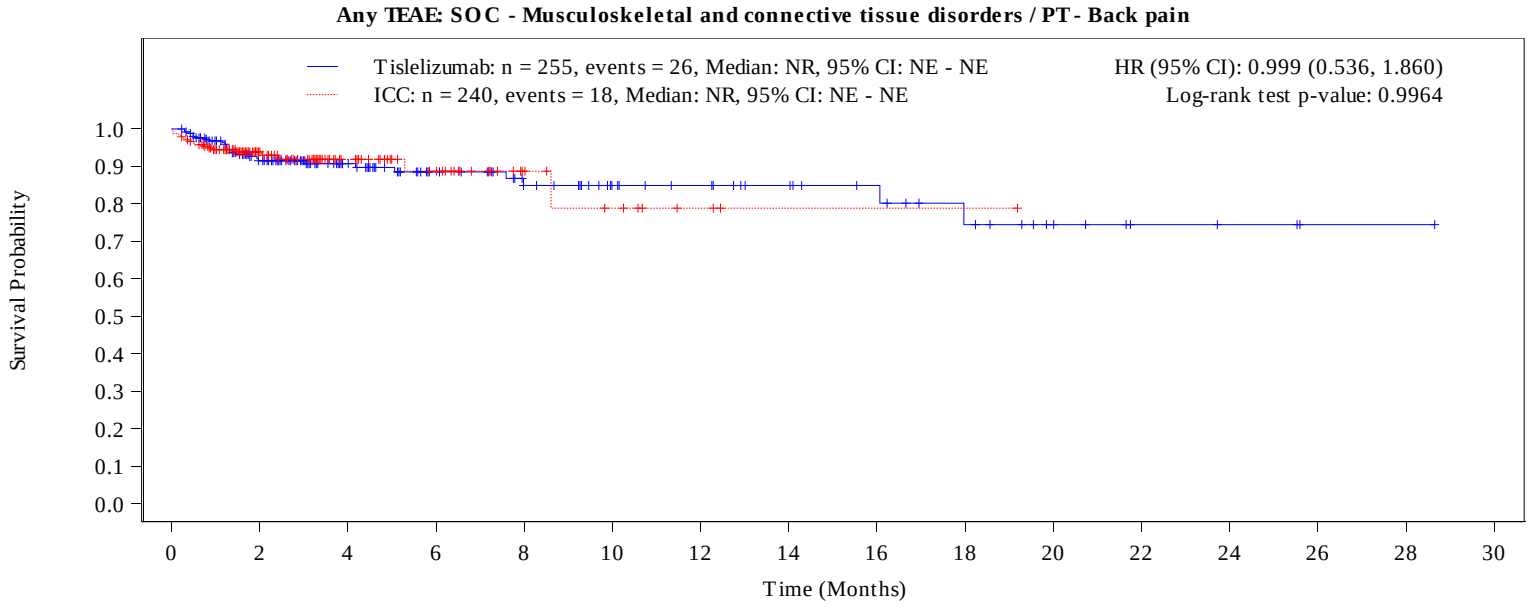
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	160	91	60	44	33	28	23	18	13	8	4	3	1	1	0
ICC	240	106	43	25	11	7	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

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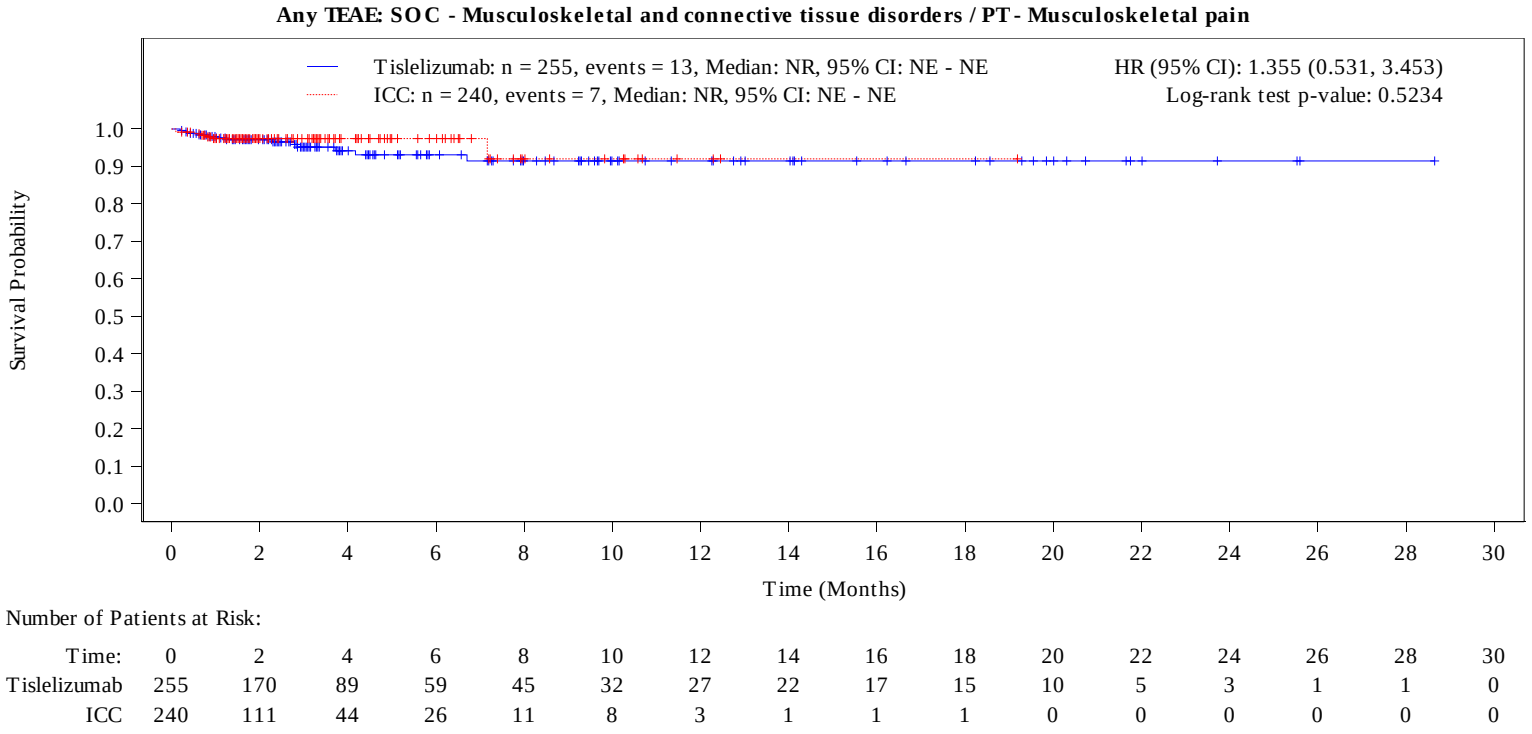
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	170	89	59	45	32	27	22	17	15	10	5	3	1	1	0
ICC	240	111	44	26	11	8	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

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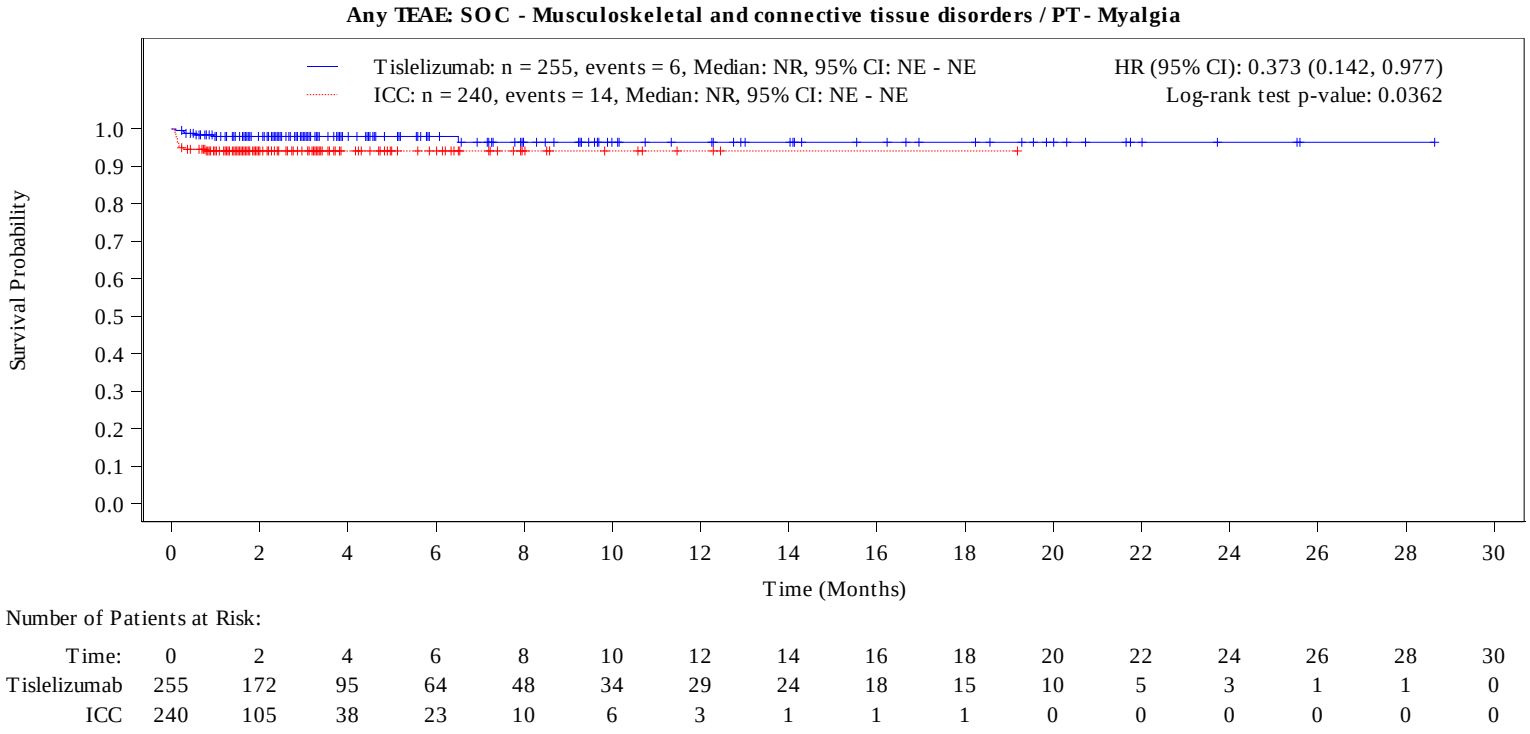

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

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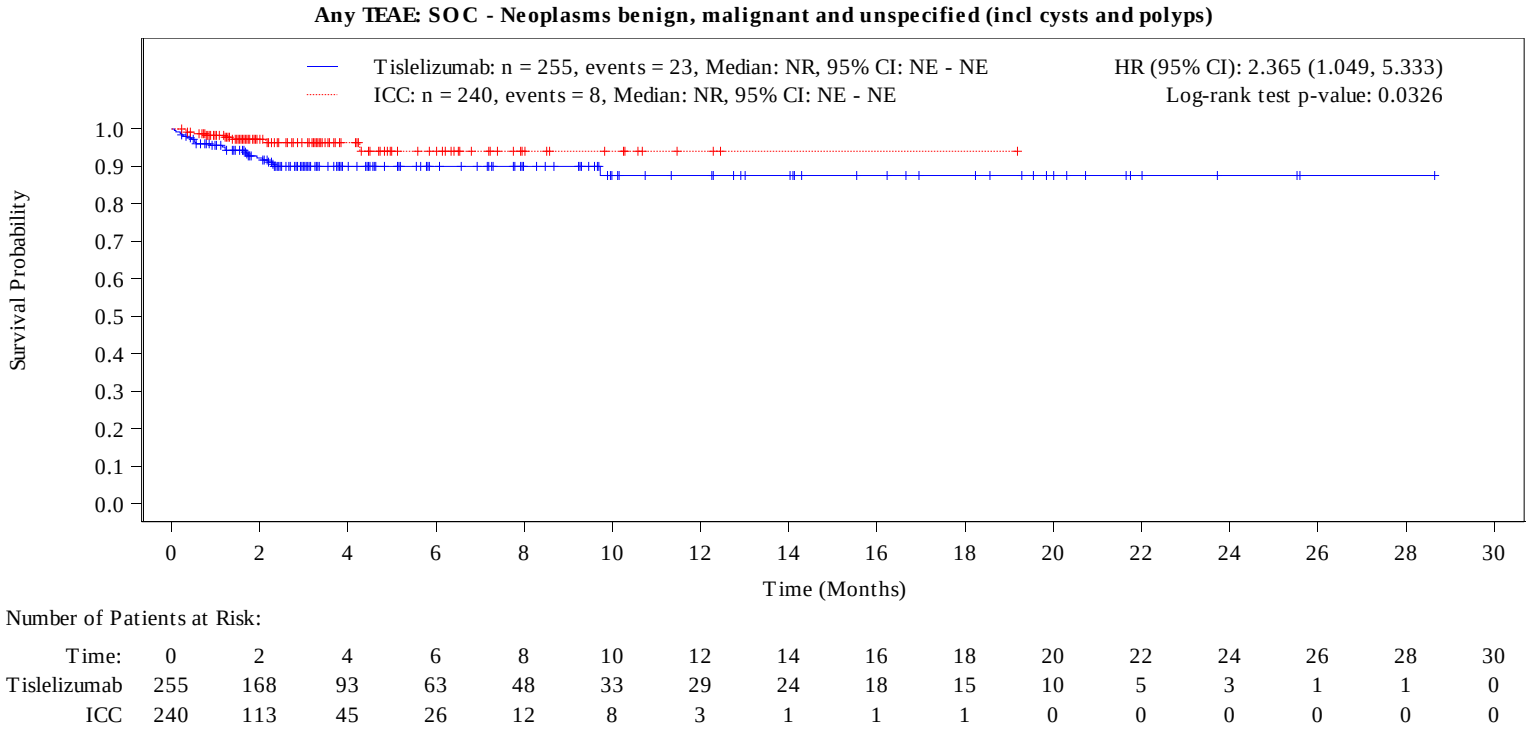

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	168	93	63	48	33	29	24	18	15	10	5	3	1	1	0
ICC	240	113	45	26	12	8	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

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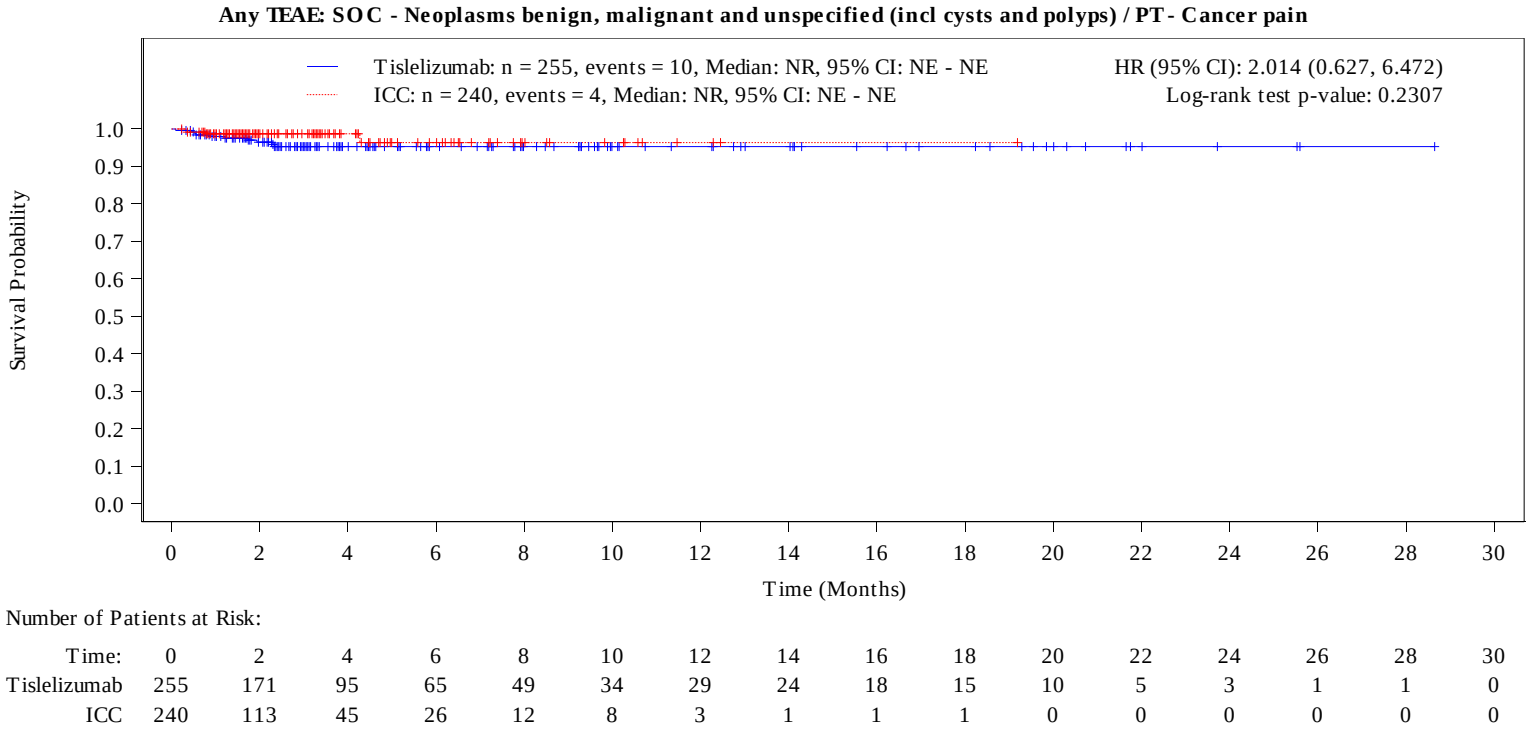

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	171	95	65	49	34	29	24	18	15	10	5	3	1	1	0
ICC	240	113	45	26	12	8	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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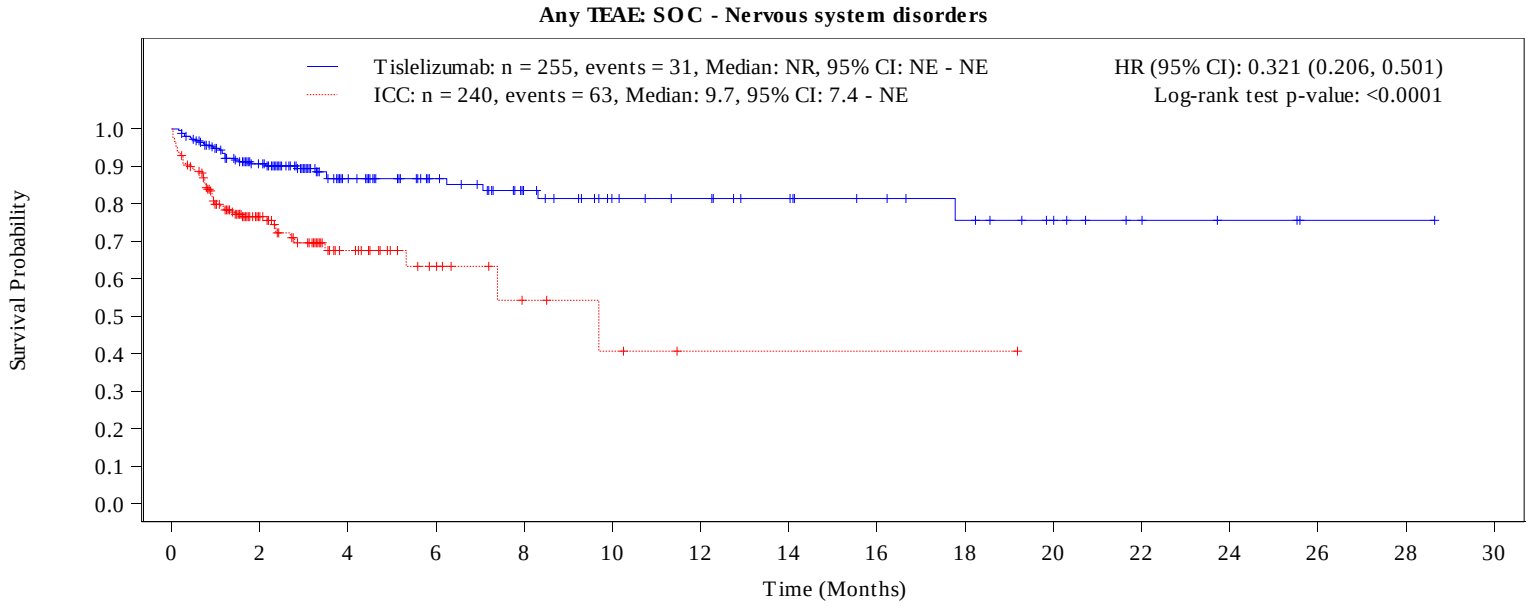
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

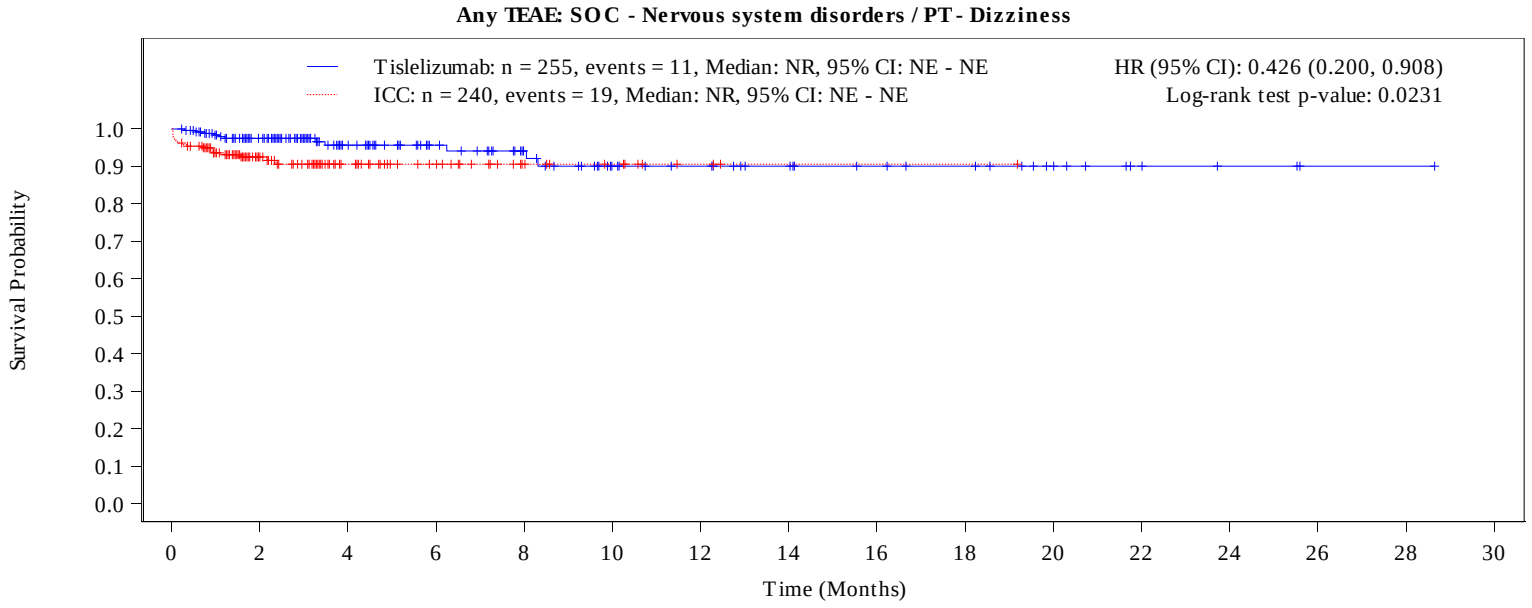


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	162	86	57	40	29	25	21	16	13	9	5	3	1	1	0
ICC	240	81	27	11	5	3	1	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	171	94	63	47	32	27	22	17	15	10	5	3	1	1	0
ICC	240	105	41	24	12	8	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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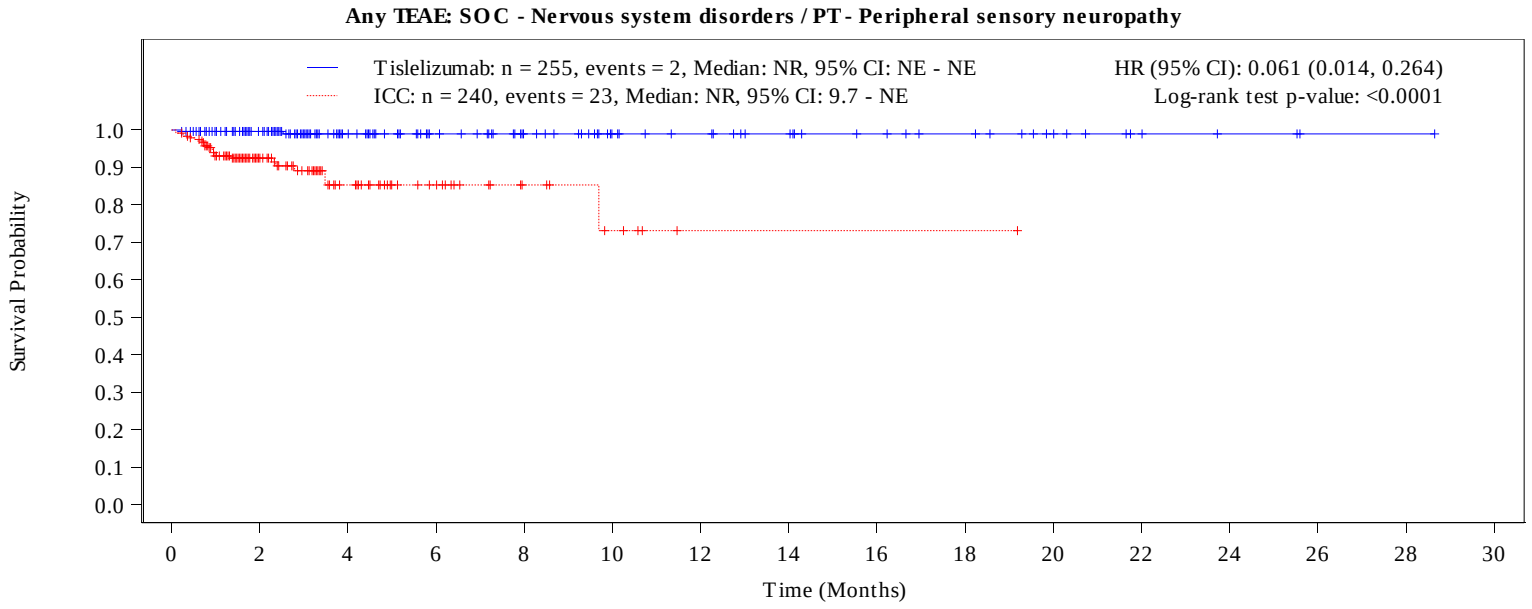
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	174	95	64	48	34	29	24	18	15	10	5	3	1	1	0
ICC	240	101	37	19	9	5	1	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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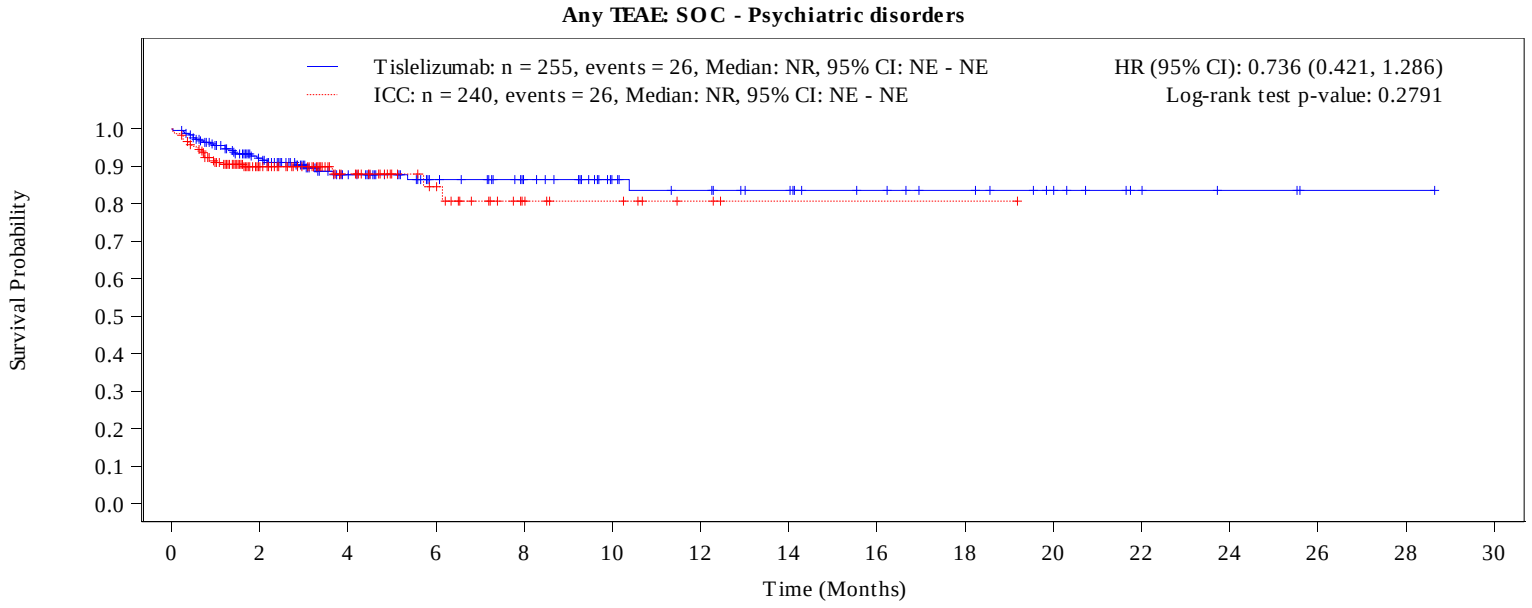
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

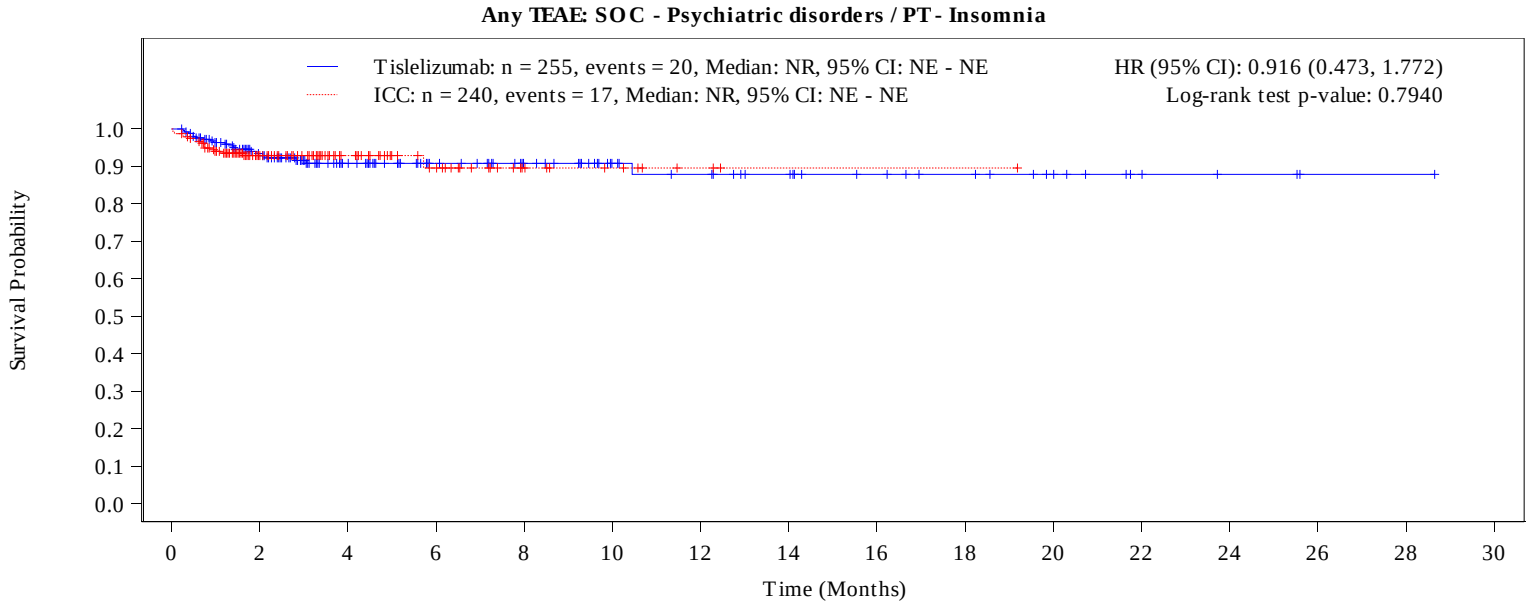


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	161	89	60	47	32	27	23	17	14	10	5	3	1	1	0
ICC	240	103	41	23	10	7	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	162	90	62	48	33	28	23	17	14	10	5	3	1	1	0
ICC	240	106	43	24	11	7	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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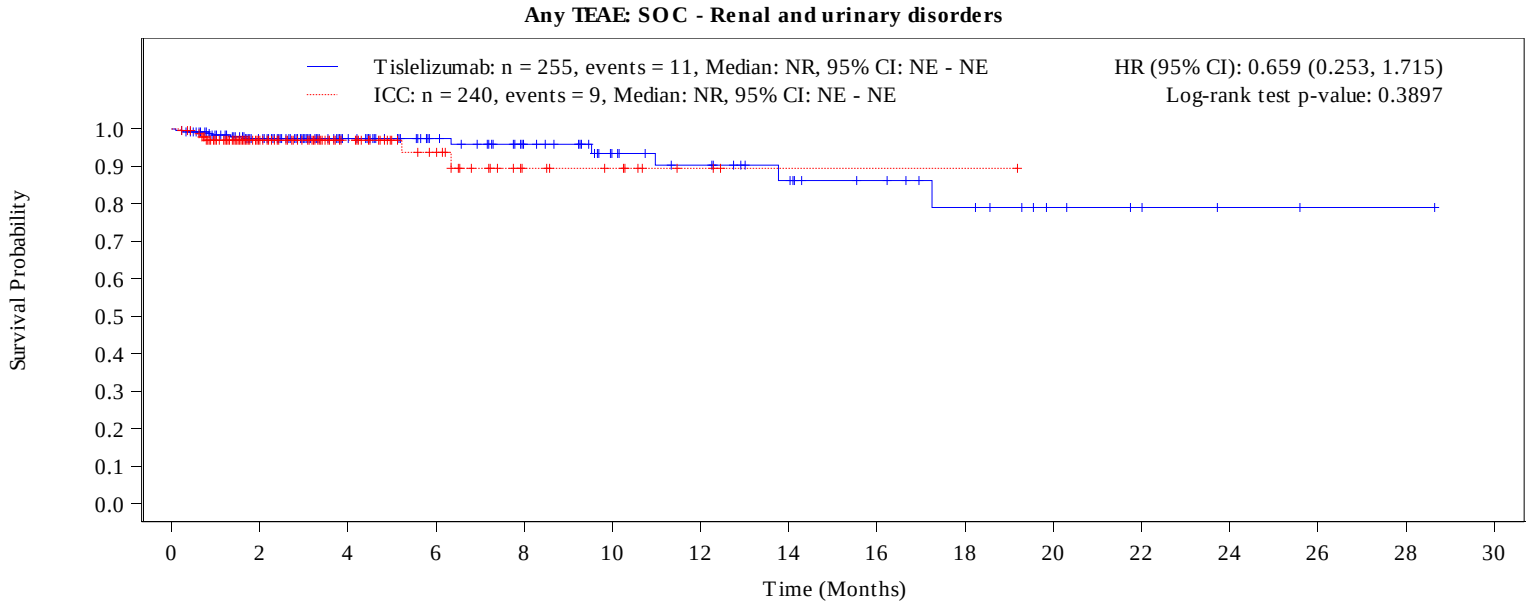
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	170	96	65	48	33	27	21	15	11	6	4	2	1	1	0
ICC	240	111	45	25	11	8	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

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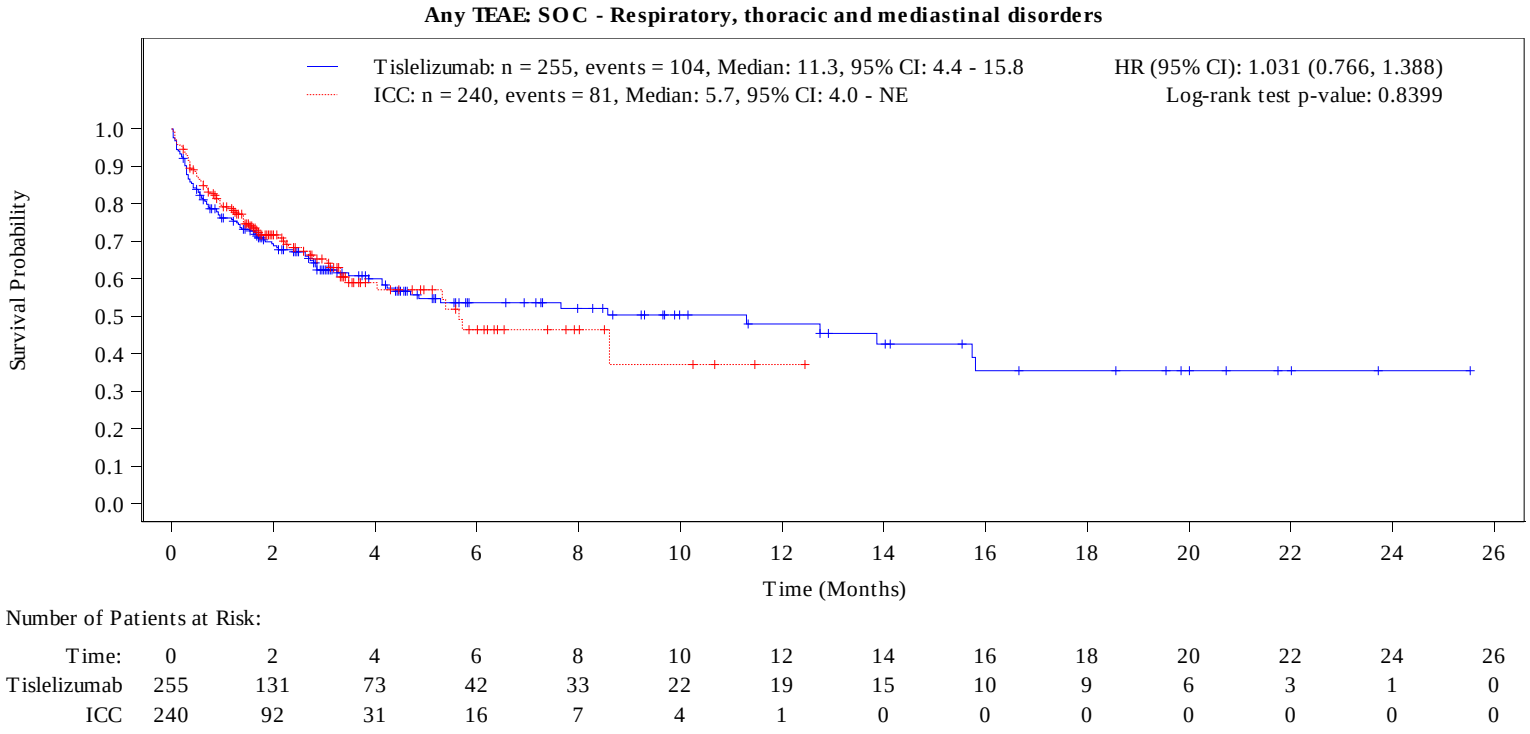
Safety Analysis Set

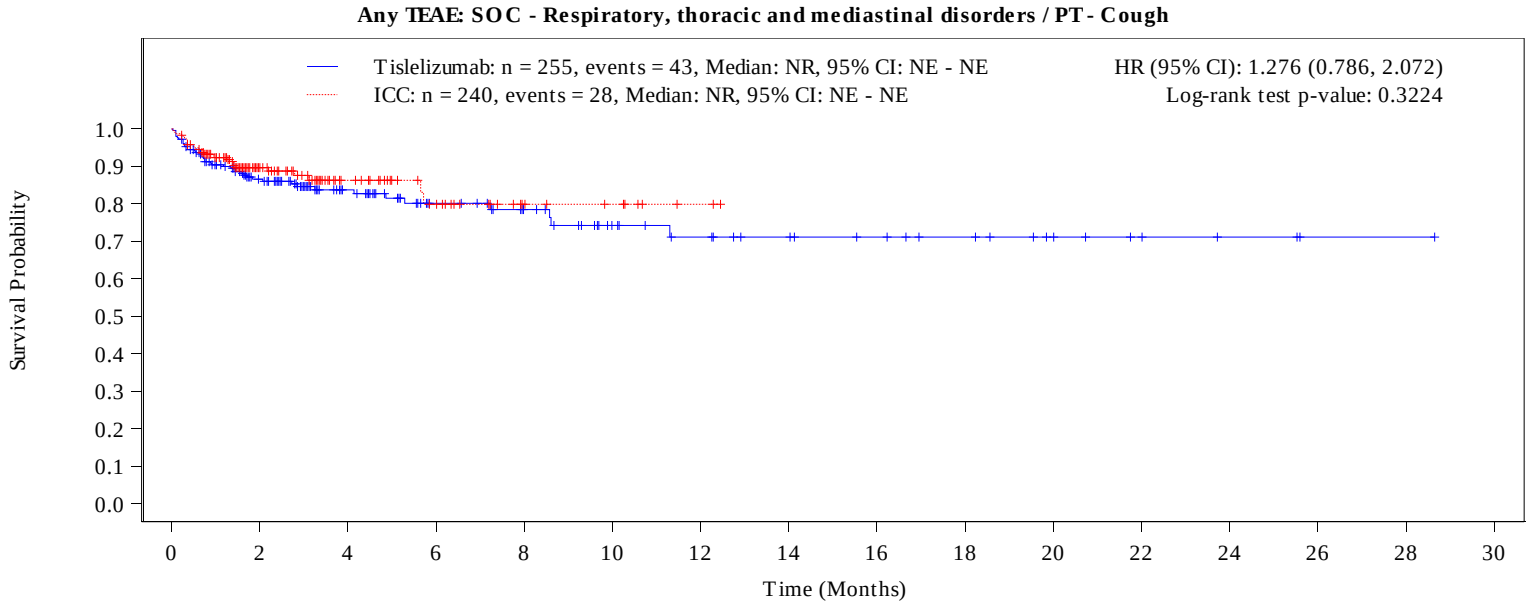


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	255	131	73	42	33	22	19	15	10	9	6	3	1	0
ICC	240	92	31	16	7	4	1	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	150	83	52	40	27	22	18	15	12	8	5	3	1	1	0
ICC	240	108	41	22	10	7	2	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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Figure 14.3.1.2:
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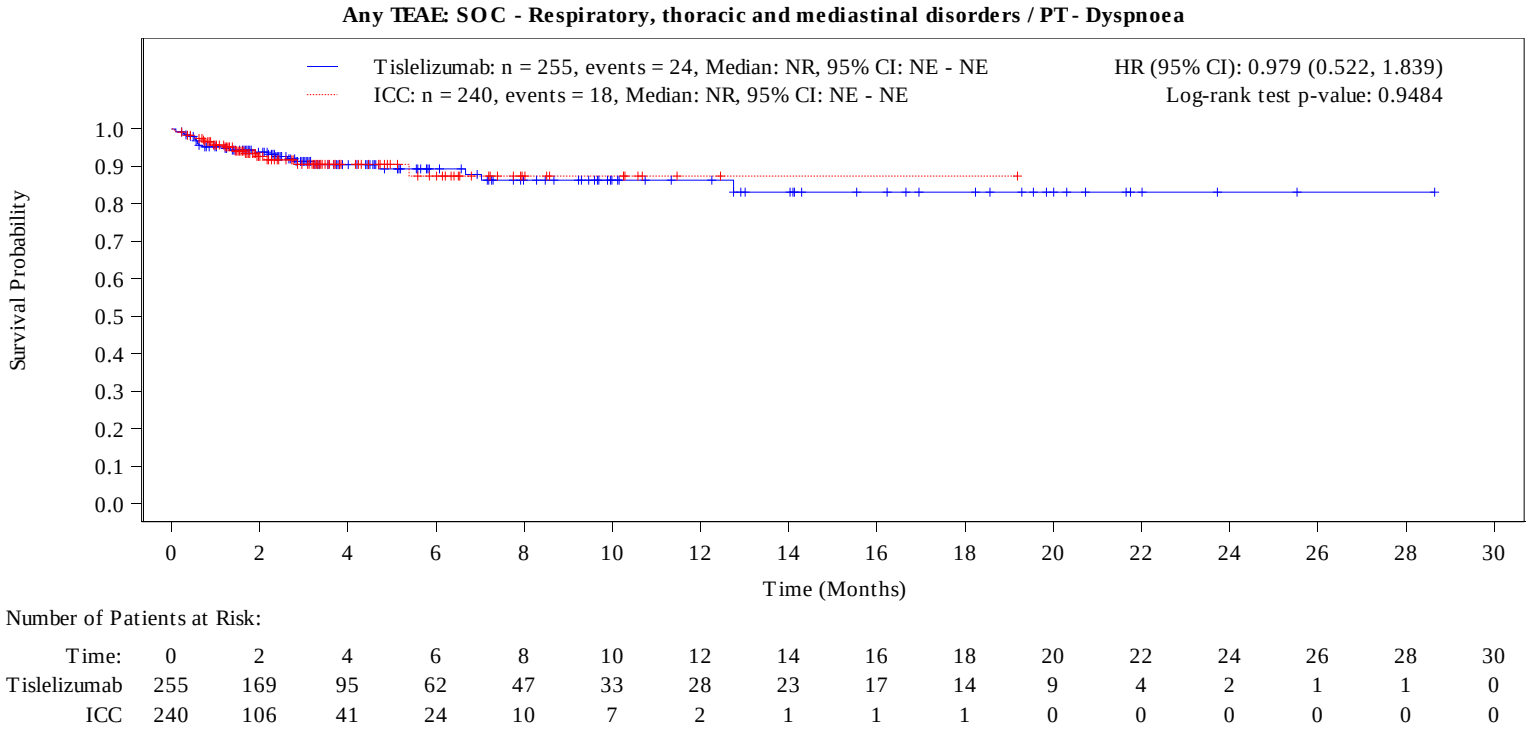
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	169	95	62	47	33	28	23	17	14	9	4	2	1	1	0
ICC	240	106	41	24	10	7	2	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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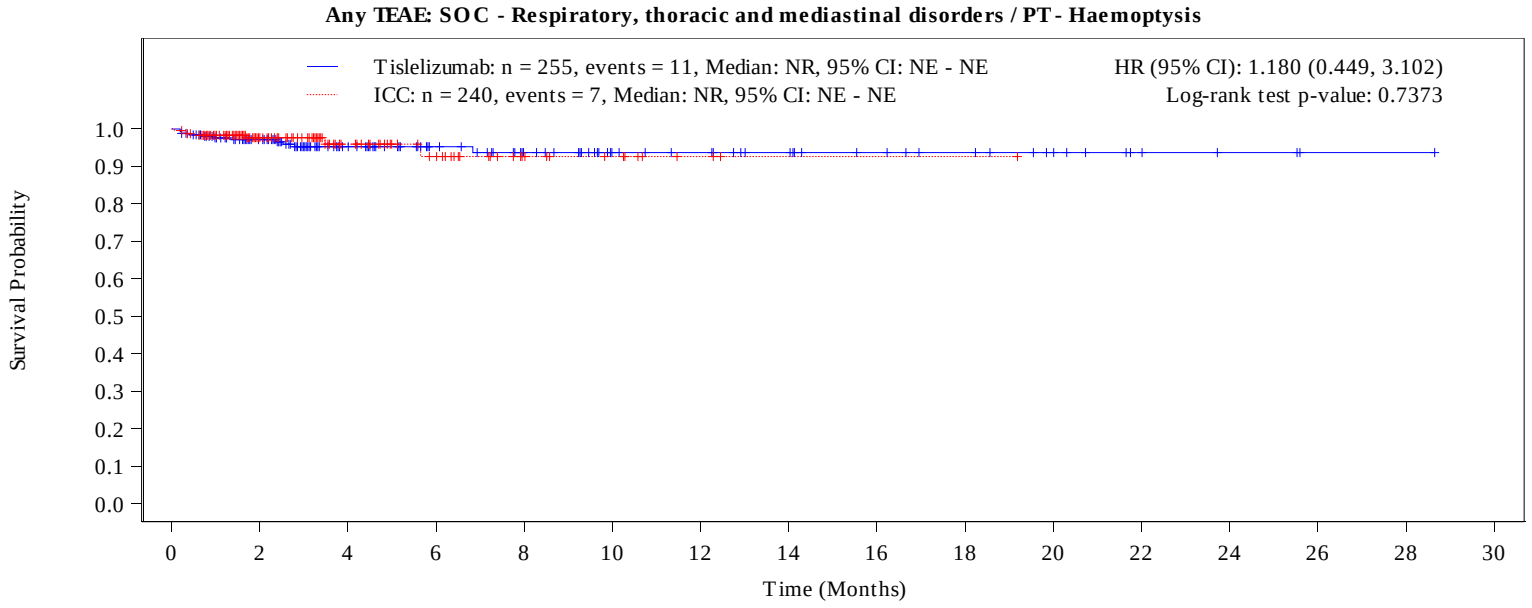
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	173	95	63	47	32	28	23	17	14	10	5	3	1	1	0
ICC	240	112	44	25	12	8	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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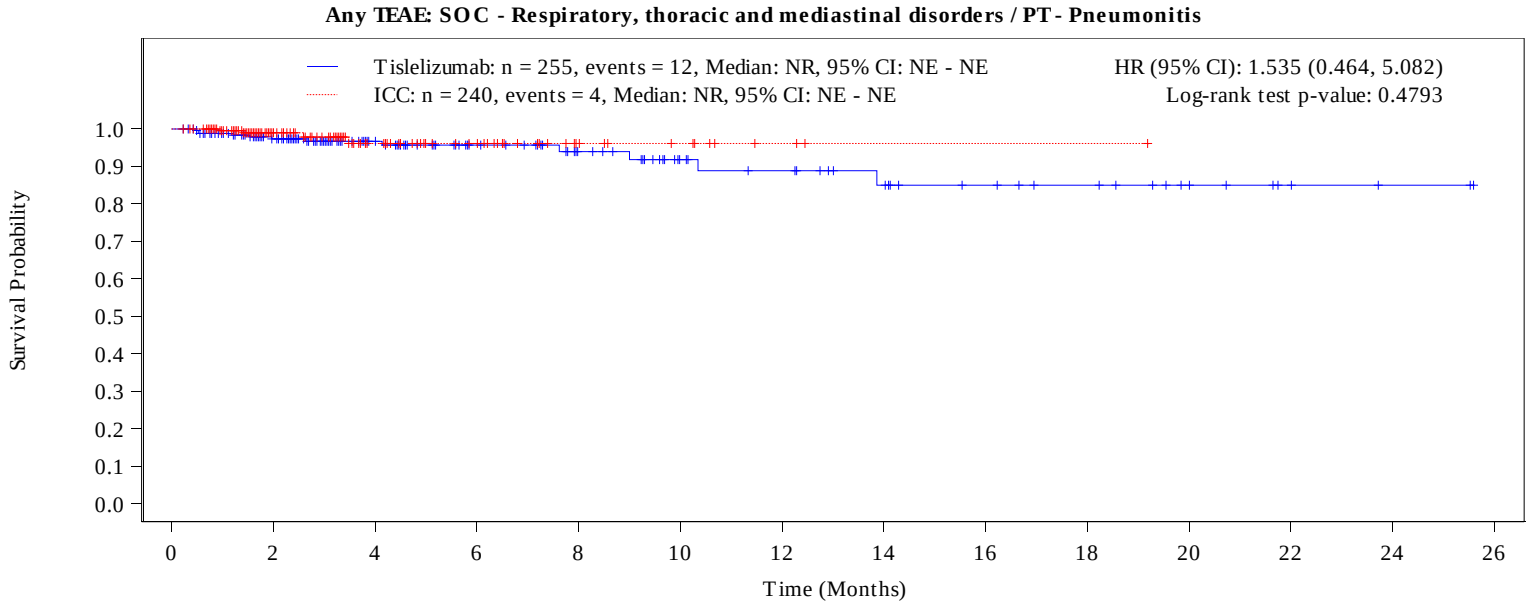
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	255	174	97	64	48	33	28	22	16	13	8	4	2	0
ICC	240	112	44	26	12	8	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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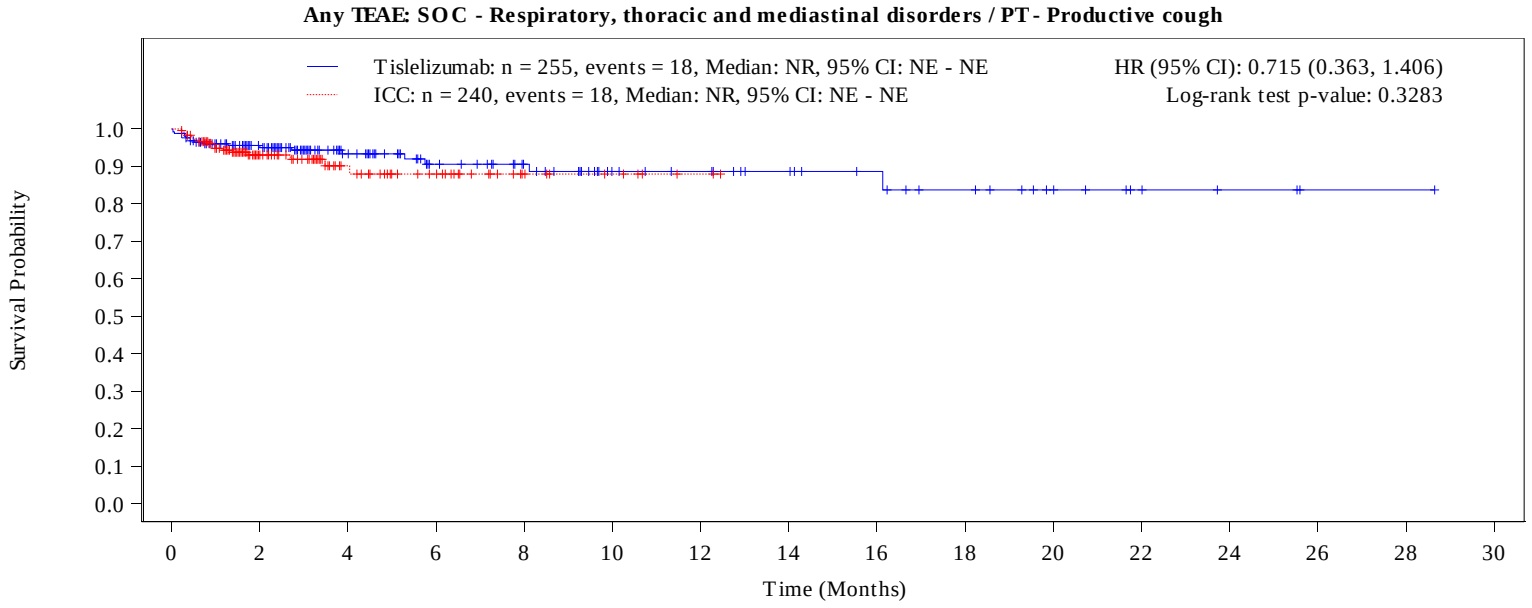
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	168	92	60	47	32	28	23	18	14	9	5	3	1	1	0
ICC	240	107	41	24	10	6	2	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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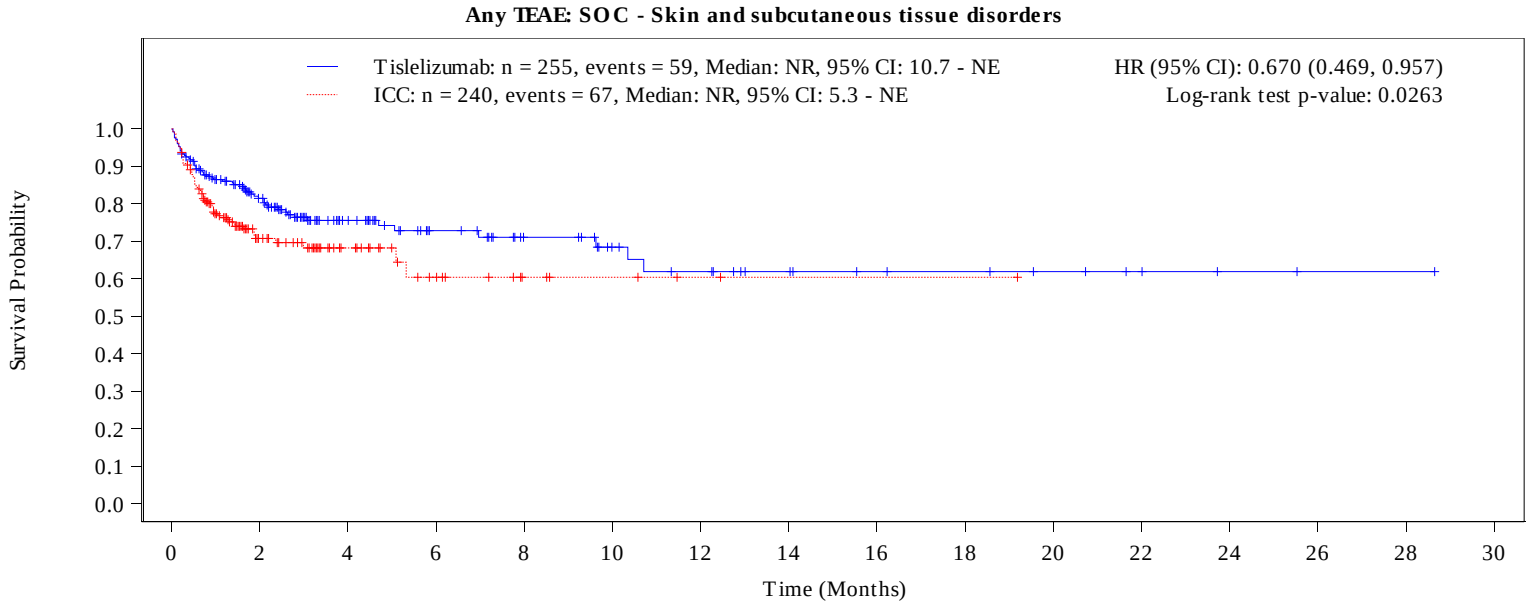
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	140	68	43	30	22	17	12	9	8	6	4	2	1	1	0
ICC	240	72	26	13	6	4	2	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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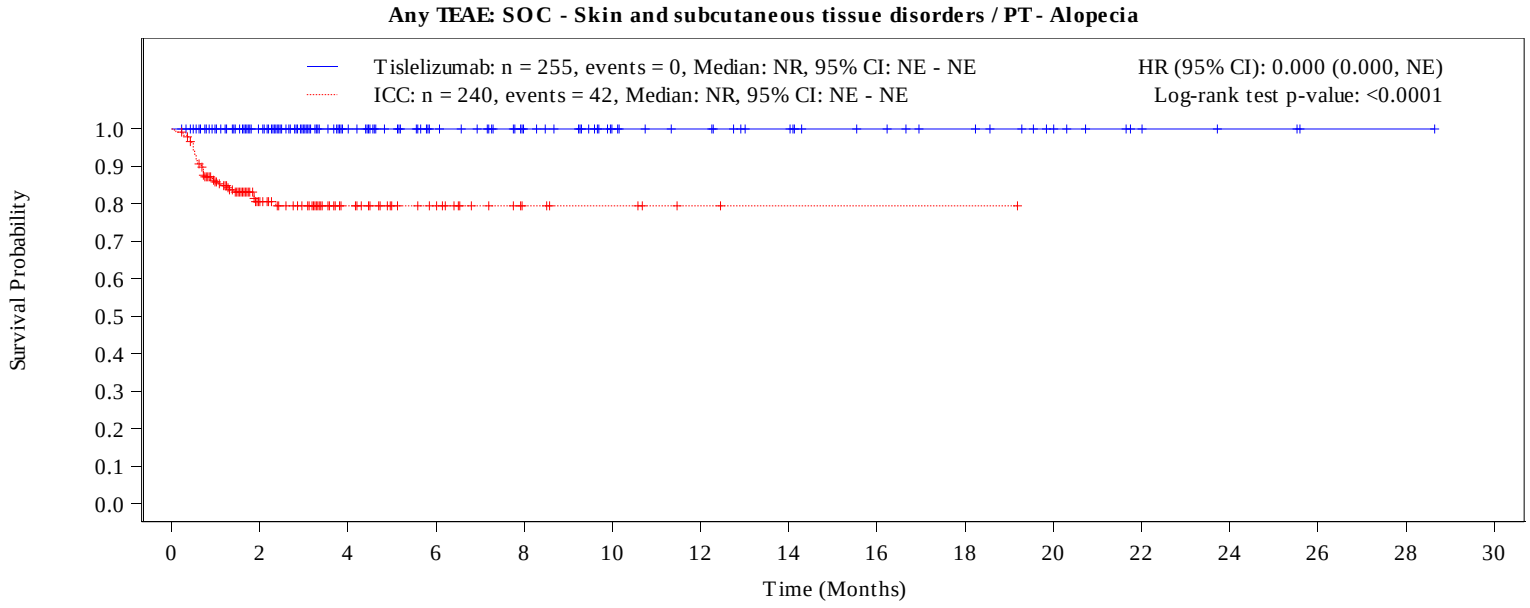
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	175	97	65	49	34	29	24	18	15	10	5	3	1	1	0
ICC	240	83	31	18	7	5	2	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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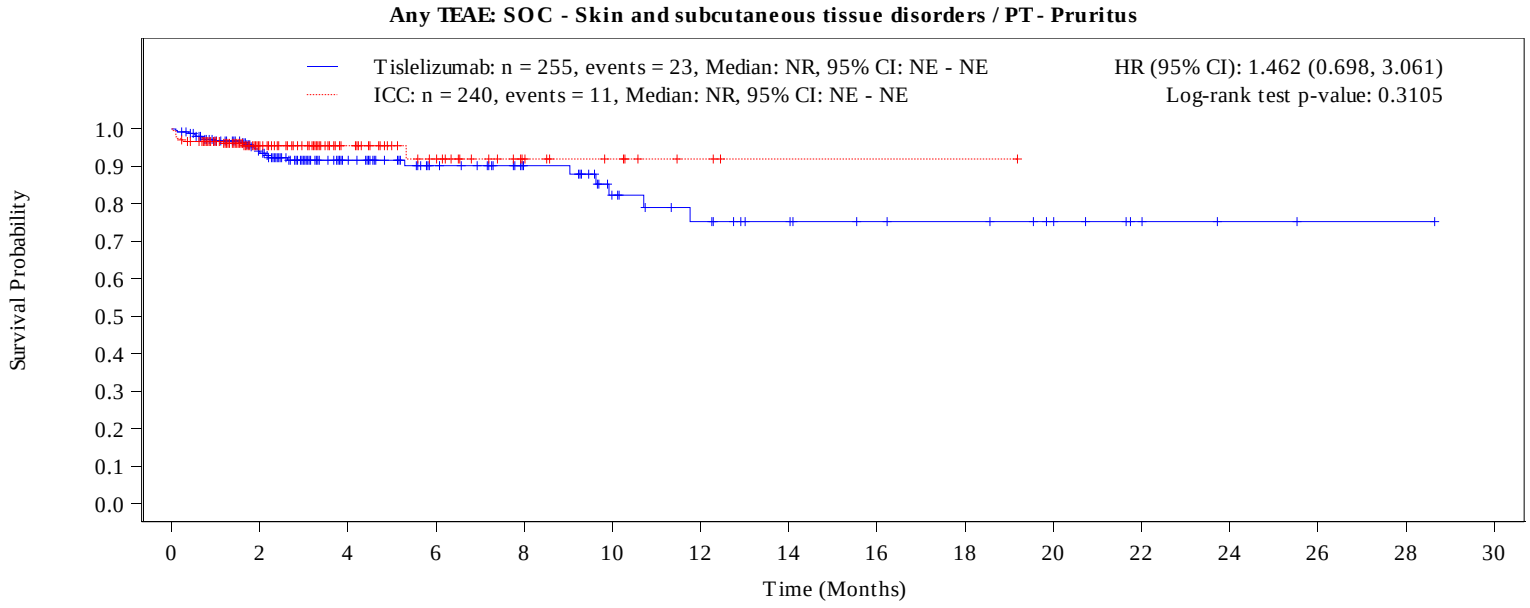
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	162	86	55	40	27	20	15	12	11	8	4	2	1	1	0
ICC	240	105	41	23	11	7	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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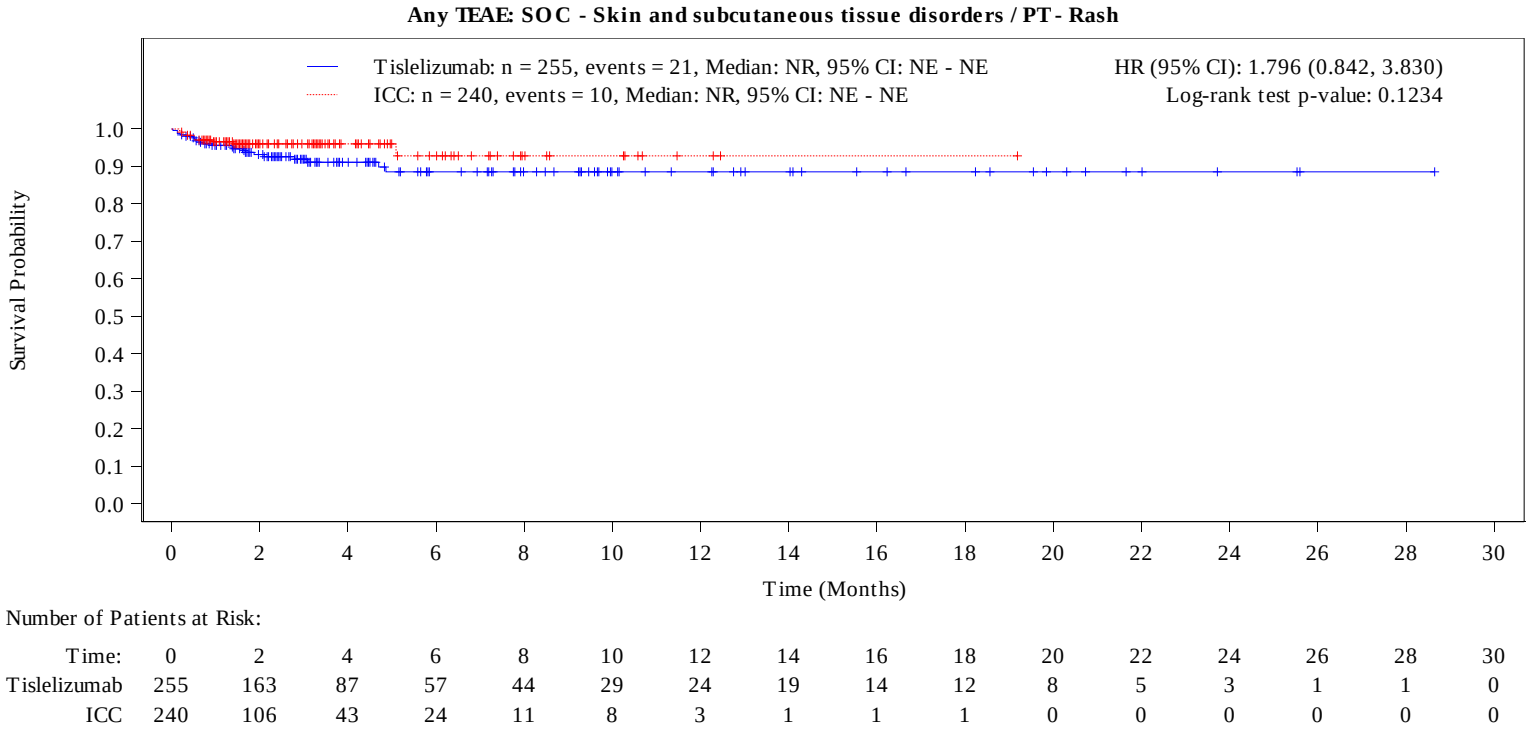

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	163	87	57	44	29	24	19	14	12	8	5	3	1	1	0
ICC	240	106	43	24	11	8	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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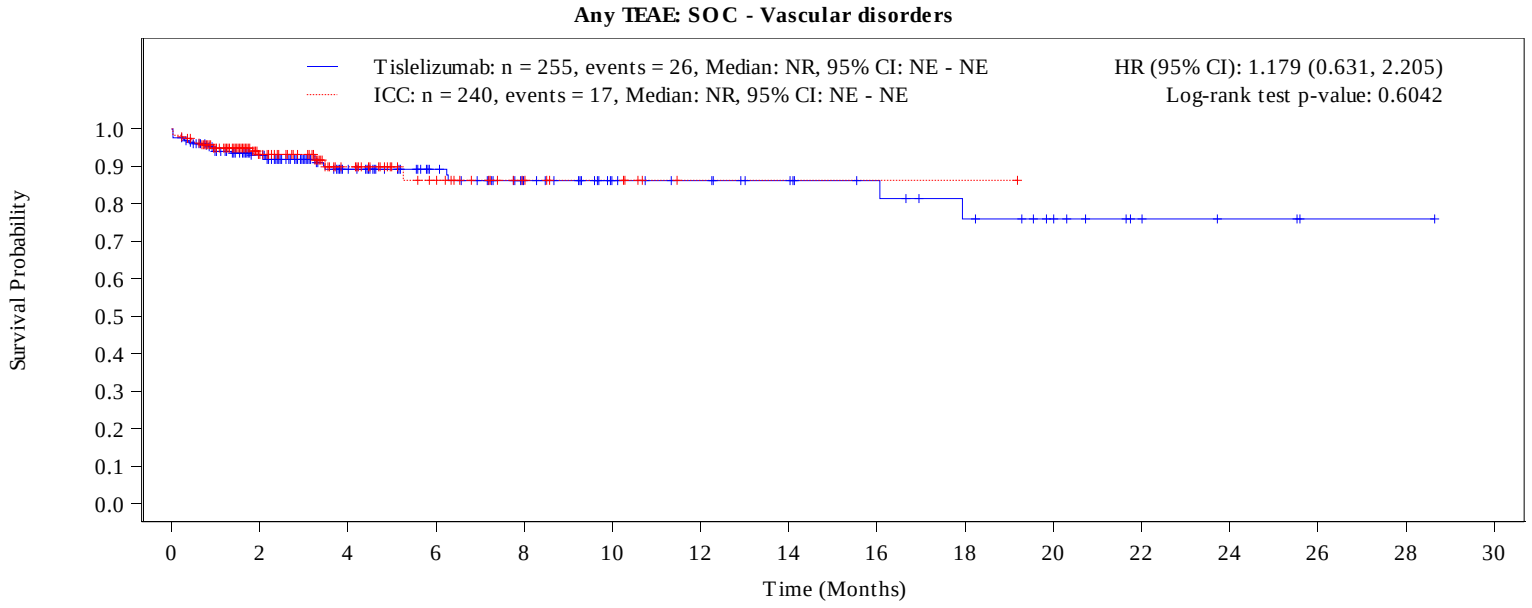

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	166	92	60	43	30	26	22	18	14	10	5	3	1	1	0
ICC	240	102	40	20	9	6	1	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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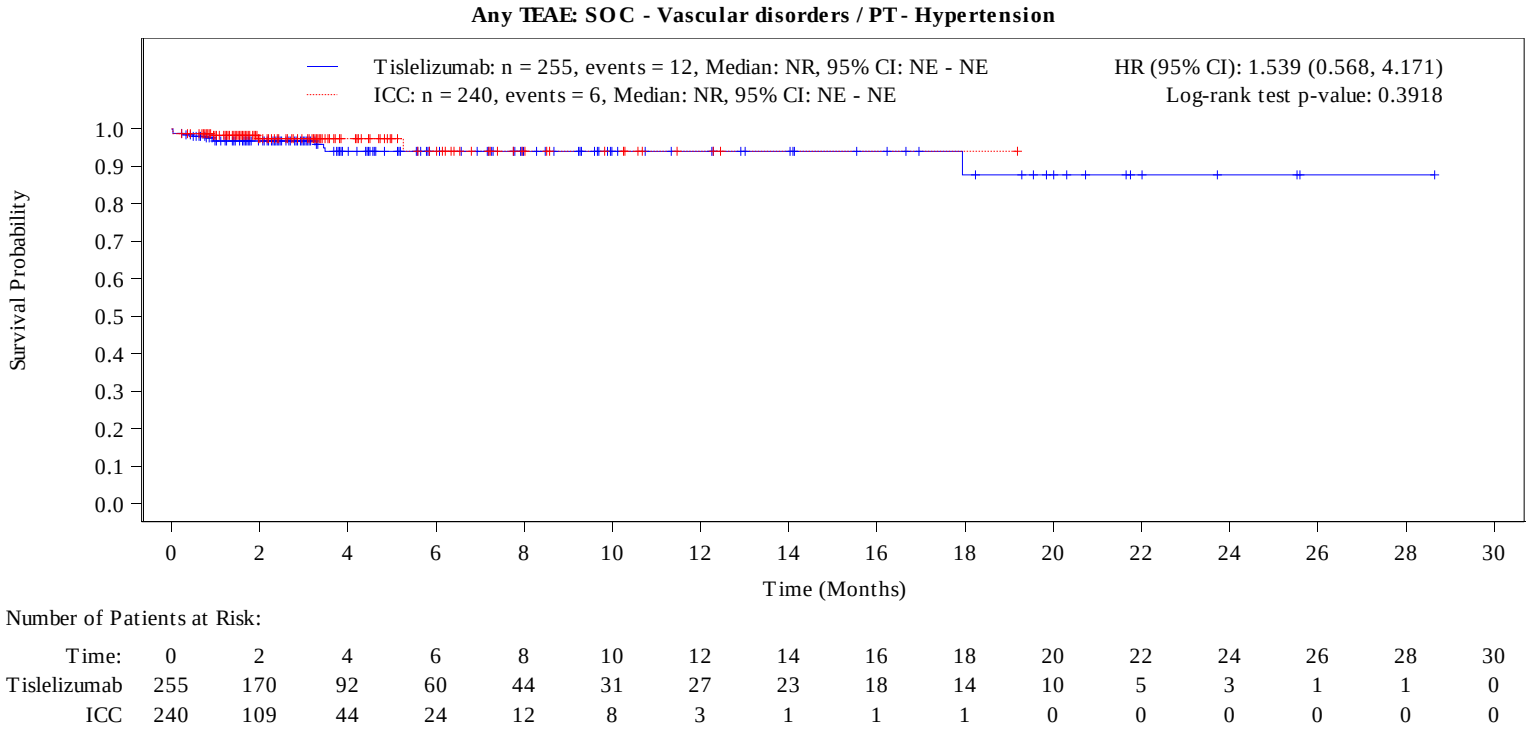
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

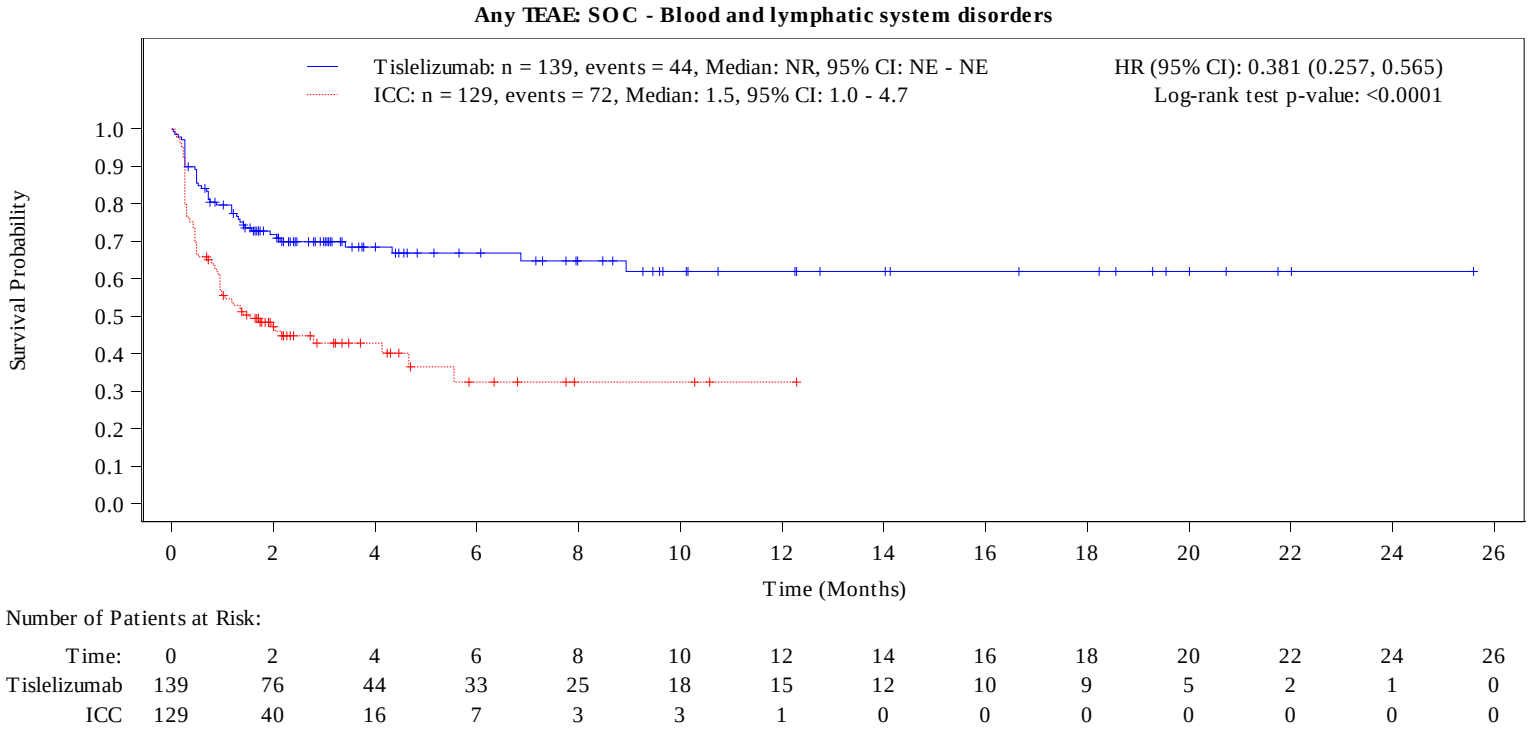


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	170	92	60	44	31	27	23	18	14	10	5	3	1	1	0
ICC	240	109	44	24	12	8	3	1	1	1	0	0	0	0	0	0

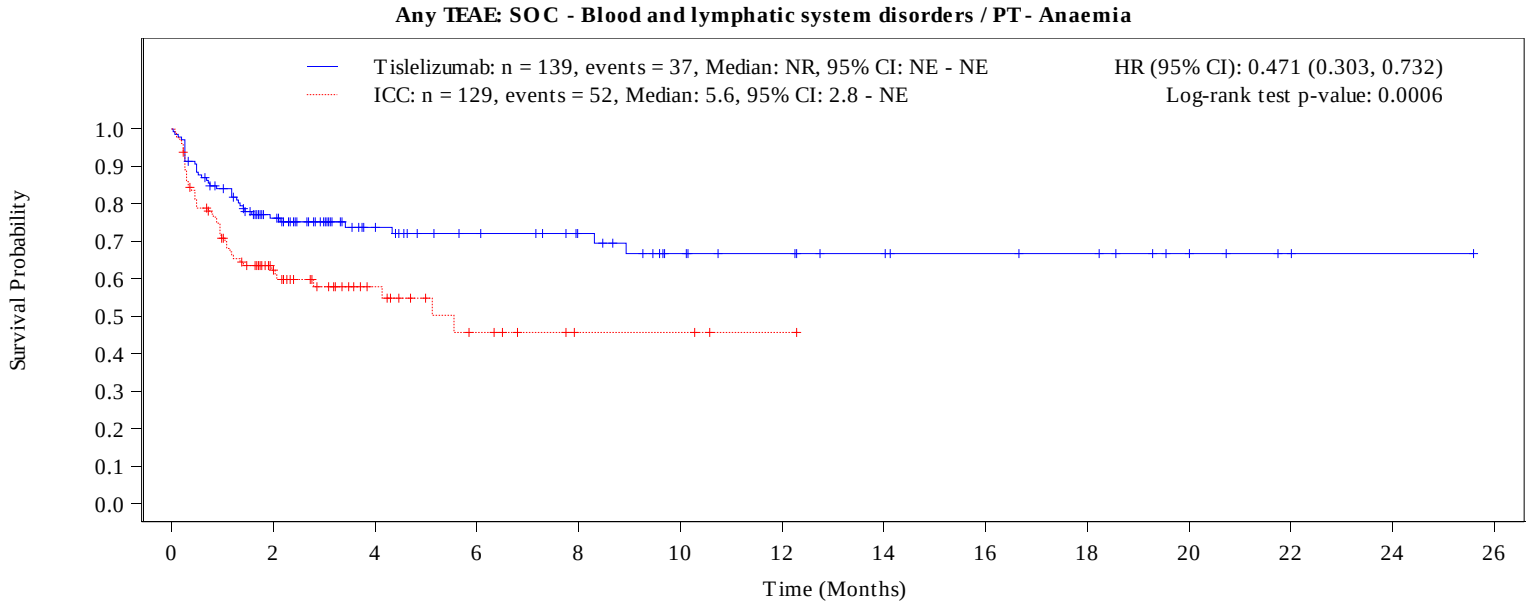
Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-km-aesocpt-safety-fa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-b-km-aesocpt-safetys-fa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

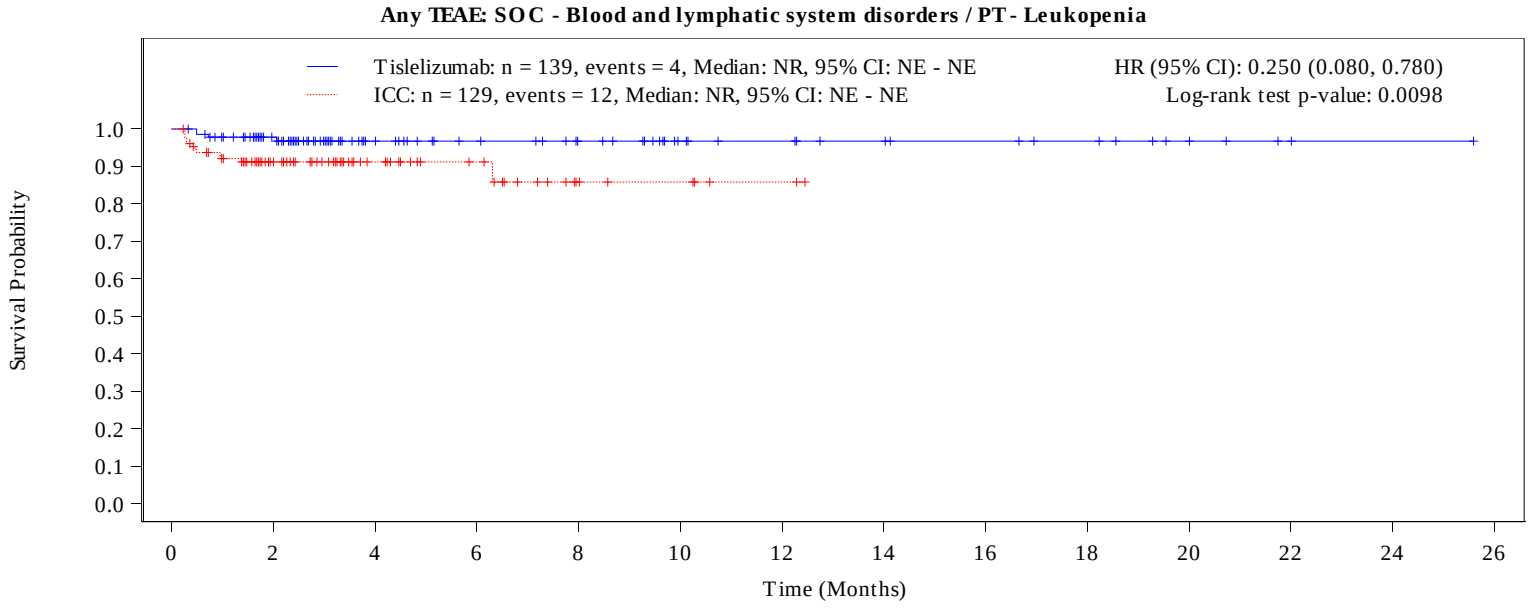


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	80	46	35	28	19	16	13	10	9	5	2	1	0
ICC	129	51	19	8	3	3	1	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-b-km-aesocpt-safetys-fa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

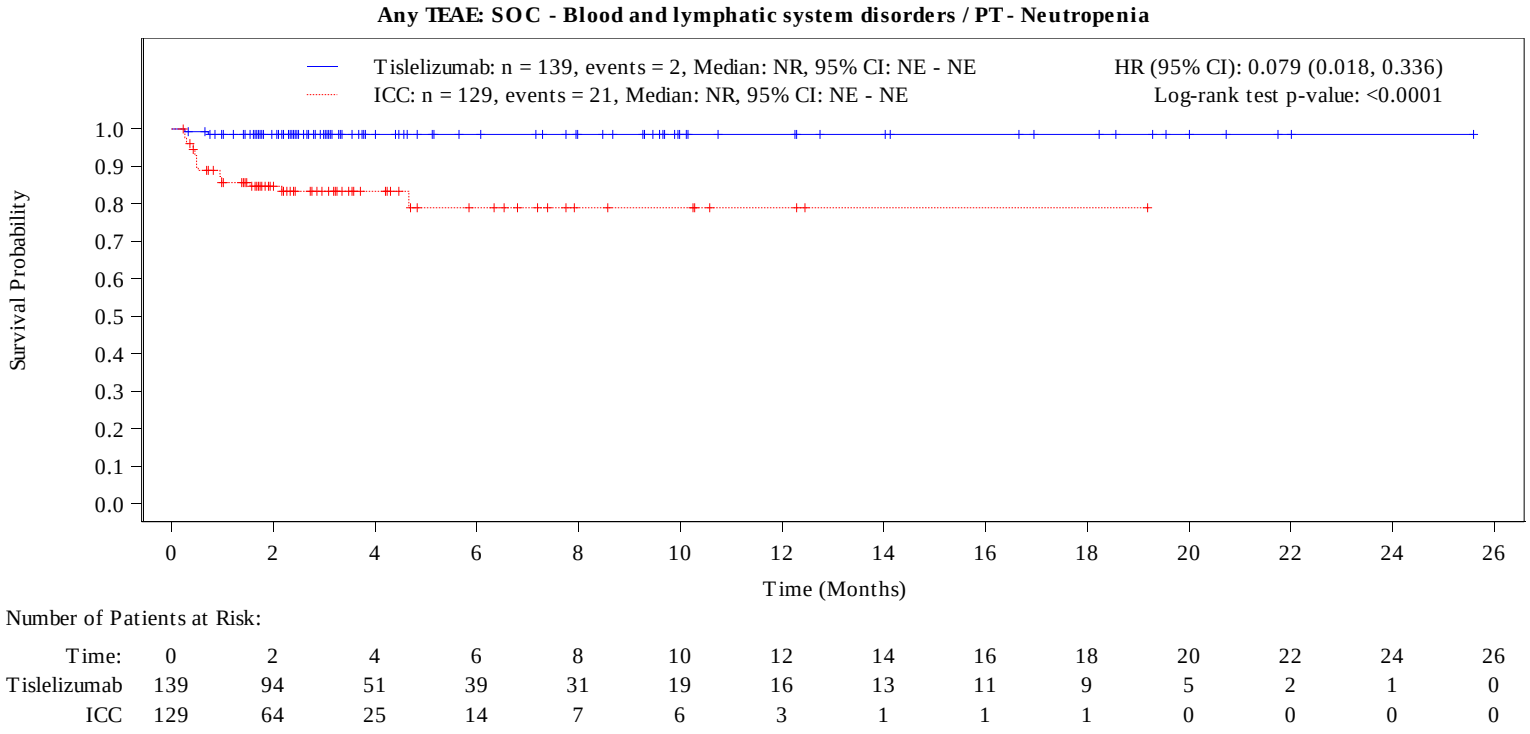


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	92	50	38	30	19	16	13	11	9	5	2	1	0
ICC	129	71	30	18	7	5	2	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-b-km-aesocpt-safetys-fa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	94	51	39	31	19	16	13	11	9	5	2	1	0
ICC	129	64	25	14	7	6	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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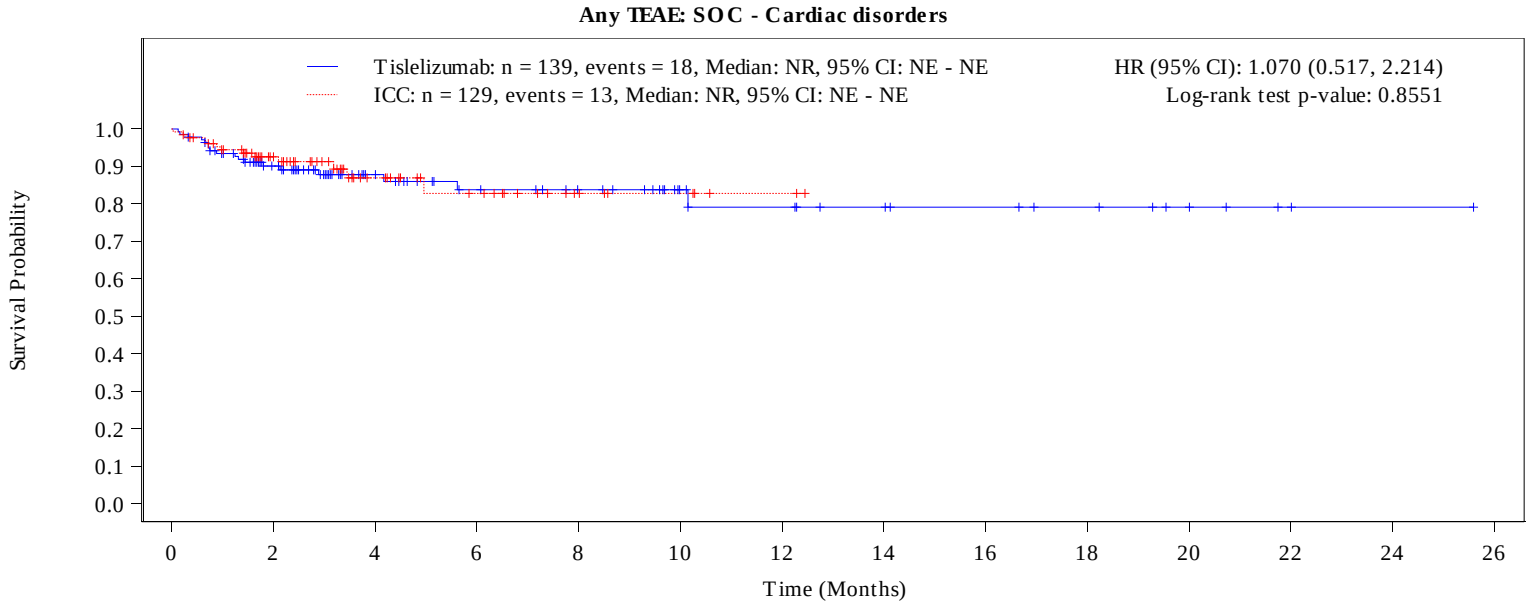
Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	88	49	37	30	19	16	13	10	8	5	2	1	0
ICC	129	73	30	17	8	5	2	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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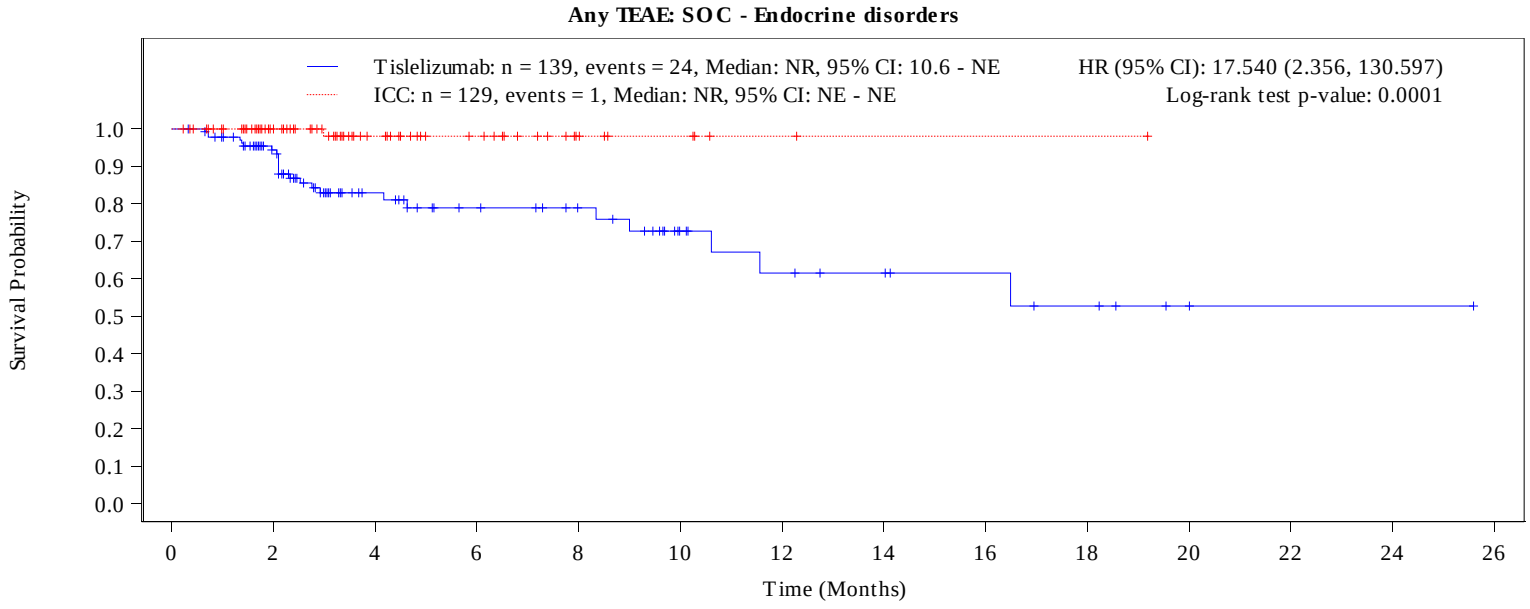
Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	89	44	31	26	15	11	9	7	5	2	1	1	0
ICC	129	75	32	18	8	5	2	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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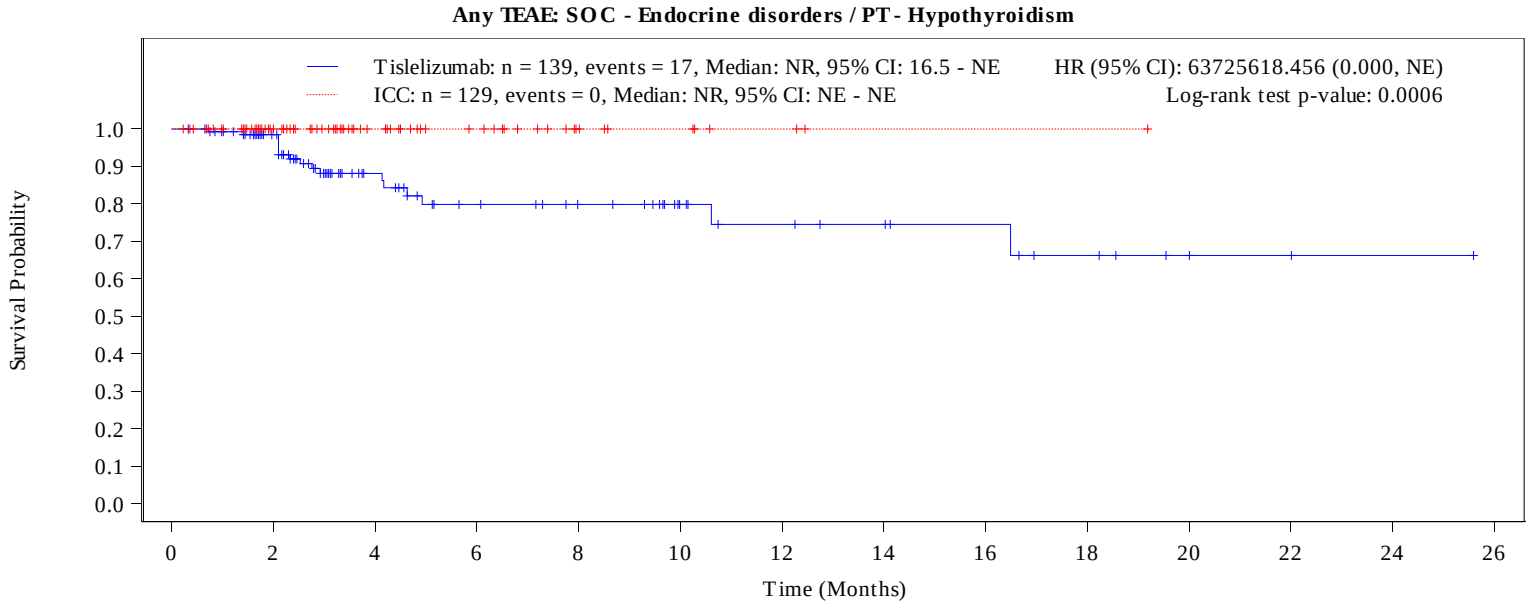
Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	93	46	31	26	17	13	11	9	6	3	2	1	0
ICC	129	75	33	19	9	6	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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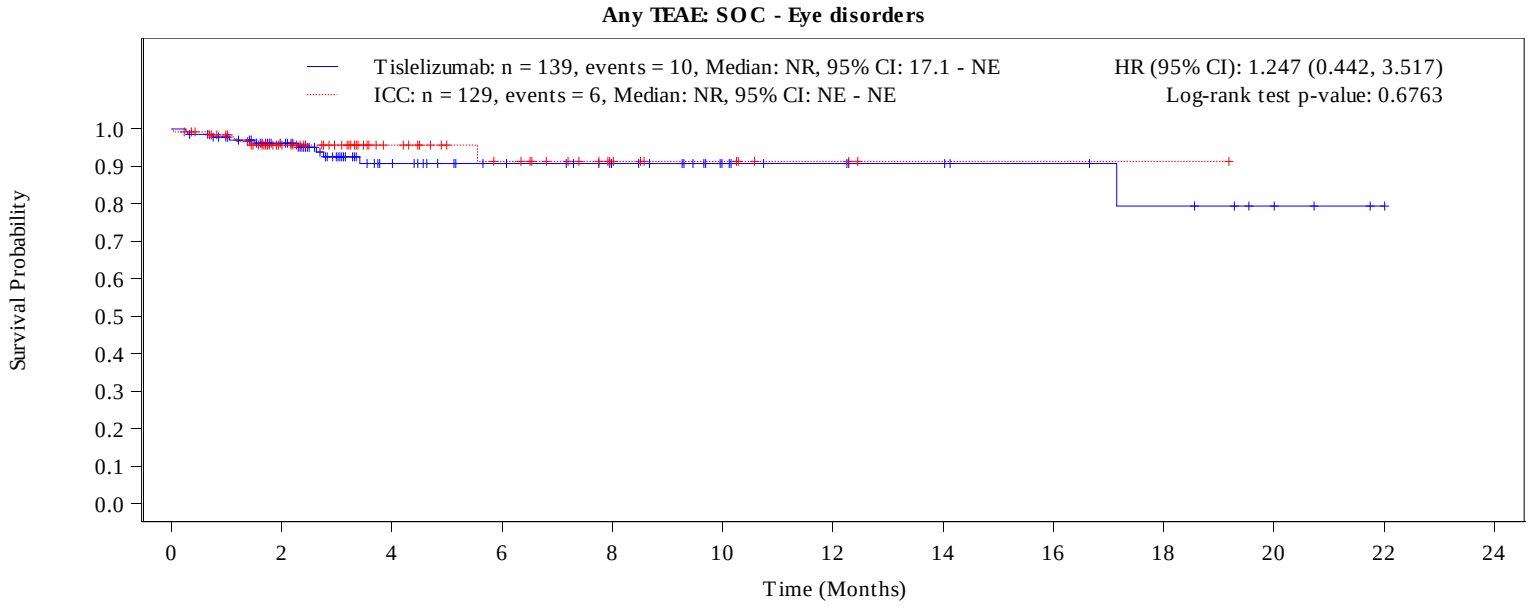
Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24
Tislelizumab	139	92	47	35	27	17	14	12	9	7	4	1	0
ICC	129	73	31	18	9	6	3	1	1	1	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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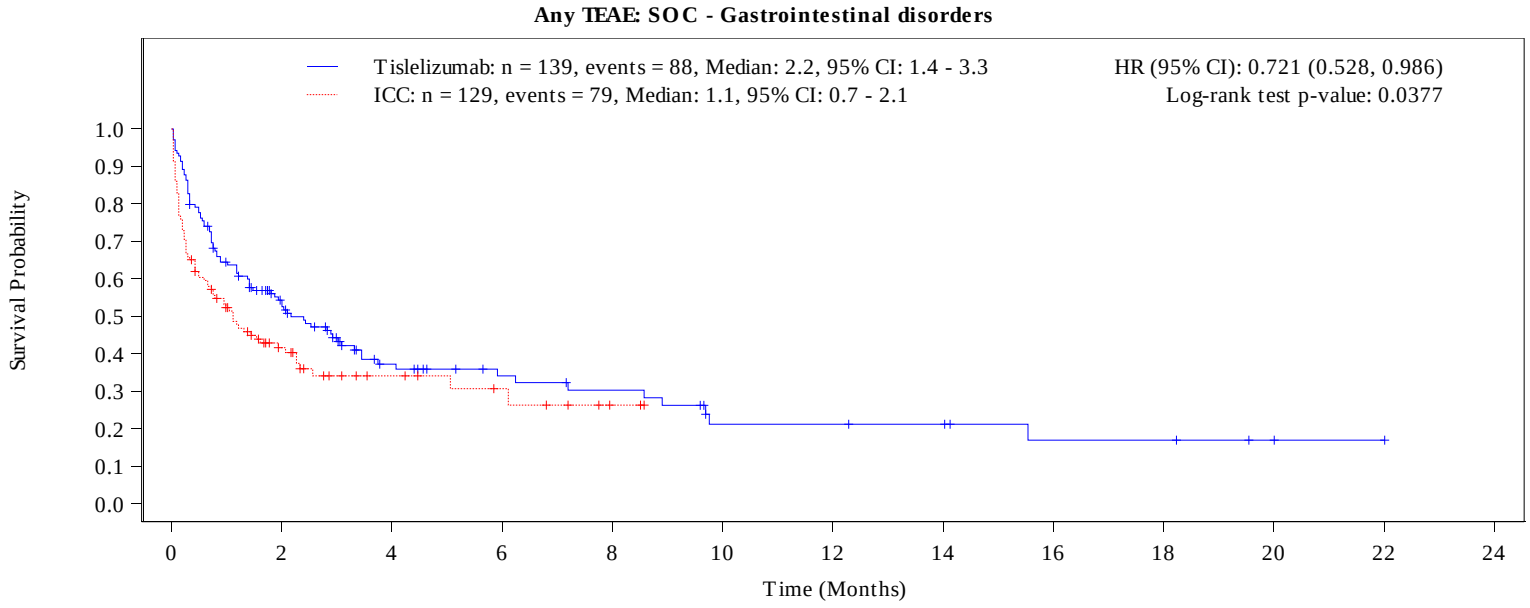
Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24
Tislelizumab	139	62	28	19	15	8	8	7	4	4	2	1	0
ICC	129	32	13	7	2	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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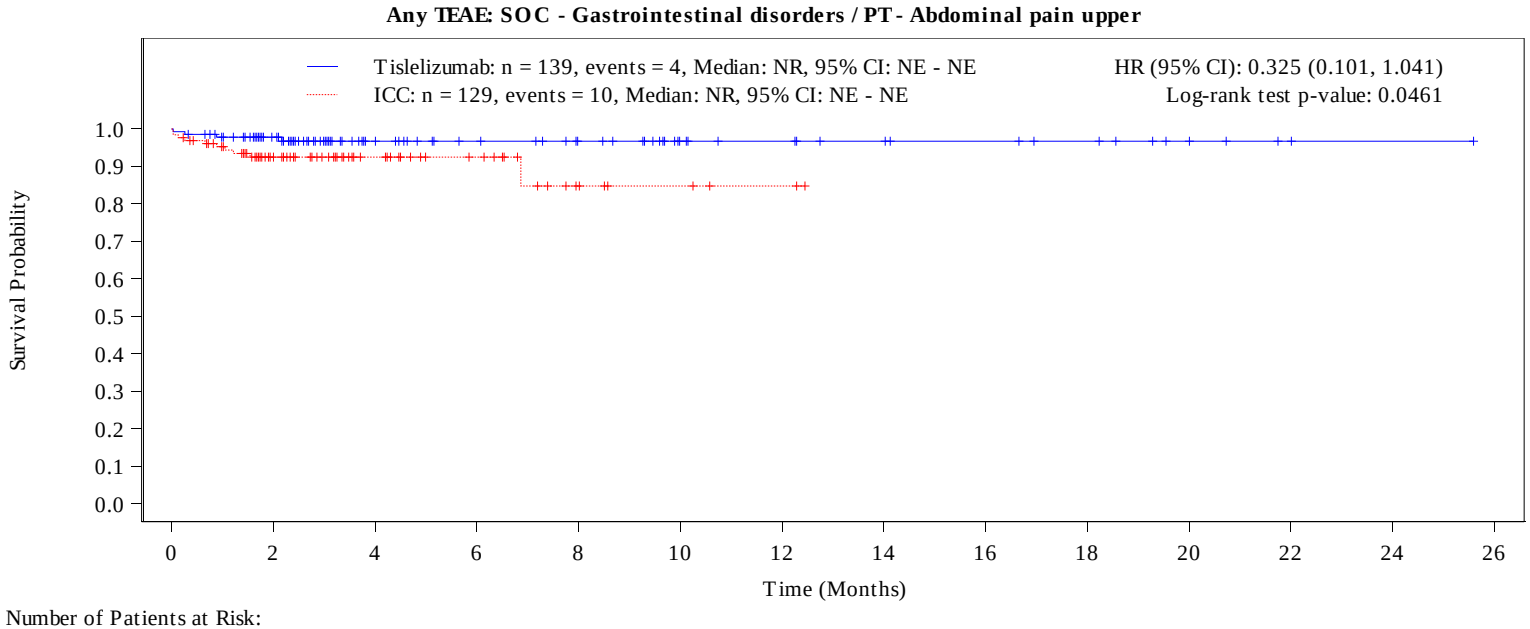
Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	93	52	40	32	20	17	14	11	9	5	2	1	0
ICC	129	68	30	17	7	4	2	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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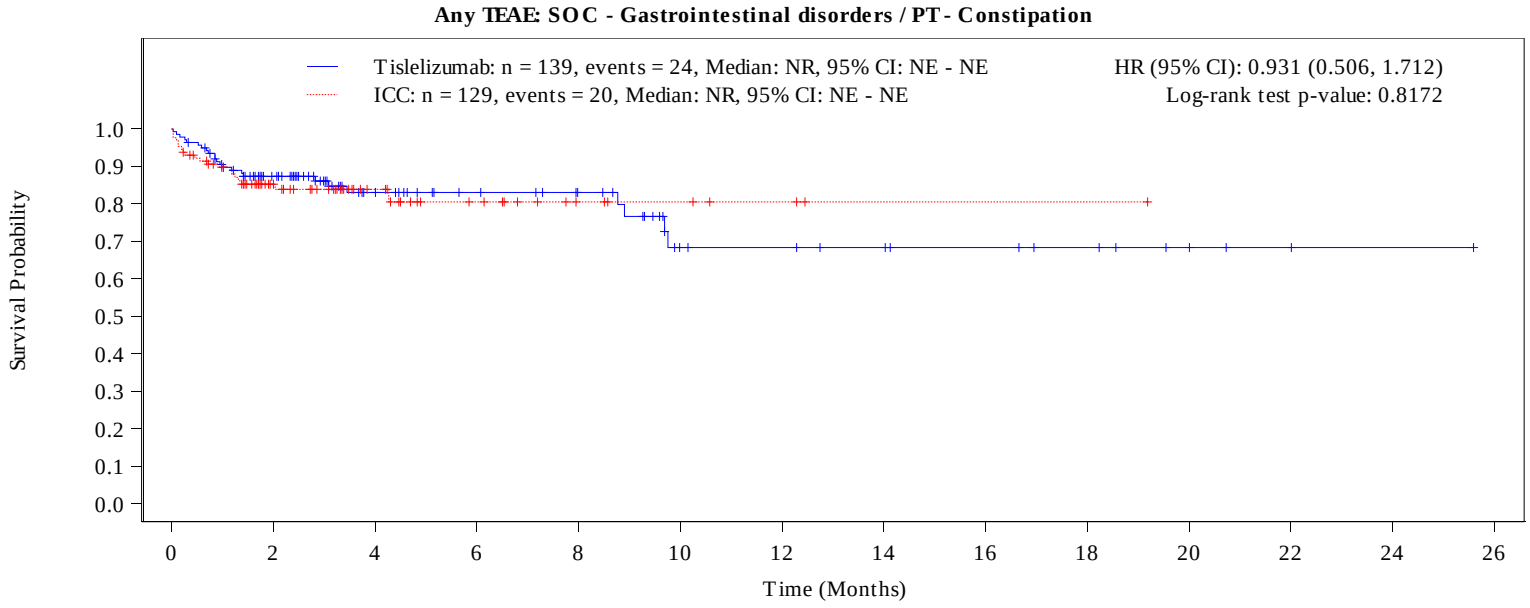
Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	86	47	35	28	14	13	11	9	7	4	2	1	0
ICC	129	63	27	14	7	5	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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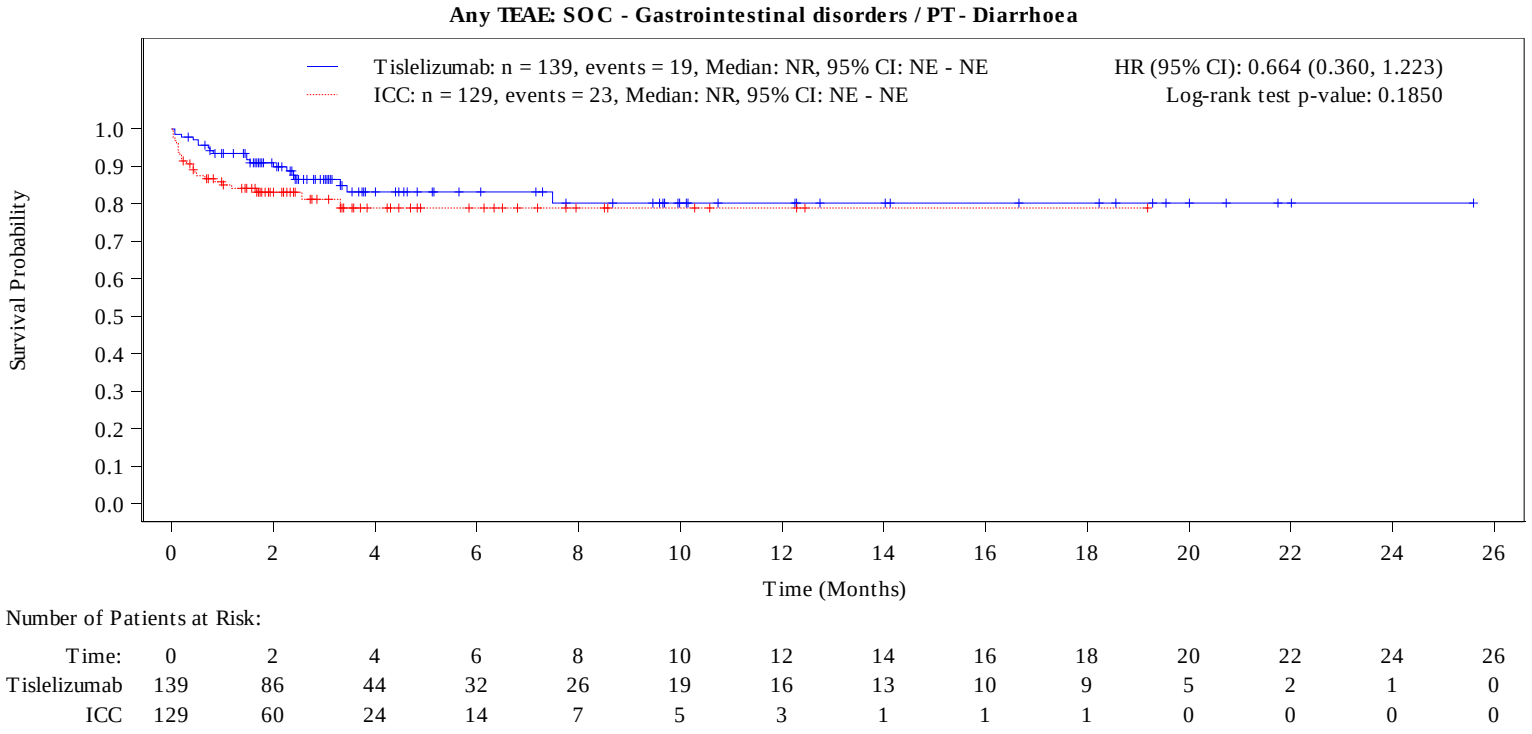
Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

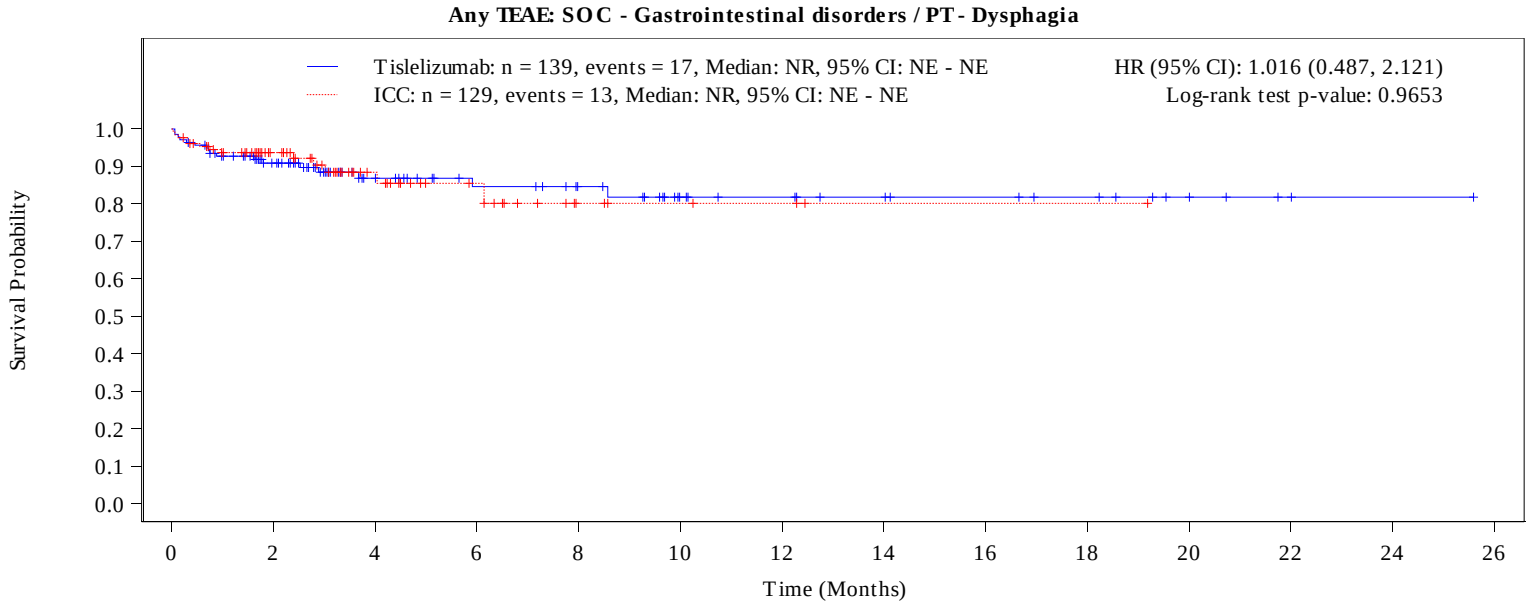


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	86	44	32	26	19	16	13	10	9	5	2	1	0
ICC	129	60	24	14	7	5	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-b-km-aesocpt-safetys-fa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

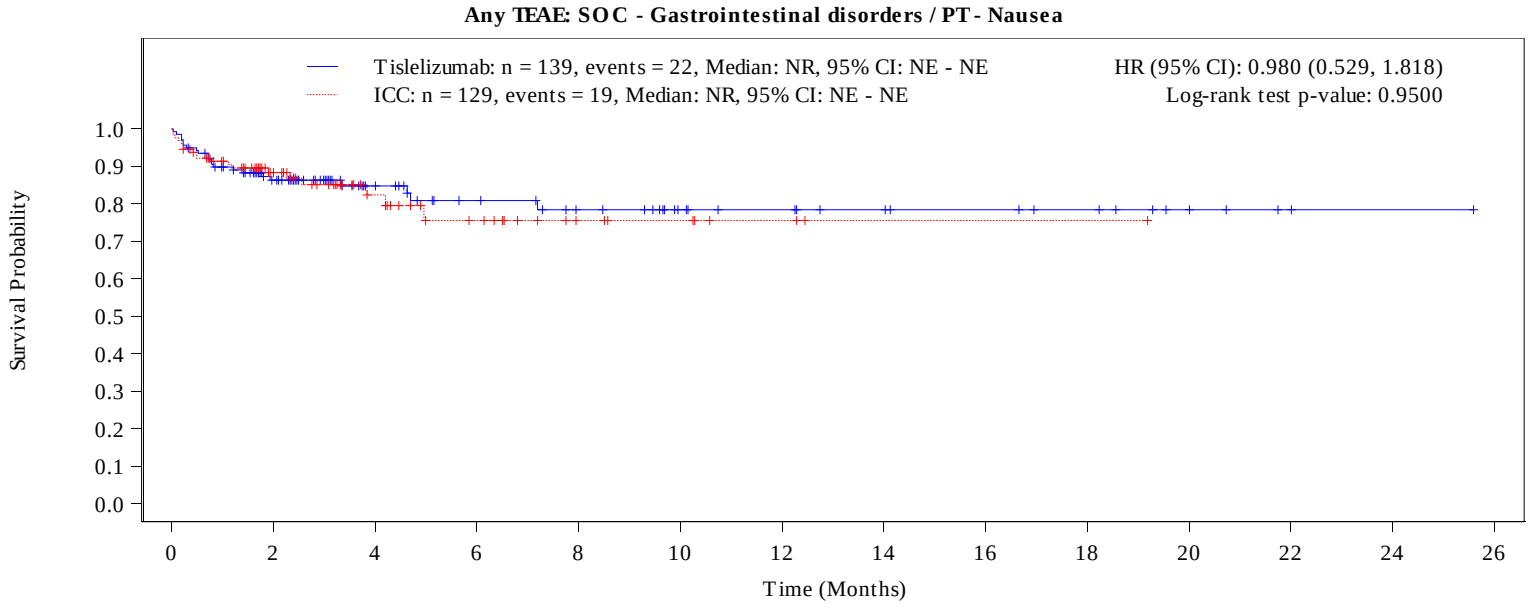


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	90	51	38	31	20	17	14	11	9	5	2	1	0
ICC	129	70	30	16	6	4	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-b-km-aesocpt-safetys-fa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

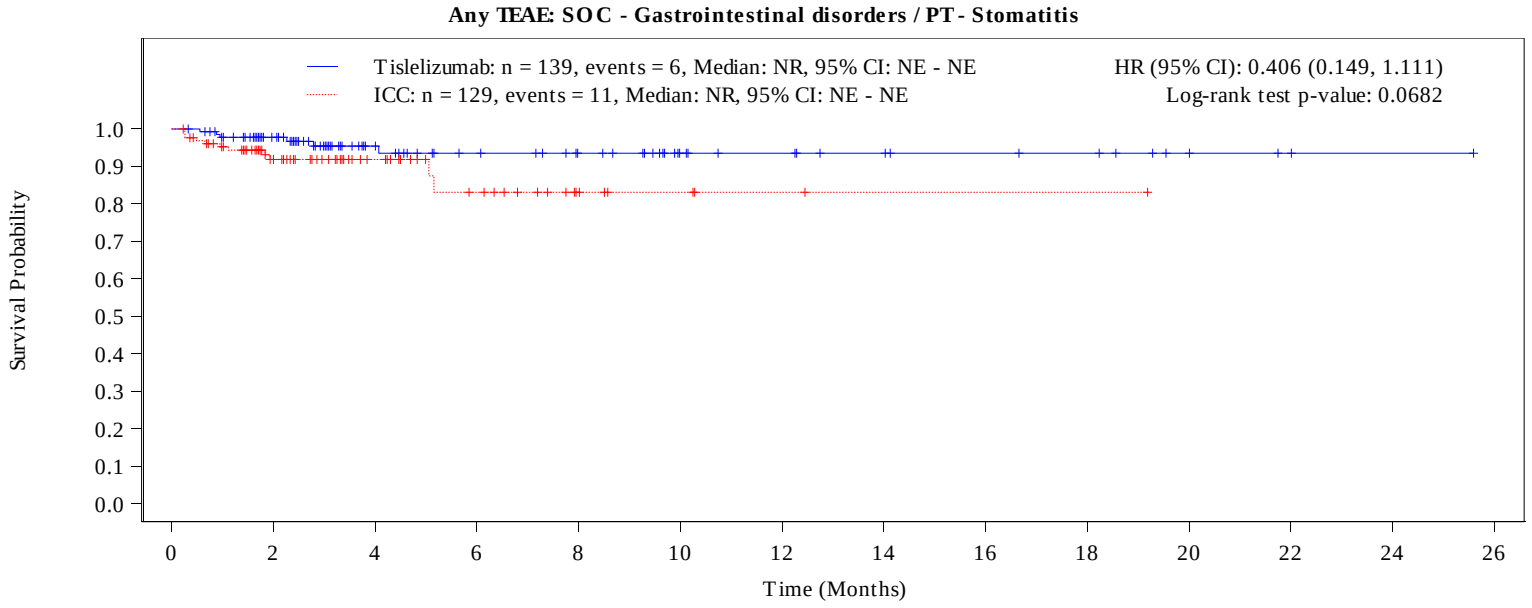


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	87	49	36	29	20	17	14	11	9	5	2	1	0
ICC	129	67	29	16	8	6	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-b-km-aesocpt-safetys-fa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

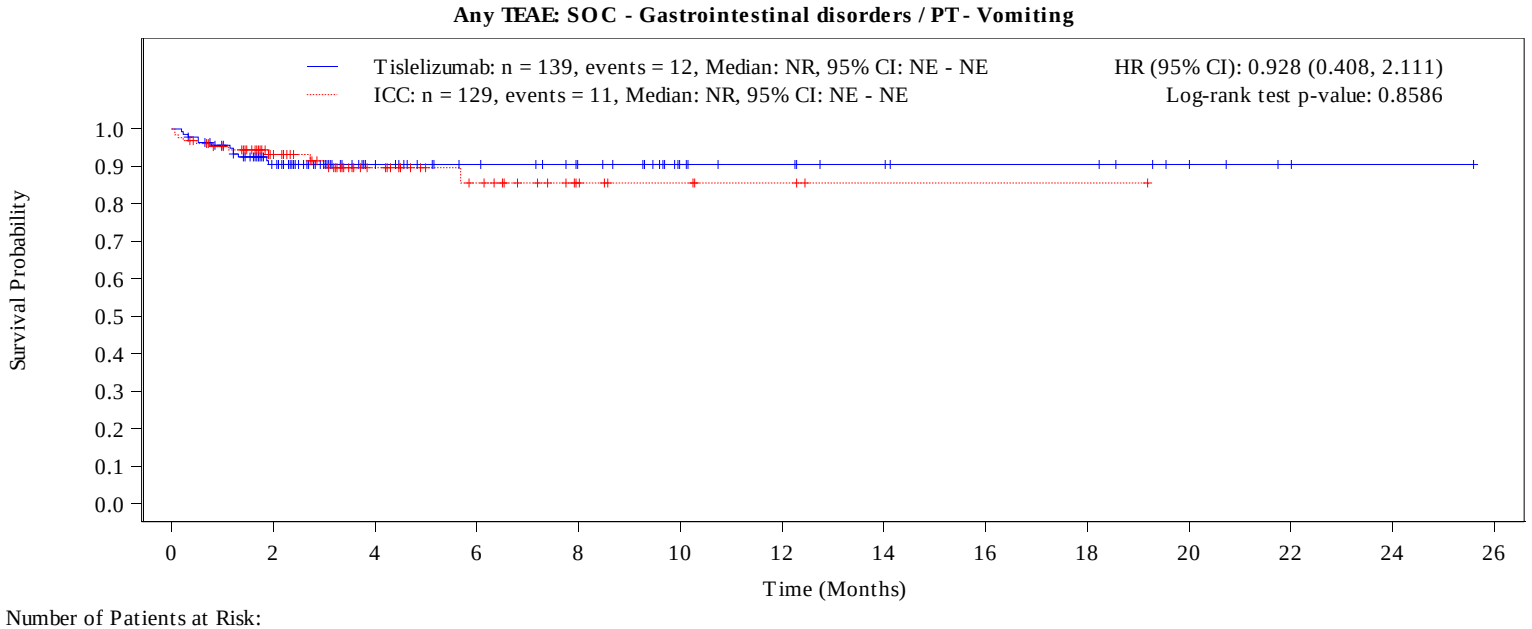


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	93	51	38	30	18	15	12	9	8	4	2	1	0
ICC	129	70	31	16	7	4	2	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-b-km-aesocpt-safetys-fa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

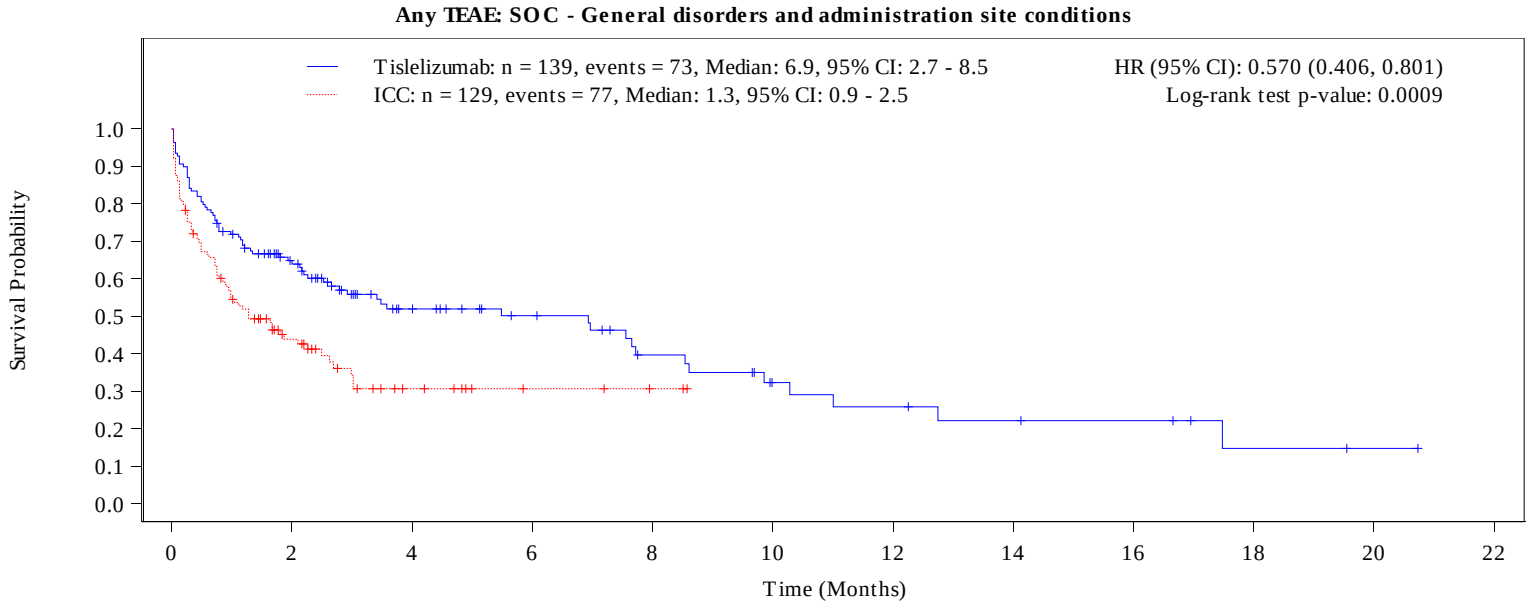


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	89	49	37	30	18	15	12	9	9	5	2	1	0
ICC	129	72	32	18	8	5	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-b-km-aesocpt-safetys-fa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

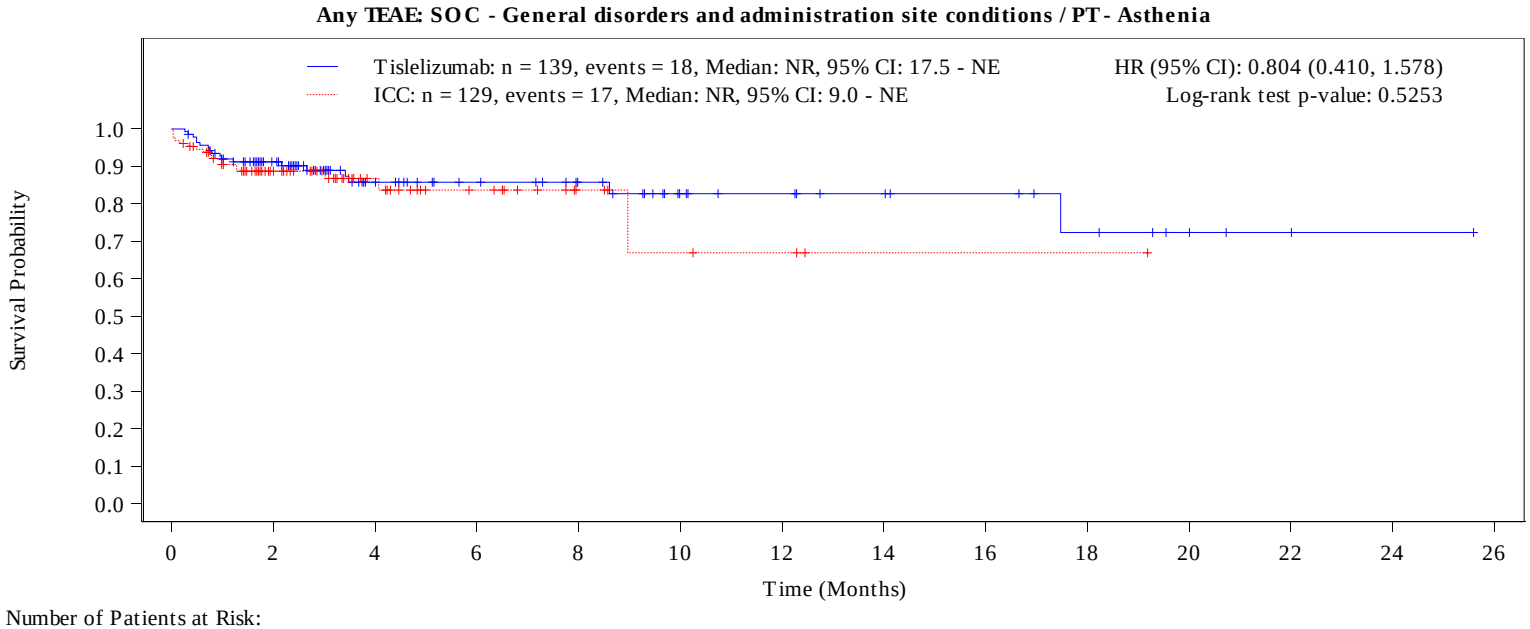


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	139	70	37	27	17	10	8	6	5	2	1	0
ICC	129	35	10	4	2	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-b-km-aesocpt-safetys-fa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	90	49	37	29	19	16	13	10	7	4	2	1	0
ICC	129	68	28	15	7	4	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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Figure 14.3.1.2.b:
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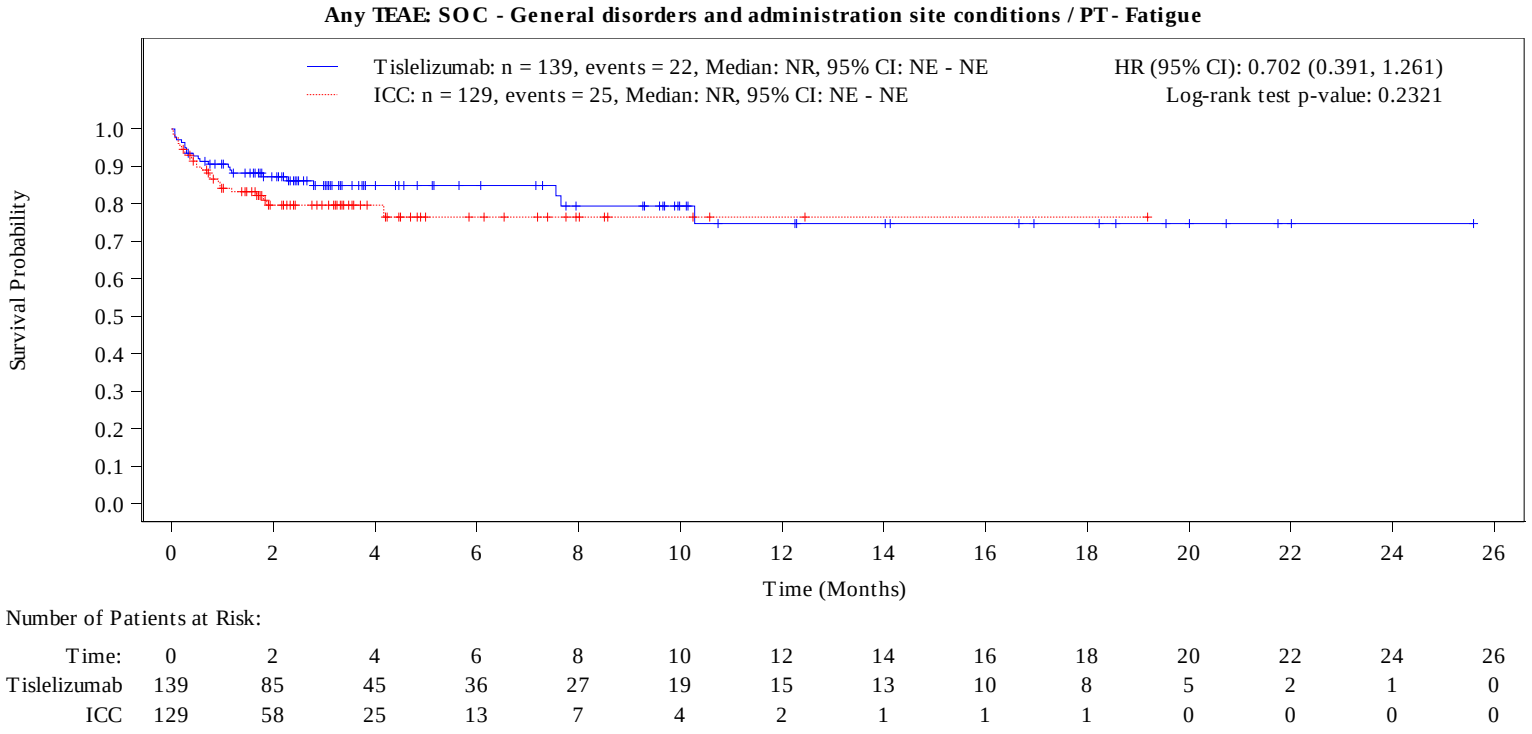
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	85	45	36	27	19	15	13	10	8	5	2	1	0
ICC	129	58	25	13	7	4	2	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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Figure 14.3.1.2.b:
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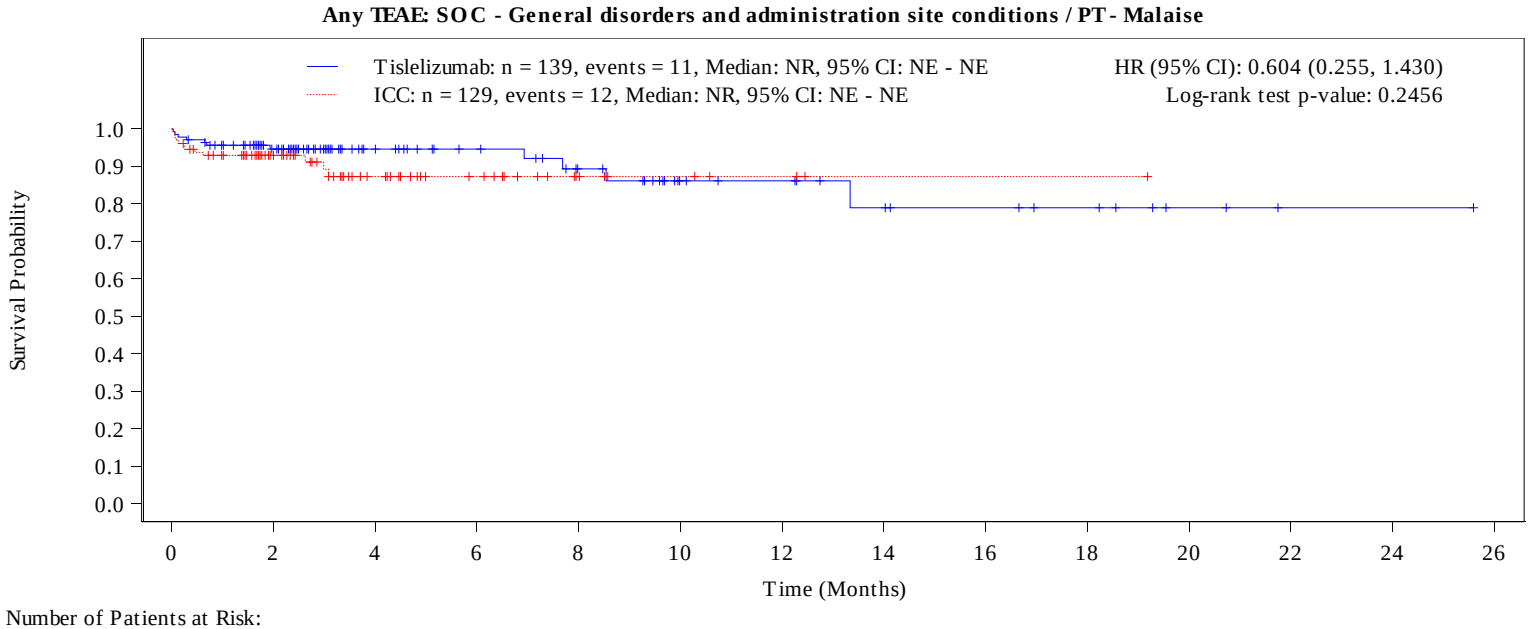
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	91	51	39	29	17	15	11	9	7	3	1	1	0
ICC	129	70	30	17	8	5	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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Figure 14.3.1.2.b:
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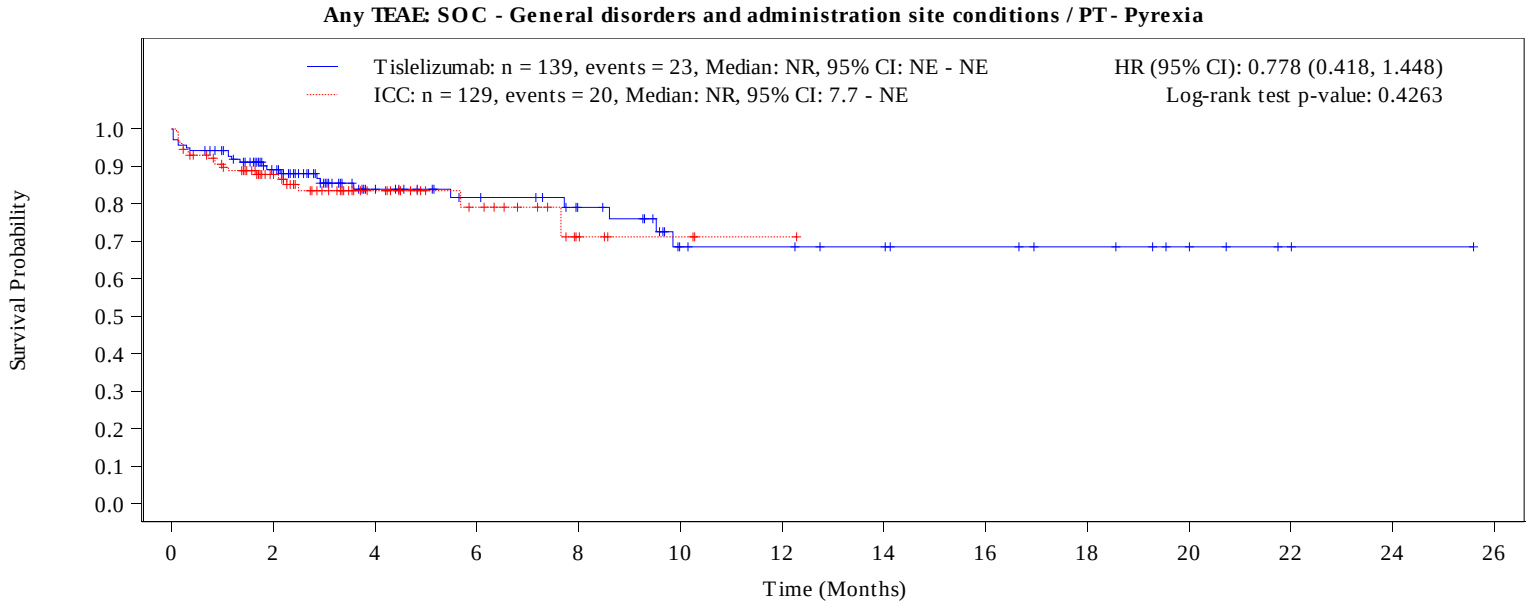
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	87	48	36	27	15	14	12	10	8	5	2	1	0
ICC	129	69	29	16	6	3	1	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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Figure 14.3.1.2.b:
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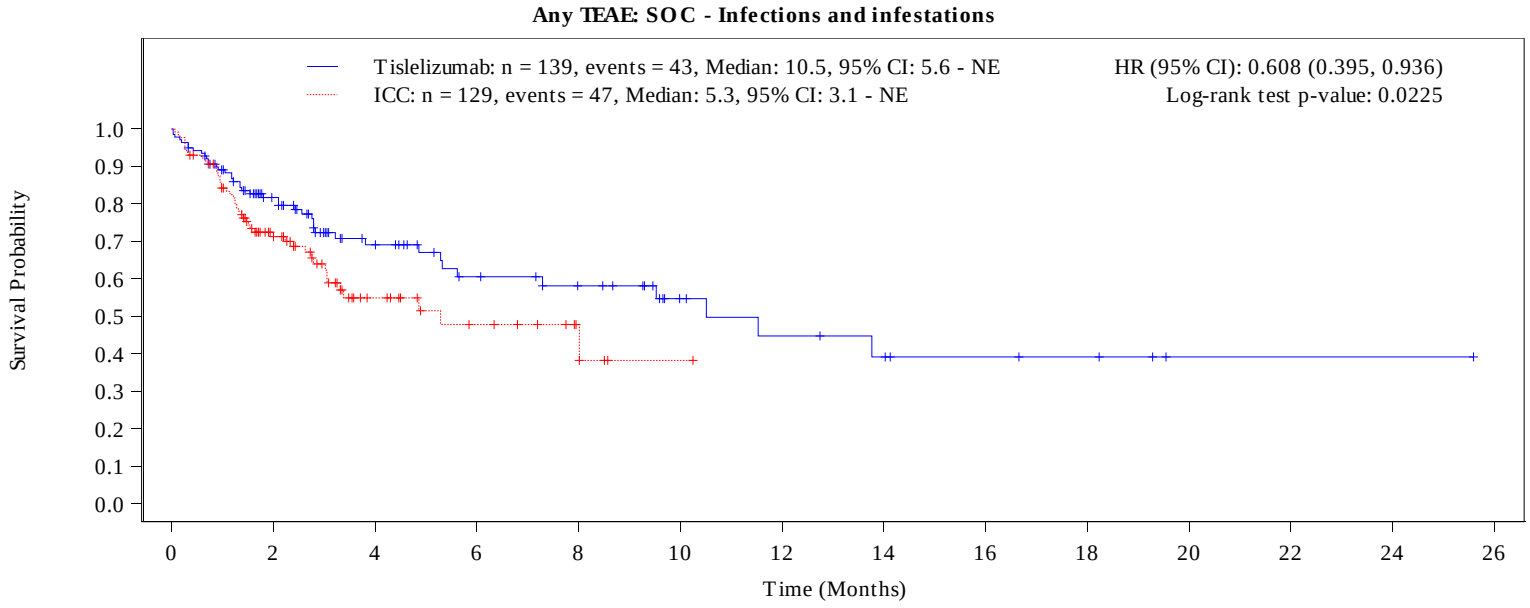
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	78	41	27	22	12	9	7	5	4	1	1	1	0
ICC	129	61	21	11	5	1	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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Figure 14.3.1.2.b:
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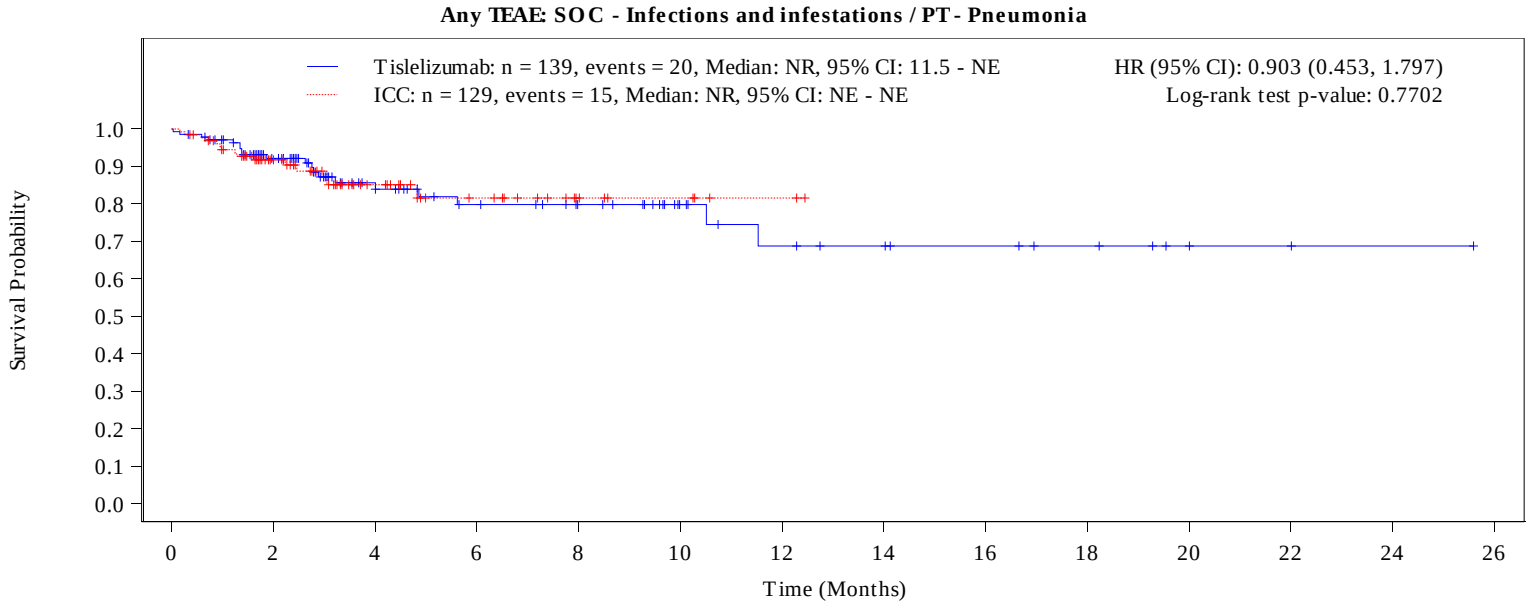
Safety Analysis Set - Subpopulation without Irinotecan

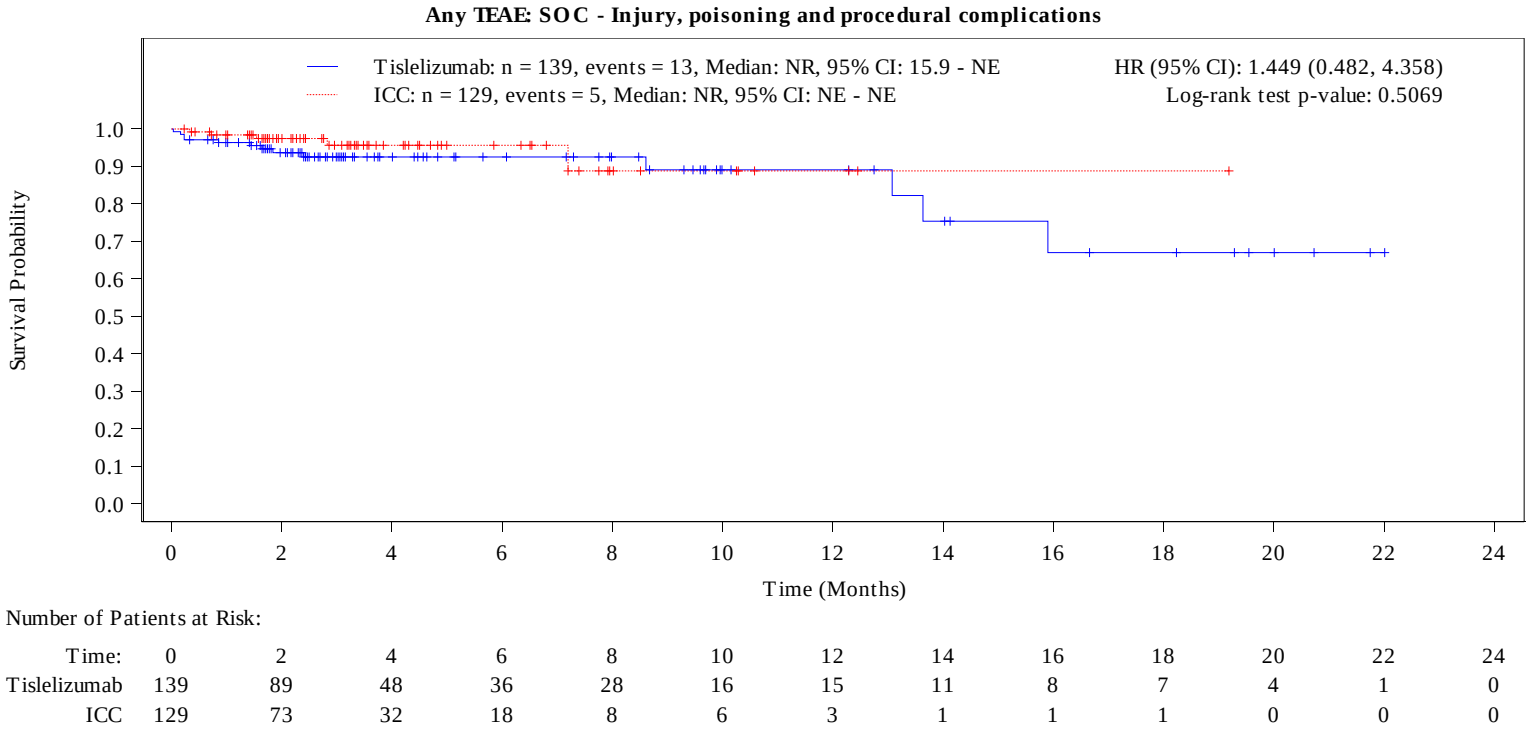


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	89	50	37	29	17	12	10	8	6	3	2	1	0
ICC	129	73	32	17	8	5	2	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-b-km-aesocpt-safetys-fa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24
Tislelizumab	139	89	48	36	28	16	15	11	8	7	4	1	0
ICC	129	73	32	18	8	6	3	1	1	1	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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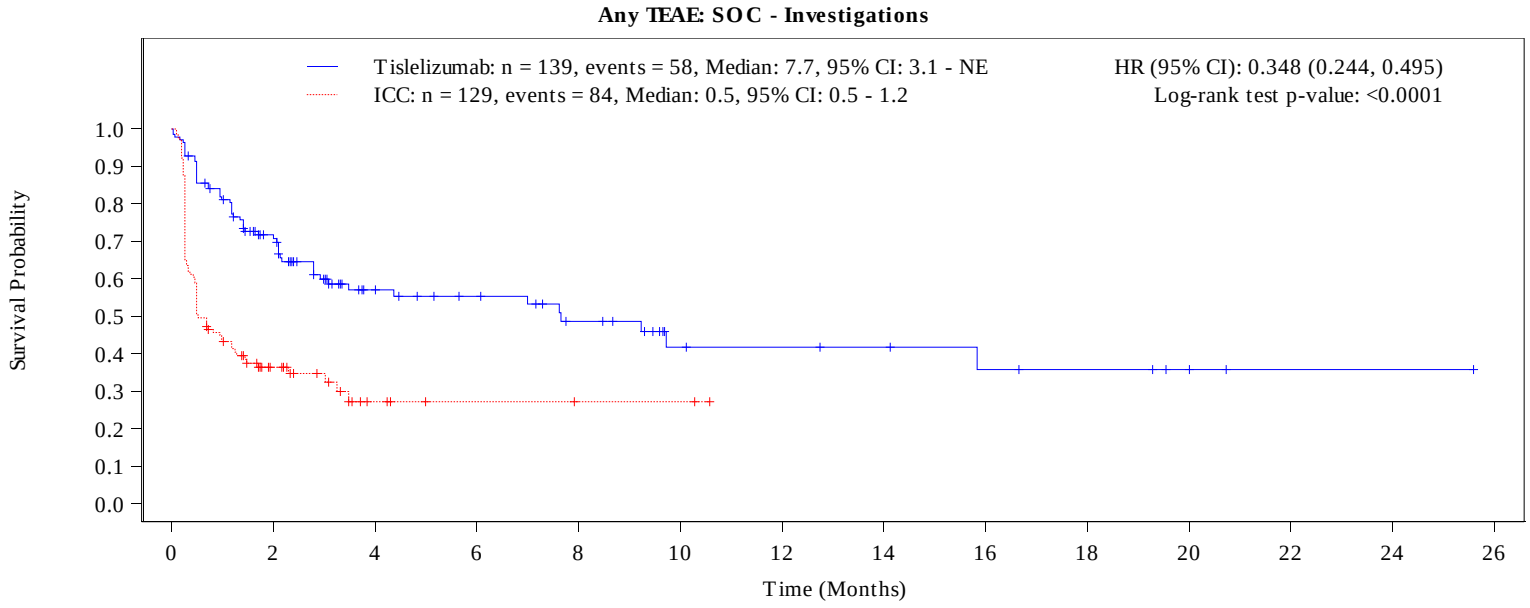
Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

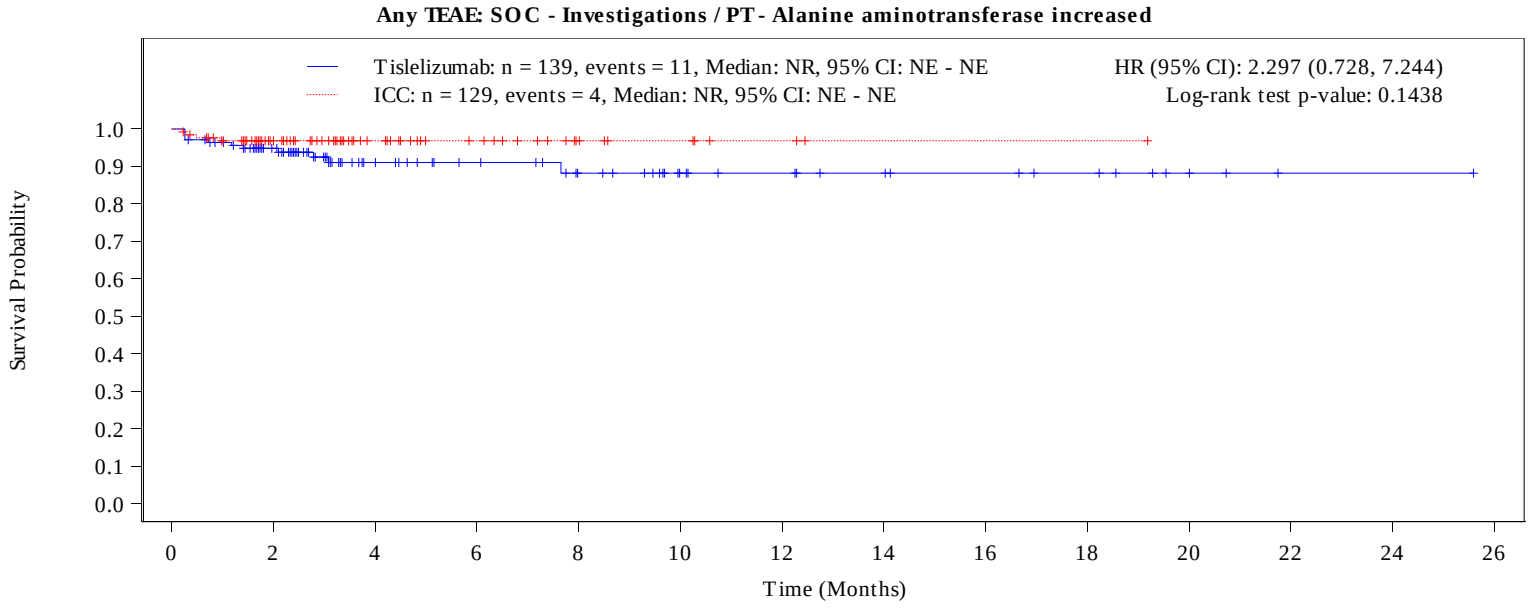


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	71	34	28	20	10	9	8	6	5	3	1	1	0
ICC	129	25	6	3	2	2	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-b-km-aesocpt-safetys-fa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	91	48	37	28	18	15	12	10	8	4	1	1	0
ICC	129	74	32	18	9	6	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-b-km-aesocpt-safetys-fa.rtf

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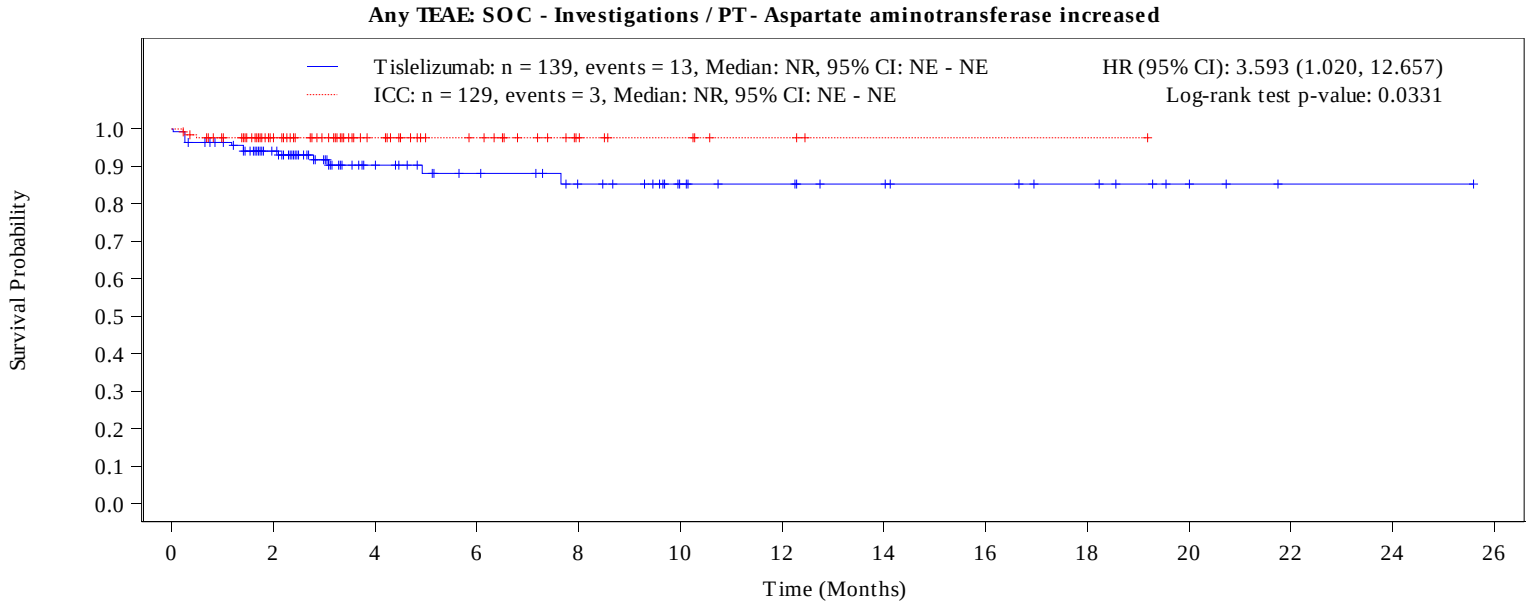
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

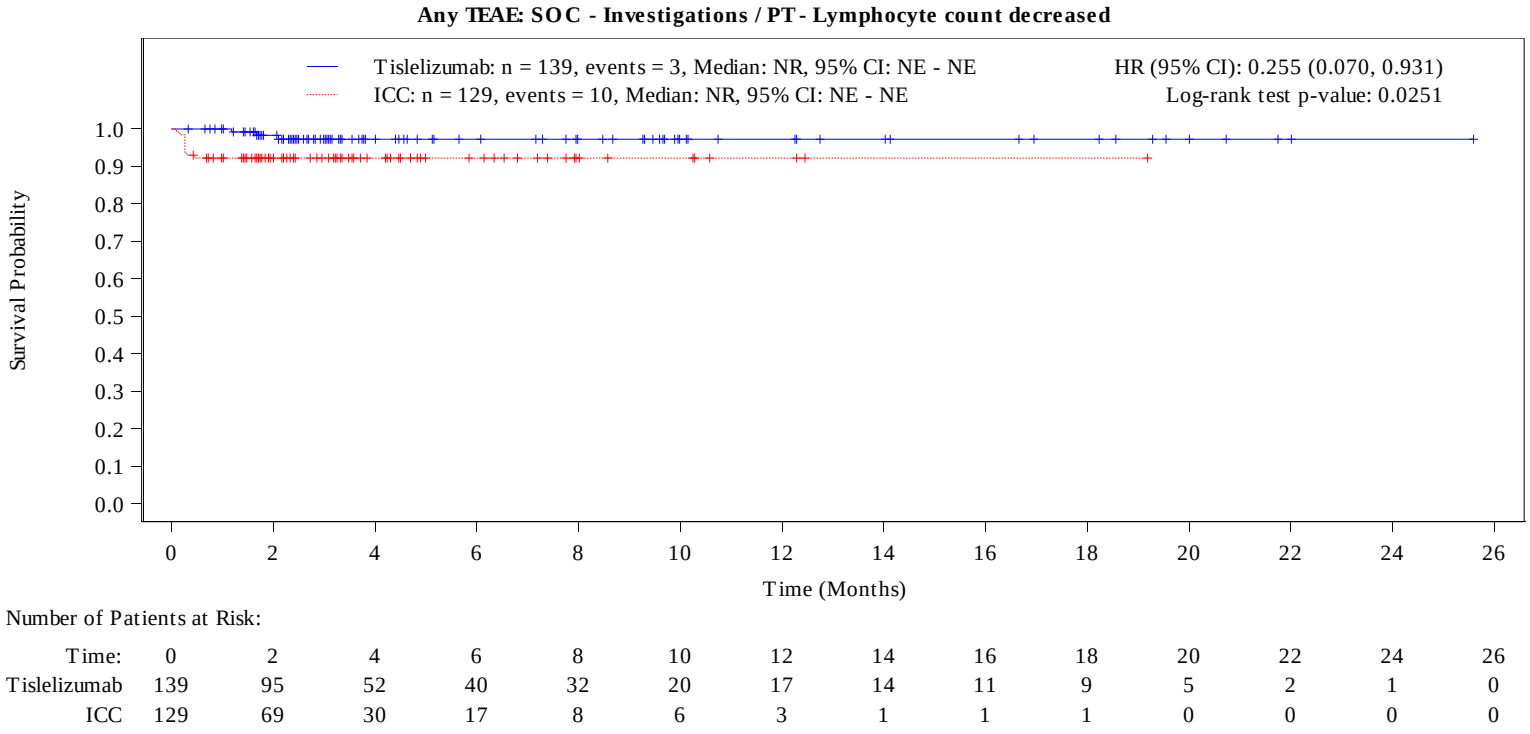


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	92	48	36	28	18	15	12	10	8	4	1	1	0
ICC	129	75	33	19	9	6	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-b-km-aesocpt-safetys-fa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	95	52	40	32	20	17	14	11	9	5	2	1	0
ICC	129	69	30	17	8	6	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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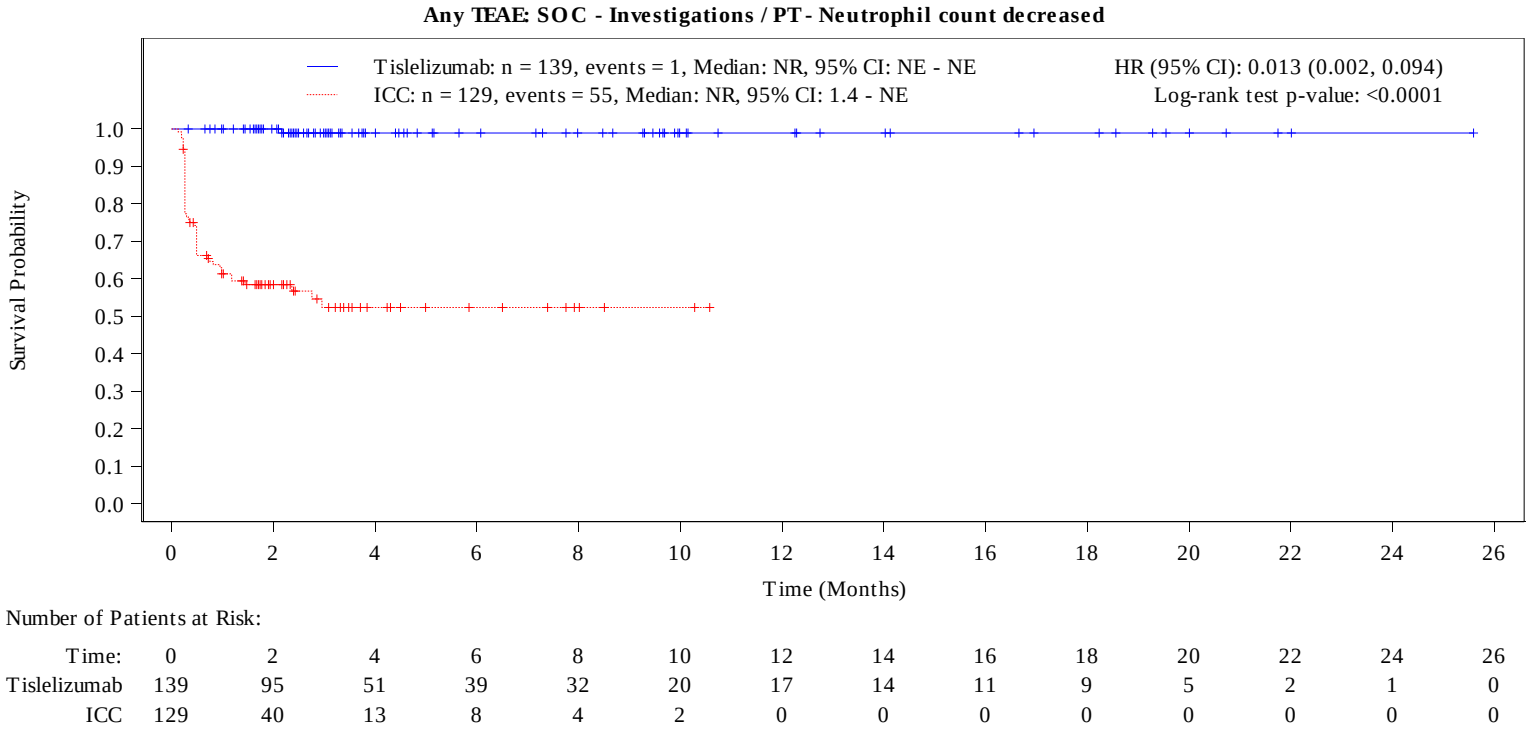
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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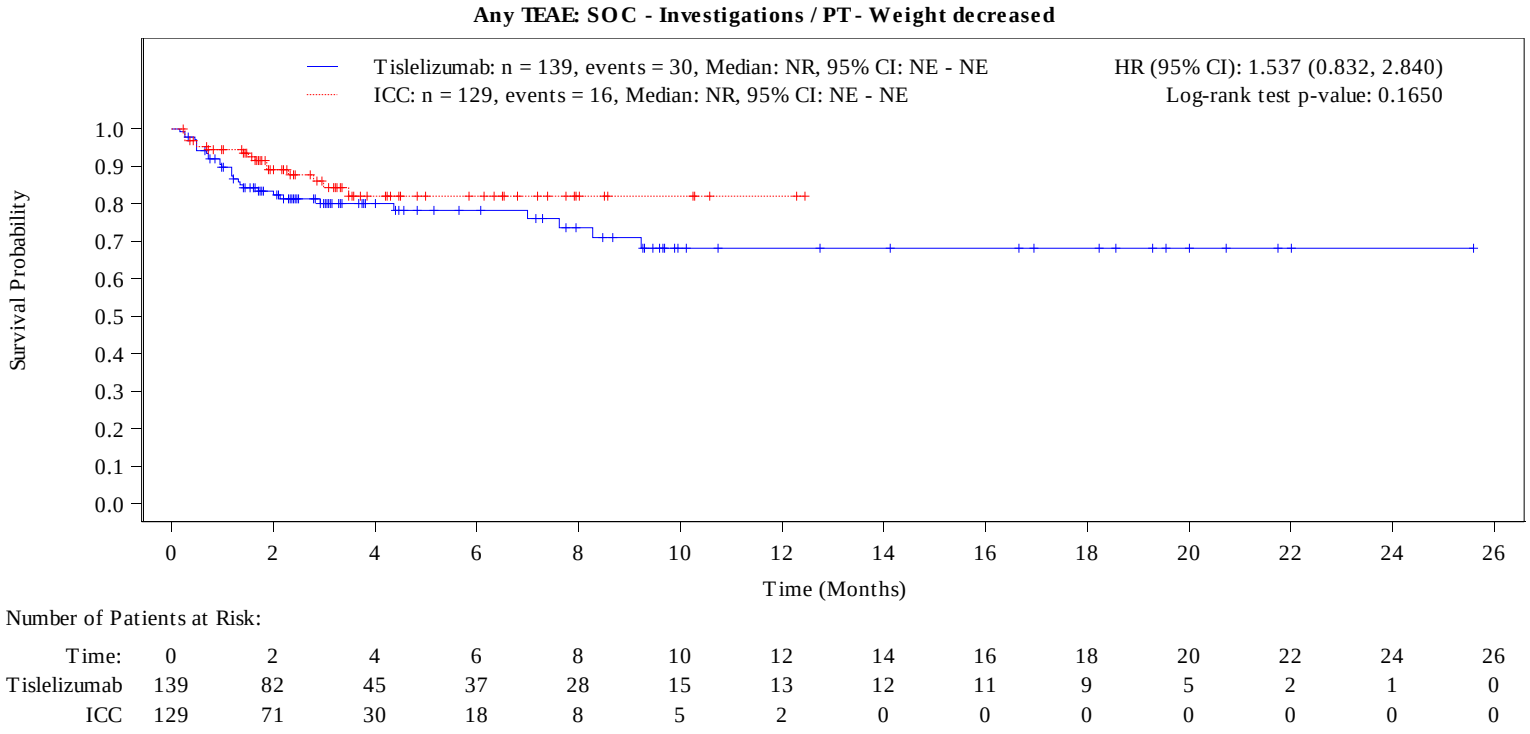
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-b-km-aesocpt-safetys-fa.rtf

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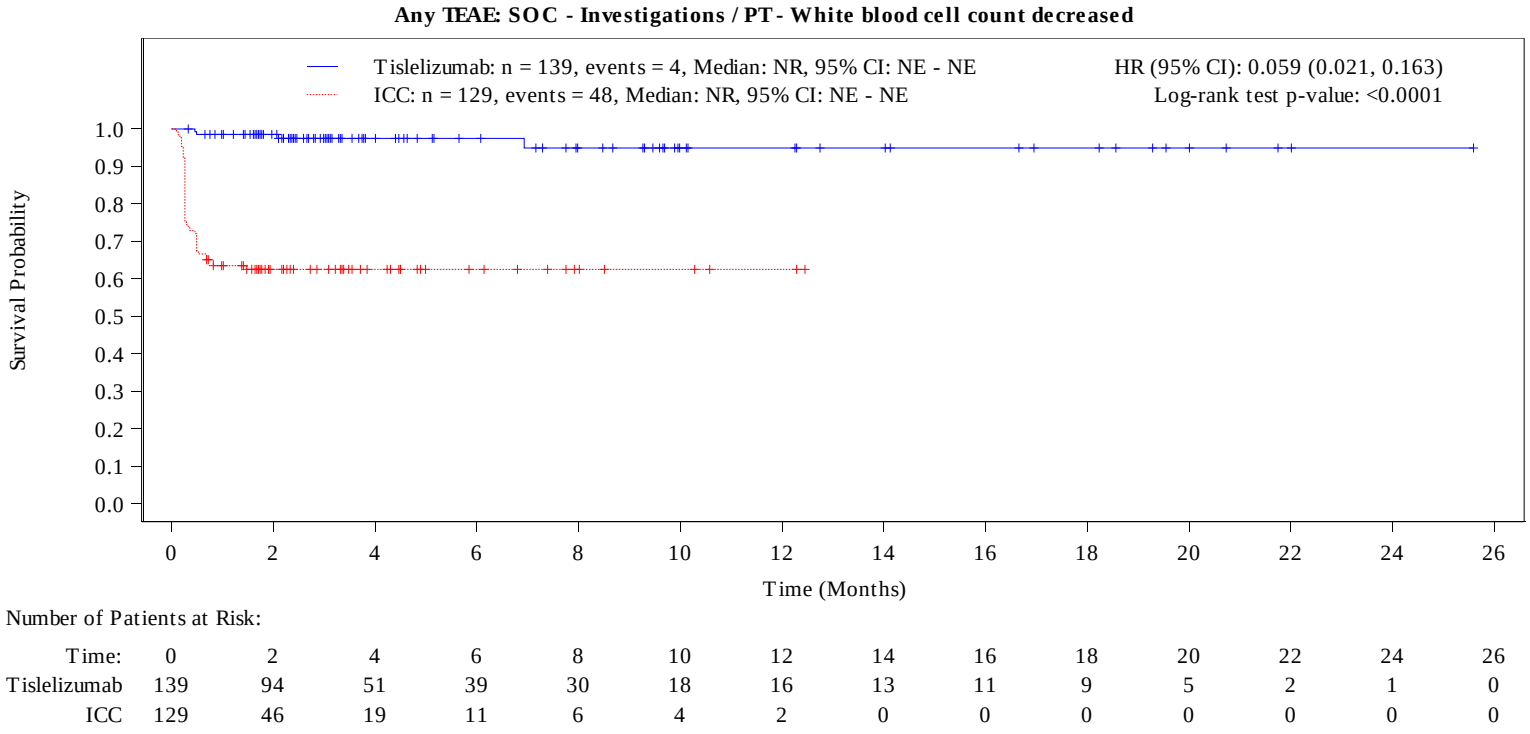

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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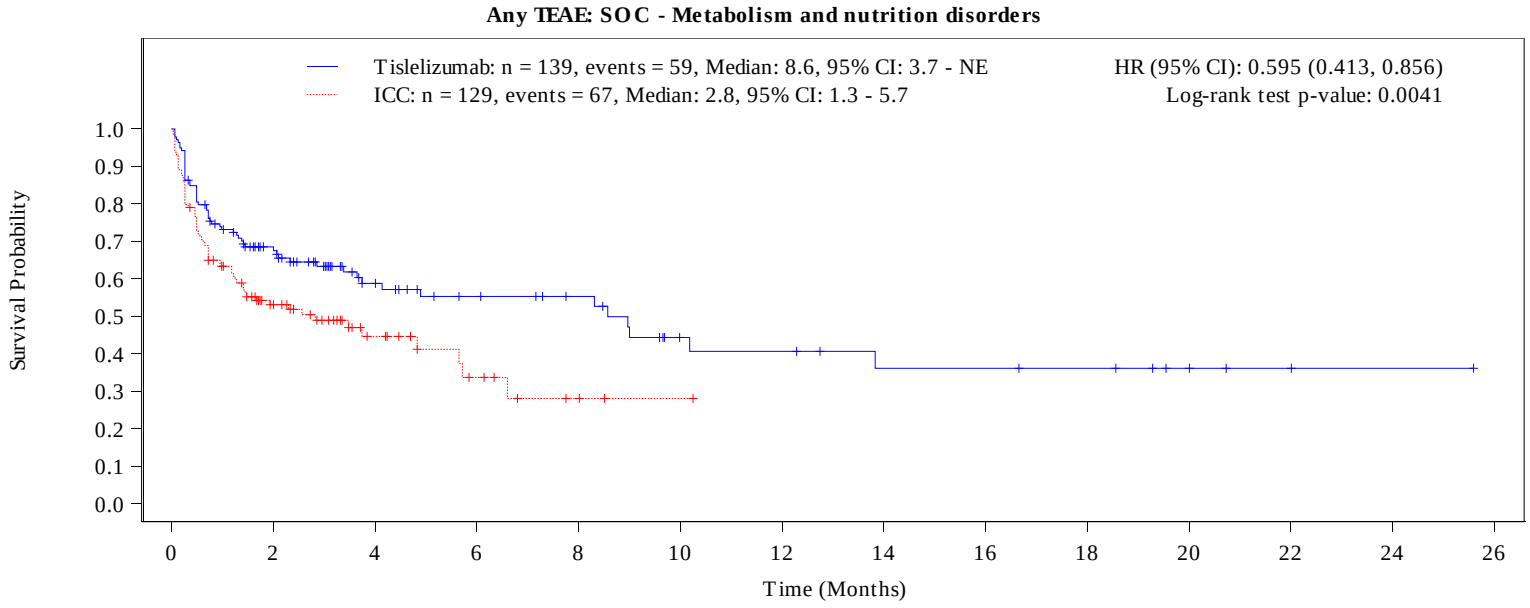
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	69	37	27	21	12	11	8	8	7	4	2	1	0
ICC	129	46	18	8	3	1	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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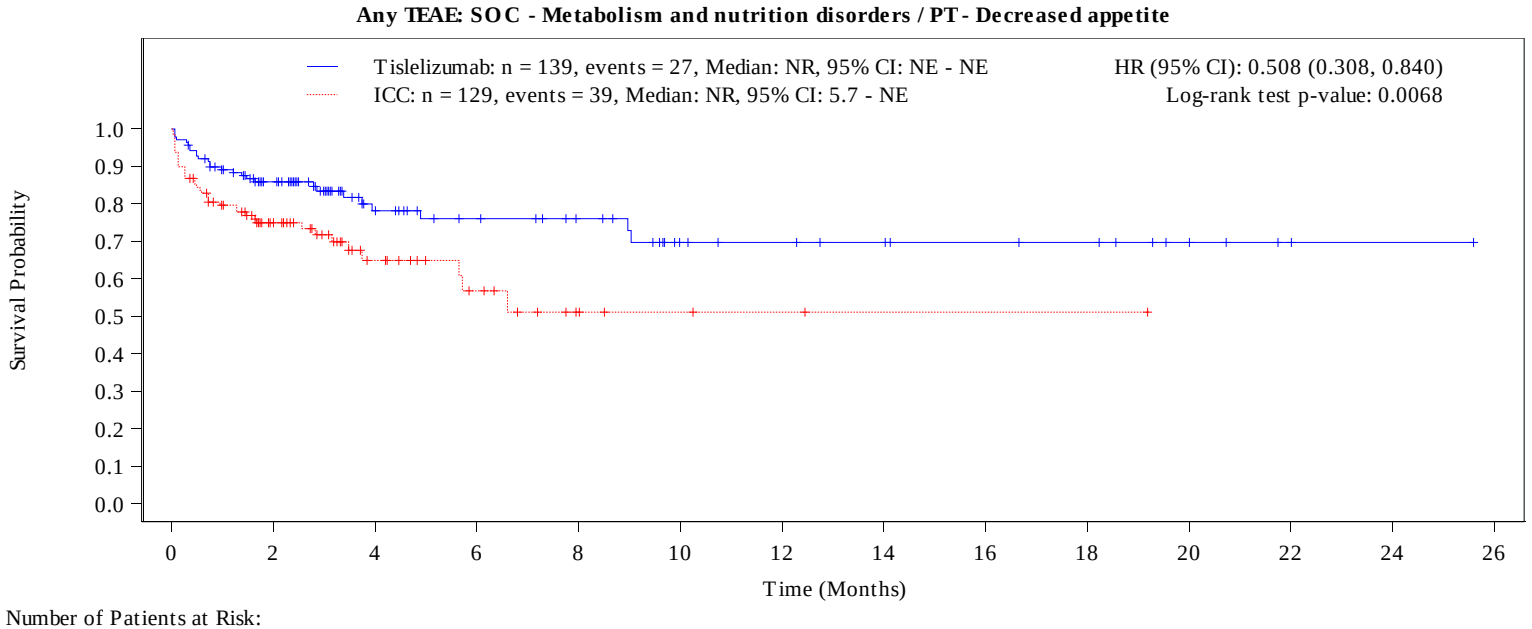
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	84	43	33	26	16	14	12	10	9	5	2	1	0
ICC	129	61	23	12	5	3	2	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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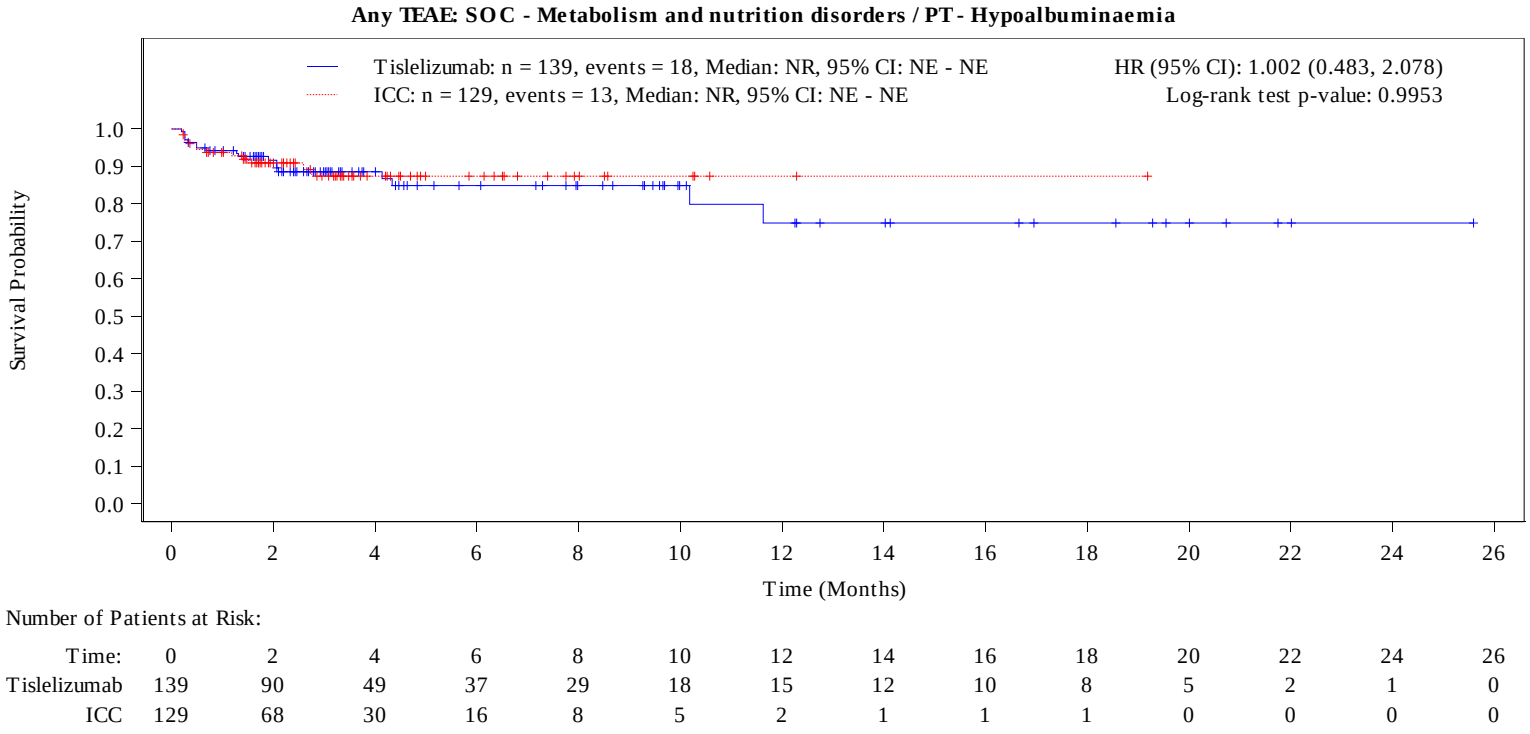
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	90	49	37	29	18	15	12	10	8	5	2	1	0
ICC	129	68	30	16	8	5	2	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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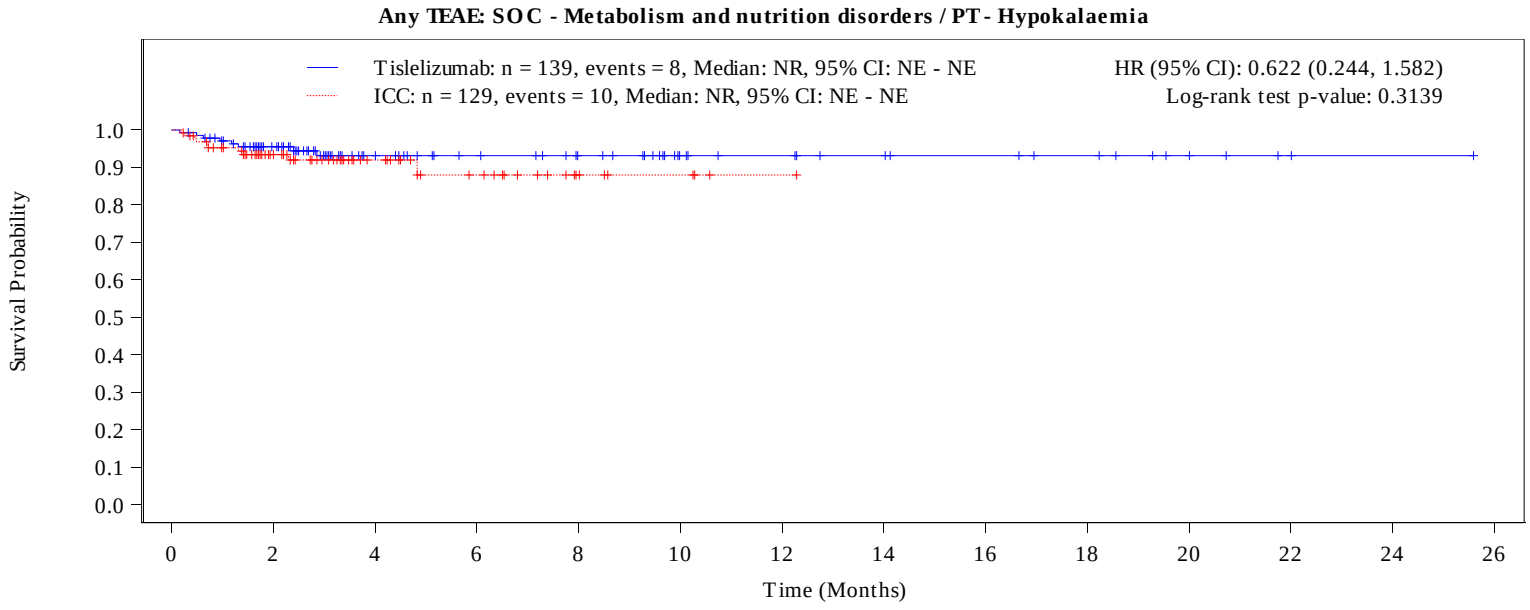
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

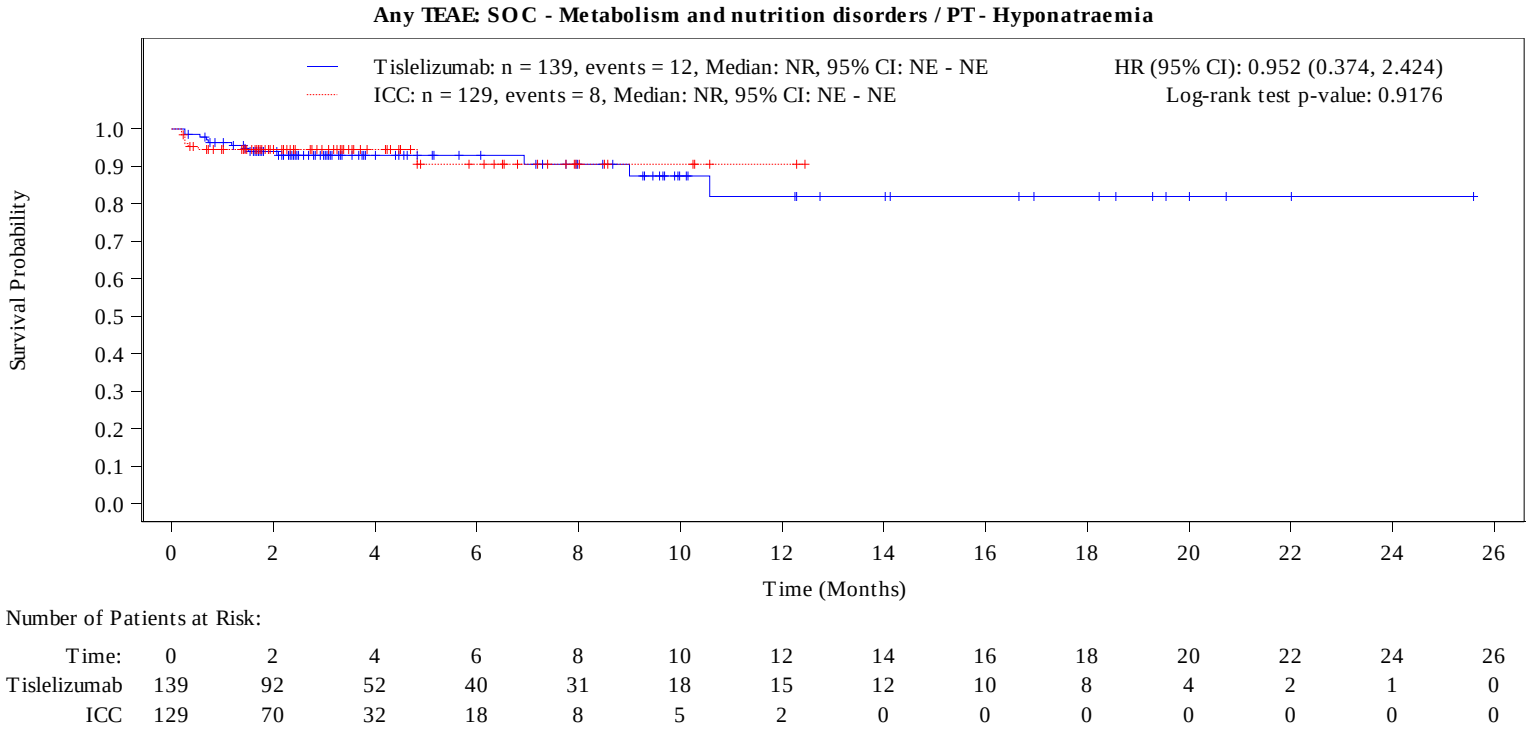


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	93	52	40	32	20	17	14	11	9	5	2	1	0
ICC	129	72	31	17	7	4	1	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-b-km-aesocpt-safetys-fa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	92	52	40	31	18	15	12	10	8	4	2	1	0
ICC	129	70	32	18	8	5	2	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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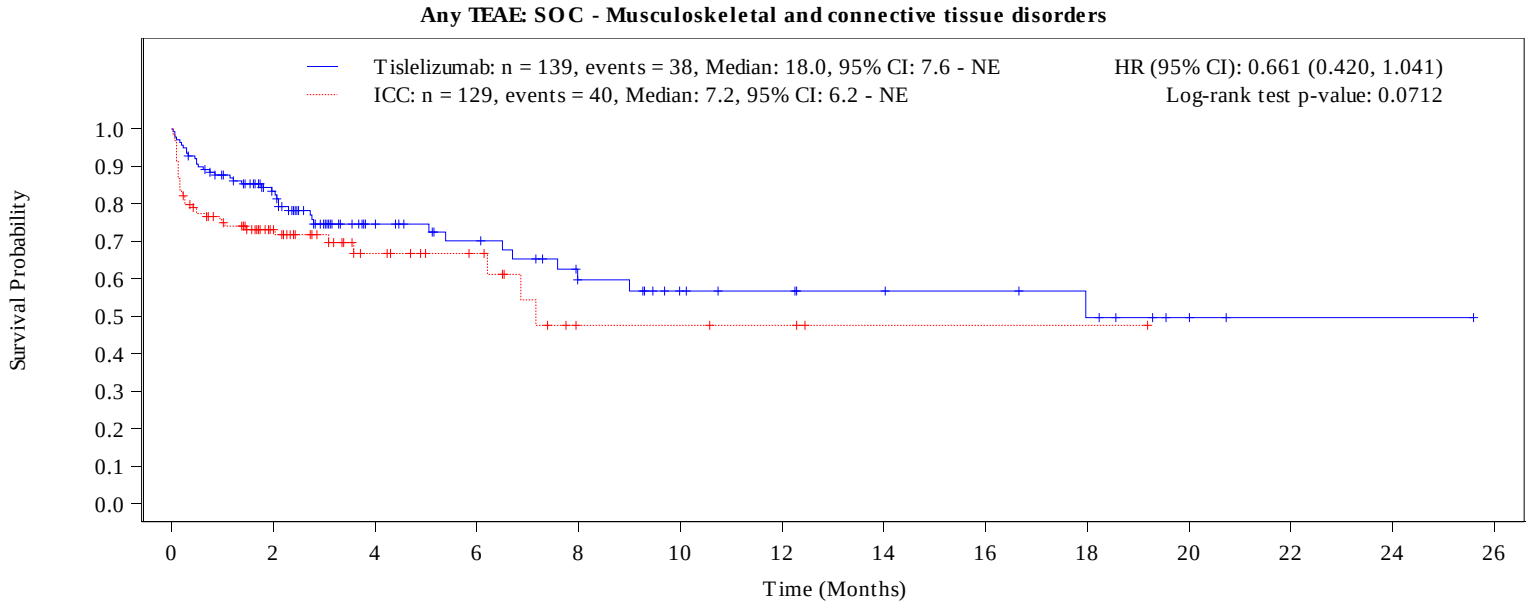
Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	82	40	30	20	14	12	10	9	7	3	1	1	0
ICC	129	56	20	13	4	4	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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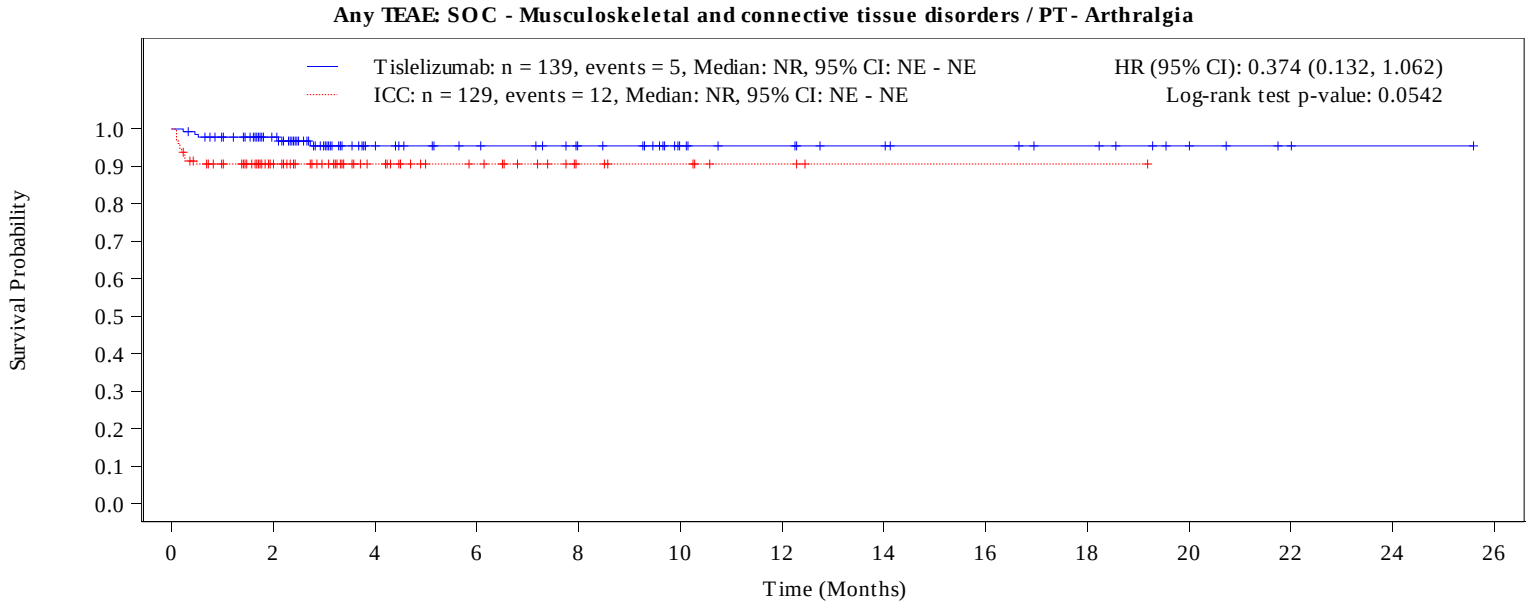
Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	94	49	39	31	20	17	14	11	9	5	2	1	0
ICC	129	70	30	17	8	6	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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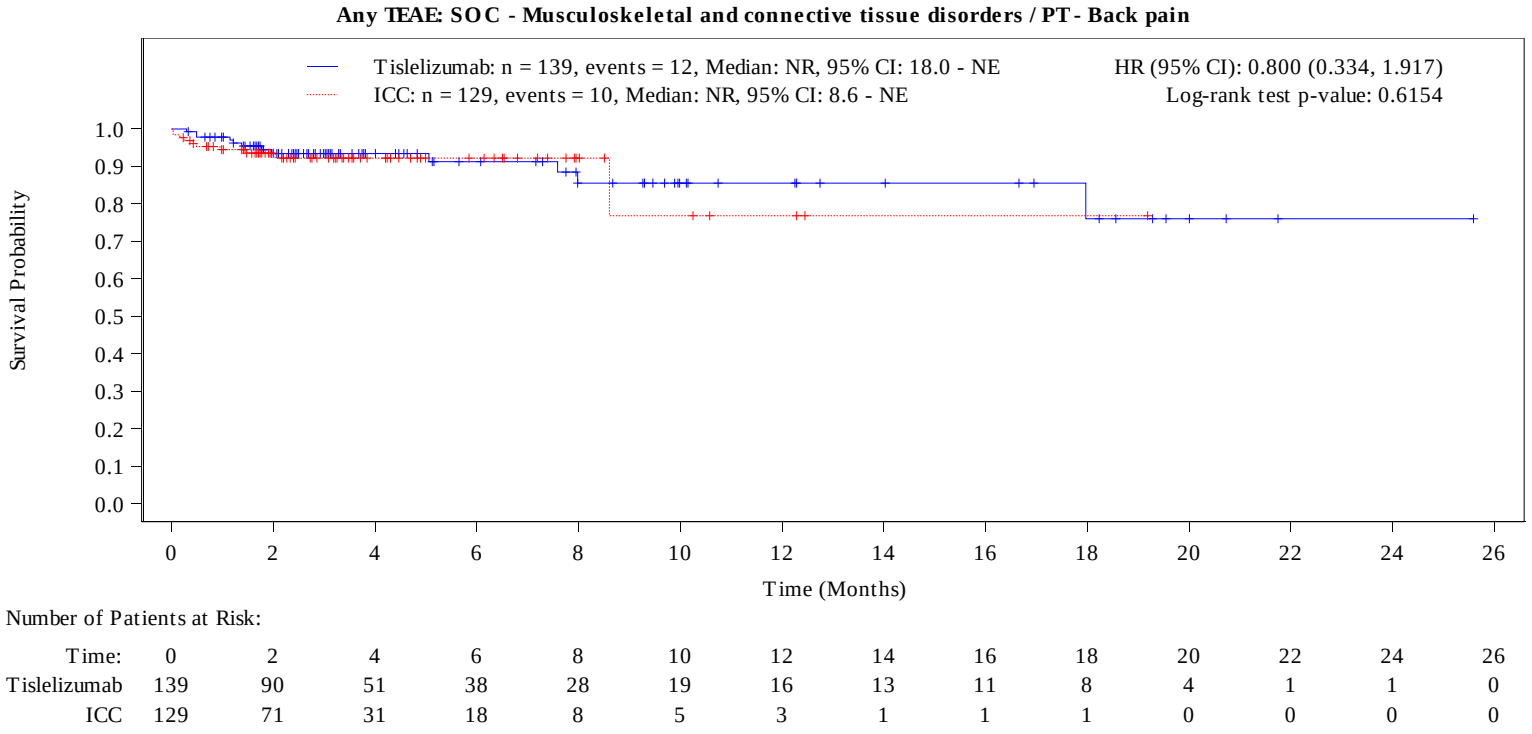
Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	90	51	38	28	19	16	13	11	8	4	1	1	0
ICC	129	71	31	18	8	5	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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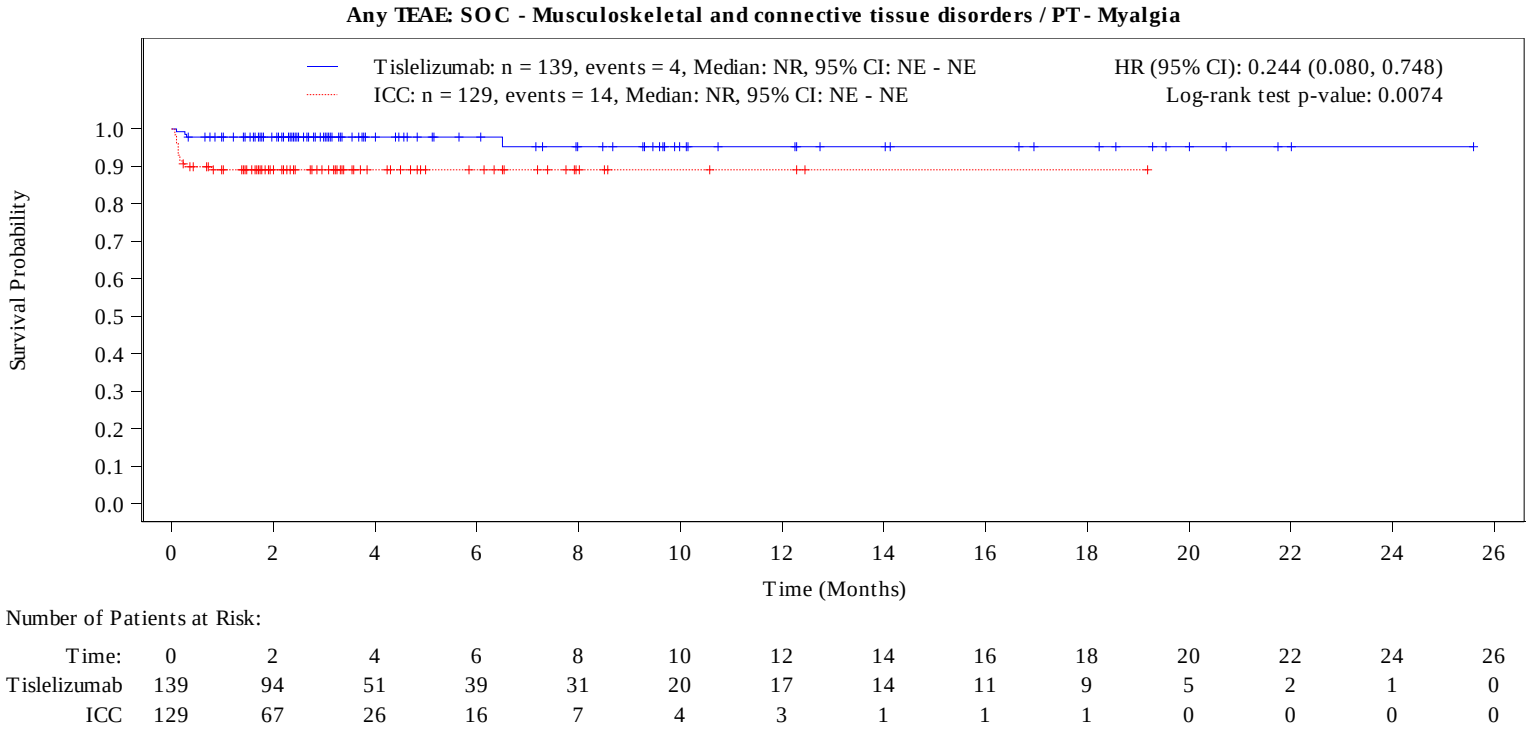
Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

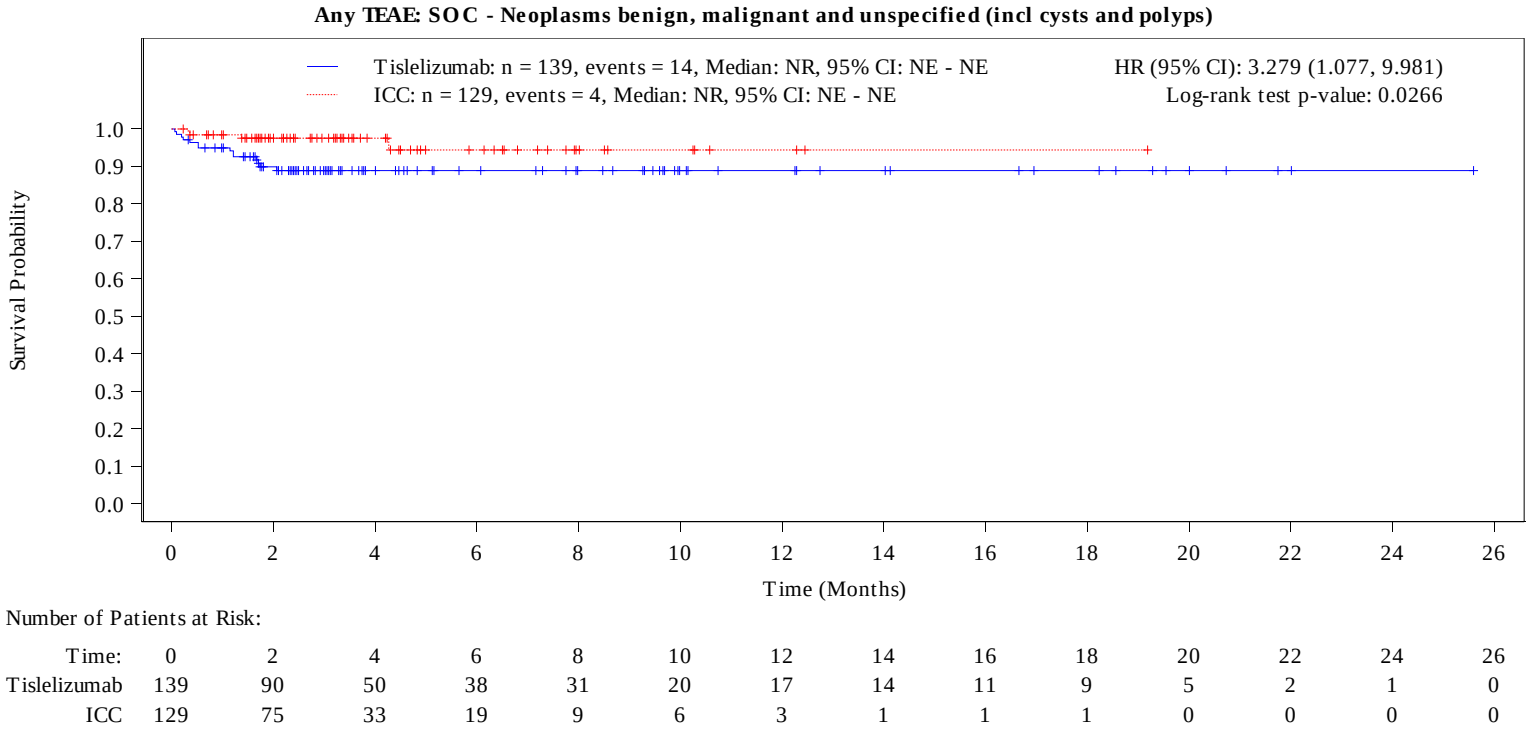


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	94	51	39	31	20	17	14	11	9	5	2	1	0
ICC	129	67	26	16	7	4	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-b-km-aesocpt-safetys-fa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

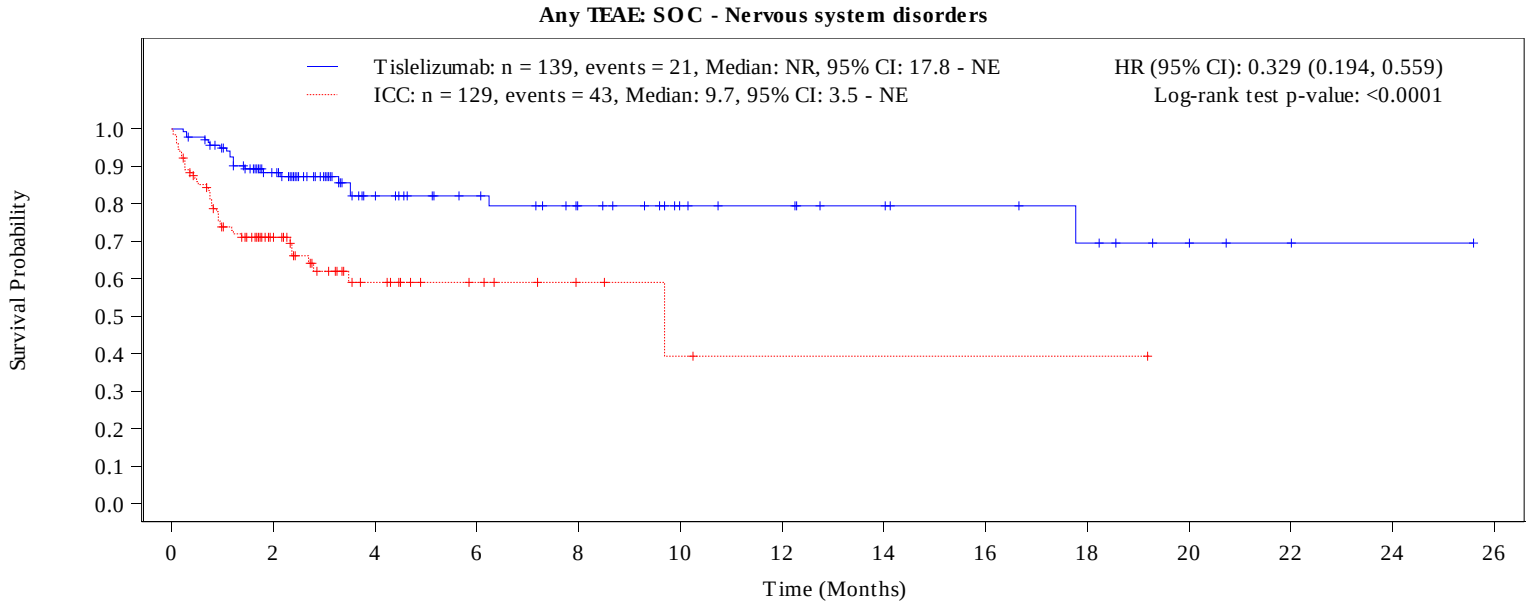


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	90	50	38	31	20	17	14	11	9	5	2	1	0
ICC	129	75	33	19	9	6	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-b-km-aesocpt-safetys-fa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

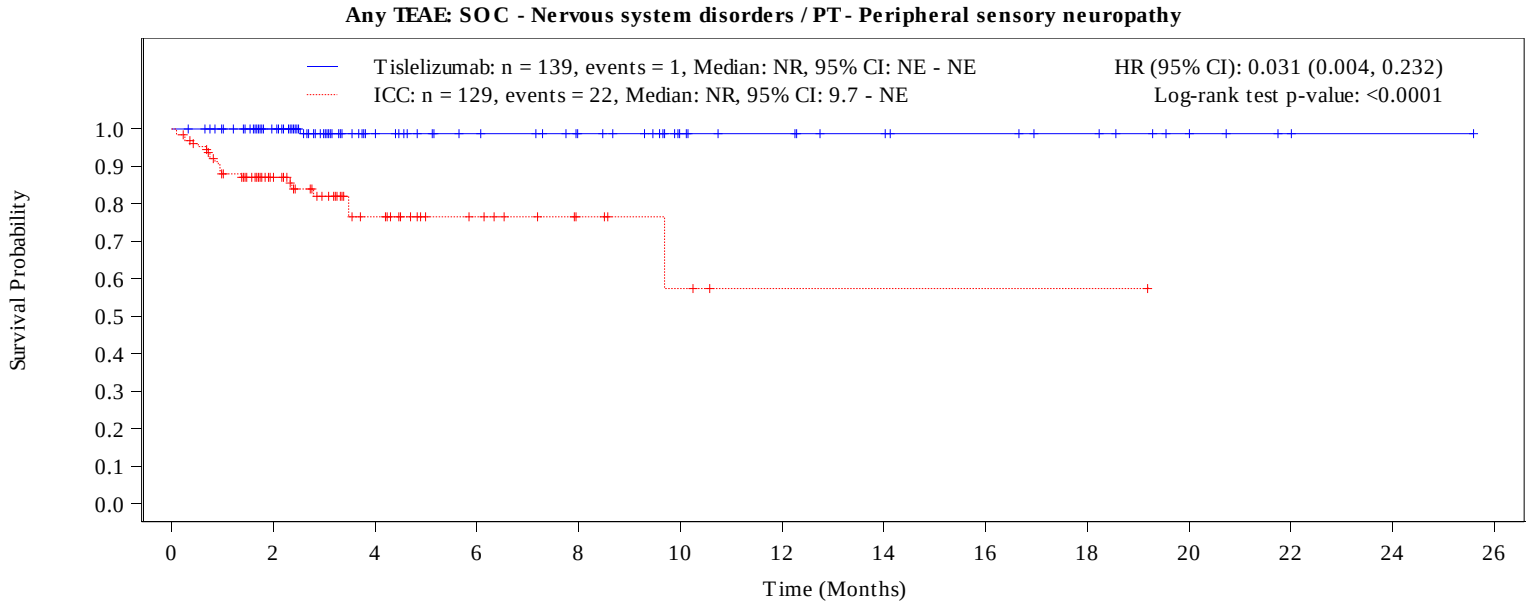


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	85	43	32	24	17	15	12	9	7	4	2	1	0
ICC	129	50	18	8	4	2	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-b-km-aesocpt-safetys-fa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

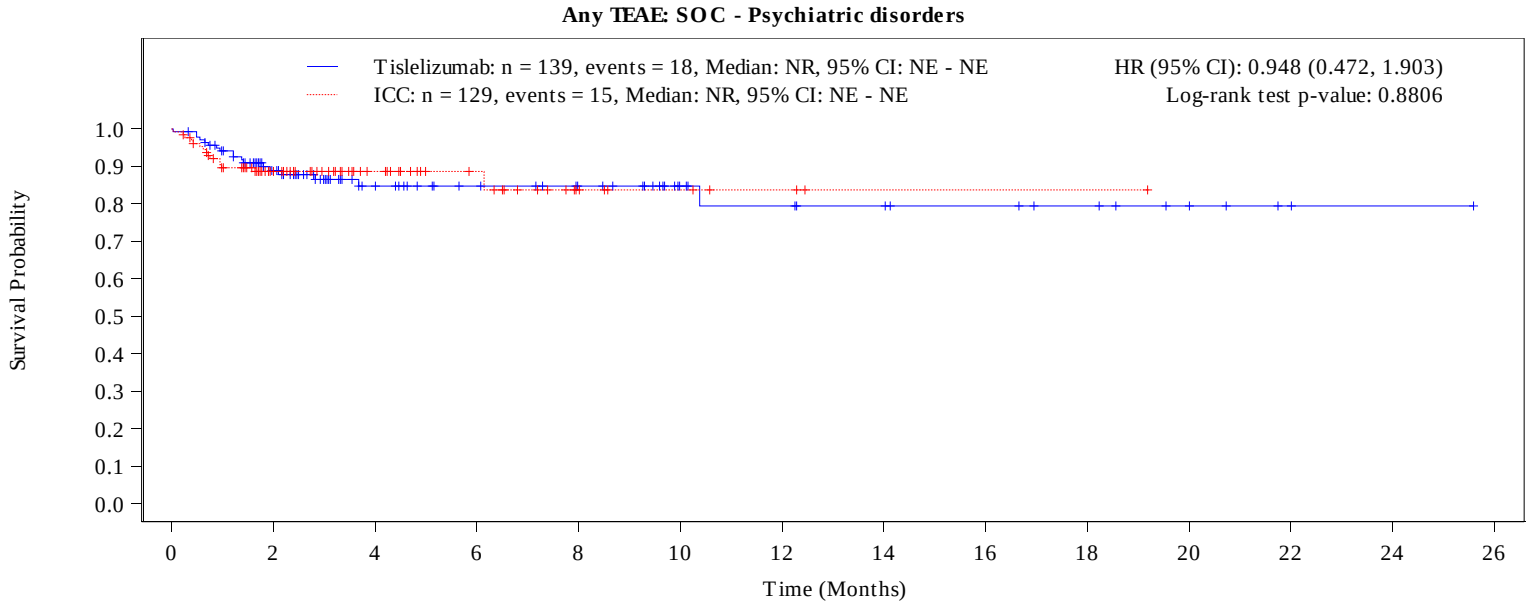


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	95	51	39	31	20	17	14	11	9	5	2	1	0
ICC	129	63	25	12	6	3	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-b-km-aesocpt-safetys-fa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

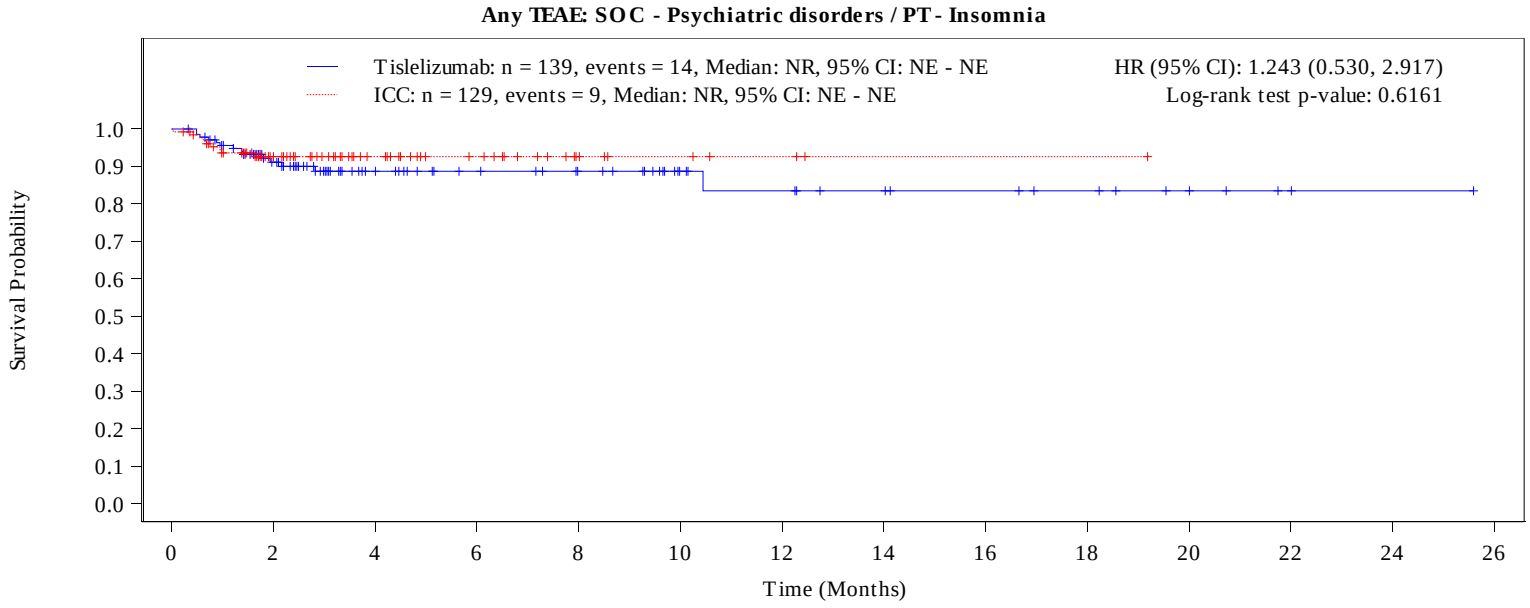


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	84	46	36	30	18	15	13	10	8	5	2	1	0
ICC	129	66	30	18	8	5	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-b-km-aesocpt-safetys-fa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

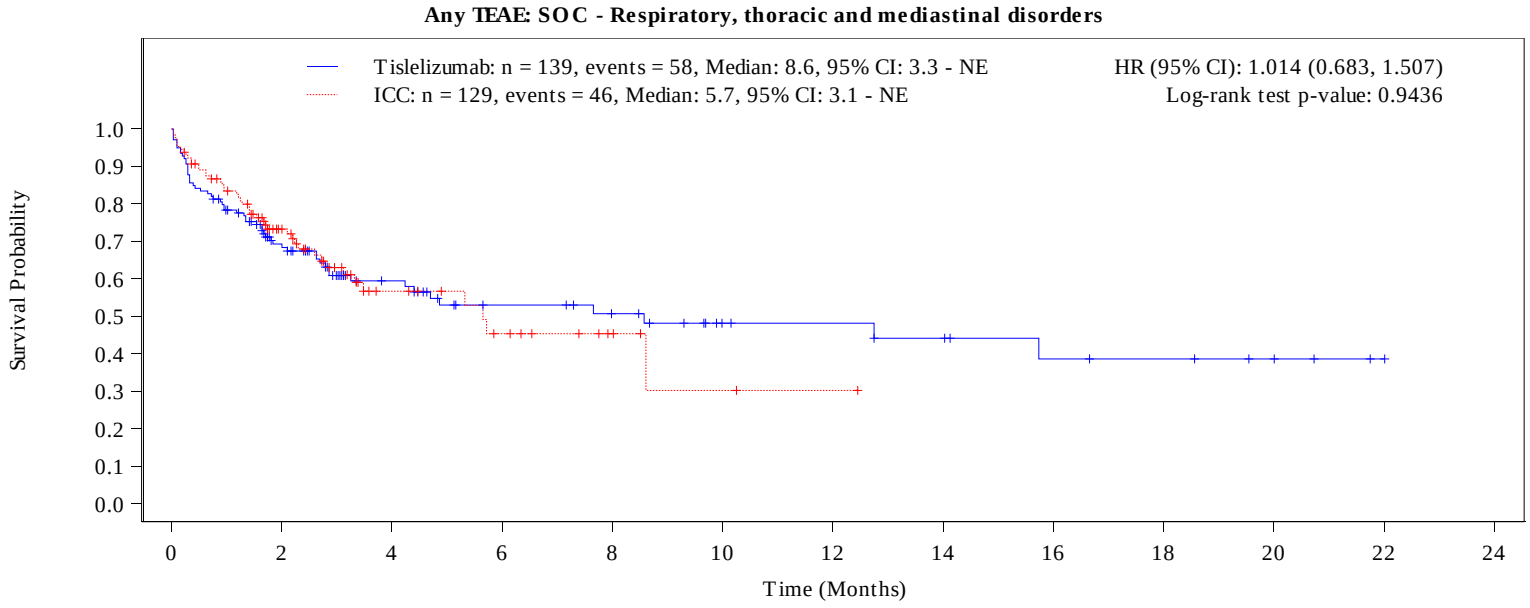


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	85	47	37	31	19	16	13	10	8	5	2	1	0
ICC	129	68	31	18	8	5	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-b-km-aesocpt-safetys-fa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24
Tislelizumab	139	74	40	27	21	13	12	10	7	6	4	1	0
ICC	129	59	20	11	5	2	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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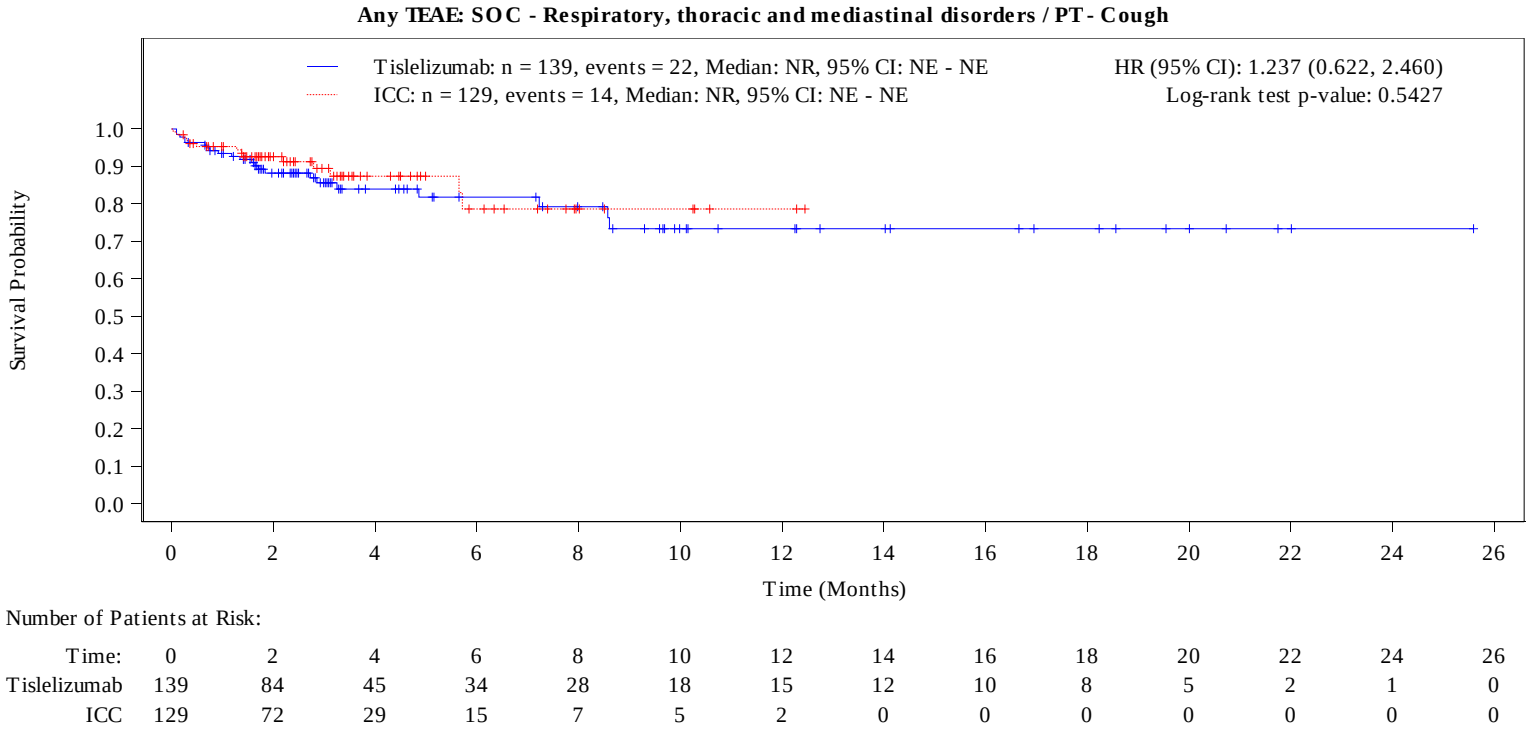
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	84	45	34	28	18	15	12	10	8	5	2	1	0
ICC	129	72	29	15	7	5	2	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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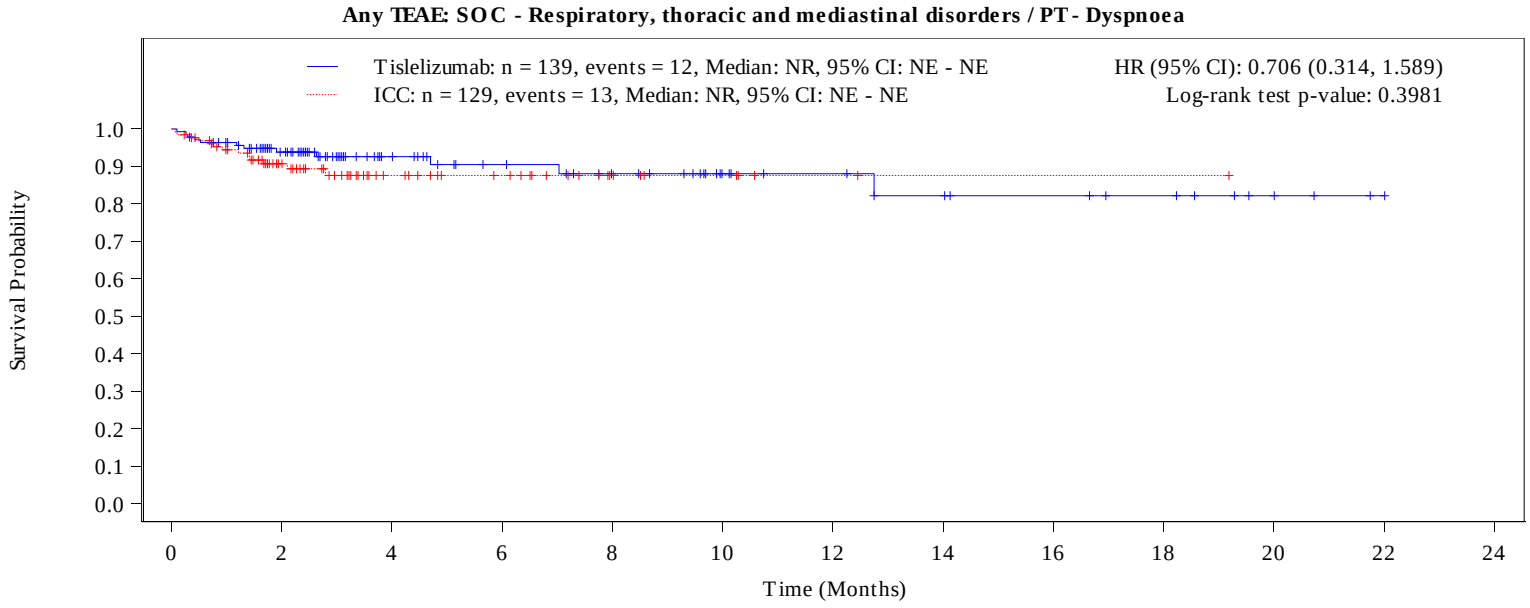
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24
Tislelizumab	139	93	51	38	30	19	16	13	10	8	4	1	0
ICC	129	69	29	18	8	5	2	1	1	1	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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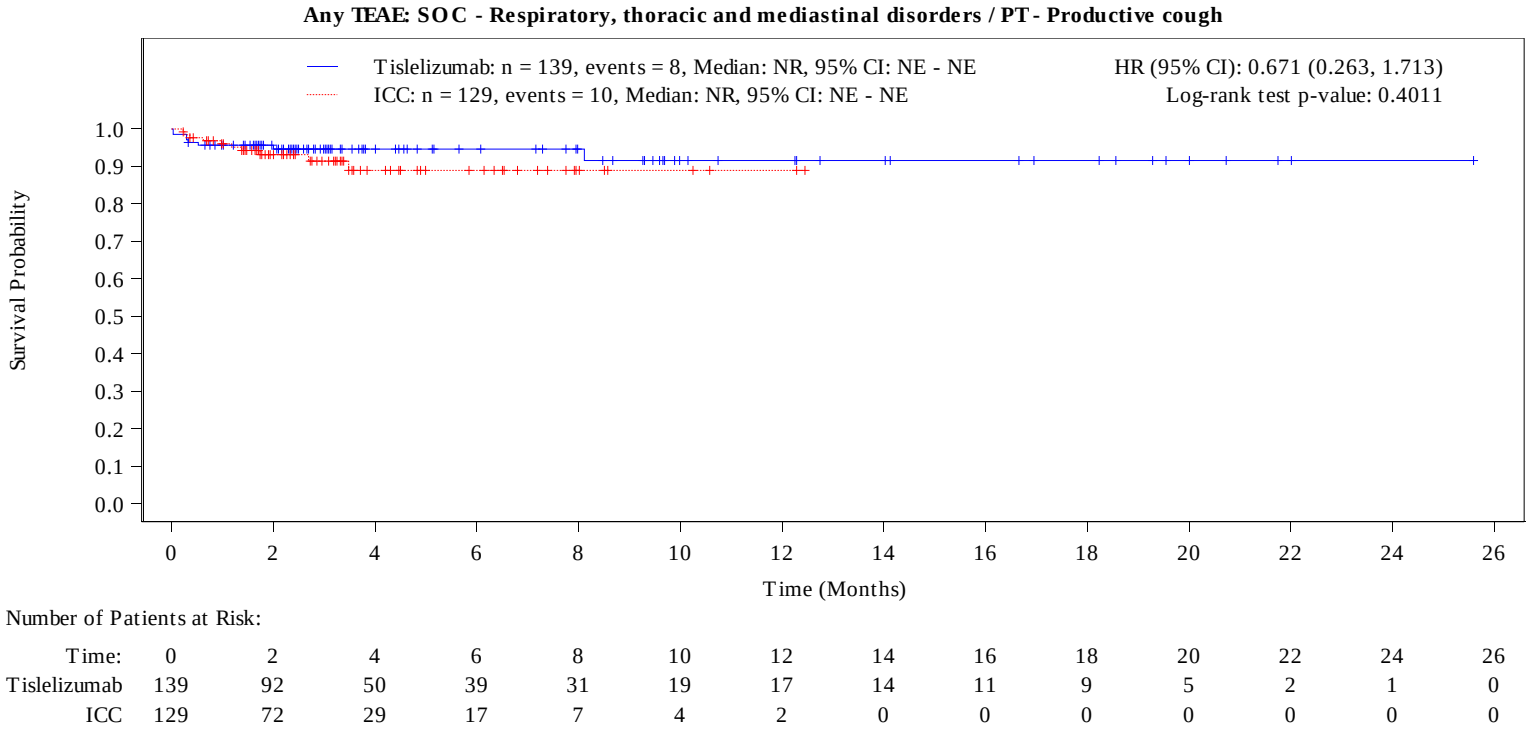
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	92	50	39	31	19	17	14	11	9	5	2	1	0
ICC	129	72	29	17	7	4	2	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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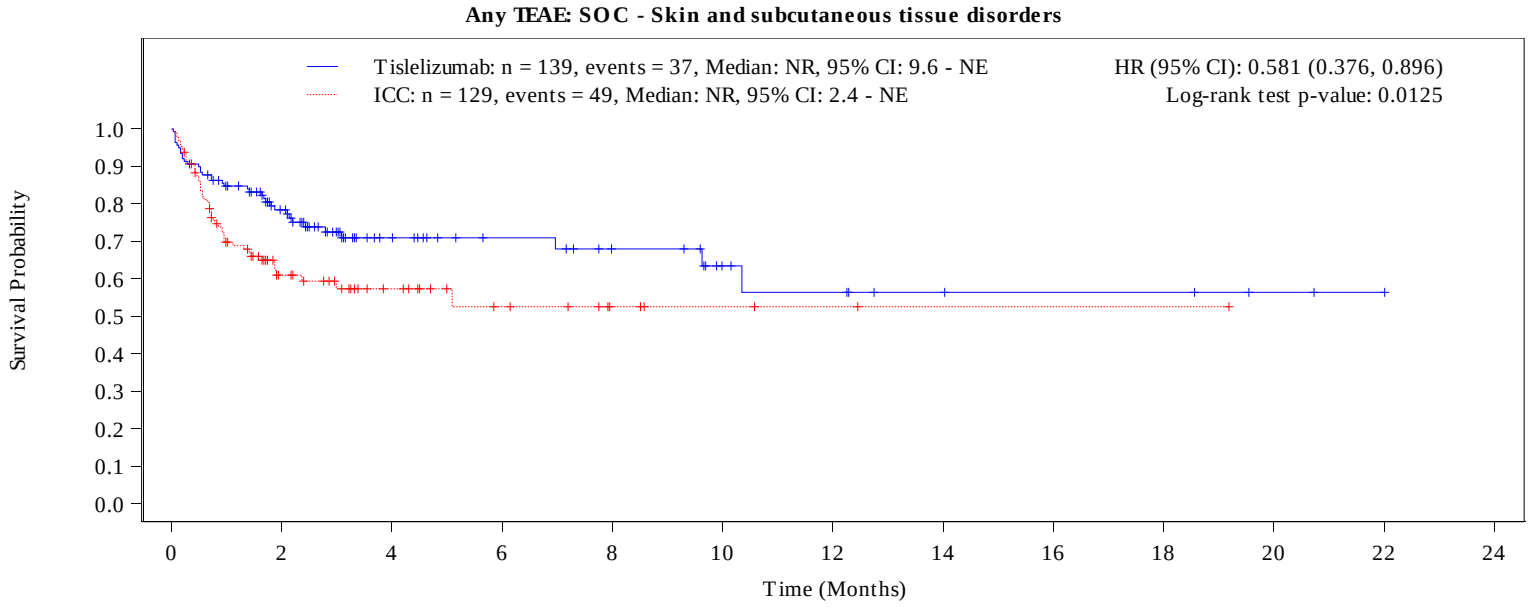
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24
Tislelizumab	139	73	33	24	17	10	8	5	4	4	2	1	0
ICC	129	43	18	10	5	3	2	1	1	1	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-b-km-aesocpt-safetys-fa.rtf

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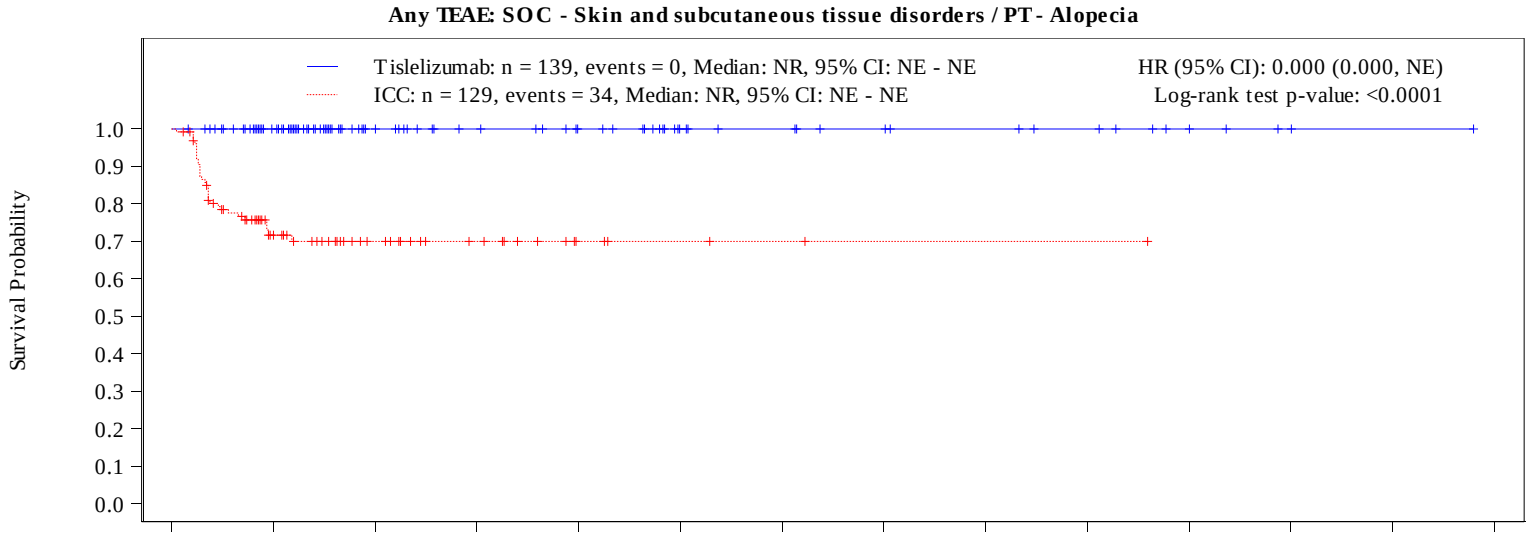

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	95	52	40	32	20	17	14	11	9	5	2	1	0
ICC	129	50	21	13	5	3	2	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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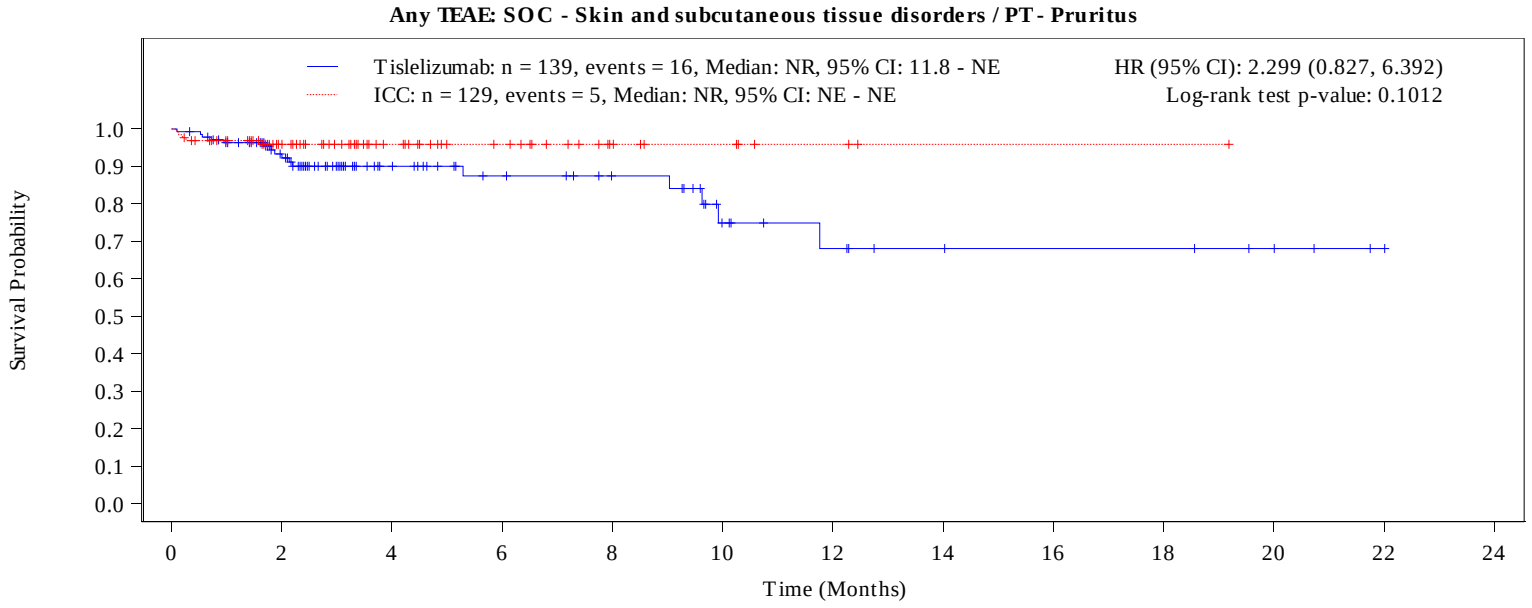
Safety Analysis Set - Subpopulation without Irinotecan

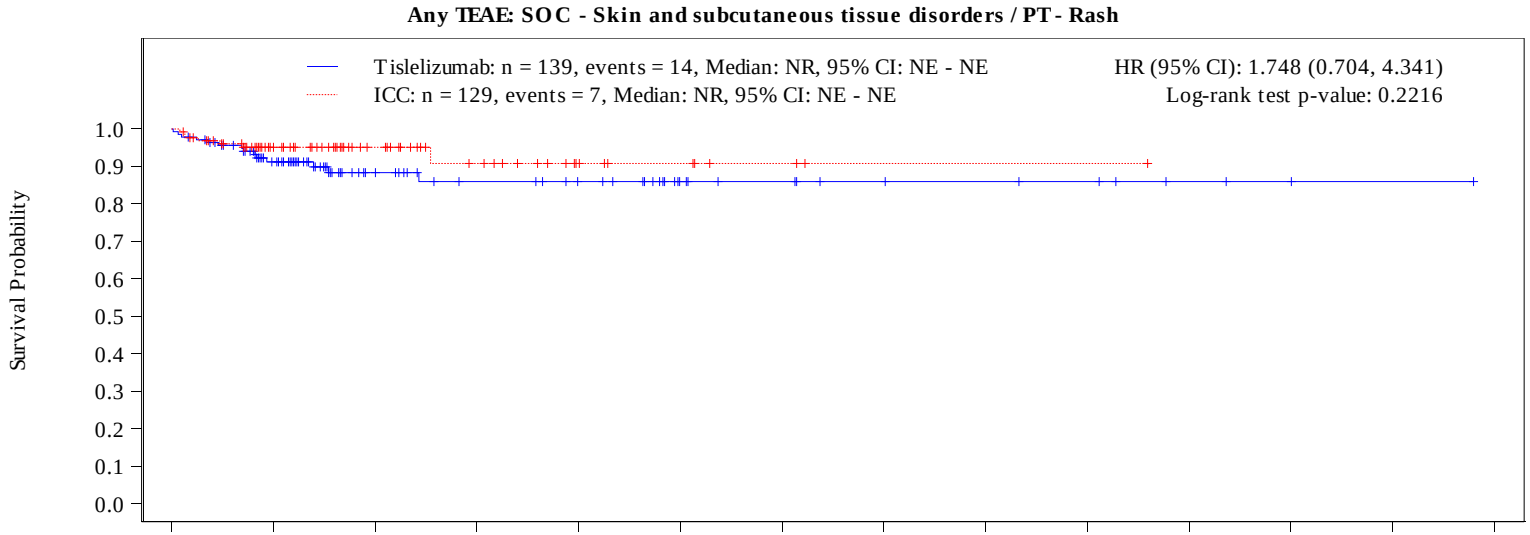


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24
Tislelizumab	139	87	45	33	26	14	10	7	6	6	4	1	0
ICC	129	71	32	19	9	6	3	1	1	1	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-b-km-aesocpt-safetys-fa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

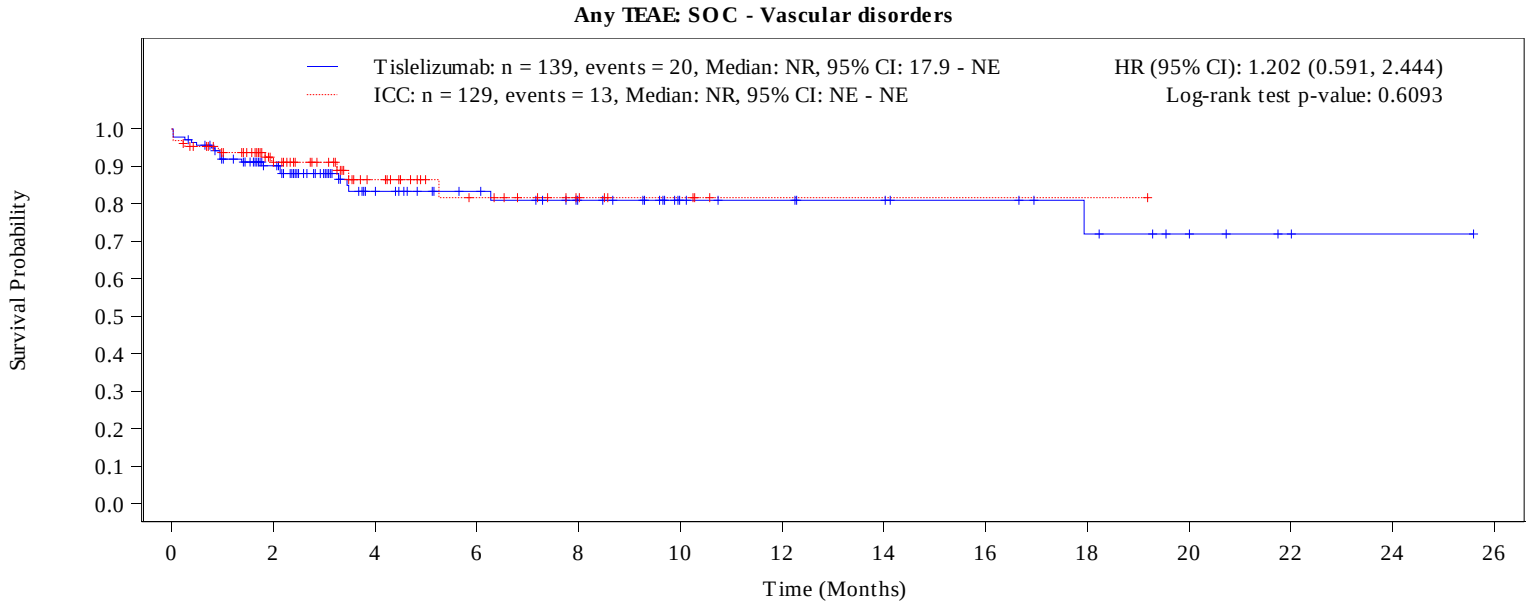


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	86	44	33	27	15	12	9	7	6	3	2	1	0
ICC	129	69	32	18	9	6	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-b-km-aesocpt-safetys-fa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

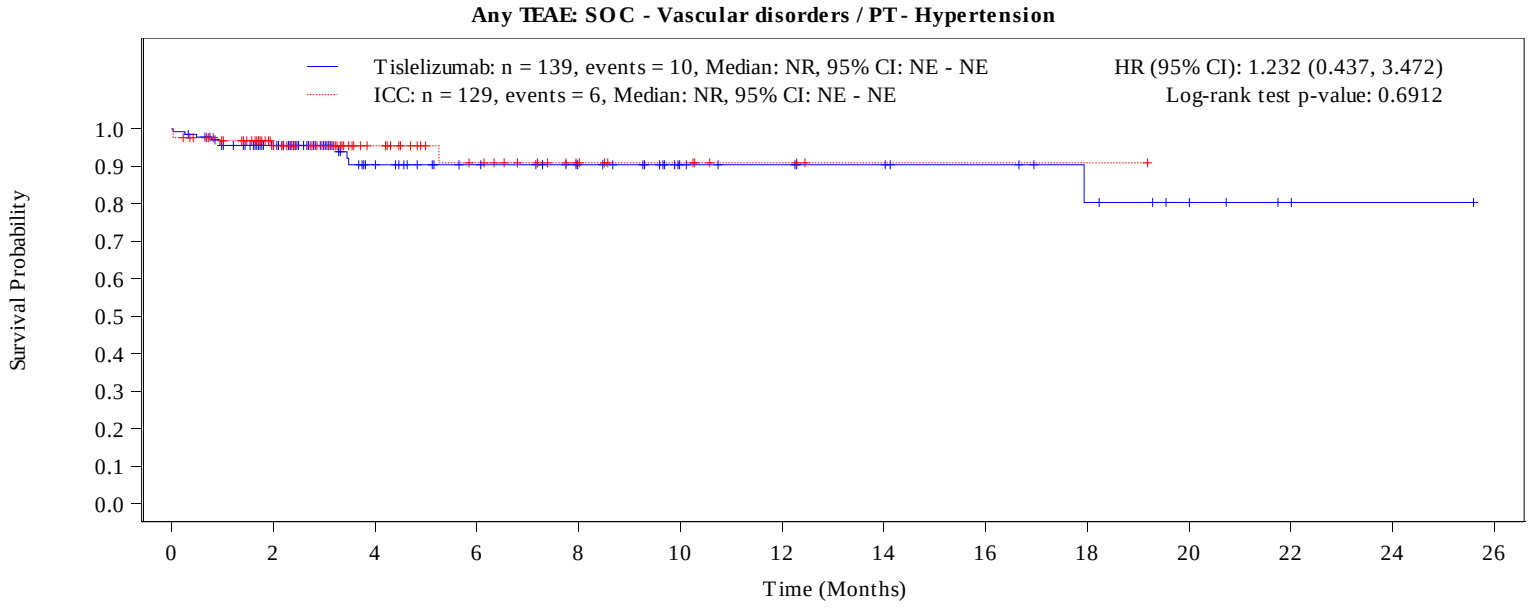


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	89	48	36	27	17	15	13	11	8	5	2	1	0
ICC	129	67	29	14	7	4	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-b-km-aesocpt-safetys-fa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

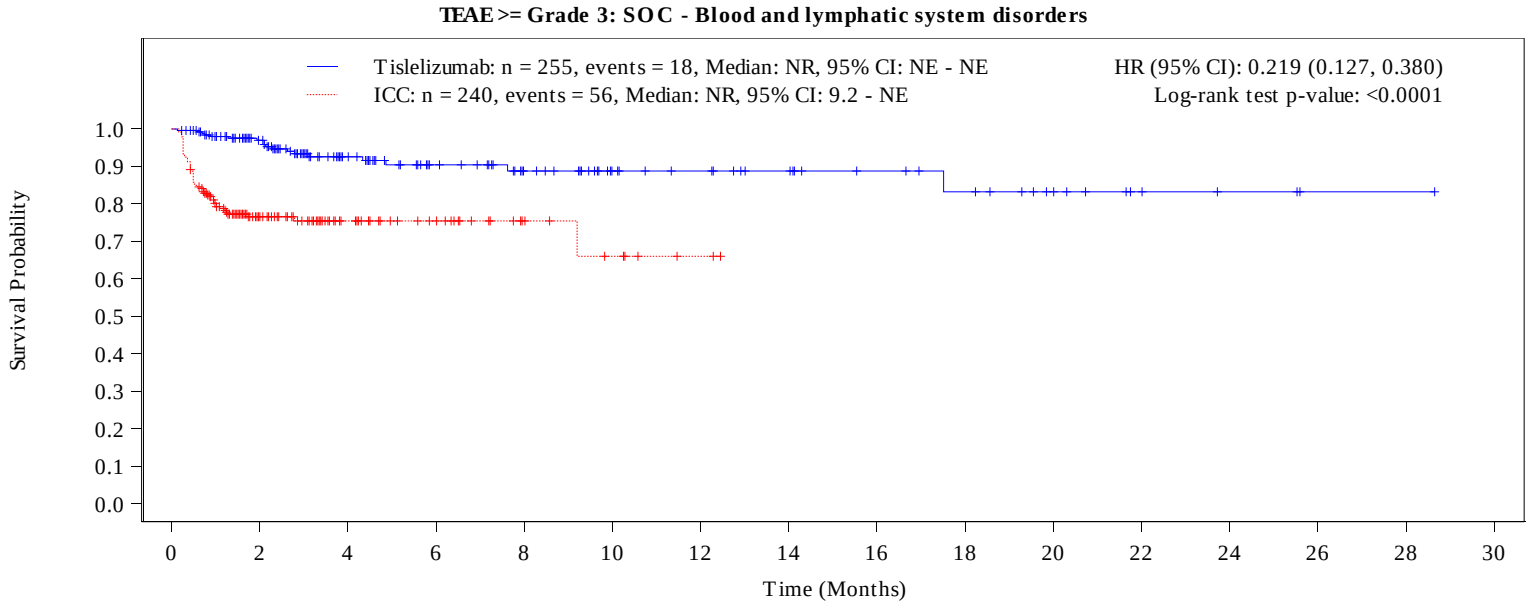


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	91	48	36	28	18	16	14	11	8	5	2	1	0
ICC	129	71	32	17	9	6	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-02-b-km-aesocpt-safetys-fa.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

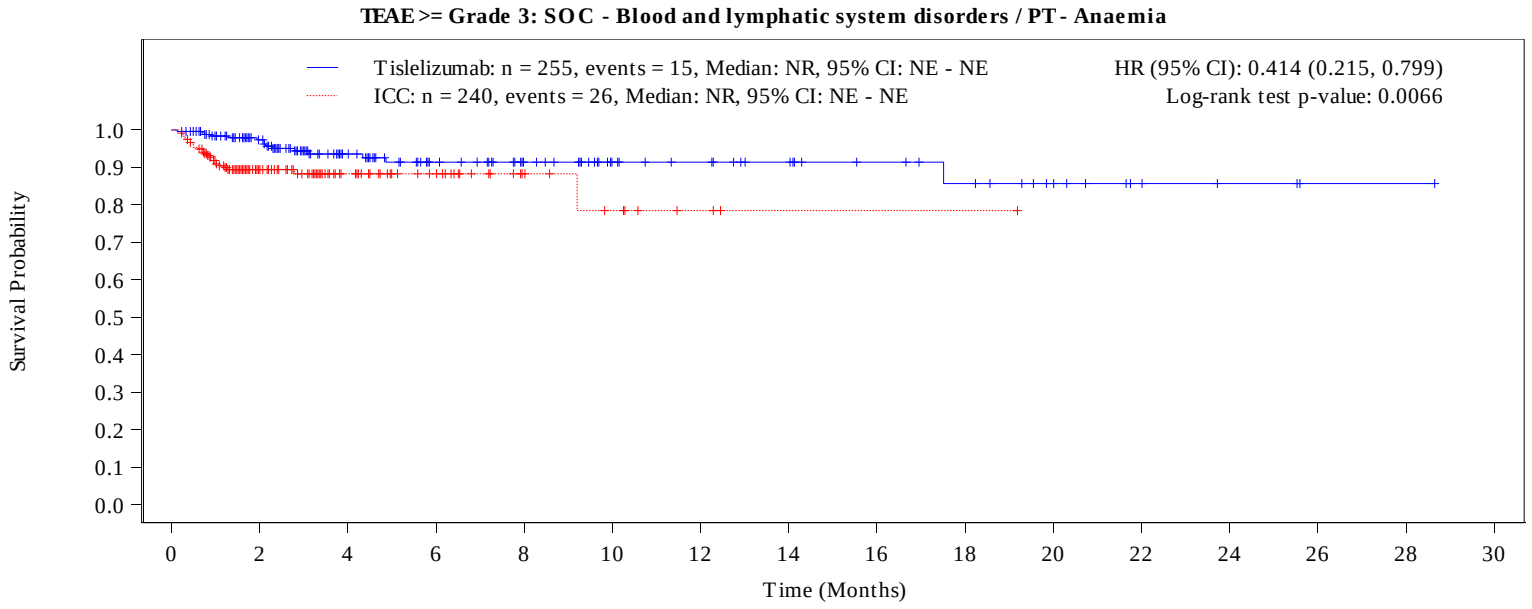


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	172	96	65	48	33	28	23	18	15	10	5	3	1	1	0
ICC	240	95	37	22	10	6	2	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-03-km-aesocpt-g3-safety-fa.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

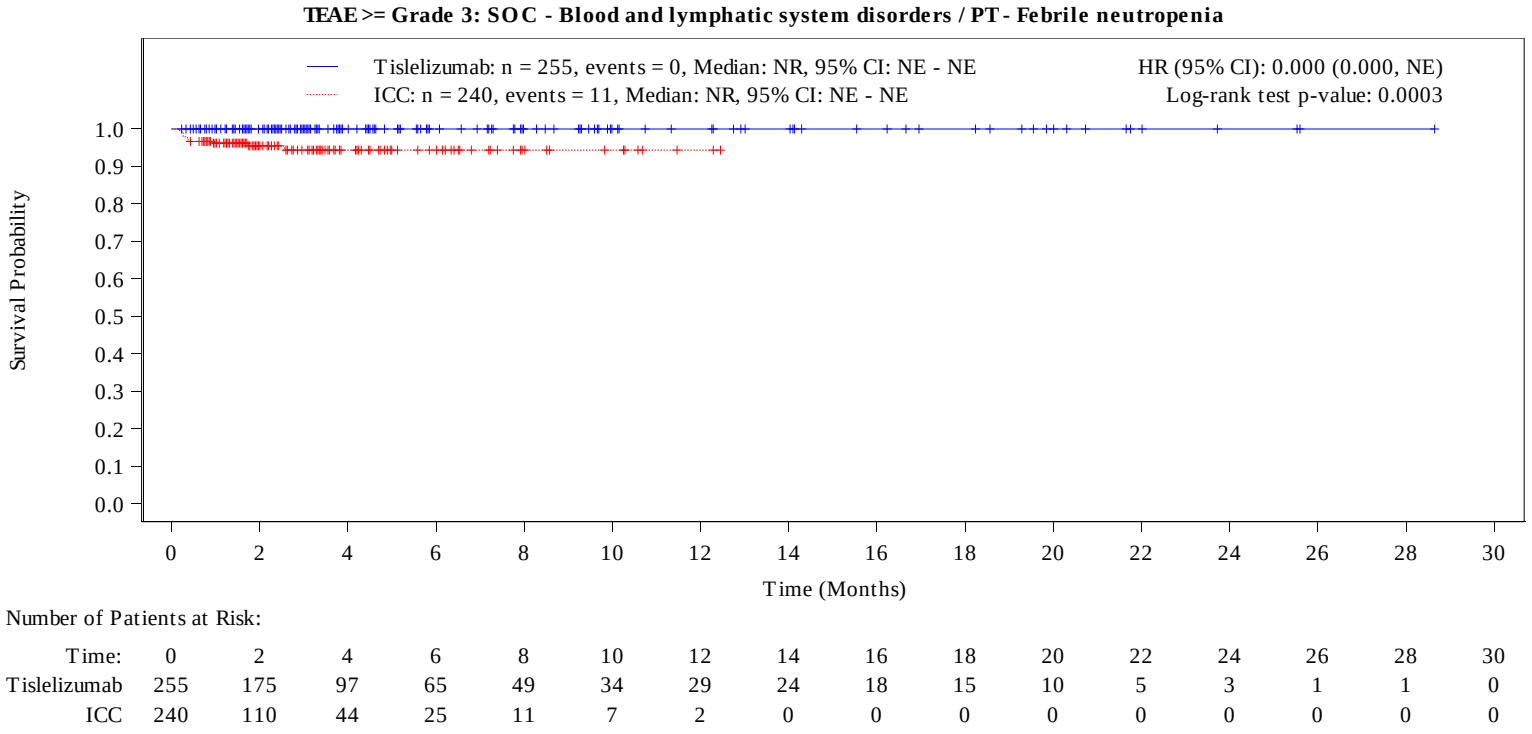


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	172	96	65	49	34	29	24	18	15	10	5	3	1	1	0
ICC	240	109	42	24	11	7	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-03-km-aesocpt-g3-safety-fa.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	175	97	65	49	34	29	24	18	15	10	5	3	1	1	0
ICC	240	110	44	25	11	7	2	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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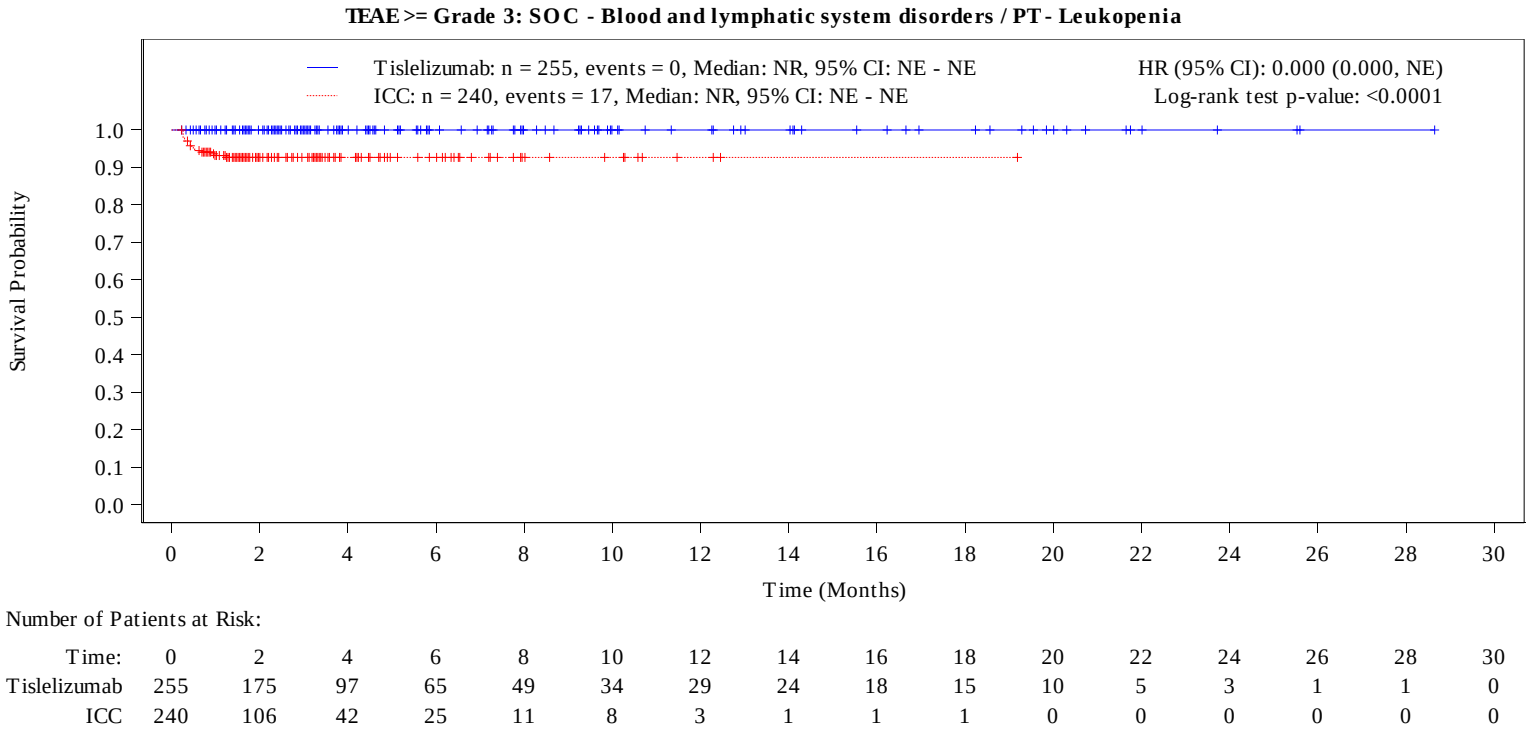
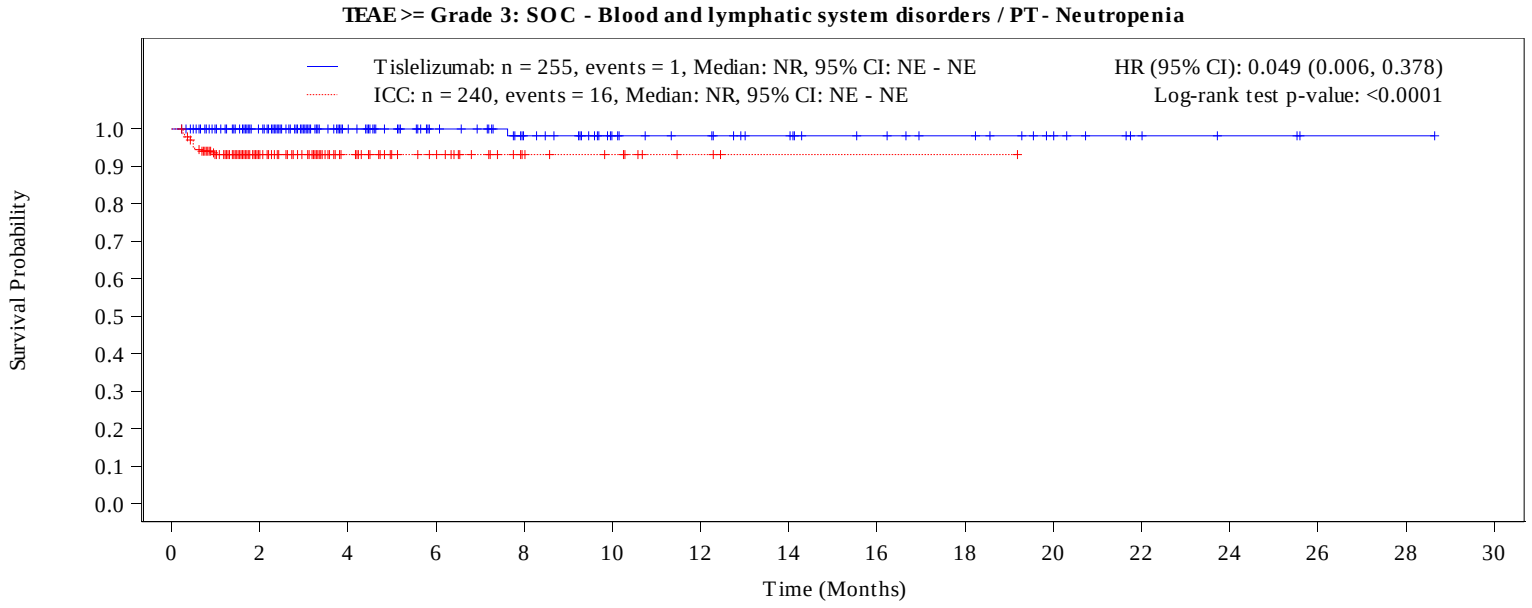
Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-03-km-aesocpt-g3-safety-fa.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	175	97	65	48	33	28	23	18	15	10	5	3	1	1	0
ICC	240	106	41	24	11	8	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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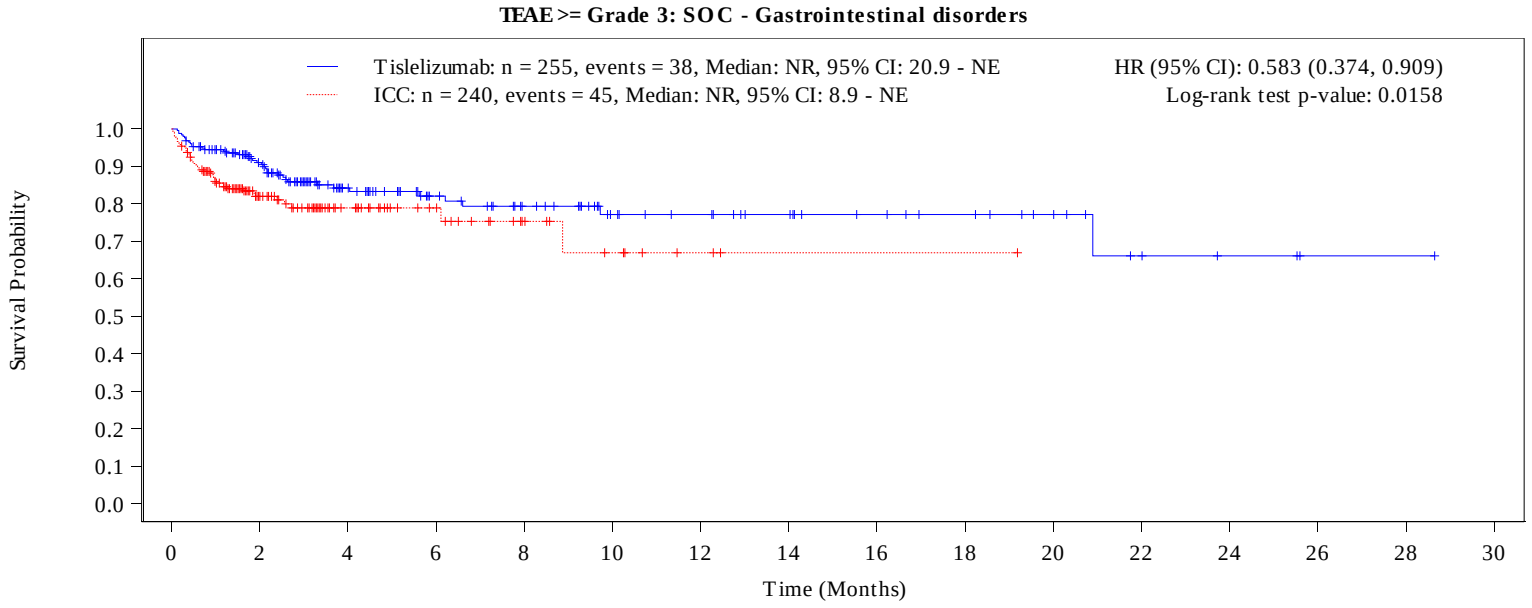
Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

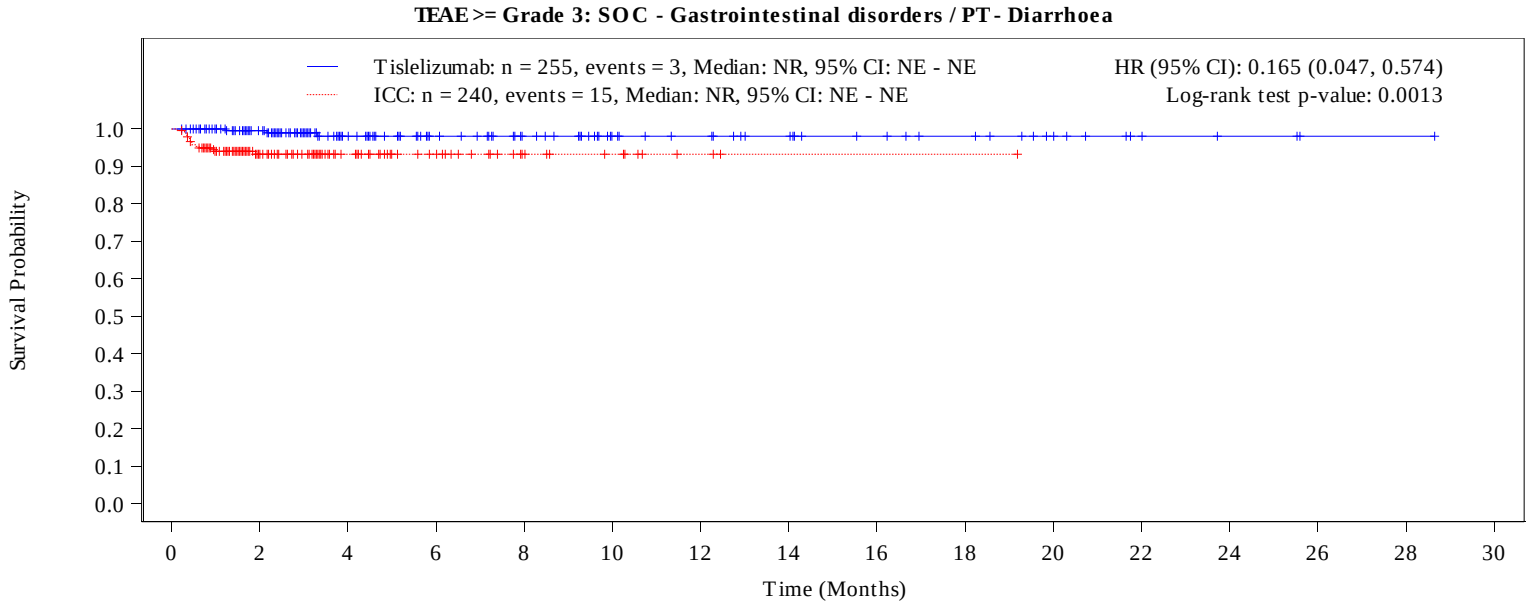


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	167	92	62	48	33	28	23	17	14	10	5	3	1	1	0
ICC	240	100	41	23	12	7	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-03-km-aesocpt-g3-safety-fa.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

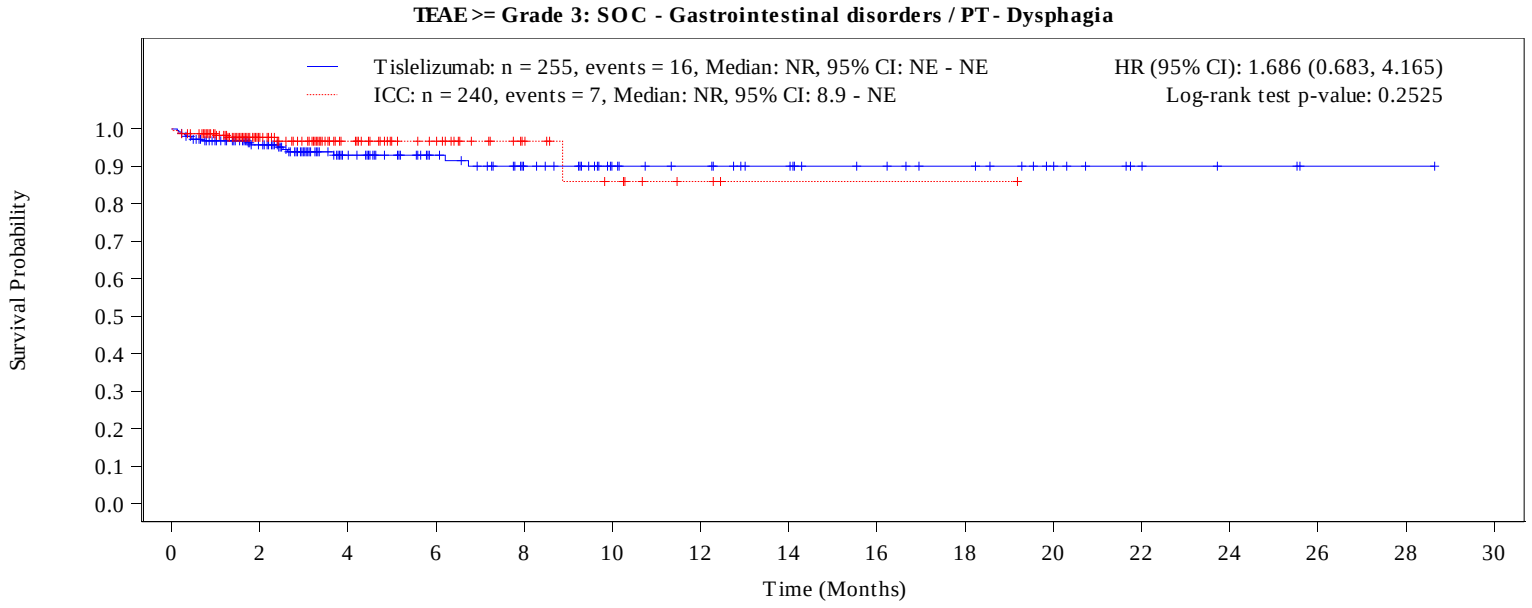


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	174	95	64	49	34	29	24	18	15	10	5	3	1	1	0
ICC	240	108	43	24	12	8	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-03-km-aesocpt-g3-safety-fa.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

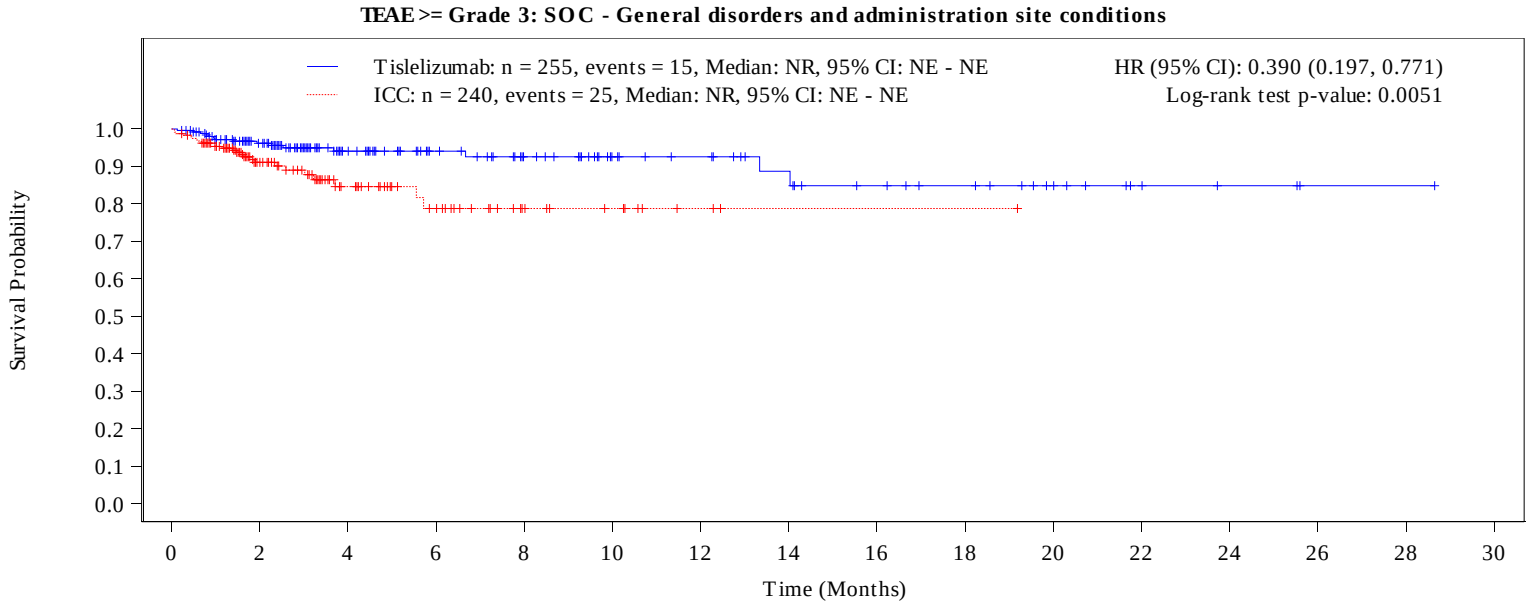


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	171	96	65	49	34	29	24	18	15	10	5	3	1	1	0
ICC	240	108	44	25	12	7	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-03-km-aesocpt-g3-safety-fa.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

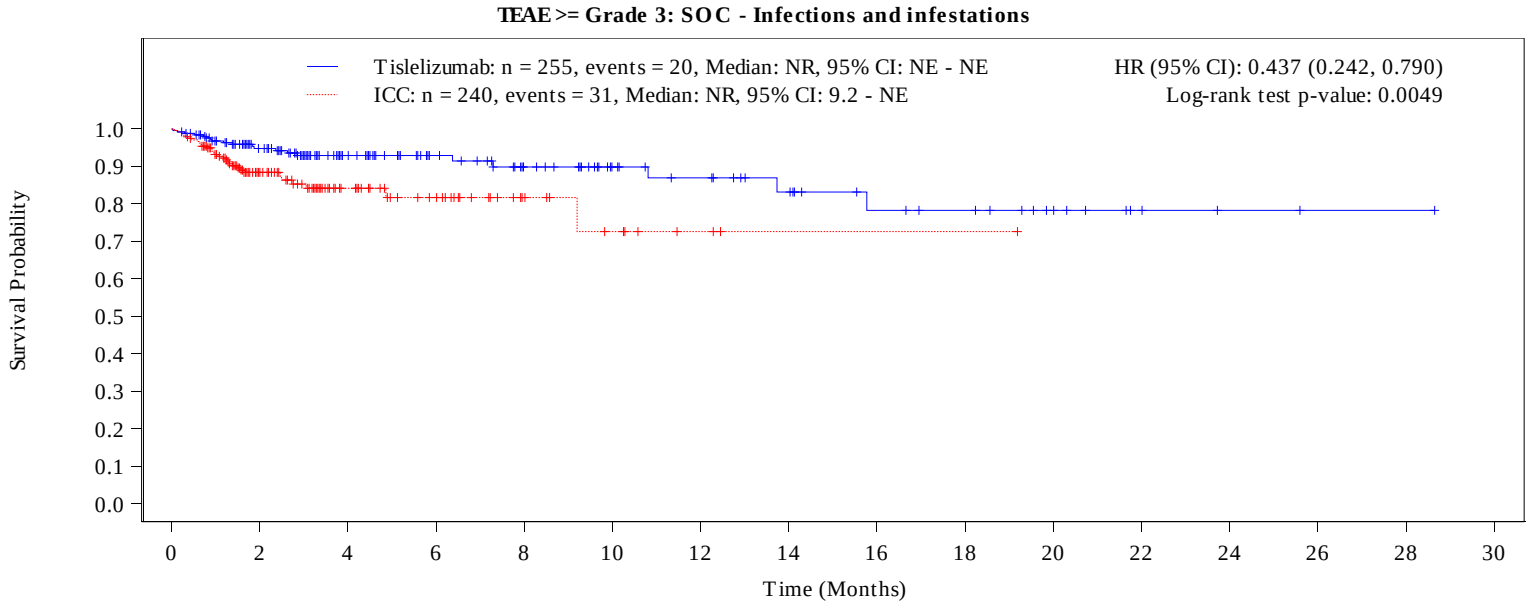


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	173	97	65	49	34	29	23	18	15	10	5	3	1	1	0
ICC	240	108	43	25	12	8	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-03-km-aesocpt-g3-safety-fa.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	169	97	65	49	34	28	22	16	14	9	4	2	1	1	0
ICC	240	110	44	26	12	7	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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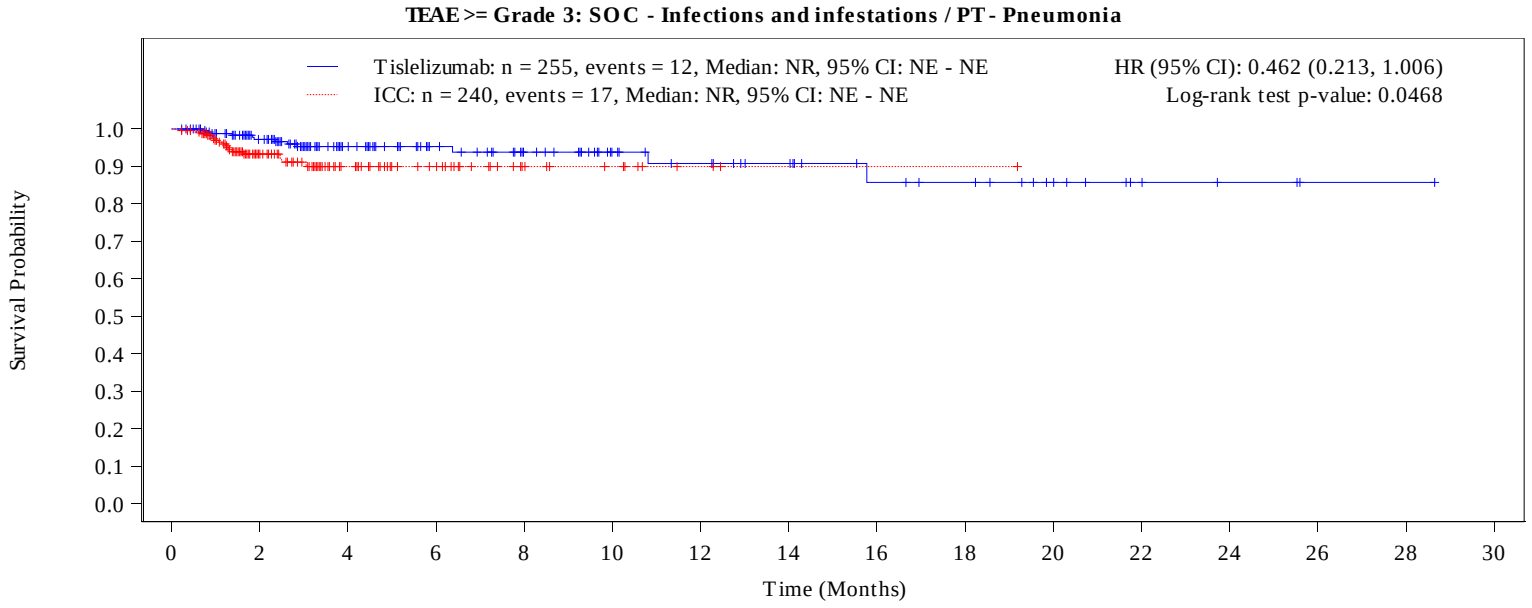
Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

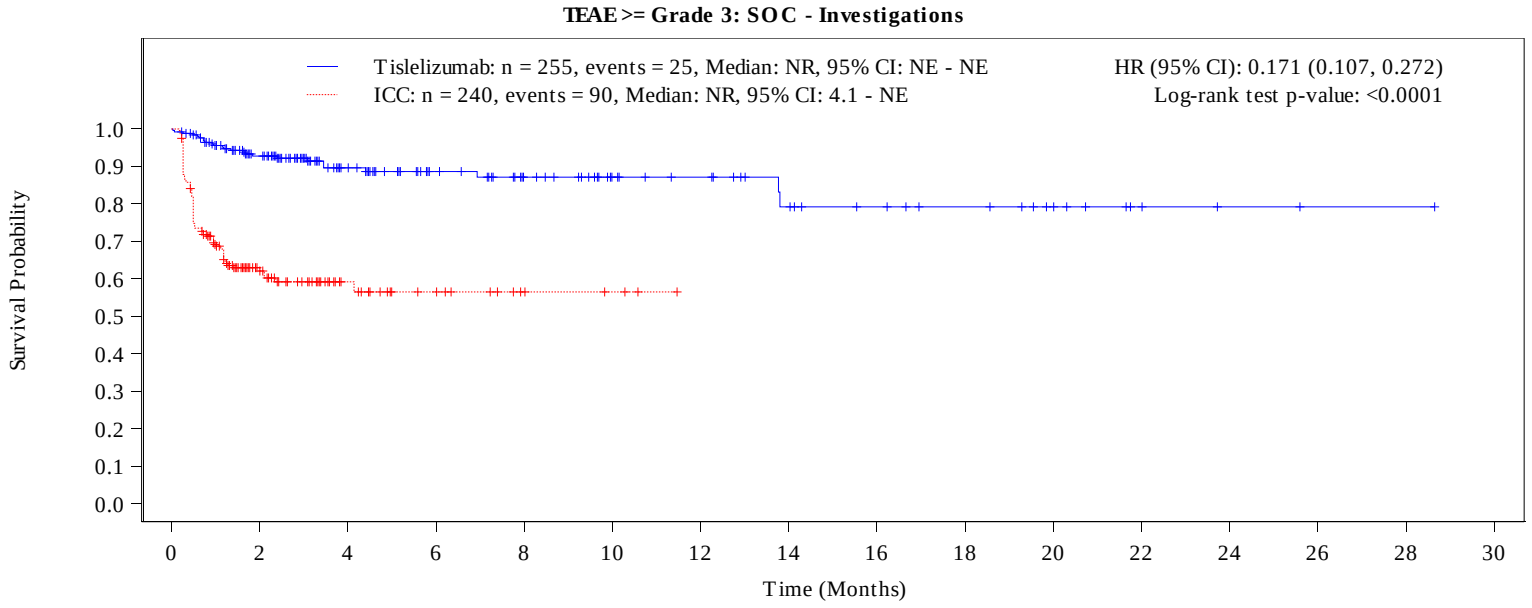


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	173	97	65	49	34	28	23	17	15	10	5	3	1	1	0
ICC	240	112	45	26	12	8	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-03-km-aesocpt-g3-safety-fa.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

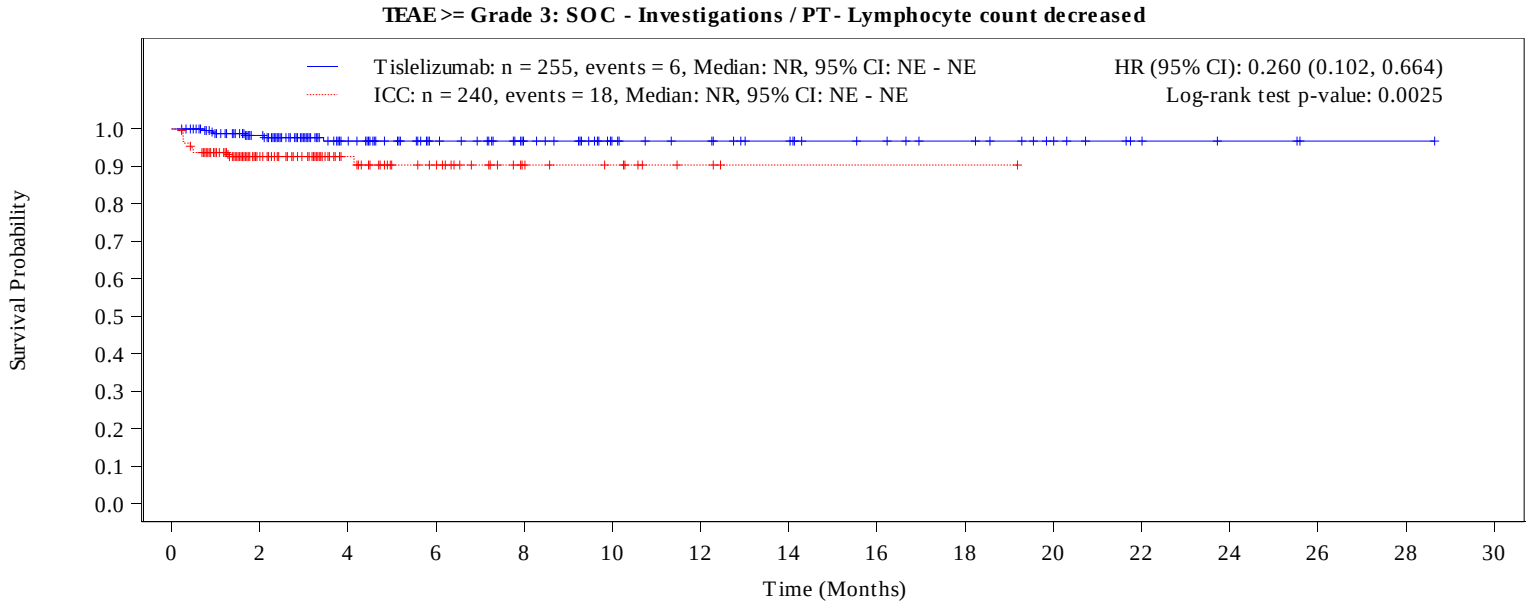


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	166	93	61	46	32	27	20	16	13	9	4	2	1	1	0
ICC	240	71	22	12	5	3	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-03-km-aesocpt-g3-safety-fa.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

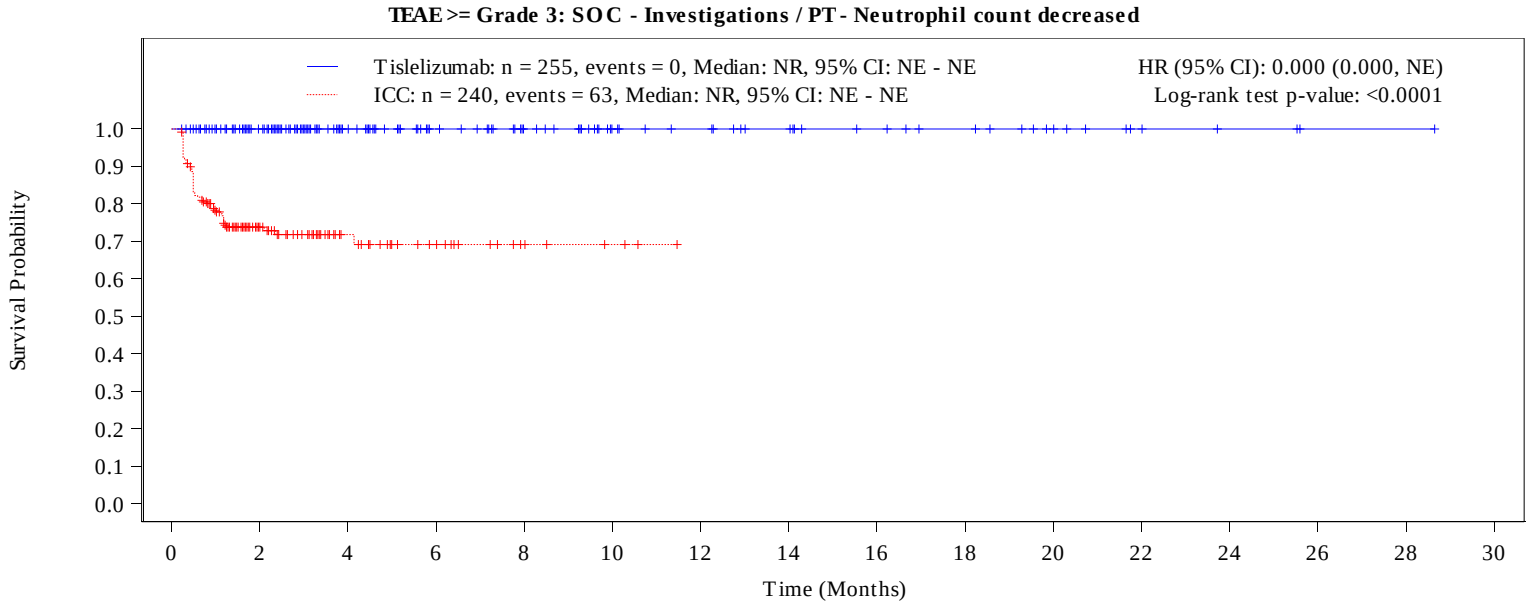


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	172	97	65	49	34	29	24	18	15	10	5	3	1	1	0
ICC	240	107	41	24	11	8	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-03-km-aesocpt-g3-safety-fa.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	175	97	65	49	34	29	24	18	15	10	5	3	1	1	0
ICC	240	81	27	15	6	3	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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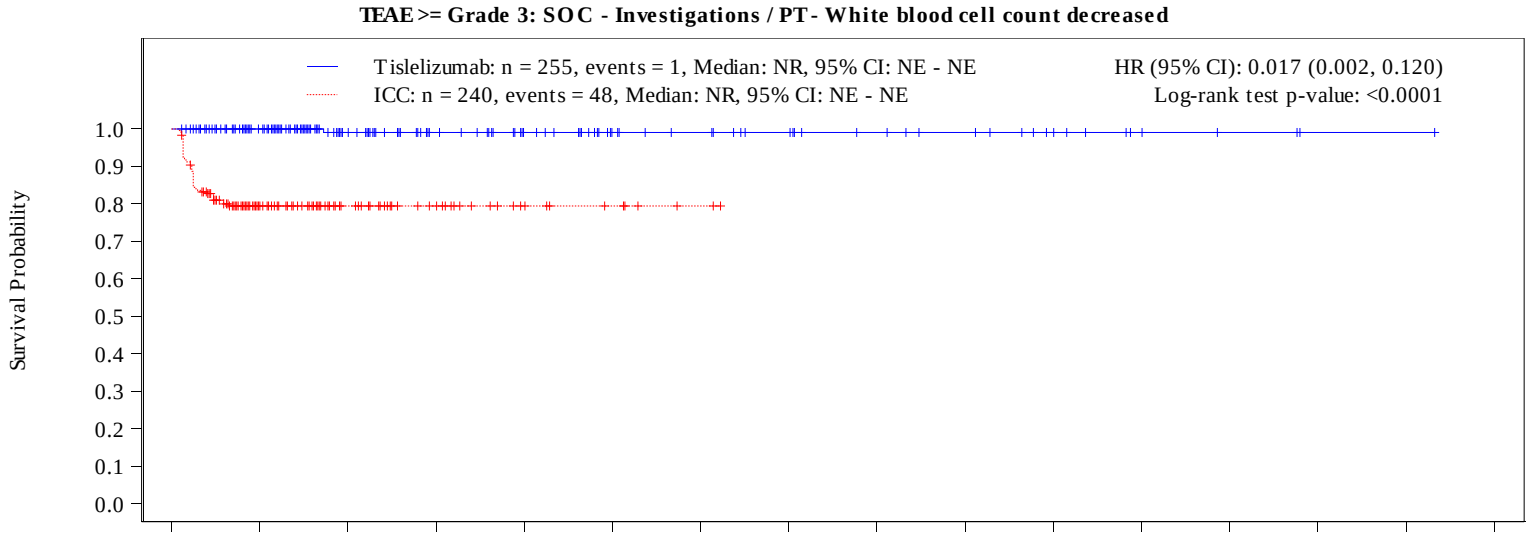
Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

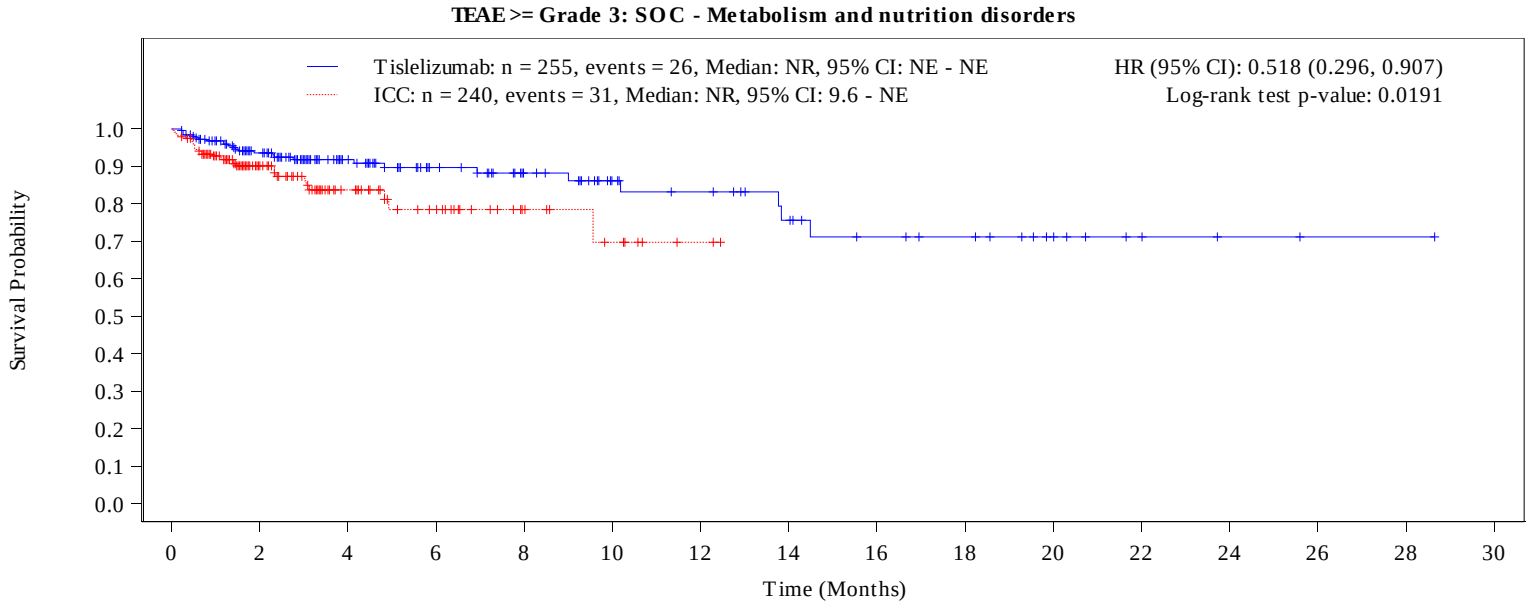


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	175	96	64	49	34	29	24	18	15	10	5	3	1	1	0
ICC	240	91	36	21	10	6	2	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-03-km-aesocpt-g3-safety-fa.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

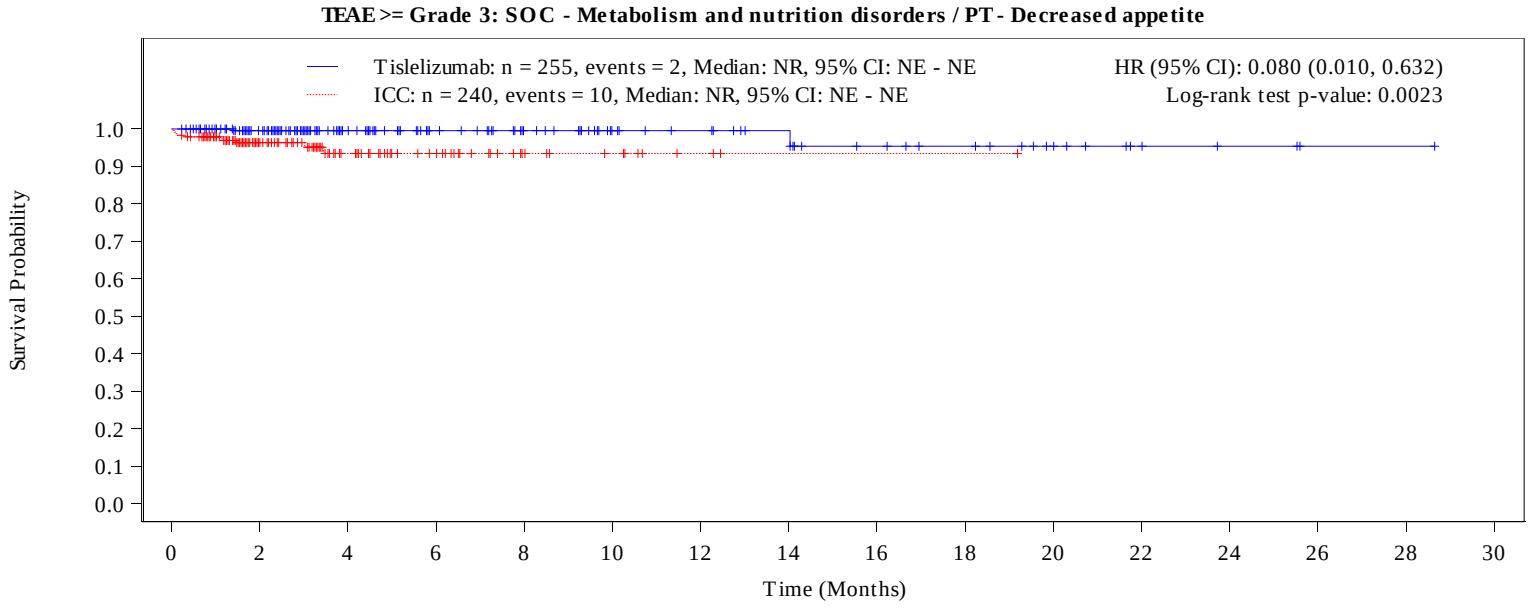


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	169	96	63	46	31	26	20	15	13	8	4	2	1	1	0
ICC	240	108	43	25	12	7	2	0	0	0	0	0	0	0	0	0

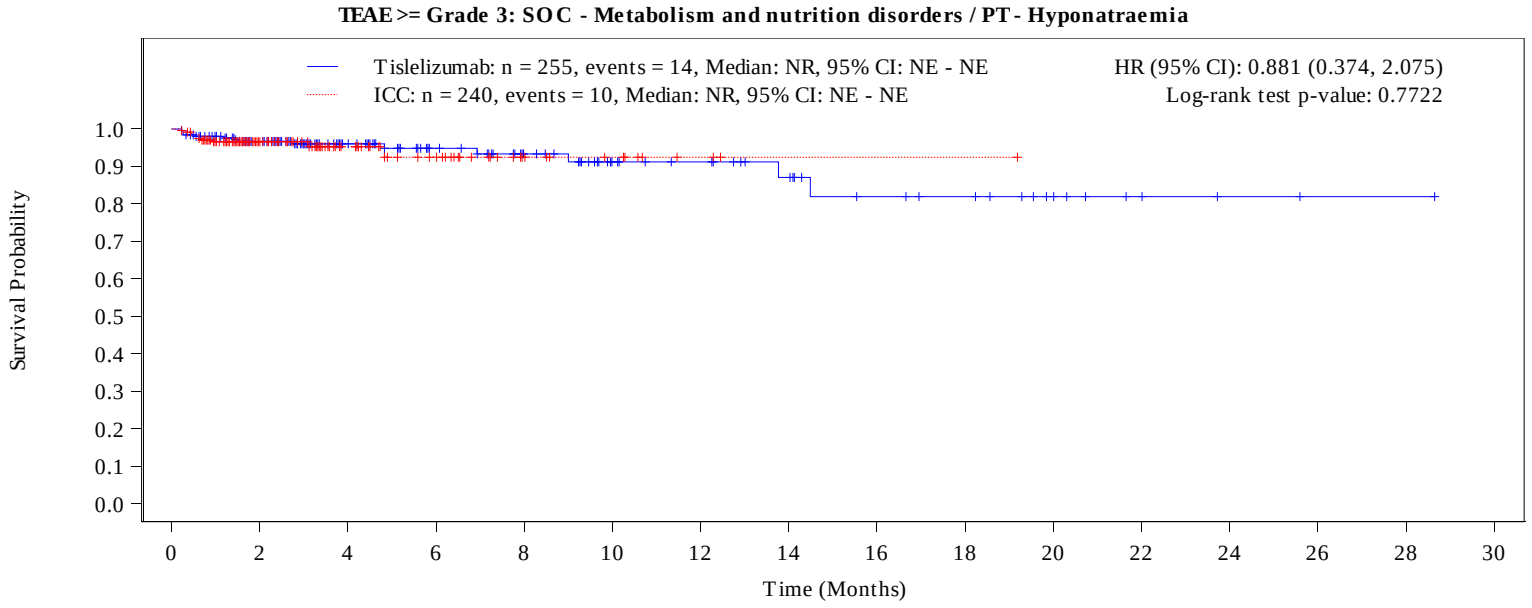
Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-03-km-aesocpt-g3-safety-fa.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-03-km-aesocpt-g3-safety-fa.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

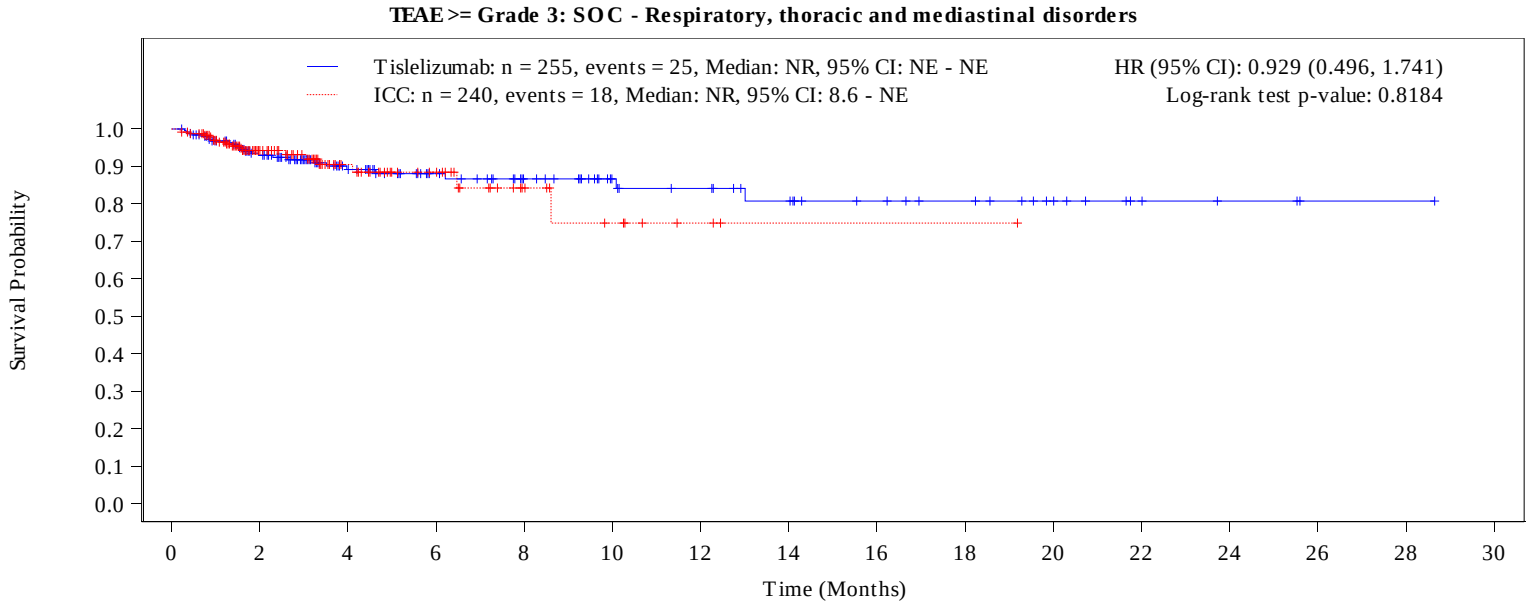


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	173	97	65	48	32	27	21	15	13	8	4	2	1	1	0
ICC	240	111	44	26	12	8	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-03-km-aesocpt-g3-safety-fa.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

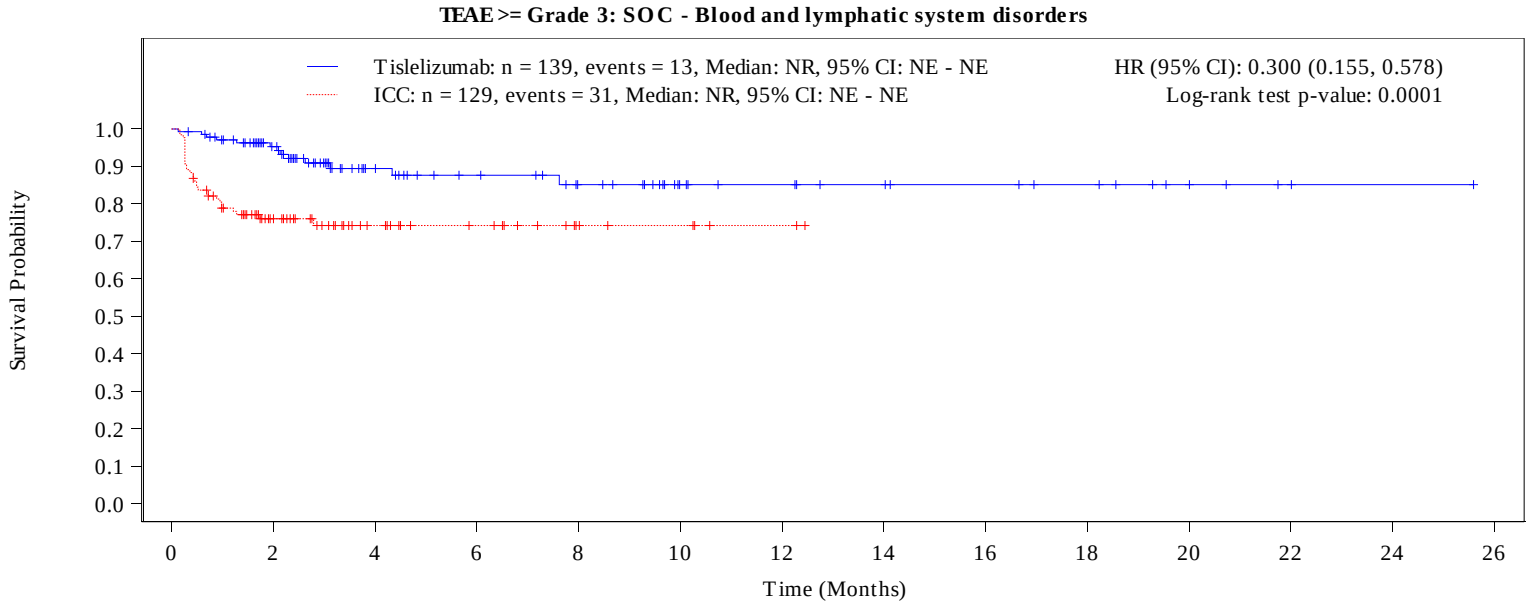


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	170	96	64	49	34	29	24	18	15	10	5	3	1	1	0
ICC	240	112	44	26	12	7	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-03-km-aesocpt-g3-safety-fa.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

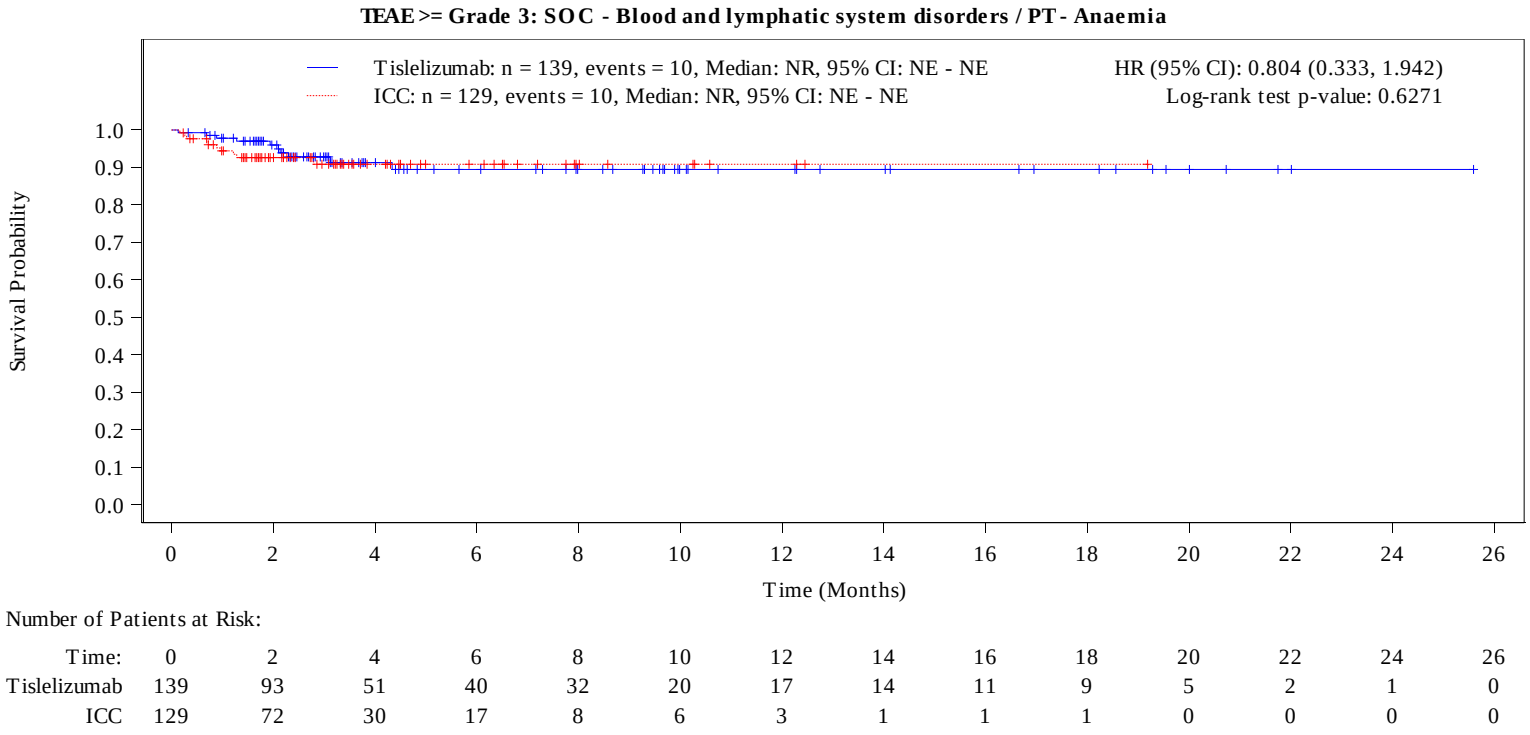


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	93	51	40	31	19	16	13	11	9	5	2	1	0
ICC	129	62	25	15	7	5	2	0	0	0	0	0	0	0

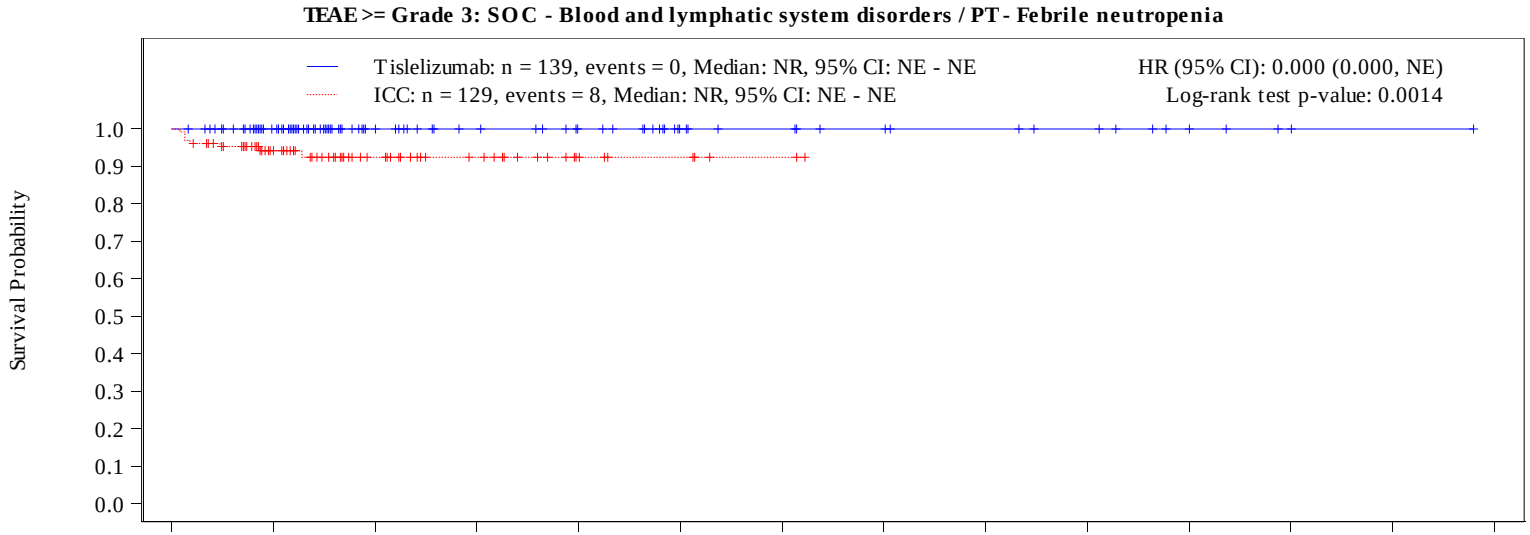
Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-03-b-km-aesocpt-g3-safetys-fa.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-03-b-km-aesocpt-g3-safetys-fa.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	95	52	40	32	20	17	14	11	9	5	2	1	0
ICC	129	72	32	18	8	5	2	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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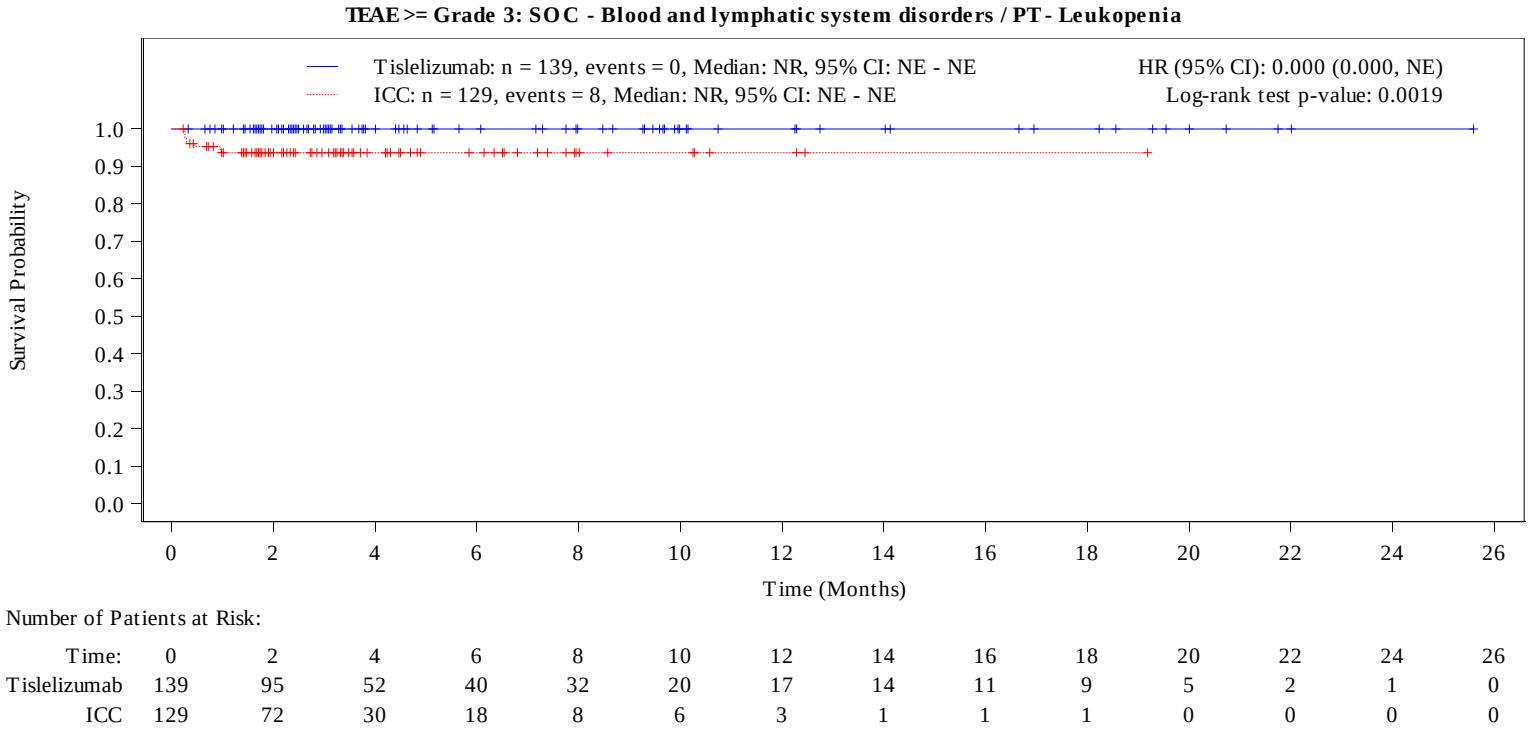
Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

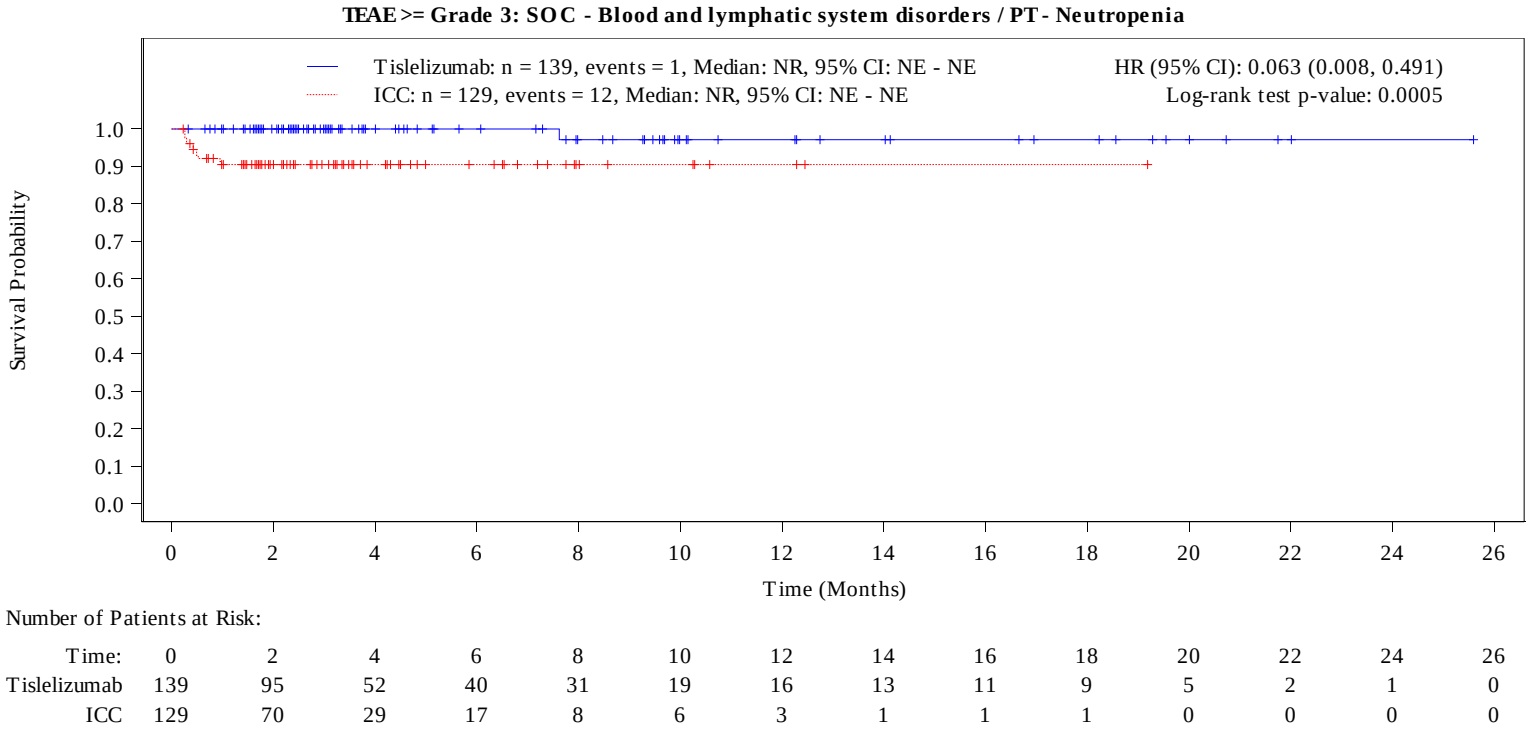


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	95	52	40	32	20	17	14	11	9	5	2	1	0
ICC	129	72	30	18	8	6	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-03-b-km-aesocpt-g3-safetys-fa.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

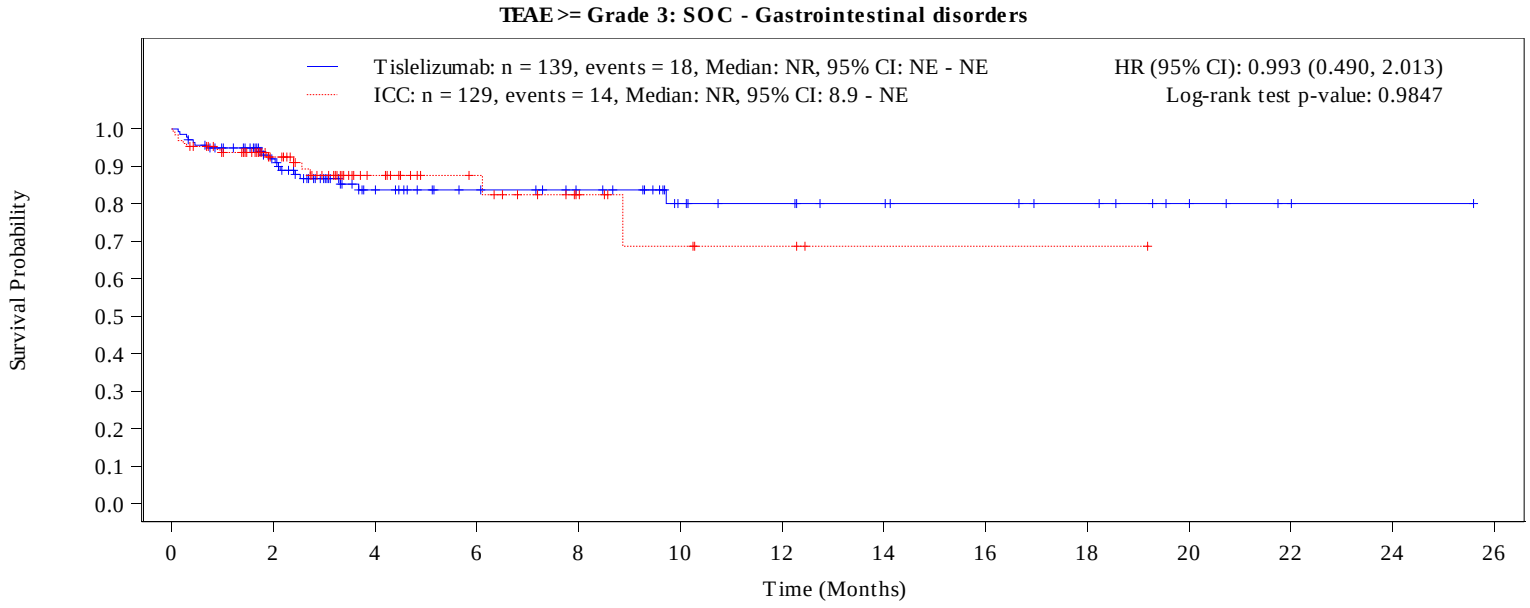


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	95	52	40	31	19	16	13	11	9	5	2	1	0
ICC	129	70	29	17	8	6	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-03-b-km-aesocpt-g3-safetys-fa.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	91	51	39	32	20	17	14	11	9	5	2	1	0
ICC	129	71	30	17	9	5	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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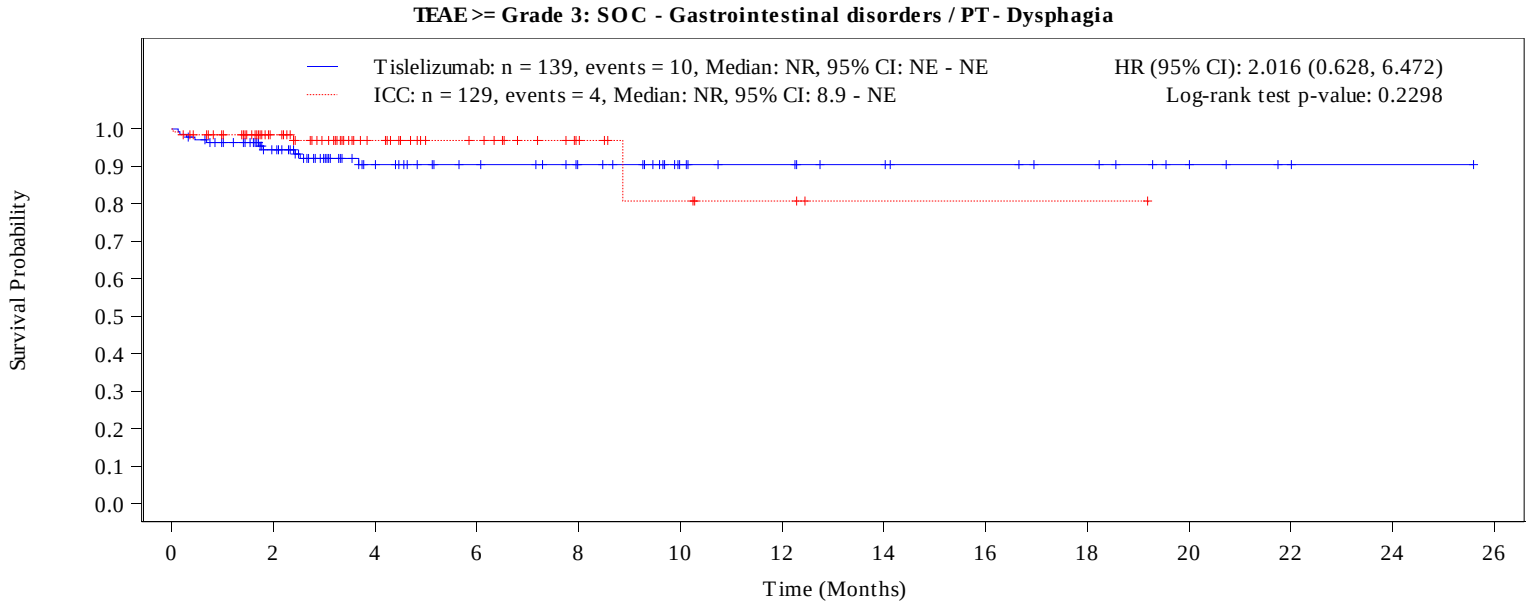
Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

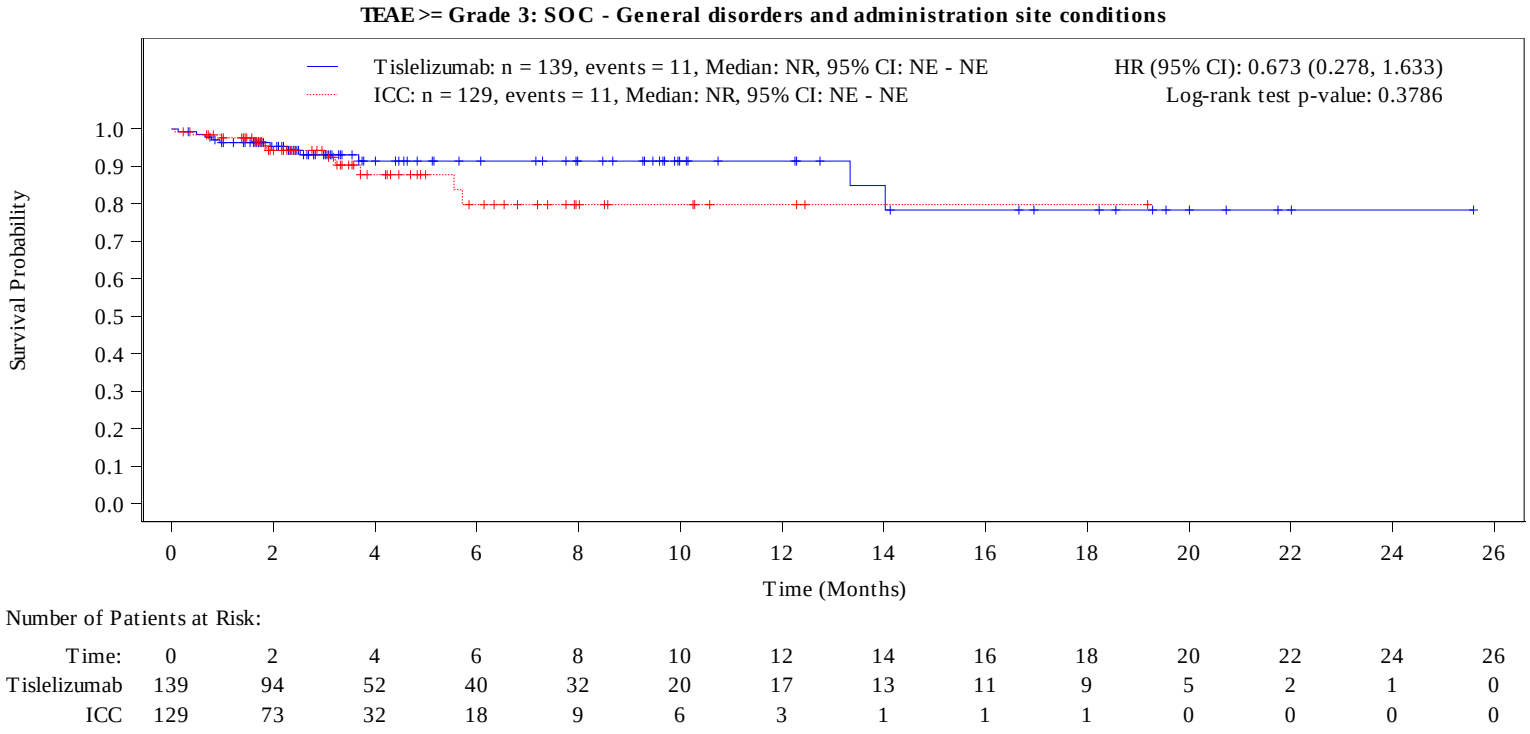


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	92	52	40	32	20	17	14	11	9	5	2	1	0
ICC	129	73	32	18	9	5	3	1	1	1	0	0	0	0

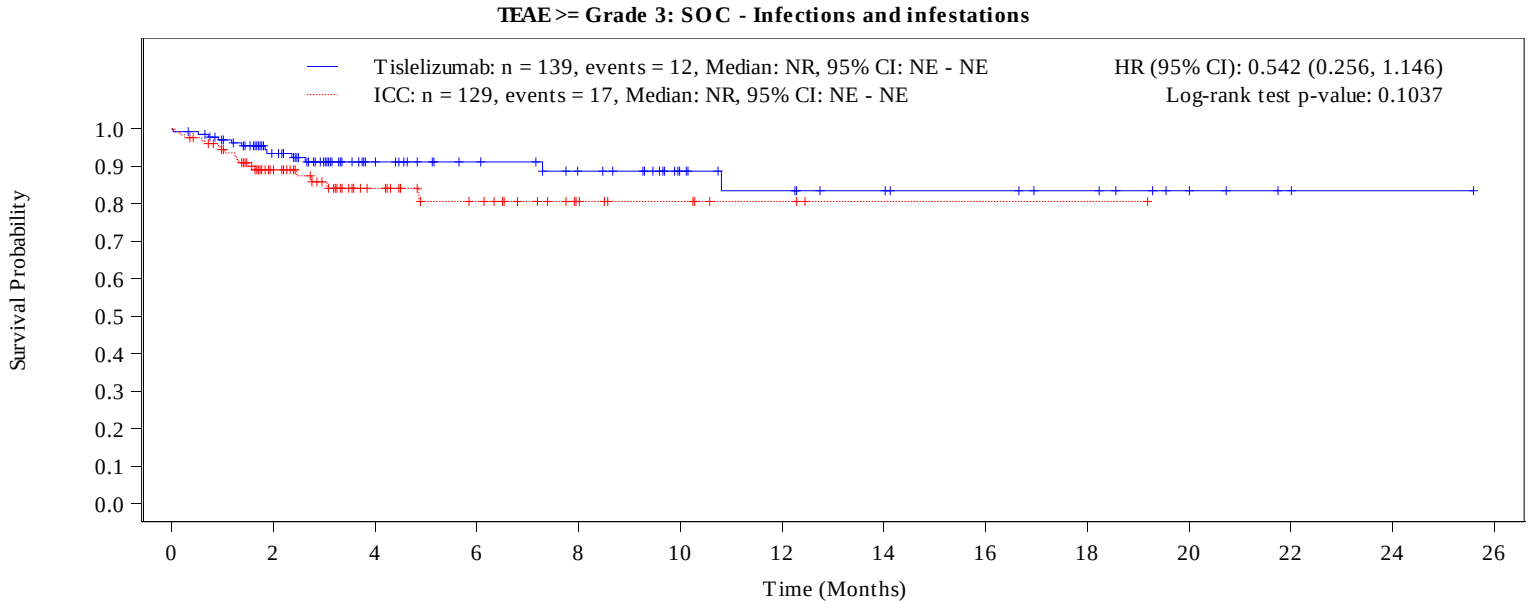
Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-03-b-km-aesocpt-g3-safetys-fa.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-03-b-km-aesocpt-g3-safetys-fa.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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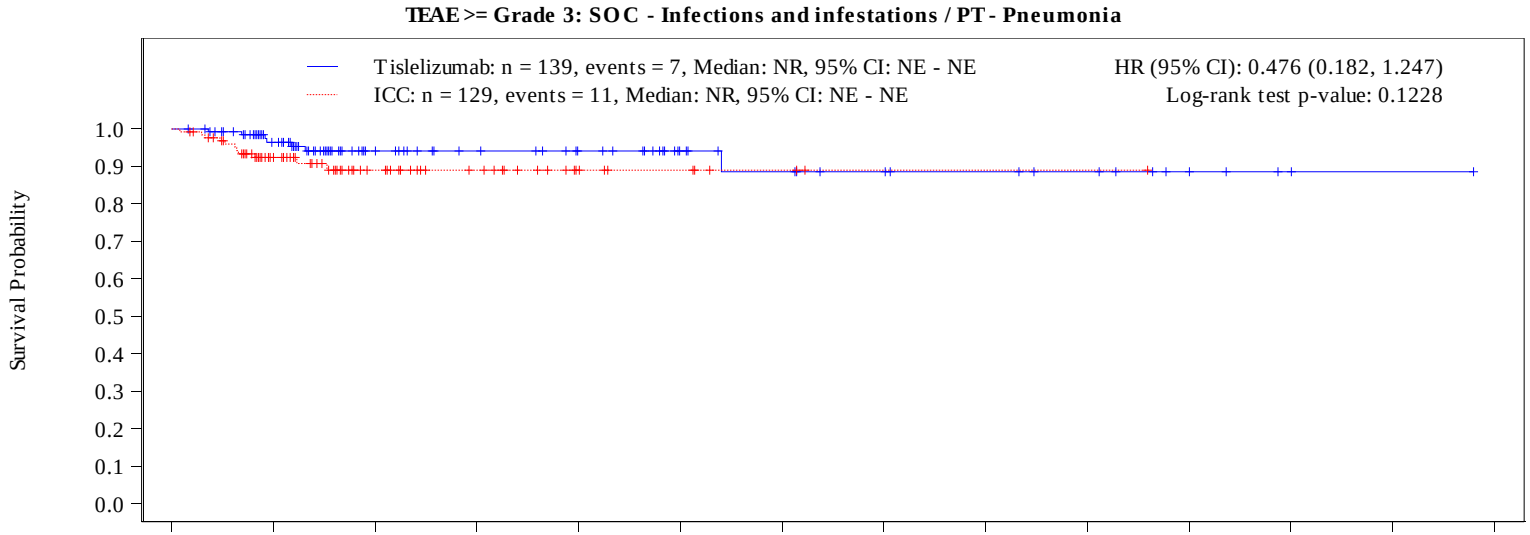
Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

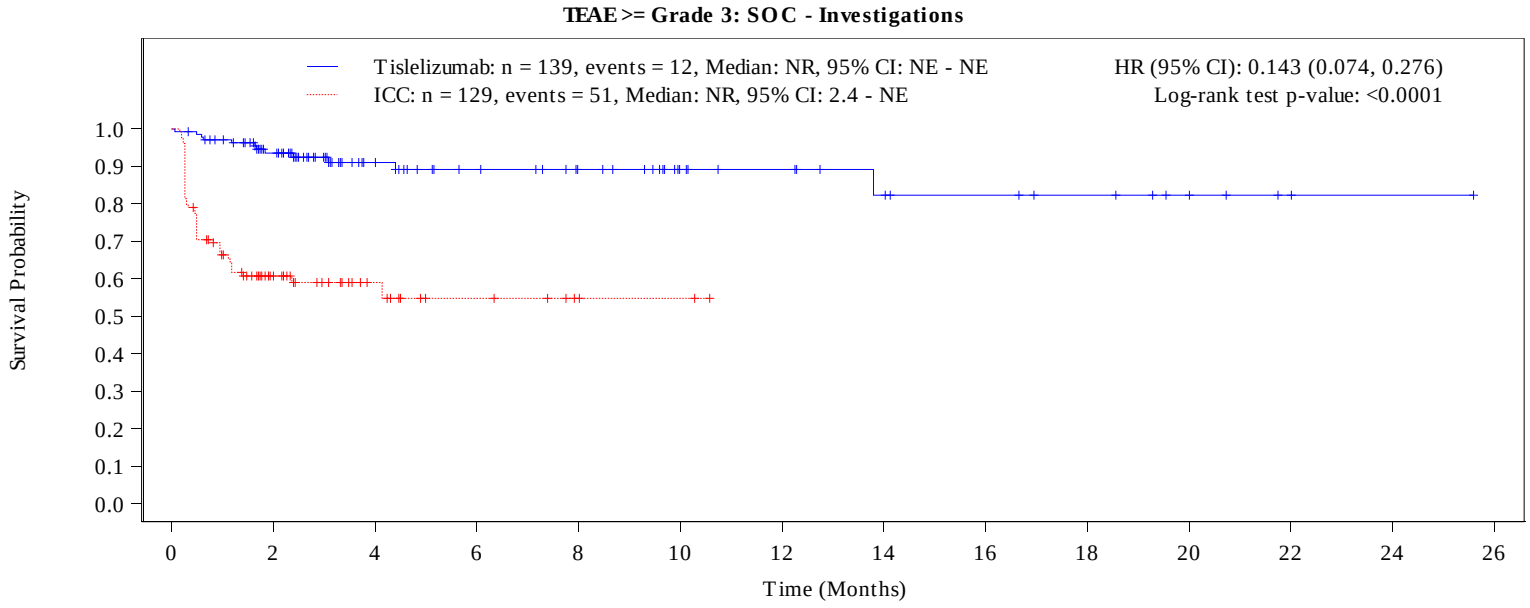


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	93	52	40	32	20	16	13	11	9	5	2	1	0
ICC	129	74	33	19	9	6	3	1	1	1	0	0	0	0

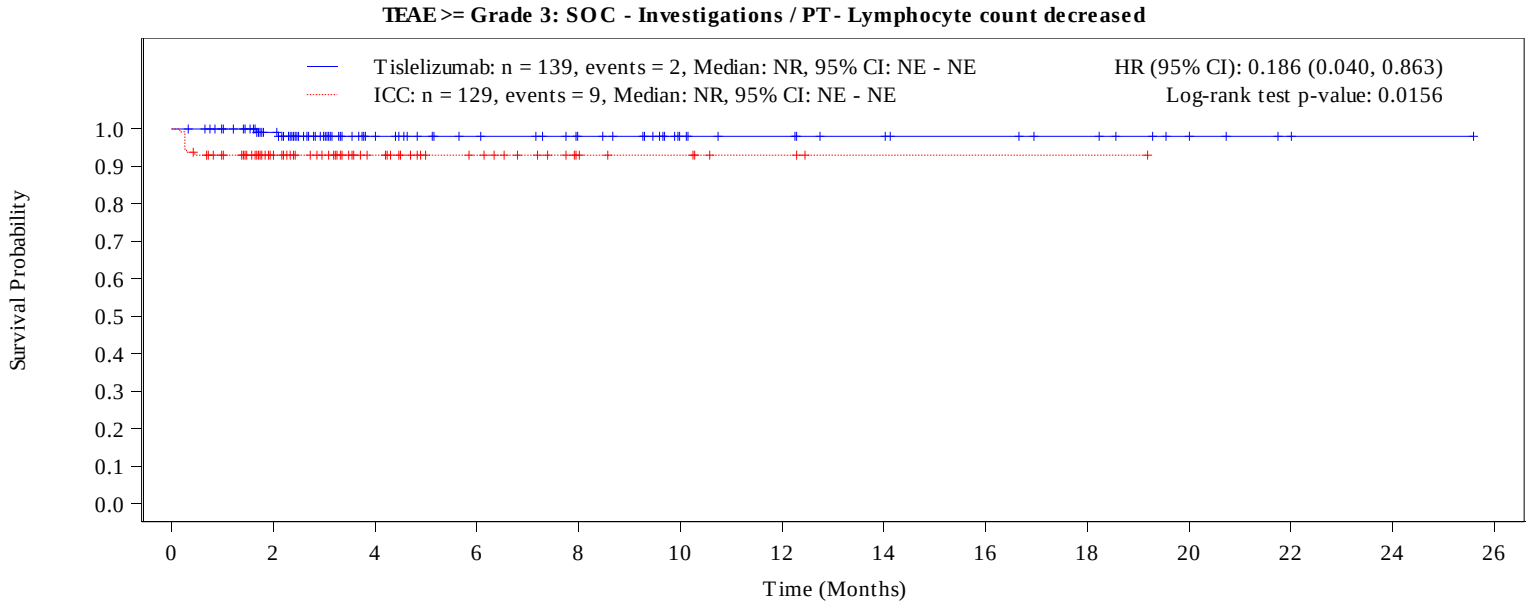
Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-03-b-km-aesocpt-g3-safetys-fa.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-03-b-km-aesocpt-g3-safetys-fa.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

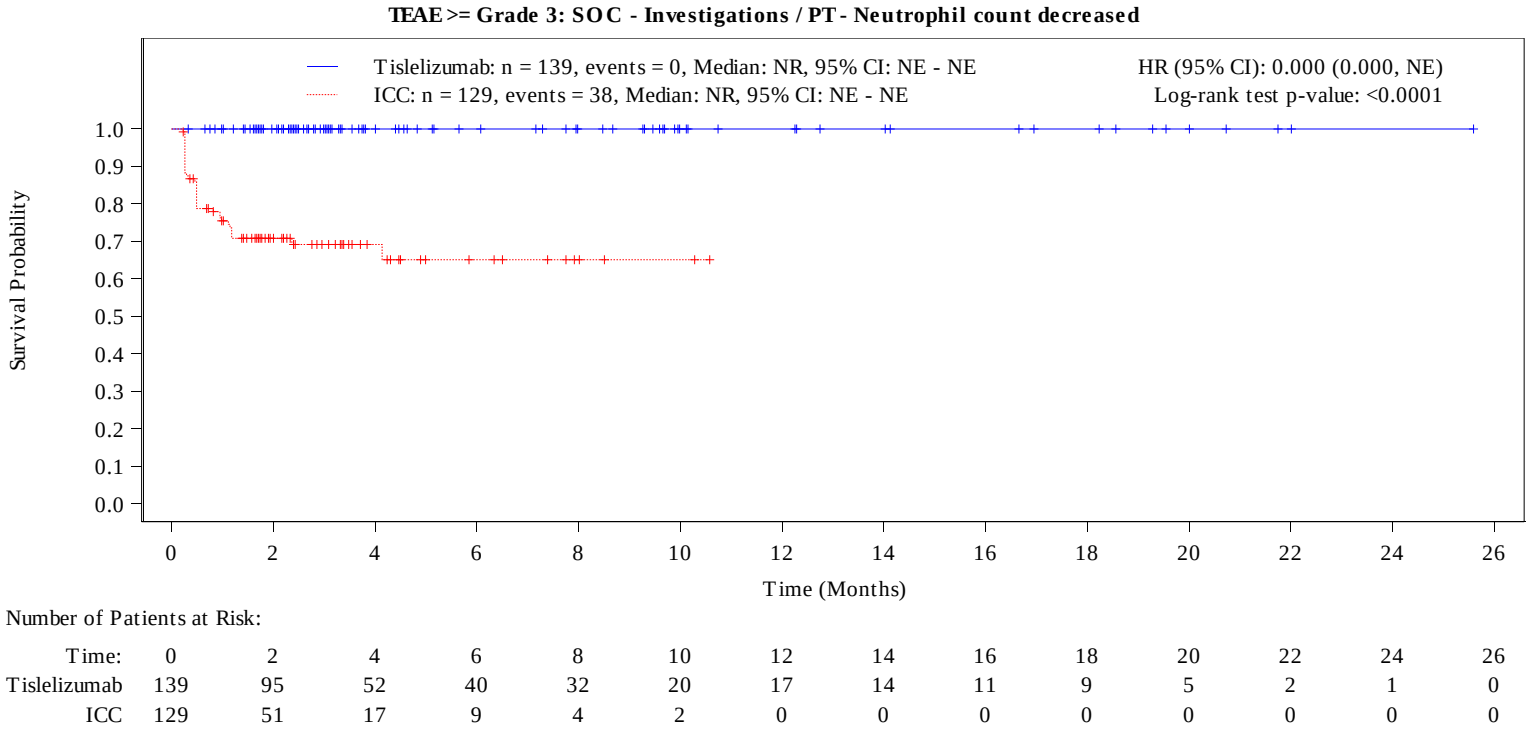


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	95	52	40	32	20	17	14	11	9	5	2	1	0
ICC	129	70	30	17	8	6	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-03-b-km-aesocpt-g3-safetys-fa.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	95	52	40	32	20	17	14	11	9	5	2	1	0
ICC	129	51	17	9	4	2	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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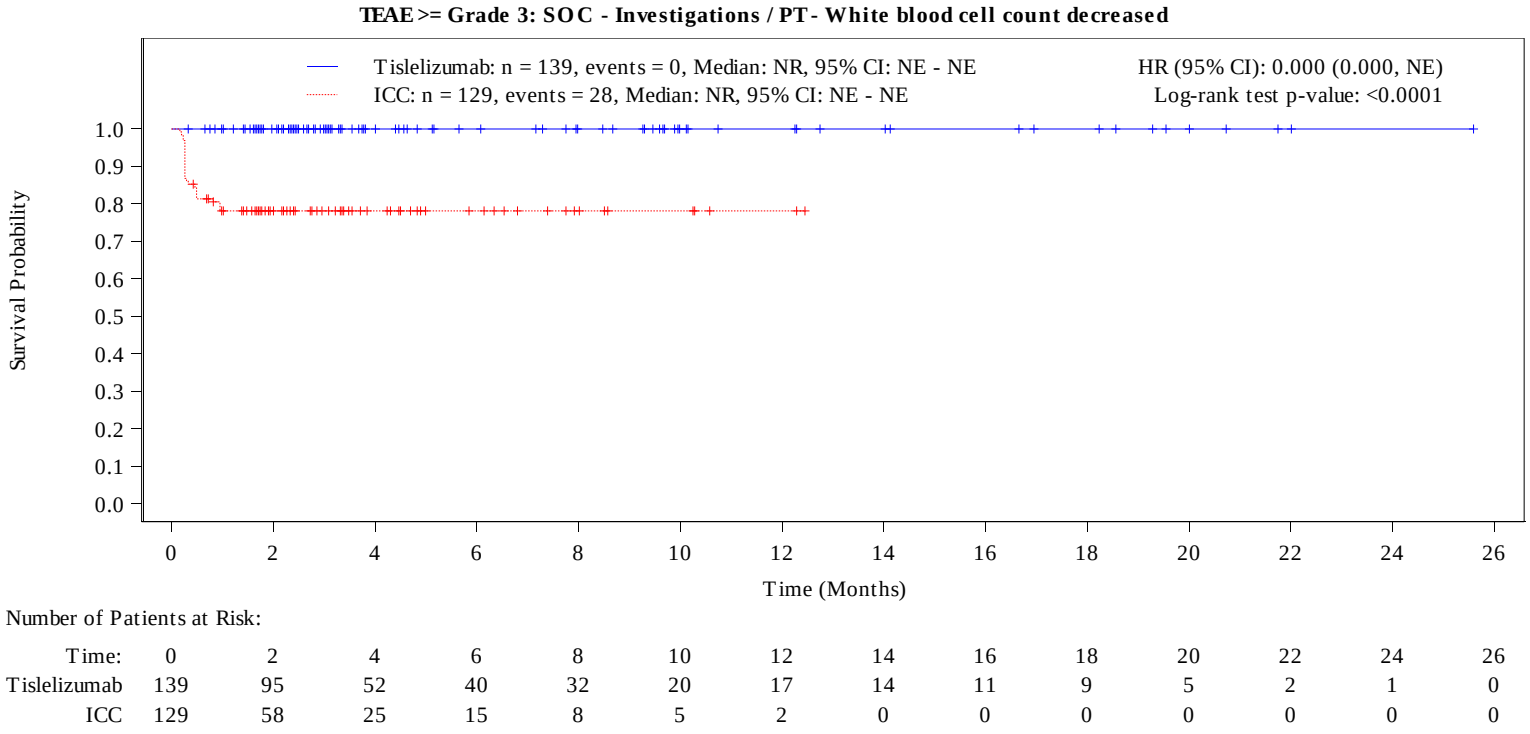
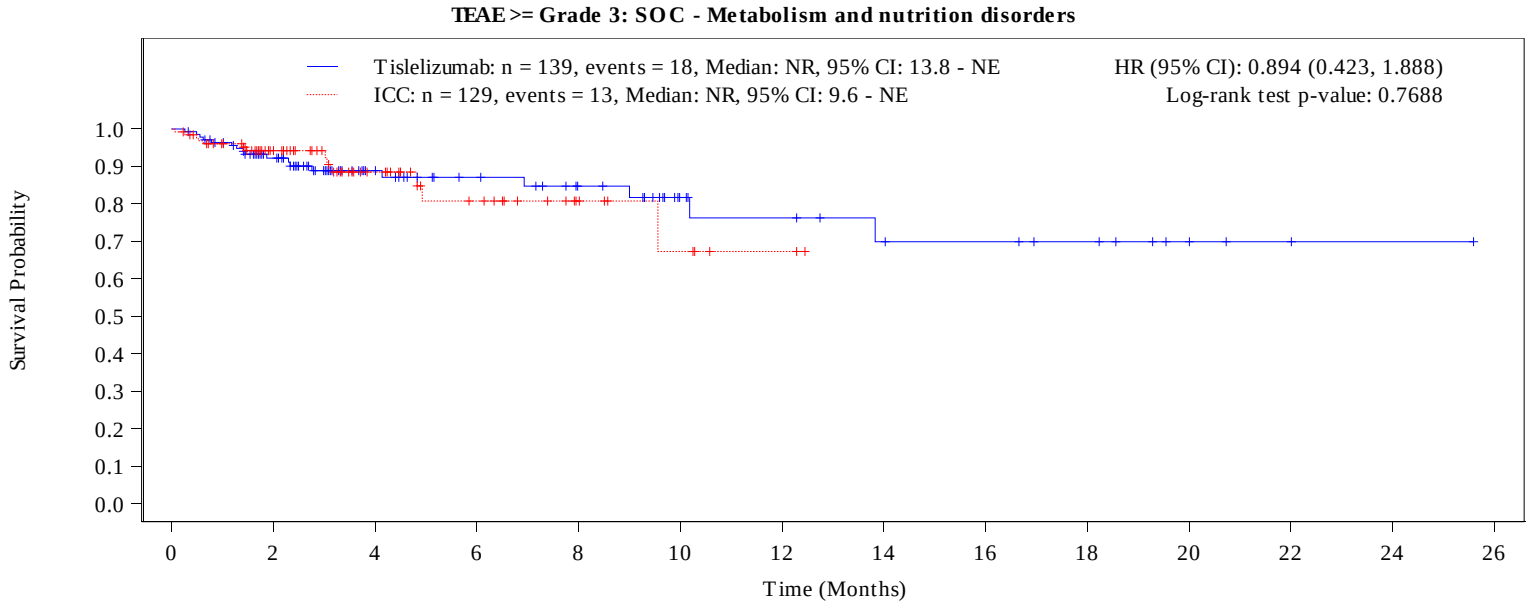
Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-03-b-km-aesocpt-g3-safetys-fa.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

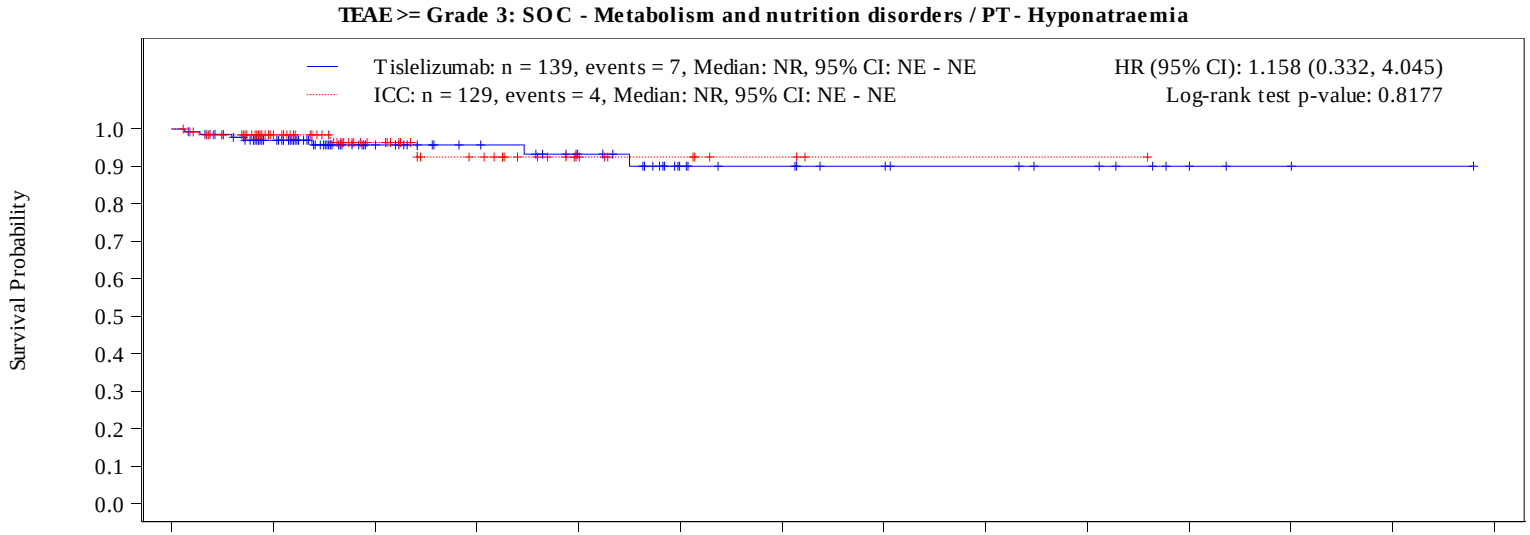


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	90	51	38	29	17	14	11	10	8	4	2	1	0
ICC	129	72	32	18	9	5	2	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-03-b-km-aesocpt-g3-safetys-fa.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

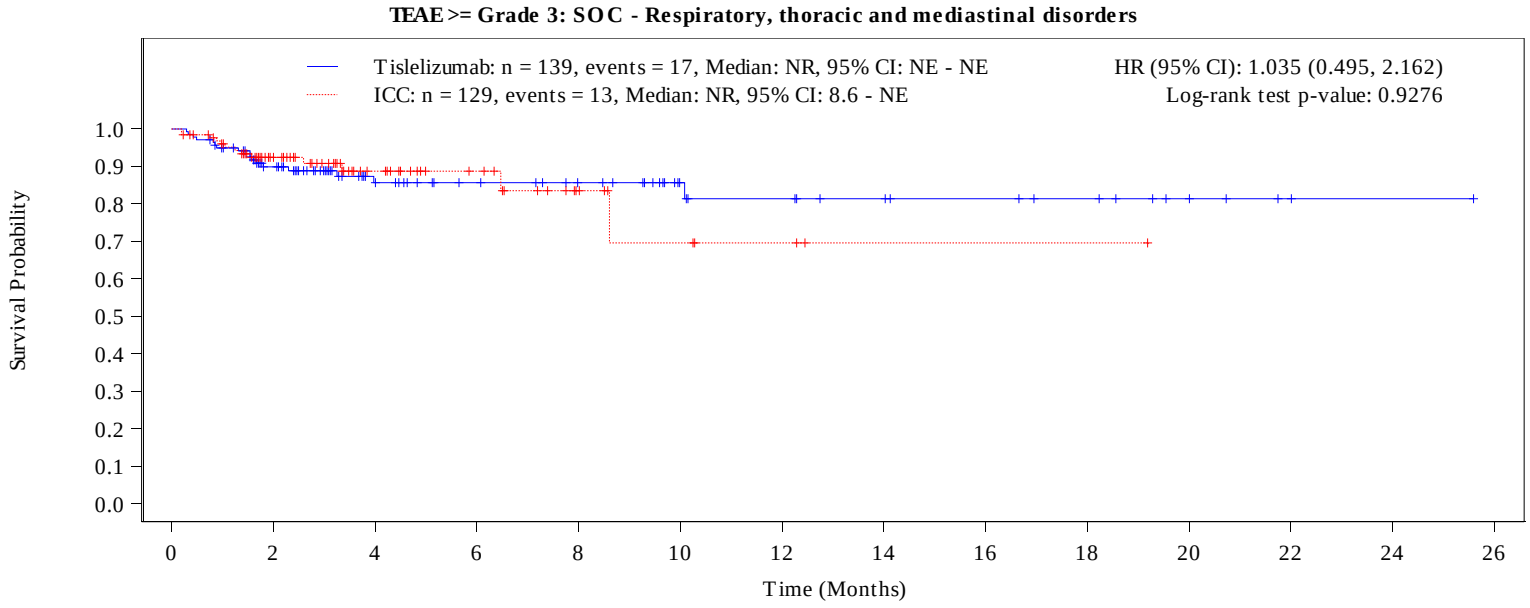


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	94	52	40	31	18	15	12	10	8	4	2	1	0
ICC	129	74	33	19	9	6	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-03-b-km-aesocpt-g3-safetys-fa.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

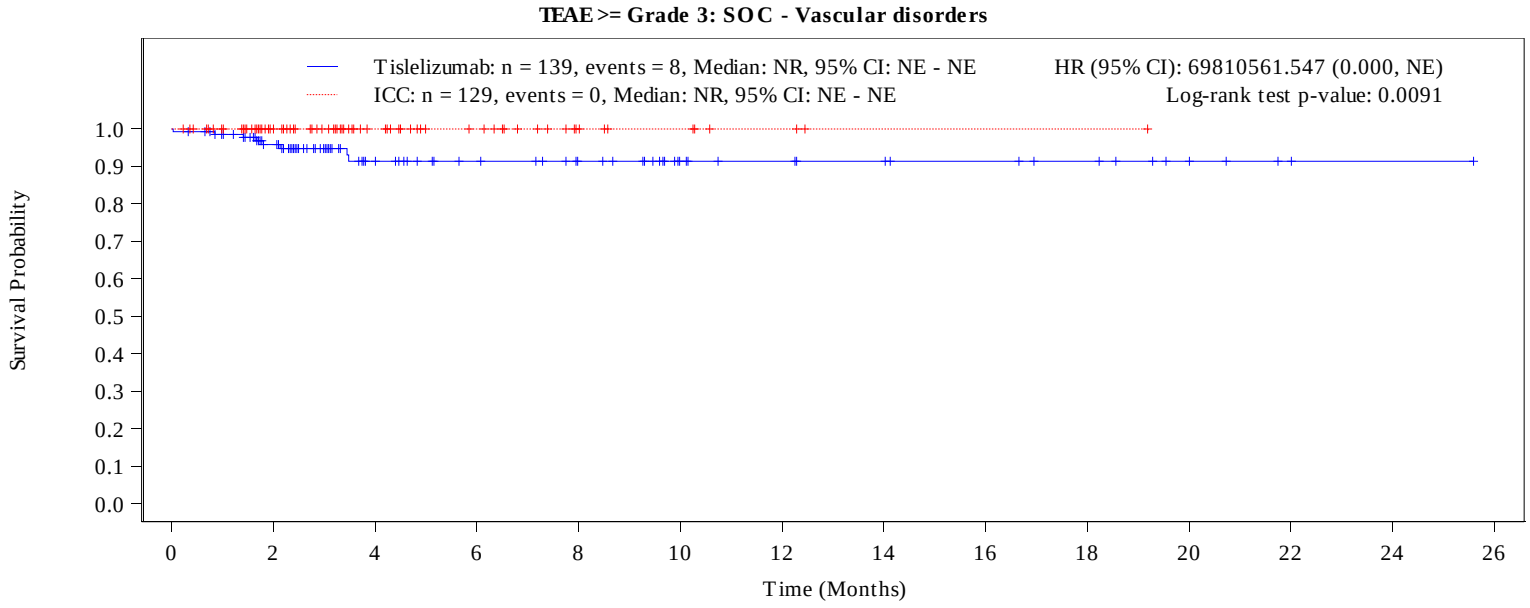


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	91	51	39	32	20	17	14	11	9	5	2	1	0
ICC	129	75	32	19	9	5	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-03-b-km-aesocpt-g3-safetys-fa.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	92	50	38	30	19	16	14	11	9	5	2	1	0
ICC	129	75	33	19	9	6	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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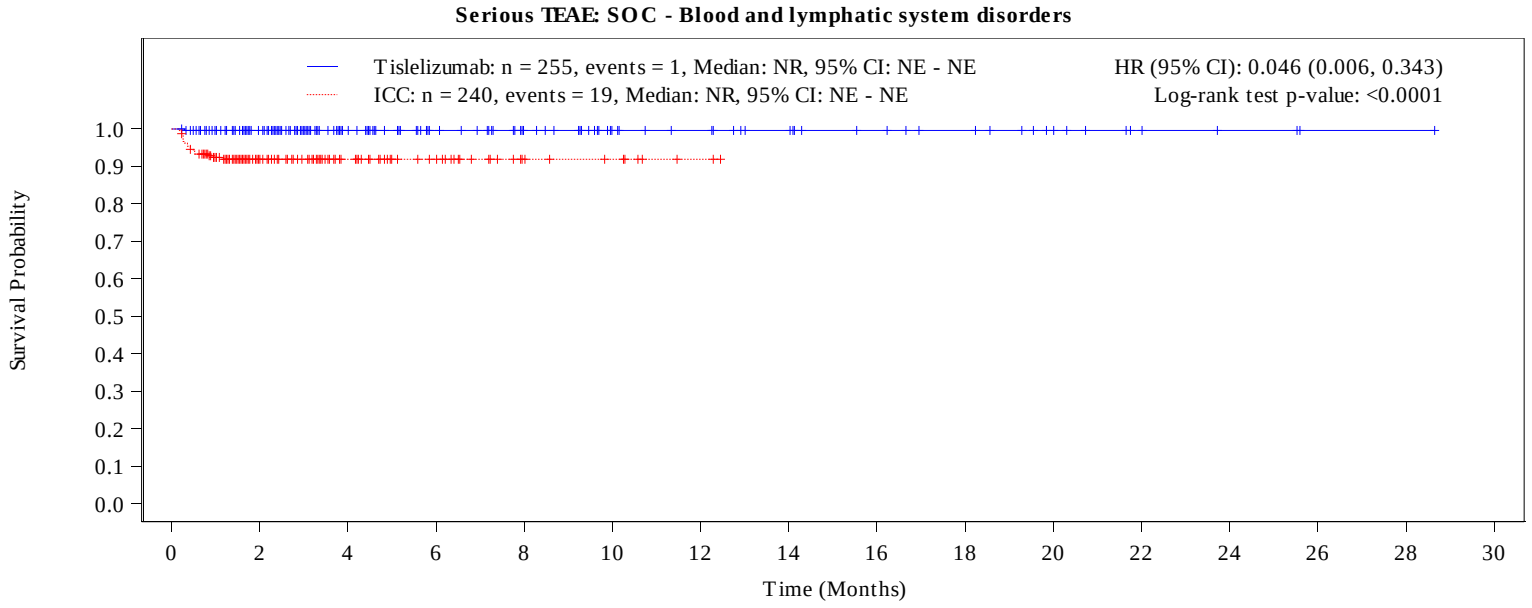
Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	175	97	65	49	34	29	24	18	15	10	5	3	1	1	0
ICC	240	107	43	24	10	7	2	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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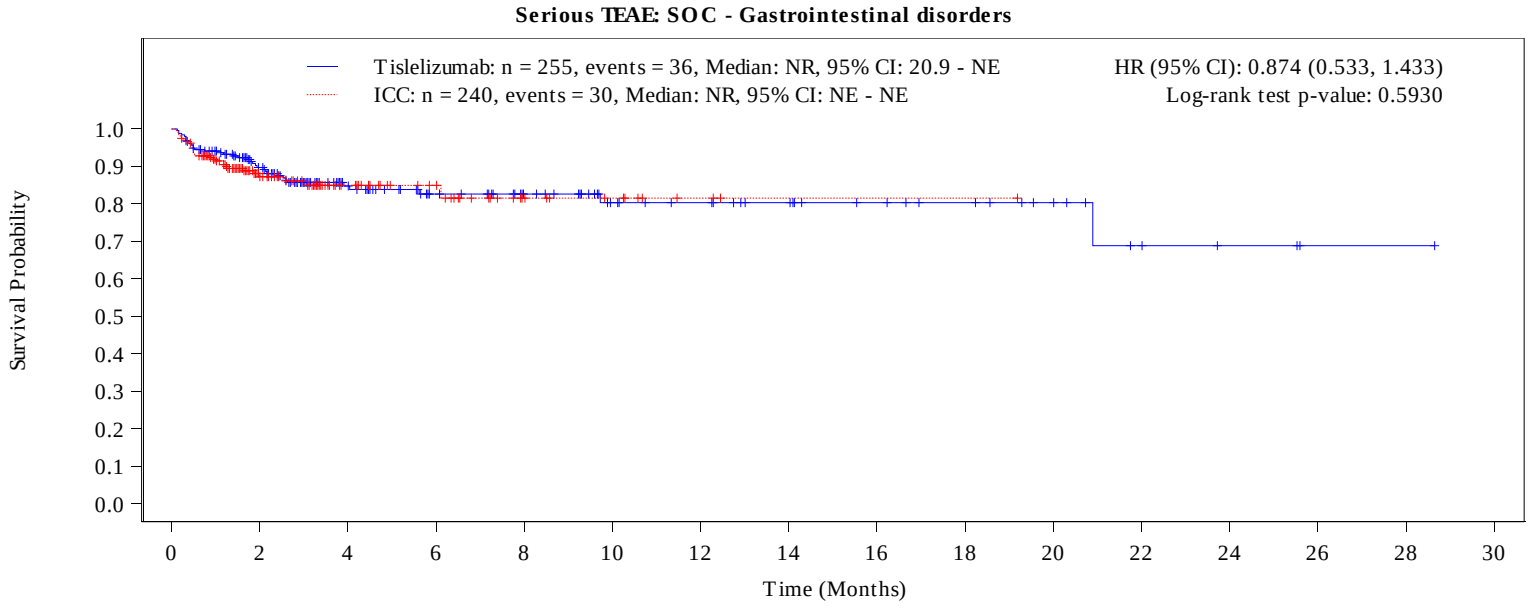
Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

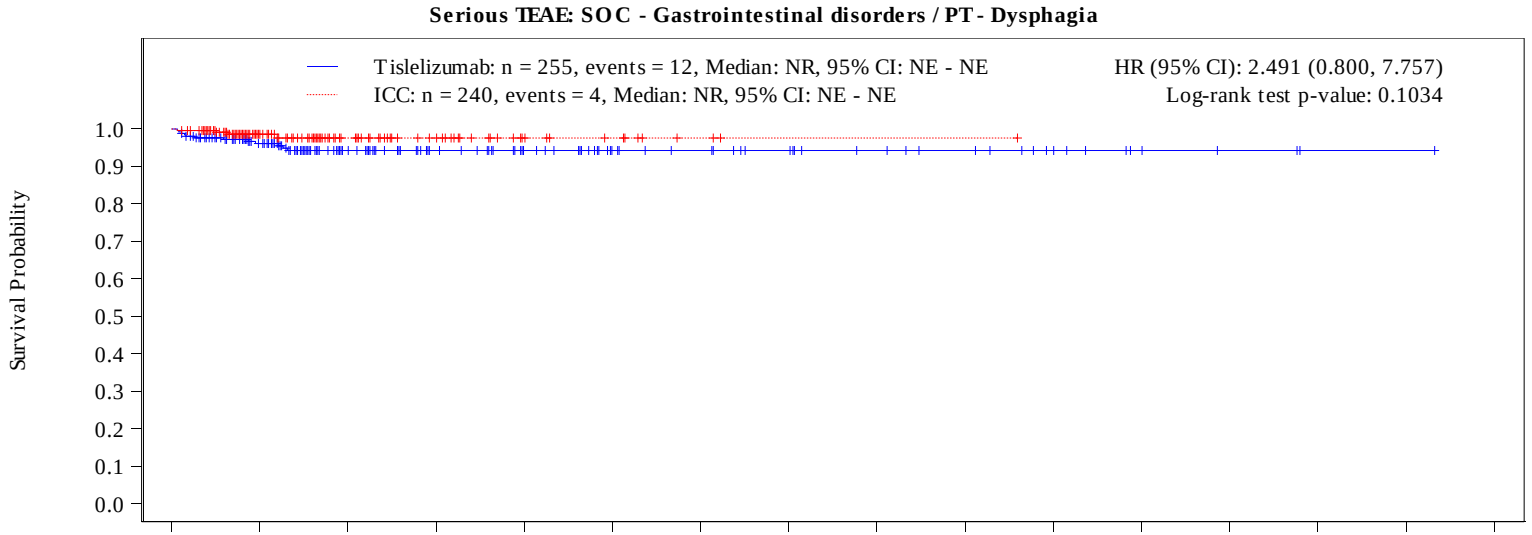


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	167	91	63	48	33	28	23	17	14	10	5	3	1	1	0
ICC	240	103	42	26	12	8	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-04-km-aesocpt-sae-safety-fa.rtf

Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

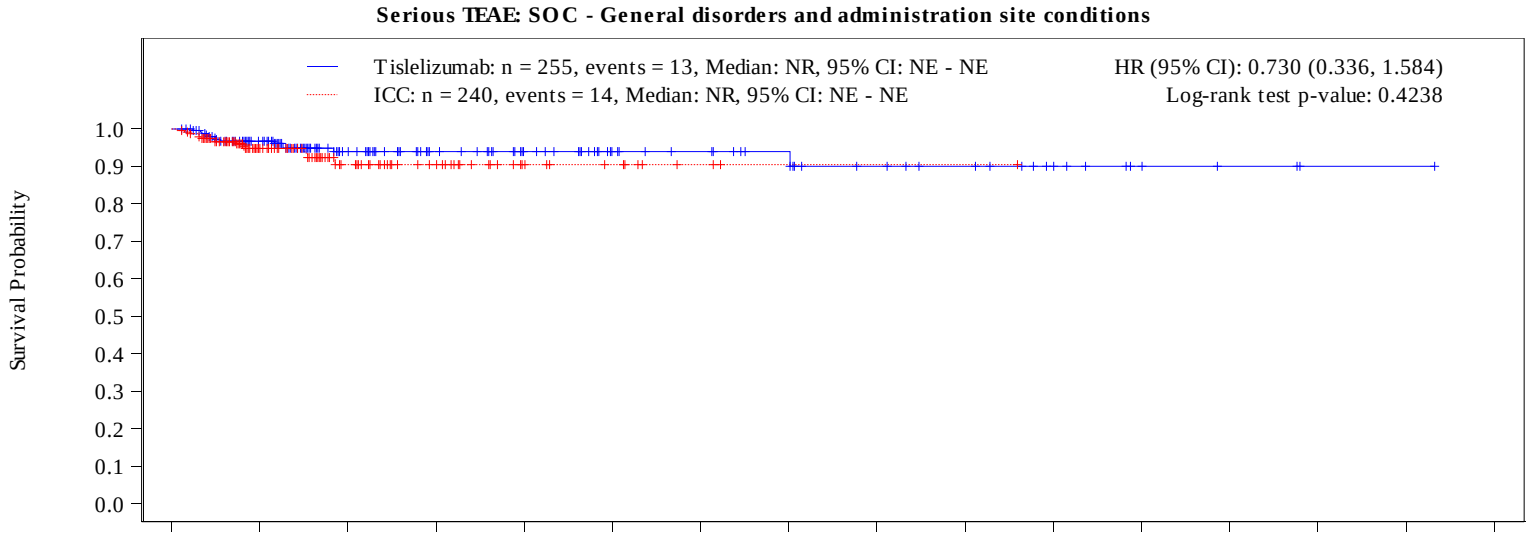


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	172	96	65	49	34	29	24	18	15	10	5	3	1	1	0
ICC	240	110	45	26	12	8	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-04-km-aesocpt-sae-safety-fa.rtf

Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

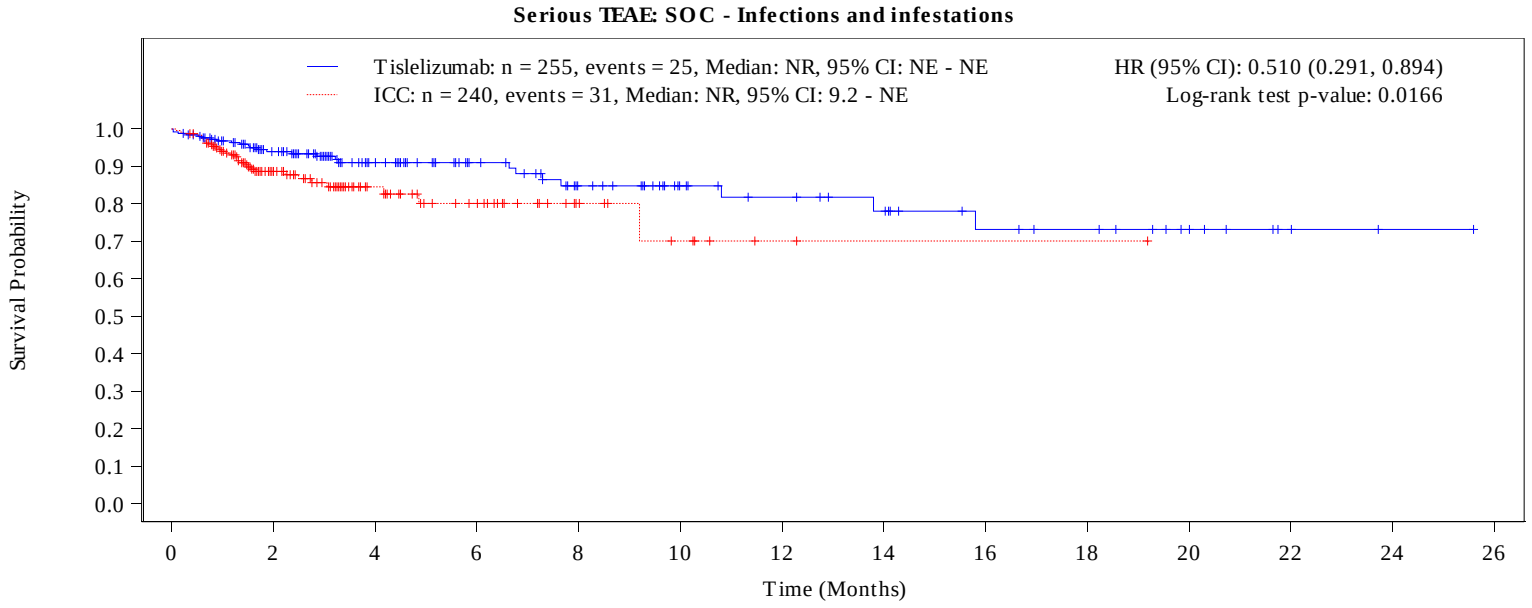


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	174	96	65	49	34	29	24	18	15	10	5	3	1	1	0
ICC	240	112	45	26	12	8	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-04-km-aesocpt-sae-safety-fa.rtf

Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

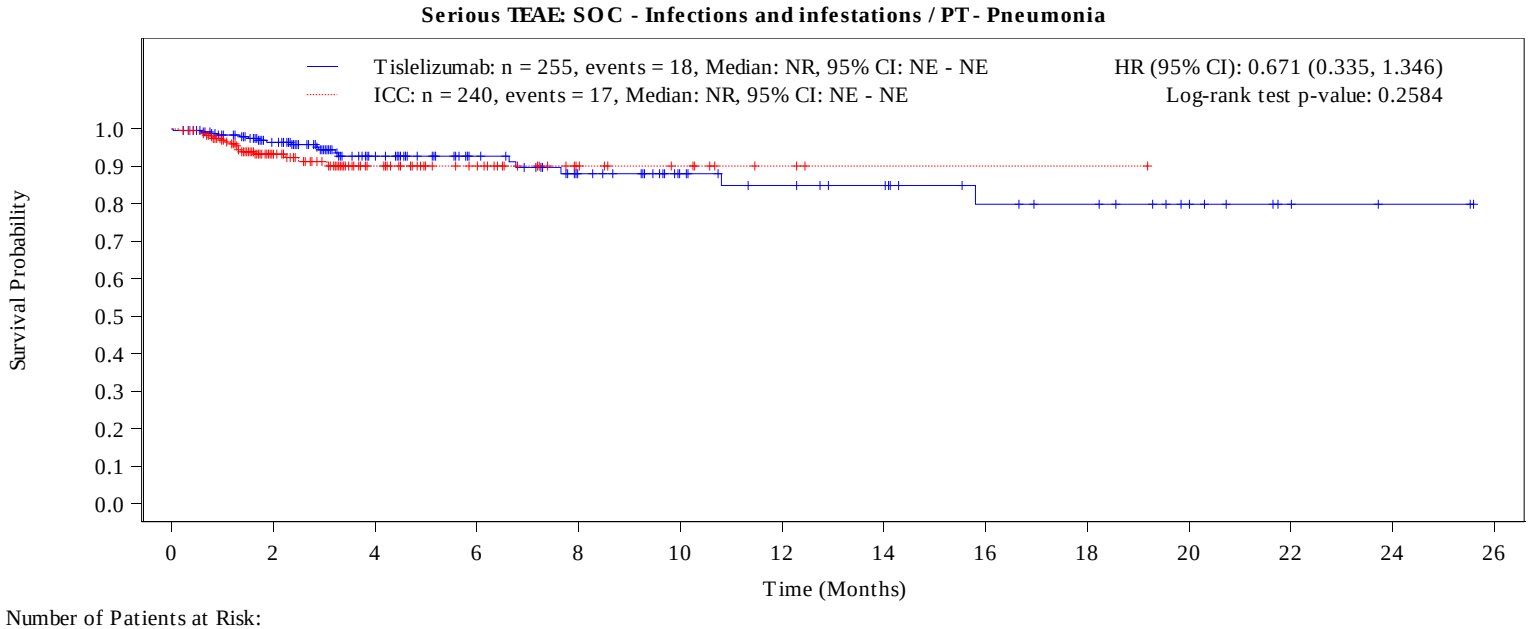


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	255	168	96	64	46	31	25	21	15	13	8	3	1	0
ICC	240	109	44	25	11	6	2	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-04-km-aesocpt-sae-safety-fa.rtf

Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	255	172	96	64	46	31	25	22	16	14	9	4	2	0
ICC	240	112	45	26	12	8	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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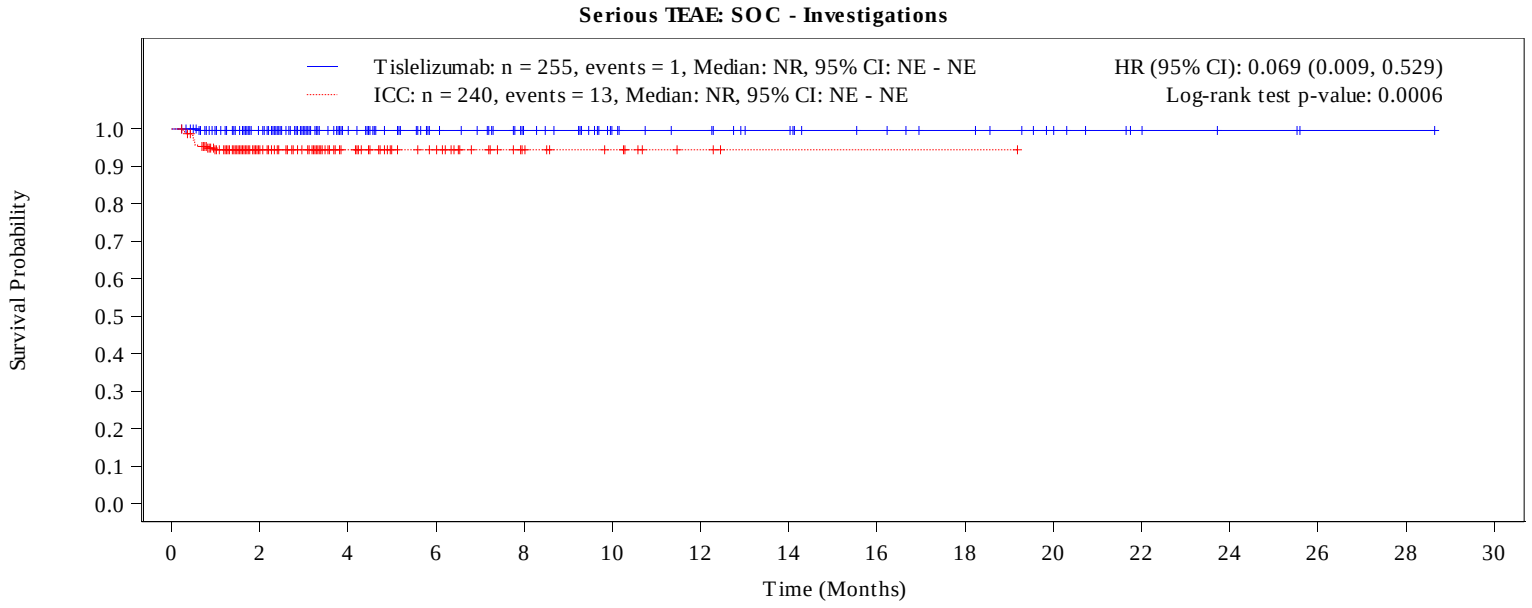
Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	175	97	65	49	34	29	24	18	15	10	5	3	1	1	0
ICC	240	111	45	26	12	8	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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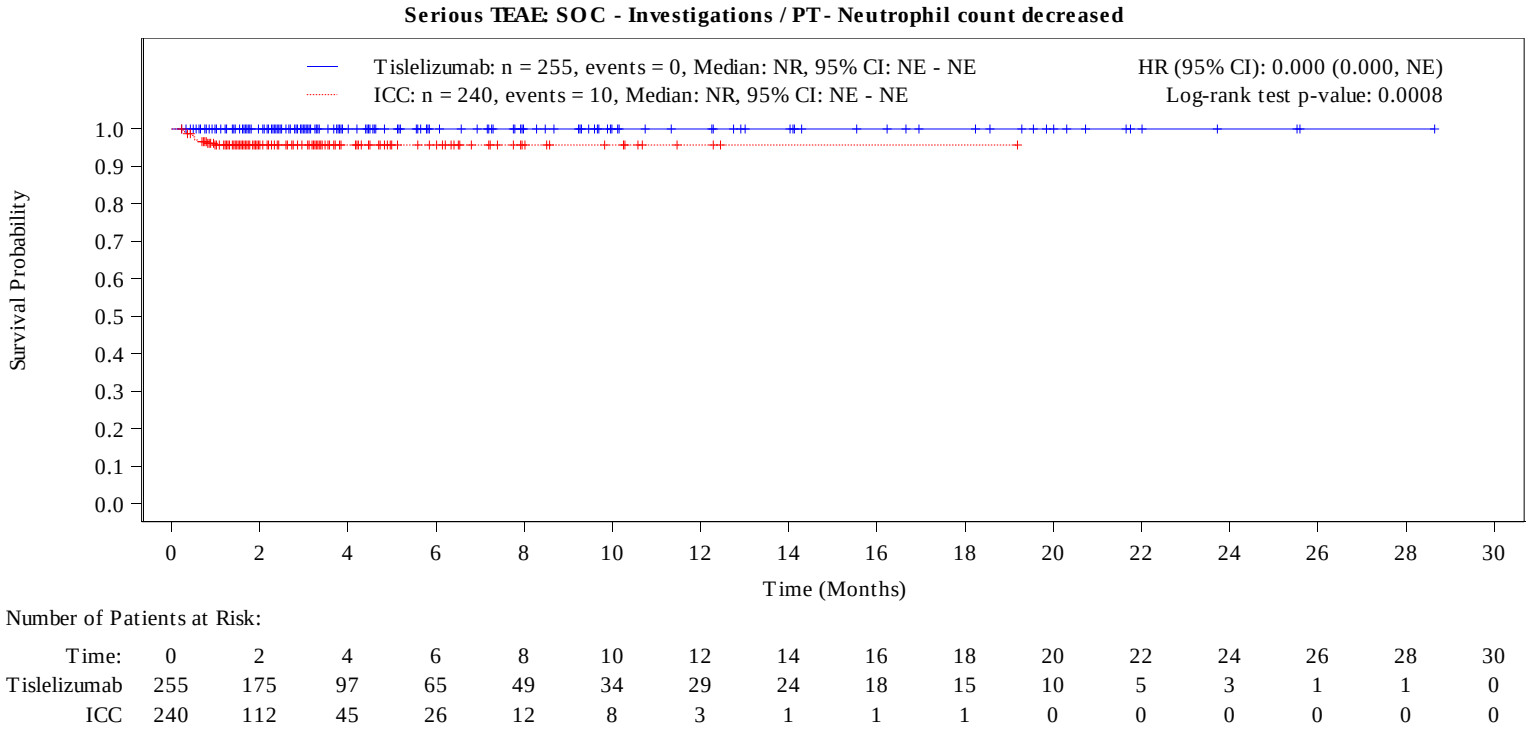
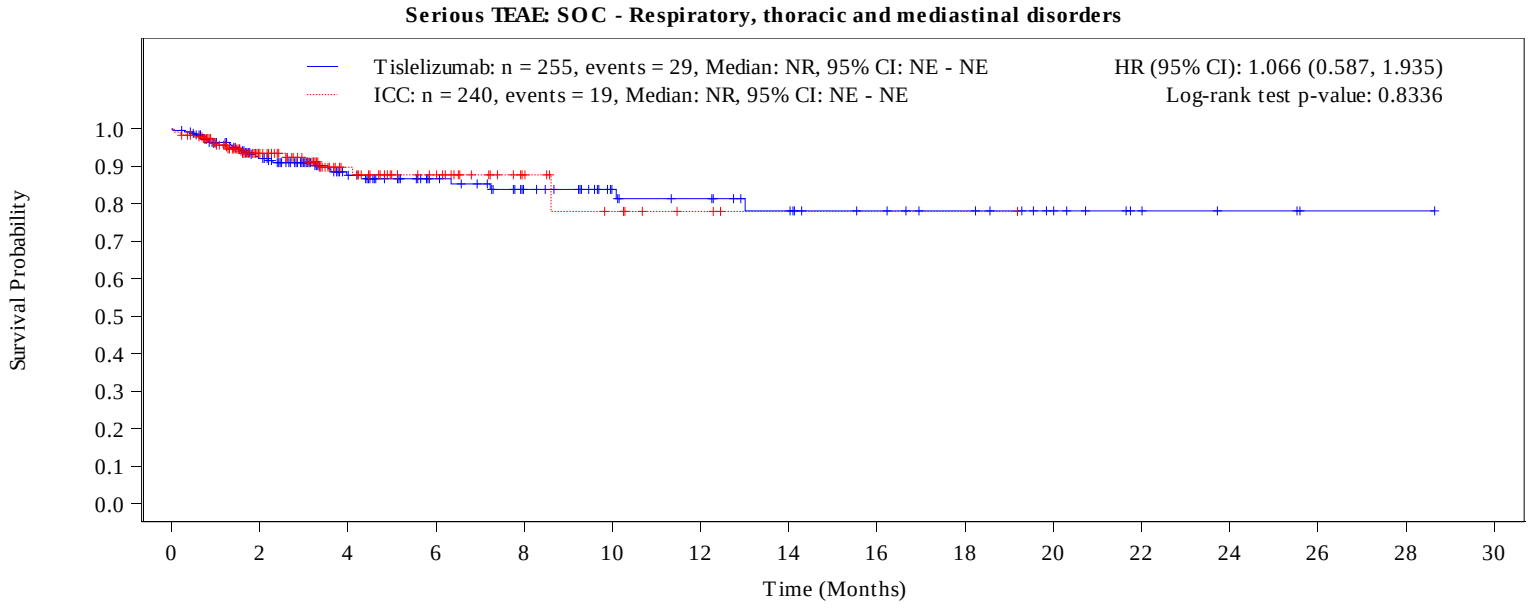
Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-04-km-aesocpt-sae-safety-fa.rtf

Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

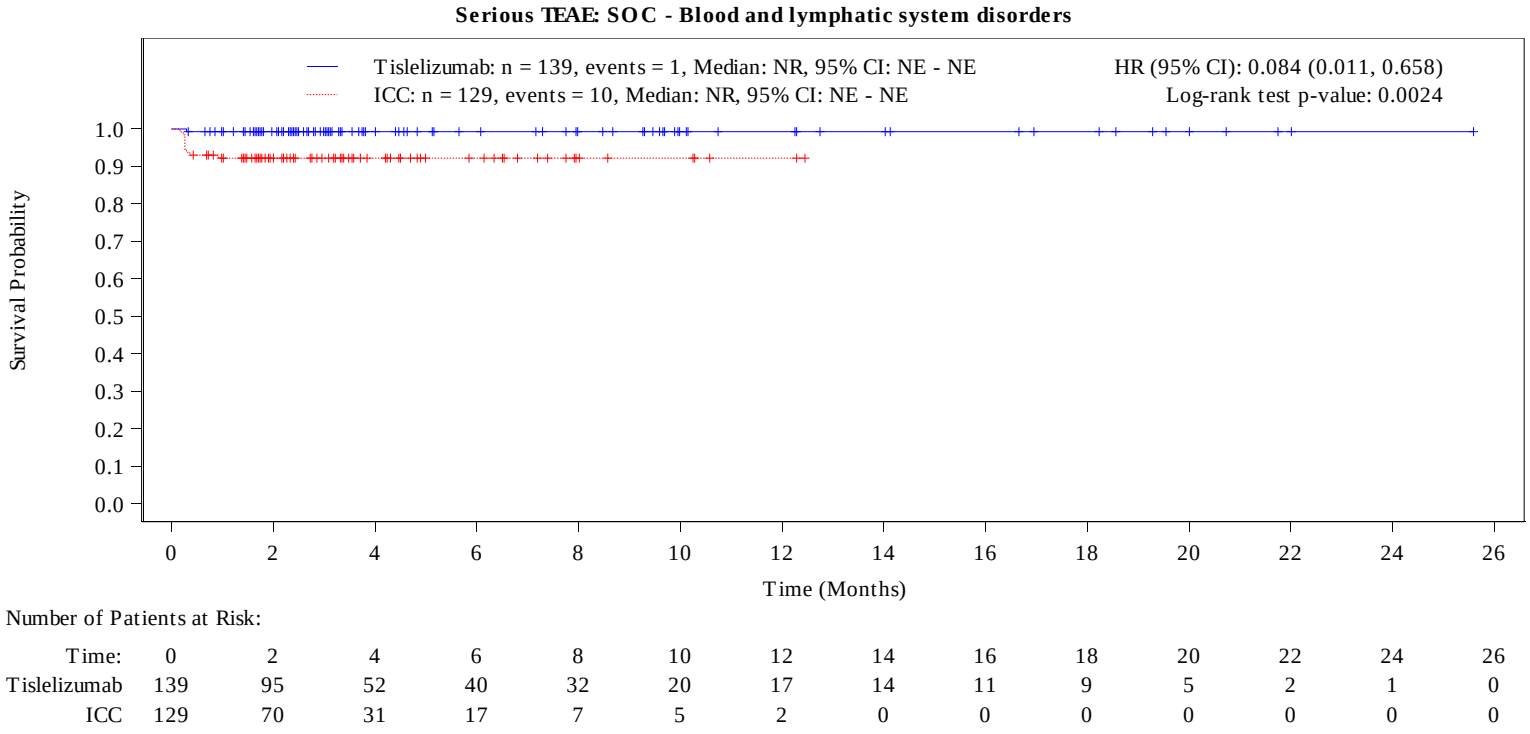


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	172	97	64	48	34	29	24	18	15	10	5	3	1	1	0
ICC	240	112	44	26	12	7	3	1	1	1	0	0	0	0	0	0

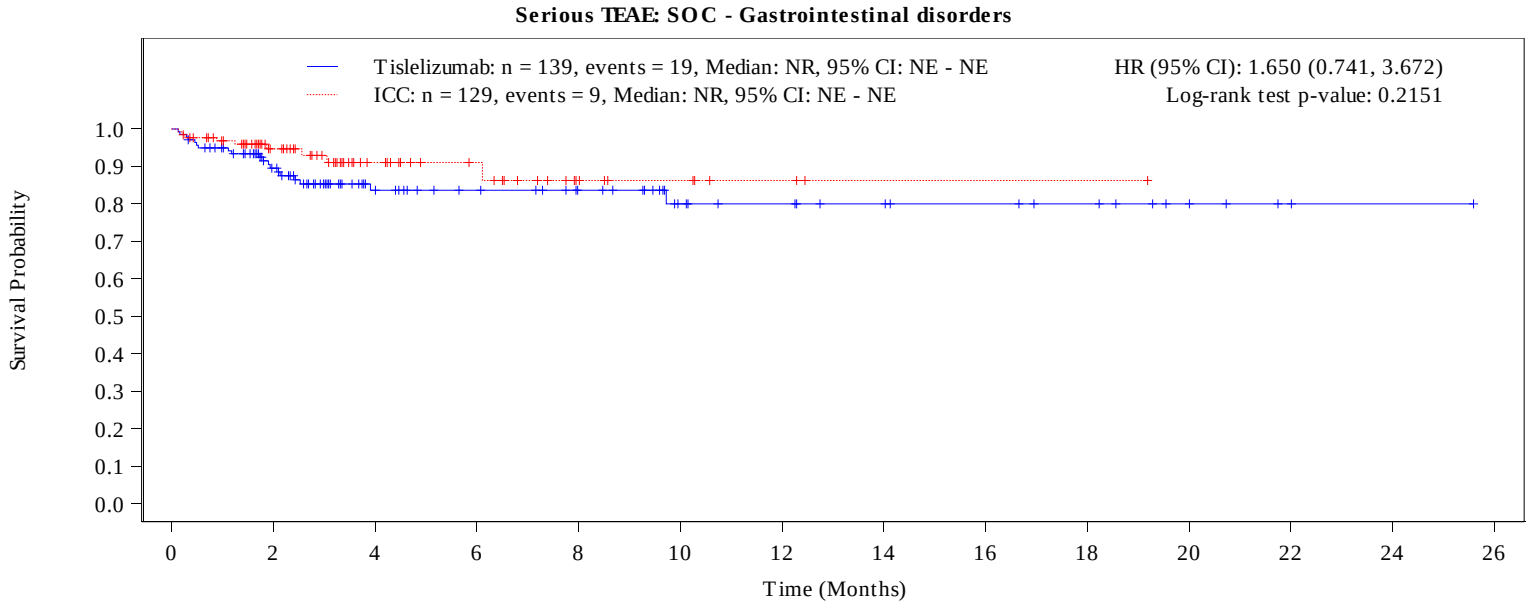
Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-04-km-aesocpt-sae-safety-fa.rtf

Figure 14.3.1.4.b:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-04-b-km-aesocpt-sae-safetys-fa.rtf

Figure 14.3.1.4.b:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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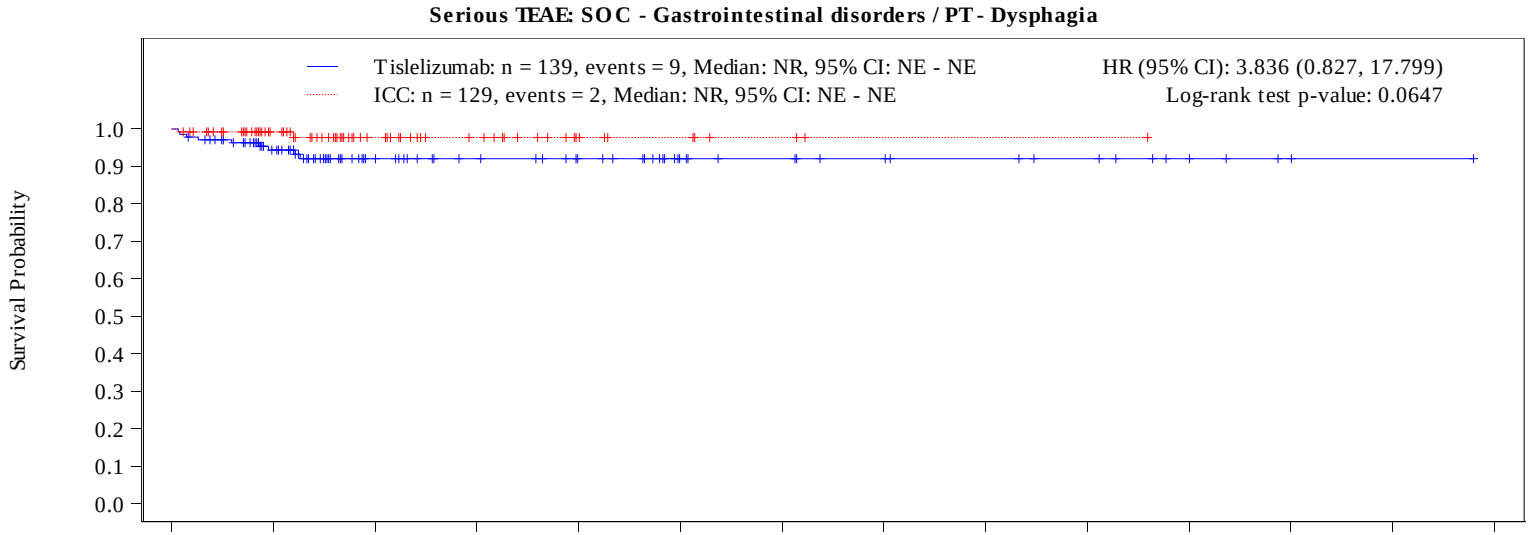
Figure 14.3.1.4.b:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	92	52	40	32	20	17	14	11	9	5	2	1	0
ICC	129	74	33	19	9	6	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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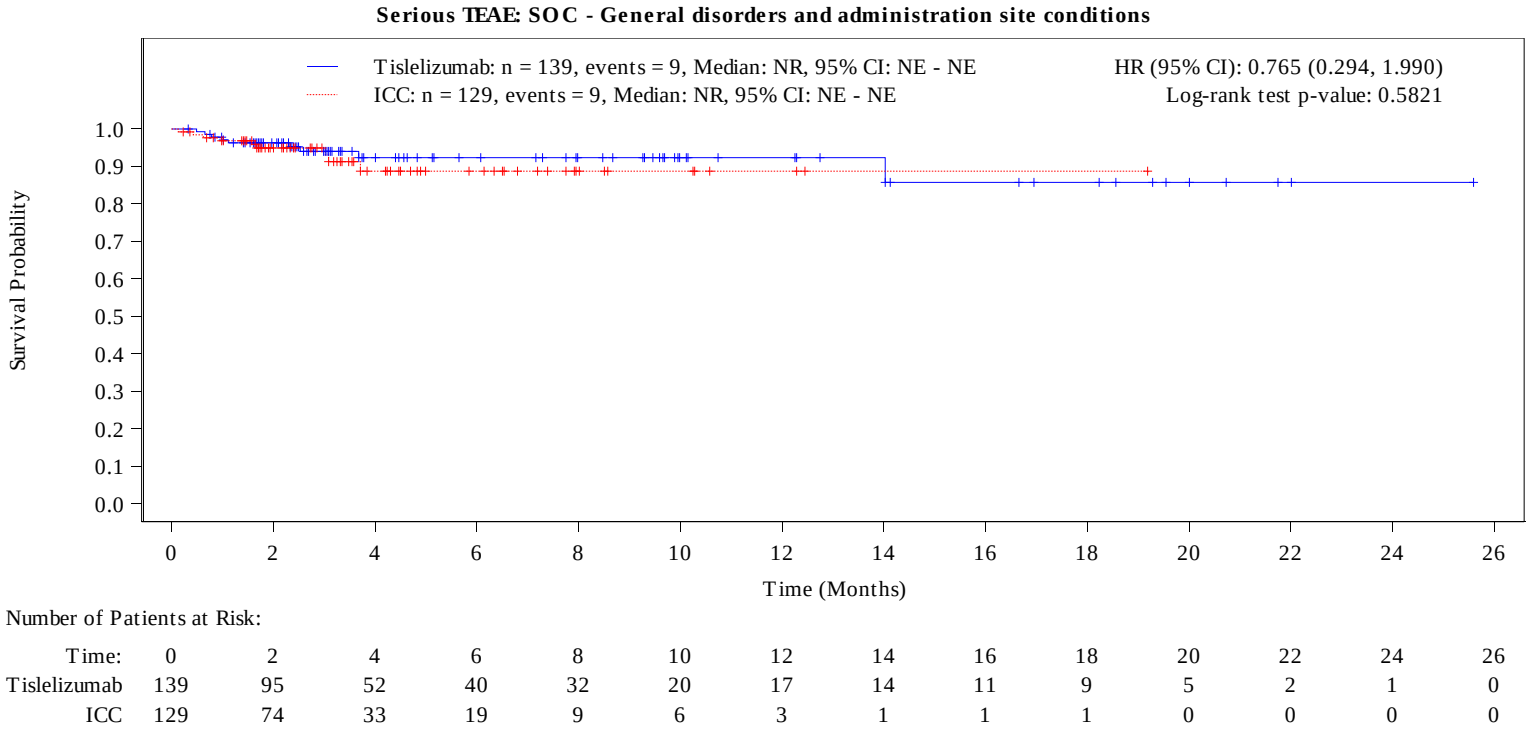
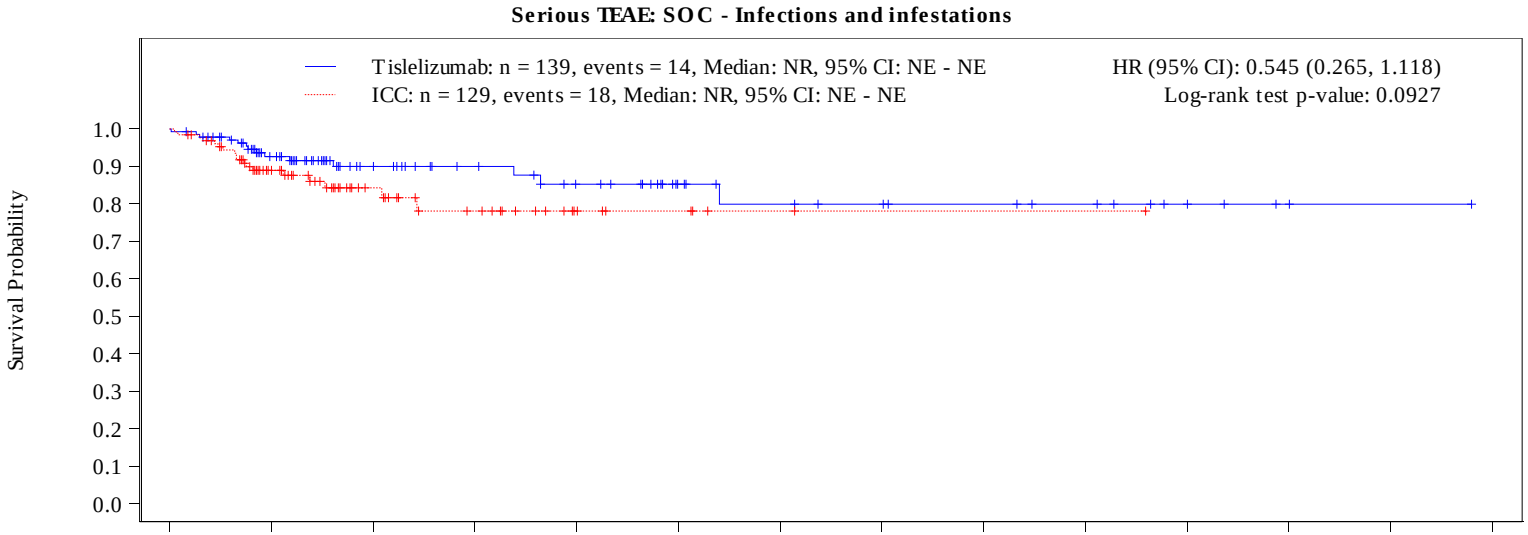
Figure 14.3.1.4.b:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-04-b-km-aesocpt-sae-safetys-fa.rtf

Figure 14.3.1.4.b:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	89	52	40	31	19	15	13	11	9	5	2	1	0
ICC	129	72	32	18	8	5	2	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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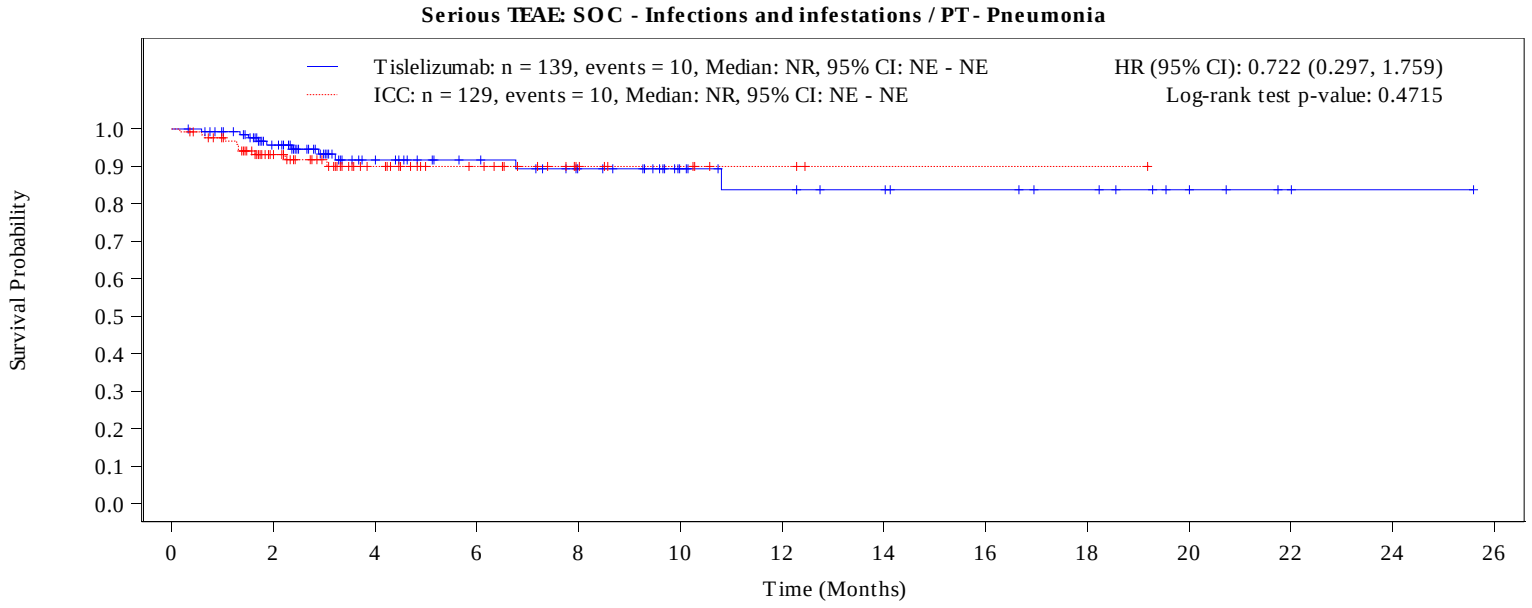
Figure 14.3.1.4.b:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	92	52	40	31	19	15	13	11	9	5	2	1	0
ICC	129	74	33	19	9	6	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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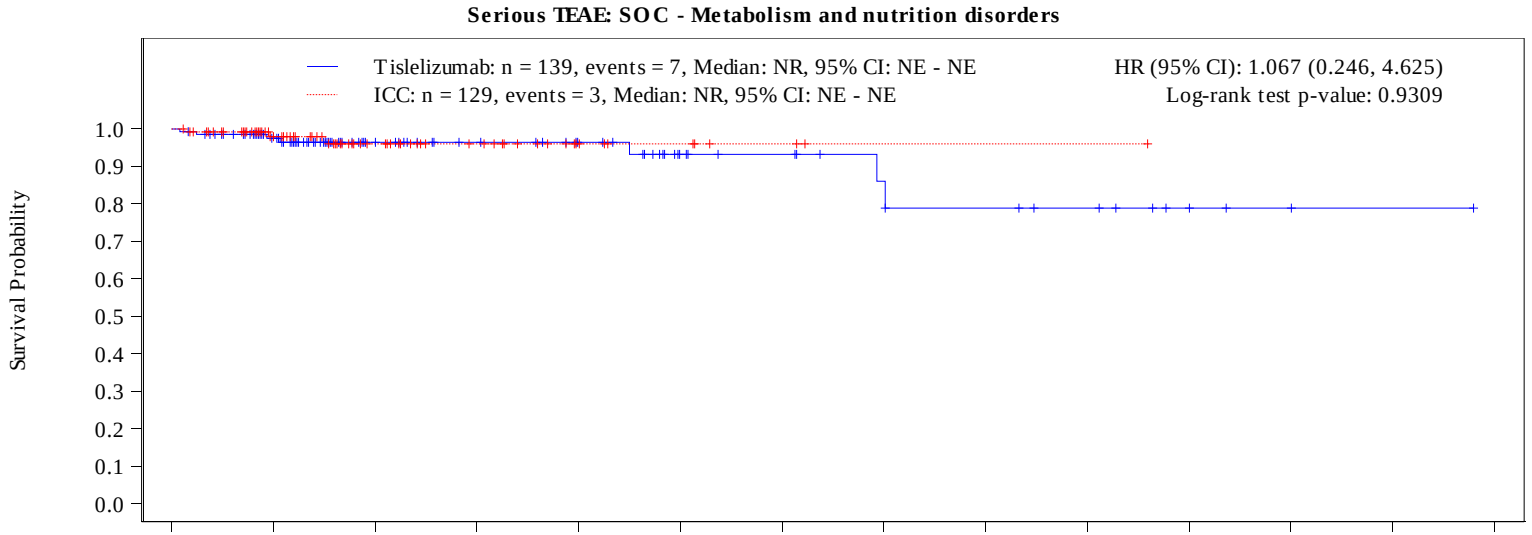
Figure 14.3.1.4.b:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

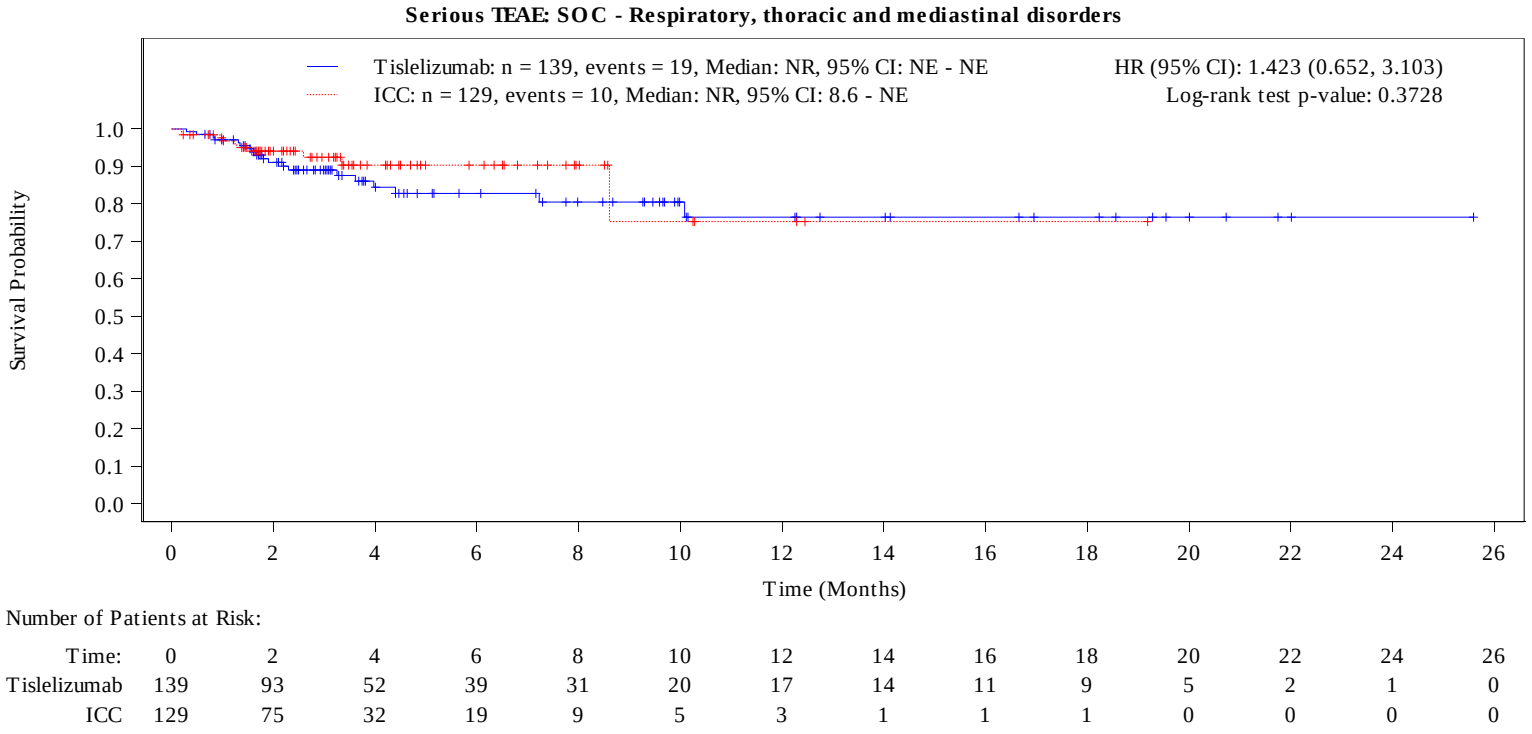


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	93	52	40	32	19	16	12	10	8	4	2	1	0
ICC	129	74	33	19	9	6	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-04-b-km-aesocpt-sae-safetys-fa.rtf

Figure 14.3.1.4.b:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 19AUG2024 23:21 f-14-03-01-04-b-km-aesocpt-sae-safetys-fa.rtf

Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	61 (38.9)	9.0 (6.9, 12.5)	149	87 (58.4)	1.0 (0.8, 2.0)	0.455 (0.326, 0.637)	<0.0001
>= 65 Years	98	31 (31.6)	19.4 (8.9, NE)	91	52 (57.1)	1.2 (0.5, 4.7)	0.347 (0.217, 0.553)	<0.0001
Interaction								0.3120
Gender								
Male	216	80 (37.0)	11.0 (7.6, NE)	204	122 (59.8)	1.0 (0.8, 2.0)	0.396 (0.295, 0.530)	<0.0001
Female	39	12 (30.8)	NR (4.9, NE)	36	17 (47.2)	NR (0.5, NE)	0.511 (0.242, 1.079)	0.0688
Interaction								0.7443

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Smoking Status								
Former/Current Smoker	187	64 (34.2)	14.7 (12.4, NE)	183	105 (57.4)	1.2 (0.9, 2.6)	0.395 (0.287, 0.545)	<0.0001
Non-Smoker	68	28 (41.2)	8.9 (4.9, NE)	57	34 (59.6)	1.0 (0.5, NE)	0.449 (0.267, 0.755)	0.0017
Interaction								0.5637

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ICC Options								
Paclitaxel	83	23 (27.7)	NR (NE, NE)	79	35 (44.3)	4.7 (1.5, NE)	0.534 (0.314, 0.907)	0.0173
Docetaxel	56	21 (37.5)	NR (3.4, NE)	50	37 (74.0)	0.9 (0.3, 1.3)	0.294 (0.168, 0.515)	<0.0001
Irinotecan	116	48 (41.4)	8.9 (4.9, 12.4)	111	67 (60.4)	0.8 (0.5, 2.3)	0.392 (0.265, 0.580)	<0.0001
Interaction								0.3941

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	17 (27.0)	NR (7.6, NE)	57	27 (47.4)	2.6 (1.7, NE)	0.389 (0.208, 0.729)	0.0021
1	192	75 (39.1)	9.0 (6.2, 19.4)	183	112 (61.2)	0.9 (0.6, 1.2)	0.407 (0.300, 0.551)	<0.0001
Interaction								0.9681
Region #1								
Asia	201	75 (37.3)	12.4 (7.6, NE)	191	116 (60.7)	1.0 (0.7, 1.3)	0.389 (0.287, 0.526)	<0.0001
Europe/North America	54	17 (31.5)	NR (4.9, NE)	49	23 (46.9)	4.7 (1.0, NE)	0.526 (0.279, 0.990)	0.0413
Interaction								0.3511

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	74 (42.0)	8.9 (4.9, 14.7)	168	110 (65.5)	0.8 (0.5, 1.0)	0.389 (0.286, 0.530)	<0.0001
Japan	25	1 (4.0)	NR (NE, NE)	23	6 (26.1)	NR (2.8, NE)	0.122 (0.015, 1.026)	0.0203
Europe/North America	54	17 (31.5)	NR (4.9, NE)	49	23 (46.9)	4.7 (1.0, NE)	0.526 (0.279, 0.990)	0.0413
Interaction								0.3093

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	203	76 (37.4)	12.4 (7.6, NE)	198	118 (59.6)	1.0 (0.8, 1.4)	0.404 (0.300, 0.546)	<0.0001
White	52	16 (30.8)	NR (4.9, NE)	42	21 (50.0)	4.7 (0.6, NE)	0.471 (0.245, 0.907)	0.0203
Interaction								0.6187

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	31 (38.8)	12.4 (6.2, NE)	60	35 (58.3)	1.0 (0.5, 4.1)	0.404 (0.244, 0.670)	0.0002
vCPS < 10%	100	38 (38.0)	9.0 (4.3, NE)	119	77 (64.7)	1.0 (0.7, 1.3)	0.385 (0.259, 0.574)	<0.0001
Missing	75	23 (30.7)	14.7 (6.9, NE)	61	27 (44.3)	4.7 (1.0, NE)	0.499 (0.280, 0.889)	0.0146
Interaction								0.7607

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	50 (31.8)	13.8 (8.3, NE)	149	69 (46.3)	2.8 (1.2, NE)	0.516 (0.356, 0.748)	0.0003
>= 65 Years	98	28 (28.6)	19.4 (14.7, NE)	91	38 (41.8)	5.1 (1.3, NE)	0.446 (0.267, 0.745)	0.0014
Interaction								0.7225
Gender								
Male	216	68 (31.5)	19.4 (9.0, NE)	204	94 (46.1)	2.8 (1.4, NE)	0.475 (0.344, 0.656)	<0.0001
Female	39	10 (25.6)	NR (4.9, NE)	36	13 (36.1)	NR (0.6, NE)	0.560 (0.243, 1.291)	0.1628
Interaction								0.8966

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	55 (29.4)	NR (13.8, NE)	183	84 (45.9)	2.8 (1.3, NE)	0.449 (0.317, 0.638)	<0.0001
Non-Smoker	68	23 (33.8)	9.0 (4.9, NE)	57	23 (40.4)	NR (1.0, NE)	0.619 (0.342, 1.122)	0.1084
Interaction								0.2861

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	20 (24.1)	NR (NE, NE)	79	26 (32.9)	NR (4.1, NE)	0.668 (0.372, 1.198)	0.1702
Docetaxel	56	17 (30.4)	NR (8.3, NE)	50	26 (52.0)	2.0 (1.0, NE)	0.353 (0.185, 0.673)	0.0009
Irinotecan	116	41 (35.3)	11.0 (6.2, 19.4)	111	55 (49.5)	2.3 (0.8, NE)	0.445 (0.291, 0.680)	0.0001
Interaction								0.6267

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	12 (19.0)	NR (13.8, NE)	57	18 (31.6)	NR (2.8, NE)	0.420 (0.196, 0.897)	0.0208
1	192	66 (34.4)	14.7 (8.3, NE)	183	89 (48.6)	2.1 (1.0, NE)	0.494 (0.356, 0.687)	<0.0001
Interaction								0.8436
Region #1								
Asia	201	62 (30.8)	19.4 (11.0, NE)	191	91 (47.6)	2.6 (1.2, NE)	0.444 (0.318, 0.621)	<0.0001
Europe/North America	54	16 (29.6)	NR (4.9, NE)	49	16 (32.7)	5.6 (5.1, NE)	0.747 (0.372, 1.502)	0.4095
Interaction								0.1530

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	61 (34.7)	13.8 (8.3, NE)	168	87 (51.8)	1.4 (1.0, 4.1)	0.445 (0.316, 0.626)	<0.0001
Japan	25	1 (4.0)	NR (NE, NE)	23	4 (17.4)	NR (2.8, NE)	0.194 (0.021, 1.743)	0.1014
Europe/North America	54	16 (29.6)	NR (4.9, NE)	49	16 (32.7)	5.6 (5.1, NE)	0.747 (0.372, 1.502)	0.4095
Interaction								0.2389

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	63 (31.0)	19.4 (11.0, NE)	198	92 (46.5)	2.8 (1.2, NE)	0.468 (0.336, 0.652)	<0.0001
White	52	15 (28.8)	NR (4.9, NE)	42	15 (35.7)	5.6 (2.3, NE)	0.636 (0.309, 1.309)	0.2127
Interaction								0.3745

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	28 (35.0)	19.4 (8.3, NE)	60	29 (48.3)	2.8 (1.0, NE)	0.453 (0.263, 0.780)	0.0032
vCPS < 10%	100	33 (33.0)	NR (4.9, NE)	119	57 (47.9)	2.8 (1.0, NE)	0.526 (0.341, 0.811)	0.0029
Missing	75	17 (22.7)	NR (11.0, NE)	61	21 (34.4)	NR (2.1, NE)	0.473 (0.242, 0.923)	0.0237
Interaction								0.9366

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	0 (0.0)	--	149	7 (4.7)	--	--	--
>= 65 Years	98	0 (0.0)	--	91	5 (5.5)	--	--	--
Interaction								--
Gender								
Male	216	0 (0.0)	NR (NE, NE)	204	11 (5.4)	NR (NE, NE)	0.000 (0.000, NE)	0.0003
Female	39	0 (0.0)	NR (NE, NE)	36	1 (2.8)	NR (NE, NE)	0.000 (0.000, NE)	0.2980
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

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Any TEAE: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Smoking Status								
Former/Current Smoker	187	0 (0.0)	--	183	9 (4.9)	--	--	--
Non-Smoker	68	0 (0.0)	--	57	3 (5.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Any TEAE: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ICC Options								
Paclitaxel	83	0 (0.0)	--	79	0 (0.0)	--	--	--
Docetaxel	56	0 (0.0)	--	50	8 (16.0)	--	--	--
Irinotecan	116	0 (0.0)	--	111	4 (3.6)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	0 (0.0)	--	57	3 (5.3)	--	--	--
1	192	0 (0.0)	--	183	9 (4.9)	--	--	--
Interaction								--
Region #1								
Asia	201	0 (0.0)	NR (NE, NE)	191	10 (5.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0006
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	2 (4.1)	NR (NE, NE)	0.000 (0.000, NE)	0.1356
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

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Safety Analysis Set
Any TEAE: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	0 (0.0)	--	168	8 (4.8)	--	--	--
Japan	25	0 (0.0)	--	23	2 (8.7)	--	--	--
Europe/North America	54	0 (0.0)	--	49	2 (4.1)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	203	0 (0.0)	NR (NE, NE)	198	10 (5.1)	NR (NE, NE)	0.000 (0.000, NE)	0.0007
White	52	0 (0.0)	NR (NE, NE)	42	2 (4.8)	NR (NE, NE)	0.000 (0.000, NE)	0.1134
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Baseline PD-L1 Status								
vCPS >= 10%	80	0 (0.0)	--	60	4 (6.7)	--	--	--
vCPS < 10%	100	0 (0.0)	--	119	3 (2.5)	--	--	--
Missing	75	0 (0.0)	--	61	5 (8.2)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	7 (4.5)	NR (NE, NE)	149	19 (12.8)	NR (NE, NE)	0.265 (0.108, 0.649)	0.0019
>= 65 Years	98	1 (1.0)	NR (NE, NE)	91	11 (12.1)	NR (NE, NE)	0.068 (0.009, 0.537)	0.0009
Interaction								0.1767
Gender								
Male	216	8 (3.7)	NR (NE, NE)	204	28 (13.7)	NR (NE, NE)	0.205 (0.091, 0.465)	<0.0001
Female	39	0 (0.0)	NR (NE, NE)	36	2 (5.6)	NR (6.3, NE)	0.000 (0.000, NE)	0.0497
Interaction								0.9860

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	5 (2.7)	NR (NE, NE)	183	20 (10.9)	NR (NE, NE)	0.185 (0.066, 0.517)	0.0003
Non-Smoker	68	3 (4.4)	NR (NE, NE)	57	10 (17.5)	NR (6.3, NE)	0.173 (0.045, 0.672)	0.0048
Interaction								0.9571

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	1 (1.2)	NR (NE, NE)	79	2 (2.5)	NR (NE, NE)	0.466 (0.042, 5.137)	0.5228
Docetaxel	56	3 (5.4)	NR (NE, NE)	50	10 (20.0)	NR (6.3, NE)	0.223 (0.061, 0.814)	0.0126
Irinotecan	116	4 (3.4)	NR (NE, NE)	111	18 (16.2)	NR (NE, NE)	0.124 (0.036, 0.429)	0.0001
Interaction								0.7887

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	3 (4.8)	NR (NE, NE)	57	5 (8.8)	NR (NE, NE)	0.350 (0.068, 1.806)	0.1890
1	192	5 (2.6)	NR (NE, NE)	183	25 (13.7)	NR (NE, NE)	0.145 (0.054, 0.389)	<0.0001
Interaction								0.2557
Region #1								
Asia	201	8 (4.0)	NR (NE, NE)	191	29 (15.2)	NR (NE, NE)	0.190 (0.084, 0.432)	<0.0001
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	0.000 (0.000, NE)	0.2888
Interaction								0.9905

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	8 (4.5)	NR (NE, NE)	168	29 (17.3)	NR (NE, NE)	0.190 (0.084, 0.431)	<0.0001
Japan	25	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	0.000 (0.000, NE)	0.2888
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	203	8 (3.9)	NR (NE, NE)	198	29 (14.6)	NR (NE, NE)	0.196 (0.087, 0.446)	<0.0001
White	52	0 (0.0)	NR (NE, NE)	42	1 (2.4)	NR (NE, NE)	0.000 (0.000, NE)	0.2601
Interaction								0.9904

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Safety Analysis Set
Any TEAE: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	3 (3.8)	NR (12.4, NE)	60	9 (15.0)	NR (6.3, NE)	0.139 (0.035, 0.548)	0.0014
vCPS < 10%	100	2 (2.0)	NR (NE, NE)	119	17 (14.3)	NR (NE, NE)	0.130 (0.030, 0.565)	0.0013
Missing	75	3 (4.0)	NR (NE, NE)	61	4 (6.6)	NR (NE, NE)	0.536 (0.119, 2.423)	0.4099
Interaction								0.3717

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	1 (0.6)	NR (NE, NE)	149	14 (9.4)	NR (NE, NE)	0.064 (0.008, 0.490)	0.0004
>= 65 Years	98	1 (1.0)	NR (NE, NE)	91	17 (18.7)	NR (NE, NE)	0.046 (0.006, 0.346)	<0.0001
Interaction								0.8660
Gender								
Male	216	2 (0.9)	NR (NE, NE)	204	28 (13.7)	NR (NE, NE)	0.059 (0.014, 0.248)	<0.0001
Female	39	0 (0.0)	NR (NE, NE)	36	3 (8.3)	NR (NE, NE)	0.000 (0.000, NE)	0.0714
Interaction								0.9889

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	1 (0.5)	NR (NE, NE)	183	20 (10.9)	NR (NE, NE)	0.043 (0.006, 0.324)	<0.0001
Non-Smoker	68	1 (1.5)	NR (NE, NE)	57	11 (19.3)	NR (NE, NE)	0.068 (0.009, 0.528)	0.0006
Interaction								0.7622

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	0 (0.0)	NR (NE, NE)	79	12 (15.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0001
Docetaxel	56	2 (3.6)	NR (NE, NE)	50	9 (18.0)	NR (NE, NE)	0.184 (0.040, 0.852)	0.0142
Irinotecan	116	0 (0.0)	NR (NE, NE)	111	10 (9.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0010
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	2 (3.2)	NR (NE, NE)	57	10 (17.5)	NR (NE, NE)	0.164 (0.036, 0.751)	0.0077
1	192	0 (0.0)	NR (NE, NE)	183	21 (11.5)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9888
Region #1								
Asia	201	2 (1.0)	NR (NE, NE)	191	19 (9.9)	NR (NE, NE)	0.096 (0.022, 0.411)	<0.0001
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	12 (24.5)	NR (4.7, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9891

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Region #2								
Asia (excluding Japan)	176	2 (1.1)	NR (NE, NE)	168	19 (11.3)	NR (NE, NE)	0.096 (0.022, 0.410)	<0.0001
Japan	25	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	12 (24.5)	NR (4.7, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	2 (1.0)	NR (NE, NE)	198	20 (10.1)	NR (NE, NE)	0.093 (0.022, 0.399)	<0.0001
White	52	0 (0.0)	NR (NE, NE)	42	11 (26.2)	NR (4.7, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9901

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	0 (0.0)	NR (NE, NE)	60	5 (8.3)	NR (NE, NE)	0.000 (0.000, NE)	0.0073
vCPS < 10%	100	1 (1.0)	NR (NE, NE)	119	20 (16.8)	NR (NE, NE)	0.052 (0.007, 0.390)	<0.0001
Missing	75	1 (1.3)	NR (NE, NE)	61	6 (9.8)	NR (NE, NE)	0.118 (0.014, 0.988)	0.0184
Interaction								0.8331

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	26 (16.6)	16.5 (16.1, NE)	149	2 (1.3)	NR (NE, NE)	7.643 (1.802, 32.421)	0.0011
>= 65 Years	98	13 (13.3)	NR (11.6, NE)	91	0 (0.0)	NR (NE, NE)	22187937.871 (0.000, NE)	0.0046
Interaction								0.9865

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Gender								
Male	216	33 (15.3)	NR (16.1, NE)	204	2 (1.0)	NR (NE, NE)	9.692 (2.309, 40.673)	0.0001
Female	39	6 (15.4)	NR (9.0, NE)	36	0 (0.0)	NR (NE, NE)	66553994.406 (0.000, NE)	0.0295
Interaction								0.9869

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	27 (14.4)	NR (16.1, NE)	183	2 (1.1)	NR (NE, NE)	8.798 (2.076, 37.285)	0.0004
Non-Smoker	68	12 (17.6)	10.6 (8.3, NE)	57	0 (0.0)	NR (NE, NE)	18518235.645 (0.000, NE)	0.0129
Interaction								0.9897

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	18 (21.7)	16.5 (9.0, NE)	79	1 (1.3)	NR (NE, NE)	13.922 (1.841, 105.255)	0.0008
Docetaxel	56	6 (10.7)	NR (11.6, NE)	50	0 (0.0)	NR (NE, NE)	18523395.133 (0.000, NE)	0.0710
Irinotecan	116	15 (12.9)	NR (16.1, NE)	111	1 (0.9)	NR (NE, NE)	7.303 (0.949, 56.192)	0.0255
Interaction								0.8965

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	12 (19.0)	16.1 (10.6, NE)	57	0 (0.0)	NR (NE, NE)	19859905.203 (0.000, NE)	0.0135
1	192	27 (14.1)	NR (16.5, NE)	183	2 (1.1)	NR (NE, NE)	9.066 (2.148, 38.255)	0.0003
Interaction								0.9884

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #1								
Asia	201	32 (15.9)	NR (11.6, NE)	191	2 (1.0)	NR (NE, NE)	8.503 (2.023, 35.744)	0.0004
Europe/North America	54	7 (13.0)	NR (NE, NE)	49	0 (0.0)	NR (NE, NE)	27493993.845 (0.000, NE)	0.0107
Interaction								0.9896

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	25 (14.2)	NR (16.1, NE)	168	2 (1.2)	NR (NE, NE)	6.970 (1.641, 29.613)	0.0021
Japan	25	7 (28.0)	11.6 (4.6, NE)	23	0 (0.0)	NR (NE, NE)	49166268.174 (0.000, NE)	0.0771
Europe/North America	54	7 (13.0)	NR (NE, NE)	49	0 (0.0)	NR (NE, NE)	27493993.845 (0.000, NE)	0.0107
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	32 (15.8)	NR (11.6, NE)	198	2 (1.0)	NR (NE, NE)	8.876 (2.111, 37.311)	0.0003
White	52	7 (13.5)	NR (NE, NE)	42	0 (0.0)	NR (NE, NE)	24583078.816 (0.000, NE)	0.0165
Interaction								0.9904

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	12 (15.0)	16.1 (11.6, NE)	60	1 (1.7)	NR (NE, NE)	4.166 (0.535, 32.436)	0.1390
vCPS < 10%	100	16 (16.0)	NR (16.5, NE)	119	1 (0.8)	NR (NE, NE)	14.407 (1.900, 109.227)	0.0006
Missing	75	11 (14.7)	NR (10.6, NE)	61	0 (0.0)	NR (NE, NE)	21444275.379 (0.000, NE)	0.0090
Interaction								0.8178

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	20 (12.7)	NR (16.1, NE)	149	1 (0.7)	NR (NE, NE)	10.474 (1.395, 78.615)	0.0043
>= 65 Years	98	9 (9.2)	NR (NE, NE)	91	0 (0.0)	NR (NE, NE)	22386682.424 (0.000, NE)	0.0134
Interaction								0.9889

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Gender								
Male	216	24 (11.1)	NR (16.5, NE)	204	1 (0.5)	NR (NE, NE)	13.346 (1.794, 99.287)	0.0010
Female	39	5 (12.8)	NR (NE, NE)	36	0 (0.0)	NR (NE, NE)	64142089.230 (0.000, NE)	0.0521
Interaction								0.9894

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	21 (11.2)	NR (16.5, NE)	183	1 (0.5)	NR (NE, NE)	12.561 (1.678, 94.026)	0.0015
Non-Smoker	68	8 (11.8)	NR (10.6, NE)	57	0 (0.0)	NR (NE, NE)	18738418.497 (0.000, NE)	0.0379
Interaction								0.9917

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	13 (15.7)	NR (10.6, NE)	79	0 (0.0)	NR (NE, NE)	24970640.163 (0.000, NE)	0.0020
Docetaxel	56	4 (7.1)	NR (NE, NE)	50	0 (0.0)	NR (NE, NE)	19015915.978 (0.000, NE)	0.1234
Irinotecan	116	12 (10.3)	NR (16.1, NE)	111	1 (0.9)	NR (NE, NE)	5.426 (0.687, 42.874)	0.0732
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	8 (12.7)	NR (16.1, NE)	57	0 (0.0)	NR (NE, NE)	18319918.753 (0.000, NE)	0.0548
1	192	21 (10.9)	NR (16.5, NE)	183	1 (0.5)	NR (NE, NE)	13.247 (1.775, 98.850)	0.0010
Interaction								0.9907

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Safety Analysis Set

Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #1								
Asia	201	24 (11.9)	NR (16.5, NE)	191	1 (0.5)	NR (NE, NE)	12.934 (1.739, 96.187)	0.0012
Europe/North America	54	5 (9.3)	NR (NE, NE)	49	0 (0.0)	NR (NE, NE)	23801941.365 (0.000, NE)	0.0484
Interaction								0.9915

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	20 (11.4)	NR (16.5, NE)	168	1 (0.6)	NR (NE, NE)	11.092 (1.480, 83.138)	0.0031
Japan	25	4 (16.0)	NR (4.6, NE)	23	0 (0.0)	NR (NE, NE)	47674440.539 (0.000, NE)	0.1771
Europe/North America	54	5 (9.3)	NR (NE, NE)	49	0 (0.0)	NR (NE, NE)	23801941.365 (0.000, NE)	0.0484
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	24 (11.8)	NR (16.5, NE)	198	1 (0.5)	NR (NE, NE)	13.525 (1.819, 100.570)	0.0009
White	52	5 (9.6)	NR (NE, NE)	42	0 (0.0)	NR (NE, NE)	21614353.280 (0.000, NE)	0.0635
Interaction								0.9921

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	8 (10.0)	NR (16.1, NE)	60	0 (0.0)	NR (NE, NE)	14654601.957 (0.000, NE)	0.1013
vCPS < 10%	100	13 (13.0)	NR (16.5, NE)	119	1 (0.8)	NR (NE, NE)	10.720 (1.390, 82.666)	0.0043
Missing	75	8 (10.7)	NR (10.6, NE)	61	0 (0.0)	NR (NE, NE)	19687134.327 (0.000, NE)	0.0412
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	93 (59.2)	2.0 (1.2, 4.0)	149	104 (69.8)	0.4 (0.2, 0.8)	0.518 (0.389, 0.690)	<0.0001
>= 65 Years	98	56 (57.1)	3.4 (2.2, 6.3)	91	67 (73.6)	0.4 (0.2, 0.7)	0.395 (0.272, 0.574)	<0.0001
Interaction								0.4722
Gender								
Male	216	123 (56.9)	3.3 (1.9, 5.8)	204	143 (70.1)	0.4 (0.3, 0.7)	0.467 (0.364, 0.599)	<0.0001
Female	39	26 (66.7)	1.4 (0.7, 4.2)	36	28 (77.8)	0.2 (0.1, 1.1)	0.466 (0.266, 0.814)	0.0052
Interaction								0.9950

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	112 (59.9)	2.4 (1.4, 4.0)	183	132 (72.1)	0.3 (0.2, 0.7)	0.488 (0.377, 0.632)	<0.0001
Non-Smoker	68	37 (54.4)	5.8 (1.3, 8.6)	57	39 (68.4)	0.5 (0.2, 1.2)	0.408 (0.253, 0.657)	0.0001
Interaction								0.8267

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	53 (63.9)	2.0 (1.2, 3.4)	79	50 (63.3)	1.1 (0.5, 2.3)	0.724 (0.489, 1.073)	0.1031
Docetaxel	56	35 (62.5)	2.9 (0.8, 7.2)	50	29 (58.0)	1.1 (0.3, 6.1)	0.709 (0.427, 1.178)	0.1776
Irinotecan	116	61 (52.6)	5.6 (1.3, 6.6)	111	92 (82.9)	0.2 (0.1, 0.3)	0.257 (0.180, 0.365)	<0.0001
Interaction								<0.0001

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	35 (55.6)	5.9 (2.0, 8.6)	57	38 (66.7)	0.8 (0.3, 1.9)	0.446 (0.274, 0.727)	0.0008
1	192	114 (59.4)	2.2 (1.2, 3.4)	183	133 (72.7)	0.3 (0.2, 0.5)	0.469 (0.363, 0.606)	<0.0001
Interaction								0.7696
Region #1								
Asia	201	108 (53.7)	3.4 (2.0, 5.9)	191	133 (69.6)	0.3 (0.2, 0.6)	0.423 (0.325, 0.549)	<0.0001
Europe/North America	54	41 (75.9)	1.3 (0.5, 2.4)	49	38 (77.6)	0.5 (0.3, 1.2)	0.642 (0.405, 1.017)	0.0525
Interaction								0.0307

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	97 (55.1)	3.4 (1.8, 5.8)	168	118 (70.2)	0.3 (0.2, 0.5)	0.421 (0.319, 0.555)	<0.0001
Japan	25	11 (44.0)	9.8 (1.5, NE)	23	15 (65.2)	1.1 (0.3, NE)	0.422 (0.187, 0.953)	0.0317
Europe/North America	54	41 (75.9)	1.3 (0.5, 2.4)	49	38 (77.6)	0.5 (0.3, 1.2)	0.642 (0.405, 1.017)	0.0525
Interaction								0.0920

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	110 (54.2)	3.4 (2.0, 5.9)	198	138 (69.7)	0.3 (0.2, 0.7)	0.433 (0.334, 0.560)	<0.0001
White	52	39 (75.0)	1.3 (0.5, 2.5)	42	33 (78.6)	0.4 (0.3, 1.2)	0.588 (0.362, 0.957)	0.0272
Interaction								0.1030

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	51 (63.8)	3.0 (1.3, 6.0)	60	48 (80.0)	0.2 (0.1, 0.4)	0.356 (0.233, 0.542)	<0.0001
vCPS < 10%	100	63 (63.0)	1.5 (0.9, 5.8)	119	86 (72.3)	0.4 (0.3, 0.9)	0.527 (0.376, 0.738)	0.0001
Missing	75	35 (46.7)	4.2 (2.5, NE)	61	37 (60.7)	0.5 (0.1, NE)	0.490 (0.306, 0.784)	0.0021
Interaction								0.3190

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Gastrointestinal disorders / PT - Abdominal pain upper

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	7 (4.5)	NR (NE, NE)	149	9 (6.0)	NR (NE, NE)	0.629 (0.232, 1.710)	0.3588
>= 65 Years	98	2 (2.0)	NR (NE, NE)	91	7 (7.7)	NR (6.9, NE)	0.195 (0.039, 0.989)	0.0302
Interaction								0.2575
Gender								
Male	216	9 (4.2)	NR (NE, NE)	204	11 (5.4)	NR (NE, NE)	0.637 (0.260, 1.558)	0.3188
Female	39	0 (0.0)	NR (NE, NE)	36	5 (13.9)	NR (NE, NE)	0.000 (0.000, NE)	0.0141
Interaction								0.9869

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Abdominal pain upper

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	7 (3.7)	NR (NE, NE)	183	10 (5.5)	NR (NE, NE)	0.590 (0.222, 1.564)	0.2828
Non-Smoker	68	2 (2.9)	NR (NE, NE)	57	6 (10.5)	NR (6.9, NE)	0.202 (0.039, 1.059)	0.0385
Interaction								0.3467

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Abdominal pain upper

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	1 (1.2)	NR (NE, NE)	79	7 (8.9)	NR (NE, NE)	0.131 (0.016, 1.067)	0.0245
Docetaxel	56	3 (5.4)	NR (NE, NE)	50	3 (6.0)	NR (6.9, NE)	0.700 (0.138, 3.536)	0.6635
Irinotecan	116	5 (4.3)	NR (NE, NE)	111	6 (5.4)	NR (NE, NE)	0.569 (0.165, 1.956)	0.3653
Interaction								0.3126

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Abdominal pain upper

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	1 (1.6)	NR (NE, NE)	57	8 (14.0)	NR (6.9, NE)	0.089 (0.011, 0.721)	0.0048
1	192	8 (4.2)	NR (NE, NE)	183	8 (4.4)	NR (NE, NE)	0.812 (0.301, 2.191)	0.6803
Interaction								0.0623
Region #1								
Asia	201	7 (3.5)	NR (NE, NE)	191	9 (4.7)	NR (NE, NE)	0.614 (0.225, 1.673)	0.3349
Europe/North America	54	2 (3.7)	NR (NE, NE)	49	7 (14.3)	NR (6.9, NE)	0.220 (0.045, 1.075)	0.0397
Interaction								0.2919

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Abdominal pain upper

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	7 (4.0)	NR (NE, NE)	168	9 (5.4)	NR (NE, NE)	0.614 (0.225, 1.673)	0.3354
Japan	25	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Europe/North America	54	2 (3.7)	NR (NE, NE)	49	7 (14.3)	NR (6.9, NE)	0.220 (0.045, 1.075)	0.0397
Interaction								0.5697

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Abdominal pain upper

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	7 (3.4)	NR (NE, NE)	198	9 (4.5)	NR (NE, NE)	0.636 (0.233, 1.730)	0.3709
White	52	2 (3.8)	NR (NE, NE)	42	7 (16.7)	NR (6.9, NE)	0.197 (0.041, 0.961)	0.0249
Interaction								0.2186

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Abdominal pain upper

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	4 (5.0)	NR (NE, NE)	60	6 (10.0)	NR (NE, NE)	0.356 (0.096, 1.319)	0.1073
vCPS < 10%	100	3 (3.0)	NR (NE, NE)	119	8 (6.7)	NR (NE, NE)	0.418 (0.111, 1.581)	0.1852
Missing	75	2 (2.7)	NR (NE, NE)	61	2 (3.3)	NR (6.9, NE)	0.638 (0.088, 4.622)	0.6532
Interaction								0.8205

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	14 (8.9)	NR (NE, NE)	149	44 (29.5)	NR (NE, NE)	0.237 (0.129, 0.434)	<0.0001
>= 65 Years	98	18 (18.4)	NR (NE, NE)	91	33 (36.3)	NR (3.3, NE)	0.374 (0.209, 0.670)	0.0006
Interaction								0.2412
Gender								
Male	216	24 (11.1)	NR (NE, NE)	204	65 (31.9)	NR (NE, NE)	0.266 (0.166, 0.427)	<0.0001
Female	39	8 (20.5)	NR (7.5, NE)	36	12 (33.3)	NR (1.7, NE)	0.451 (0.180, 1.128)	0.0801
Interaction								0.2017

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	27 (14.4)	NR (NE, NE)	183	63 (34.4)	NR (4.4, NE)	0.308 (0.195, 0.485)	<0.0001
Non-Smoker	68	5 (7.4)	NR (NE, NE)	57	14 (24.6)	NR (NE, NE)	0.268 (0.096, 0.744)	0.0066
Interaction								0.6837

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	13 (15.7)	NR (NE, NE)	79	15 (19.0)	NR (NE, NE)	0.704 (0.334, 1.484)	0.3525
Docetaxel	56	6 (10.7)	NR (NE, NE)	50	8 (16.0)	NR (NE, NE)	0.553 (0.191, 1.607)	0.2696
Irinotecan	116	13 (11.2)	NR (NE, NE)	111	54 (48.6)	4.4 (0.4, NE)	0.140 (0.074, 0.266)	<0.0001
Interaction								0.0020

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	4 (6.3)	NR (NE, NE)	57	16 (28.1)	NR (NE, NE)	0.164 (0.053, 0.501)	0.0003
1	192	28 (14.6)	NR (NE, NE)	183	61 (33.3)	NR (4.4, NE)	0.332 (0.211, 0.521)	<0.0001
Interaction								0.2730
Region #1								
Asia	201	16 (8.0)	NR (NE, NE)	191	56 (29.3)	NR (NE, NE)	0.213 (0.122, 0.372)	<0.0001
Europe/North America	54	16 (29.6)	NR (7.5, NE)	49	21 (42.9)	NR (0.5, NE)	0.486 (0.250, 0.944)	0.0290
Interaction								0.0286

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	14 (8.0)	NR (NE, NE)	168	53 (31.5)	NR (NE, NE)	0.194 (0.107, 0.351)	<0.0001
Japan	25	2 (8.0)	NR (NE, NE)	23	3 (13.0)	NR (2.6, NE)	0.539 (0.089, 3.271)	0.4952
Europe/North America	54	16 (29.6)	NR (7.5, NE)	49	21 (42.9)	NR (0.5, NE)	0.486 (0.250, 0.944)	0.0290
Interaction								0.0556

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	17 (8.4)	NR (NE, NE)	198	56 (28.3)	NR (NE, NE)	0.236 (0.137, 0.407)	<0.0001
White	52	15 (28.8)	NR (7.5, NE)	42	21 (50.0)	1.7 (0.4, NE)	0.373 (0.189, 0.733)	0.0028
Interaction								0.1650

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	12 (15.0)	NR (NE, NE)	60	20 (33.3)	NR (3.3, NE)	0.327 (0.158, 0.677)	0.0015
vCPS < 10%	100	16 (16.0)	NR (NE, NE)	119	42 (35.3)	NR (NE, NE)	0.333 (0.186, 0.597)	<0.0001
Missing	75	4 (5.3)	NR (NE, NE)	61	15 (24.6)	NR (4.4, NE)	0.184 (0.061, 0.557)	0.0008
Interaction								0.5263

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Nausea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	24 (15.3)	NR (NE, NE)	149	47 (31.5)	NR (5.1, NE)	0.394 (0.240, 0.646)	0.0001
>= 65 Years	98	12 (12.2)	NR (NE, NE)	91	25 (27.5)	NR (5.0, NE)	0.325 (0.162, 0.652)	0.0009
Interaction								0.8969
Gender								
Male	216	28 (13.0)	NR (NE, NE)	204	58 (28.4)	NR (5.1, NE)	0.358 (0.227, 0.565)	<0.0001
Female	39	8 (20.5)	NR (4.7, NE)	36	14 (38.9)	NR (1.1, NE)	0.363 (0.148, 0.890)	0.0212
Interaction								0.8159

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Nausea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	29 (15.5)	NR (NE, NE)	183	54 (29.5)	NR (5.0, NE)	0.406 (0.257, 0.641)	<0.0001
Non-Smoker	68	7 (10.3)	NR (NE, NE)	57	18 (31.6)	NR (3.8, NE)	0.261 (0.109, 0.629)	0.0013
Interaction								0.3322

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Nausea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	15 (18.1)	NR (NE, NE)	79	14 (17.7)	NR (NE, NE)	0.924 (0.445, 1.919)	0.8328
Docetaxel	56	7 (12.5)	NR (NE, NE)	50	5 (10.0)	NR (4.2, NE)	1.090 (0.342, 3.469)	0.8841
Irinotecan	116	14 (12.1)	NR (NE, NE)	111	53 (47.7)	2.4 (1.1, 5.1)	0.159 (0.087, 0.292)	<0.0001
Interaction								0.0001

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Nausea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	3 (4.8)	NR (NE, NE)	57	10 (17.5)	NR (NE, NE)	0.233 (0.064, 0.851)	0.0163
1	192	33 (17.2)	NR (NE, NE)	183	62 (33.9)	5.1 (3.0, NE)	0.377 (0.246, 0.579)	<0.0001
Interaction								0.4142
Region #1								
Asia	201	25 (12.4)	NR (NE, NE)	191	57 (29.8)	NR (5.1, NE)	0.321 (0.200, 0.517)	<0.0001
Europe/North America	54	11 (20.4)	NR (NE, NE)	49	15 (30.6)	NR (2.6, NE)	0.544 (0.248, 1.194)	0.1228
Interaction								0.1922

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Nausea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	21 (11.9)	NR (NE, NE)	168	56 (33.3)	NR (3.8, NE)	0.268 (0.162, 0.445)	<0.0001
Japan	25	4 (16.0)	NR (NE, NE)	23	1 (4.3)	NR (NE, NE)	3.318 (0.369, 29.832)	0.2564
Europe/North America	54	11 (20.4)	NR (NE, NE)	49	15 (30.6)	NR (2.6, NE)	0.544 (0.248, 1.194)	0.1228
Interaction								0.0316

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Nausea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	25 (12.3)	NR (NE, NE)	198	59 (29.8)	NR (5.1, NE)	0.321 (0.200, 0.515)	<0.0001
White	52	11 (21.2)	NR (NE, NE)	42	13 (31.0)	5.0 (2.6, NE)	0.547 (0.243, 1.235)	0.1403
Interaction								0.1896

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Nausea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	14 (17.5)	NR (NE, NE)	60	19 (31.7)	NR (3.0, NE)	0.401 (0.198, 0.809)	0.0081
vCPS < 10%	100	13 (13.0)	NR (NE, NE)	119	37 (31.1)	NR (3.8, NE)	0.329 (0.174, 0.621)	0.0003
Missing	75	9 (12.0)	NR (NE, NE)	61	16 (26.2)	NR (5.0, NE)	0.379 (0.167, 0.861)	0.0155
Interaction								0.9399

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Vomiting

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	21 (13.4)	NR (NE, NE)	149	33 (22.1)	NR (NE, NE)	0.466 (0.267, 0.815)	0.0059
>= 65 Years	98	6 (6.1)	NR (NE, NE)	91	15 (16.5)	NR (NE, NE)	0.339 (0.132, 0.875)	0.0187
Interaction								0.4494
Gender								
Male	216	24 (11.1)	NR (NE, NE)	204	38 (18.6)	NR (NE, NE)	0.476 (0.283, 0.802)	0.0042
Female	39	3 (7.7)	NR (NE, NE)	36	10 (27.8)	NR (2.7, NE)	0.239 (0.066, 0.869)	0.0178
Interaction								0.2766

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Vomiting

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	19 (10.2)	NR (NE, NE)	183	34 (18.6)	NR (NE, NE)	0.447 (0.252, 0.792)	0.0045
Non-Smoker	68	8 (11.8)	NR (NE, NE)	57	14 (24.6)	NR (3.0, NE)	0.374 (0.155, 0.900)	0.0222
Interaction								0.8099

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Vomiting

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	8 (9.6)	NR (NE, NE)	79	6 (7.6)	NR (NE, NE)	1.198 (0.415, 3.462)	0.7379
Docetaxel	56	4 (7.1)	NR (NE, NE)	50	5 (10.0)	NR (NE, NE)	0.611 (0.163, 2.282)	0.4576
Irinotecan	116	15 (12.9)	NR (14.0, NE)	111	37 (33.3)	NR (3.5, NE)	0.264 (0.141, 0.493)	<0.0001
Interaction								0.0458

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Vomiting

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	3 (4.8)	NR (14.0, NE)	57	4 (7.0)	NR (NE, NE)	0.393 (0.072, 2.165)	0.2668
1	192	24 (12.5)	NR (NE, NE)	183	44 (24.0)	NR (NE, NE)	0.421 (0.255, 0.695)	0.0005
Interaction								0.6699
Region #1								
Asia	201	21 (10.4)	NR (NE, NE)	191	41 (21.5)	NR (NE, NE)	0.380 (0.222, 0.650)	0.0002
Europe/North America	54	6 (11.1)	NR (NE, NE)	49	7 (14.3)	NR (5.7, NE)	0.727 (0.244, 2.165)	0.5640
Interaction								0.3106

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Vomiting

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	20 (11.4)	NR (NE, NE)	168	40 (23.8)	NR (NE, NE)	0.365 (0.211, 0.631)	0.0002
Japan	25	1 (4.0)	NR (NE, NE)	23	1 (4.3)	NR (NE, NE)	0.895 (0.056, 14.318)	0.9378
Europe/North America	54	6 (11.1)	NR (NE, NE)	49	7 (14.3)	NR (5.7, NE)	0.727 (0.244, 2.165)	0.5640
Interaction								0.5108

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Vomiting

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	21 (10.3)	NR (NE, NE)	198	42 (21.2)	NR (NE, NE)	0.383 (0.225, 0.654)	0.0002
White	52	6 (11.5)	NR (NE, NE)	42	6 (14.3)	NR (5.7, NE)	0.753 (0.242, 2.337)	0.6214
Interaction								0.3050

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Vomiting

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	7 (8.8)	NR (14.0, NE)	60	12 (20.0)	NR (5.7, NE)	0.302 (0.116, 0.786)	0.0095
vCPS < 10%	100	15 (15.0)	NR (NE, NE)	119	25 (21.0)	NR (NE, NE)	0.616 (0.324, 1.171)	0.1338
Missing	75	5 (6.7)	NR (NE, NE)	61	11 (18.0)	NR (NE, NE)	0.340 (0.118, 0.980)	0.0356
Interaction								0.4357

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	61 (38.9)	10.3 (7.7, NE)	149	89 (59.7)	1.0 (0.7, 2.1)	0.436 (0.311, 0.611)	<0.0001
>= 65 Years	98	55 (56.1)	3.6 (2.1, 7.6)	91	58 (63.7)	1.0 (0.7, 2.3)	0.549 (0.371, 0.811)	0.0020
Interaction								0.1621
Gender								
Male	216	95 (44.0)	7.7 (5.5, 11.0)	204	123 (60.3)	1.0 (0.8, 1.6)	0.466 (0.352, 0.616)	<0.0001
Female	39	21 (53.8)	2.4 (1.0, 8.5)	36	24 (66.7)	1.3 (0.5, 2.6)	0.563 (0.305, 1.039)	0.0588
Interaction								0.3968

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	87 (46.5)	7.6 (2.8, 11.0)	183	118 (64.5)	1.0 (0.7, 1.3)	0.469 (0.352, 0.626)	<0.0001
Non-Smoker	68	29 (42.6)	7.0 (2.8, 17.5)	57	29 (50.9)	1.9 (0.7, NE)	0.520 (0.301, 0.898)	0.0165
Interaction								0.4257

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	46 (55.4)	3.5 (1.9, 9.9)	79	49 (62.0)	1.7 (0.8, 2.6)	0.614 (0.403, 0.936)	0.0211
Docetaxel	56	27 (48.2)	5.5 (2.9, 8.6)	50	28 (56.0)	1.3 (0.8, NE)	0.548 (0.315, 0.951)	0.0281
Irinotecan	116	43 (37.1)	13.8 (6.1, NE)	111	70 (63.1)	0.8 (0.5, 1.5)	0.384 (0.258, 0.571)	<0.0001
Interaction								0.0781

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	34 (54.0)	6.9 (2.7, 8.5)	57	33 (57.9)	2.1 (0.9, 3.0)	0.588 (0.352, 0.981)	0.0378
1	192	82 (42.7)	7.6 (3.5, 12.7)	183	114 (62.3)	0.9 (0.6, 1.6)	0.446 (0.332, 0.599)	<0.0001
Interaction								0.1507
Region #1								
Asia	201	77 (38.3)	9.9 (6.4, 17.5)	191	111 (58.1)	1.1 (0.8, 2.0)	0.408 (0.301, 0.555)	<0.0001
Europe/North America	54	39 (72.2)	1.0 (0.6, 2.5)	49	36 (73.5)	1.0 (0.5, 1.9)	0.757 (0.475, 1.206)	0.2312
Interaction								0.0143

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	64 (36.4)	11.0 (6.4, NE)	168	97 (57.7)	1.0 (0.8, 2.0)	0.404 (0.290, 0.562)	<0.0001
Japan	25	13 (52.0)	6.9 (1.9, NE)	23	14 (60.9)	1.7 (0.4, NE)	0.432 (0.187, 1.000)	0.0431
Europe/North America	54	39 (72.2)	1.0 (0.6, 2.5)	49	36 (73.5)	1.0 (0.5, 1.9)	0.757 (0.475, 1.206)	0.2312
Interaction								0.0381

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	77 (37.9)	9.9 (6.4, 17.5)	198	115 (58.1)	1.1 (0.8, 2.0)	0.404 (0.298, 0.547)	<0.0001
White	52	39 (75.0)	0.8 (0.5, 2.5)	42	32 (76.2)	0.8 (0.5, 1.5)	0.751 (0.465, 1.213)	0.2305
Interaction								0.0213

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	41 (51.3)	6.4 (2.1, 8.5)	60	44 (73.3)	0.7 (0.3, 1.1)	0.382 (0.245, 0.597)	<0.0001
vCPS < 10%	100	46 (46.0)	7.7 (2.7, 11.0)	119	65 (54.6)	1.9 (0.9, 2.7)	0.574 (0.385, 0.855)	0.0053
Missing	75	29 (38.7)	9.9 (2.8, NE)	61	38 (62.3)	0.9 (0.5, 1.7)	0.425 (0.259, 0.698)	0.0004
Interaction								0.2375

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	14 (8.9)	NR (17.5, NE)	149	23 (15.4)	NR (9.0, NE)	0.405 (0.200, 0.819)	0.0093
>= 65 Years	98	12 (12.2)	NR (NE, NE)	91	12 (13.2)	NR (NE, NE)	0.792 (0.351, 1.784)	0.5715
Interaction								0.3114
Gender								
Male	216	24 (11.1)	NR (NE, NE)	204	29 (14.2)	NR (NE, NE)	0.600 (0.343, 1.050)	0.0702
Female	39	2 (5.1)	NR (NE, NE)	36	6 (16.7)	9.0 (9.0, NE)	0.241 (0.048, 1.223)	0.0635
Interaction								0.3448

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Smoking Status								
Former/Current Smoker	187	22 (11.8)	NR (NE, NE)	183	31 (16.9)	NR (9.0, NE)	0.529 (0.302, 0.927)	0.0236
Non-Smoker	68	4 (5.9)	NR (17.5, NE)	57	4 (7.0)	NR (NE, NE)	0.740 (0.182, 3.002)	0.6723
Interaction								0.6883

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
Adverse events were classified based on MedDRA v23.0.
System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.
Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.
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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	12 (14.5)	NR (NE, NE)	79	7 (8.9)	NR (9.0, NE)	1.491 (0.582, 3.814)	0.4012
Docetaxel	56	6 (10.7)	17.5 (8.6, NE)	50	10 (20.0)	NR (4.1, NE)	0.377 (0.133, 1.067)	0.0564
Irinotecan	116	8 (6.9)	NR (14.5, NE)	111	18 (16.2)	NR (NE, NE)	0.315 (0.131, 0.757)	0.0063
Interaction								0.0627

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	6 (9.5)	NR (14.5, NE)	57	6 (10.5)	NR (NE, NE)	0.638 (0.193, 2.109)	0.4571
1	192	20 (10.4)	NR (NE, NE)	183	29 (15.8)	NR (9.0, NE)	0.515 (0.287, 0.923)	0.0230
Interaction								0.5760
Region #1								
Asia	201	10 (5.0)	NR (NE, NE)	191	24 (12.6)	NR (9.0, NE)	0.284 (0.130, 0.619)	0.0008
Europe/North America	54	16 (29.6)	NR (8.6, NE)	49	11 (22.4)	NR (4.1, NE)	1.130 (0.521, 2.453)	0.7549
Interaction								0.0100

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	10 (5.7)	NR (NE, NE)	168	24 (14.3)	NR (9.0, NE)	0.286 (0.132, 0.620)	0.0008
Japan	25	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Europe/North America	54	16 (29.6)	NR (8.6, NE)	49	11 (22.4)	NR (4.1, NE)	1.130 (0.521, 2.453)	0.7549
Interaction								0.0377

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	10 (4.9)	NR (NE, NE)	198	24 (12.1)	NR (9.0, NE)	0.292 (0.134, 0.637)	0.0011
White	52	16 (30.8)	NR (8.6, NE)	42	11 (26.2)	NR (3.0, NE)	0.980 (0.452, 2.127)	0.9589
Interaction								0.0237

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	9 (11.3)	NR (14.5, NE)	60	10 (16.7)	NR (9.0, NE)	0.480 (0.191, 1.208)	0.1110
vCPS < 10%	100	12 (12.0)	NR (17.5, NE)	119	16 (13.4)	NR (NE, NE)	0.685 (0.316, 1.489)	0.3362
Missing	75	5 (6.7)	NR (NE, NE)	61	9 (14.8)	NR (NE, NE)	0.417 (0.140, 1.244)	0.1048
Interaction								0.4929

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - General disorders and administration site conditions / PT - Malaise

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	7 (4.5)	NR (NE, NE)	149	25 (16.8)	NR (NE, NE)	0.183 (0.074, 0.451)	<0.0001
>= 65 Years	98	9 (9.2)	NR (NE, NE)	91	11 (12.1)	NR (NE, NE)	0.612 (0.248, 1.507)	0.2797
Interaction								0.0821
Gender								
Male	216	12 (5.6)	NR (NE, NE)	204	32 (15.7)	NR (NE, NE)	0.271 (0.136, 0.542)	<0.0001
Female	39	4 (10.3)	NR (7.7, NE)	36	4 (11.1)	NR (NE, NE)	0.632 (0.151, 2.641)	0.5258
Interaction								0.1665

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - General disorders and administration site conditions / PT - Malaise

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Smoking Status								
Former/Current Smoker	187	10 (5.3)	NR (NE, NE)	183	26 (14.2)	NR (NE, NE)	0.288 (0.134, 0.618)	0.0007
Non-Smoker	68	6 (8.8)	NR (8.5, NE)	57	10 (17.5)	NR (NE, NE)	0.346 (0.121, 0.994)	0.0400
Interaction								0.6350

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
Adverse events were classified based on MedDRA v23.0.
System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.
Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.
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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - General disorders and administration site conditions / PT - Malaise

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ICC Options								
Paclitaxel	83	6 (7.2)	NR (NE, NE)	79	5 (6.3)	NR (NE, NE)	0.794 (0.233, 2.709)	0.7119
Docetaxel	56	5 (8.9)	NR (13.3, NE)	50	7 (14.0)	NR (NE, NE)	0.532 (0.166, 1.705)	0.2784
Irinotecan	116	5 (4.3)	NR (NE, NE)	111	24 (21.6)	NR (NE, NE)	0.156 (0.059, 0.415)	<0.0001
Interaction								0.0365

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - General disorders and administration site conditions / PT - Malaise

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	5 (7.9)	NR (13.3, NE)	57	10 (17.5)	NR (NE, NE)	0.249 (0.075, 0.824)	0.0147
1	192	11 (5.7)	NR (NE, NE)	183	26 (14.2)	NR (NE, NE)	0.341 (0.167, 0.694)	0.0019
Interaction								0.9852
Region #1								
Asia	201	16 (8.0)	NR (NE, NE)	191	35 (18.3)	NR (NE, NE)	0.313 (0.169, 0.578)	<0.0001
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	0.000 (0.000, NE)	0.2888
Interaction								0.9881

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - General disorders and administration site conditions / PT - Malaise

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	11 (6.3)	NR (NE, NE)	168	31 (18.5)	NR (NE, NE)	0.268 (0.132, 0.542)	<0.0001
Japan	25	5 (20.0)	NR (7.7, NE)	23	4 (17.4)	NR (2.6, NE)	0.596 (0.144, 2.472)	0.4708
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	0.000 (0.000, NE)	0.2888
Interaction								0.2655

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - General disorders and administration site conditions / PT - Malaise

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	16 (7.9)	NR (NE, NE)	198	35 (17.7)	NR (NE, NE)	0.322 (0.174, 0.597)	0.0002
White	52	0 (0.0)	NR (NE, NE)	42	1 (2.4)	NR (NE, NE)	0.000 (0.000, NE)	0.2601
Interaction								0.9879

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - General disorders and administration site conditions / PT - Malaise

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	7 (8.8)	NR (NE, NE)	60	11 (18.3)	NR (NE, NE)	0.351 (0.133, 0.925)	0.0269
vCPS < 10%	100	3 (3.0)	NR (13.3, NE)	119	14 (11.8)	NR (NE, NE)	0.155 (0.035, 0.682)	0.0045
Missing	75	6 (8.0)	NR (NE, NE)	61	11 (18.0)	NR (NE, NE)	0.356 (0.130, 0.975)	0.0355
Interaction								0.7727

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	49 (31.2)	15.8 (7.3, NE)	149	42 (28.2)	8.0 (4.9, NE)	0.864 (0.568, 1.316)	0.4959
>= 65 Years	98	26 (26.5)	11.5 (9.5, NE)	91	33 (36.3)	9.2 (2.8, NE)	0.448 (0.256, 0.785)	0.0039
Interaction								0.2182
Gender								
Male	216	65 (30.1)	13.7 (9.5, NE)	204	60 (29.4)	8.0 (5.3, NE)	0.757 (0.527, 1.088)	0.1303
Female	39	10 (25.6)	11.3 (2.7, NE)	36	15 (41.7)	3.0 (2.4, NE)	0.396 (0.166, 0.941)	0.0297
Interaction								0.2058

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	53 (28.3)	13.8 (9.5, NE)	183	60 (32.8)	8.0 (3.4, NE)	0.602 (0.410, 0.885)	0.0090
Non-Smoker	68	22 (32.4)	10.5 (3.2, NE)	57	15 (26.3)	NR (3.1, NE)	0.992 (0.510, 1.931)	0.9820
Interaction								0.2270

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	25 (30.1)	13.8 (5.3, NE)	79	25 (31.6)	8.0 (3.3, NE)	0.766 (0.431, 1.359)	0.3591
Docetaxel	56	18 (32.1)	9.5 (3.2, NE)	50	22 (44.0)	3.1 (1.4, NE)	0.479 (0.251, 0.914)	0.0223
Irinotecan	116	32 (27.6)	15.8 (11.3, NE)	111	28 (25.2)	9.2 (5.8, NE)	0.781 (0.460, 1.325)	0.3572
Interaction								0.6563

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	18 (28.6)	13.8 (11.3, NE)	57	14 (24.6)	8.0 (5.3, NE)	0.745 (0.354, 1.569)	0.4366
1	192	57 (29.7)	10.5 (5.6, NE)	183	61 (33.3)	5.8 (2.8, NE)	0.657 (0.453, 0.953)	0.0256
Interaction								0.3857
Region #1								
Asia	201	59 (29.4)	13.7 (6.3, NE)	191	54 (28.3)	NR (5.8, NE)	0.725 (0.495, 1.063)	0.0973
Europe/North America	54	16 (29.6)	11.3 (7.3, NE)	49	21 (42.9)	4.9 (2.5, 9.2)	0.567 (0.289, 1.111)	0.0931
Interaction								0.6809

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	51 (29.0)	13.7 (6.3, NE)	168	46 (27.4)	NR (5.8, NE)	0.736 (0.488, 1.110)	0.1413
Japan	25	8 (32.0)	11.5 (5.6, NE)	23	8 (34.8)	NR (3.0, NE)	0.633 (0.219, 1.834)	0.3952
Europe/North America	54	16 (29.6)	11.3 (7.3, NE)	49	21 (42.9)	4.9 (2.5, 9.2)	0.567 (0.289, 1.111)	0.0931
Interaction								0.9170

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	60 (29.6)	13.7 (6.3, NE)	198	56 (28.3)	NR (5.8, NE)	0.738 (0.506, 1.076)	0.1127
White	52	15 (28.8)	11.3 (7.3, NE)	42	19 (45.2)	4.9 (2.5, 9.2)	0.520 (0.258, 1.045)	0.0613
Interaction								0.5001

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Safety Analysis Set

Any TEAE: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	20 (25.0)	15.8 (9.5, NE)	60	21 (35.0)	8.0 (2.6, NE)	0.414 (0.213, 0.803)	0.0072
vCPS < 10%	100	39 (39.0)	7.3 (3.8, NE)	119	41 (34.5)	5.3 (3.3, NE)	0.922 (0.590, 1.441)	0.7215
Missing	75	16 (21.3)	13.7 (11.5, NE)	61	13 (21.3)	NR (NE, NE)	0.739 (0.346, 1.578)	0.4326
Interaction								0.1217

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	79 (50.3)	2.8 (2.1, 7.6)	149	101 (67.8)	0.5 (0.5, 0.8)	0.473 (0.350, 0.640)	<0.0001
>= 65 Years	98	49 (50.0)	4.4 (2.7, 9.7)	91	65 (71.4)	0.5 (0.4, 1.0)	0.364 (0.246, 0.539)	<0.0001
Interaction								0.3988
Gender								
Male	216	111 (51.4)	3.4 (2.1, 7.6)	204	146 (71.6)	0.5 (0.5, 0.7)	0.419 (0.324, 0.541)	<0.0001
Female	39	17 (43.6)	2.8 (2.1, NE)	36	20 (55.6)	1.0 (0.3, NE)	0.522 (0.271, 1.004)	0.0439
Interaction								0.5106

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	93 (49.7)	3.5 (2.1, 9.7)	183	125 (68.3)	0.7 (0.5, 0.9)	0.429 (0.325, 0.566)	<0.0001
Non-Smoker	68	35 (51.5)	2.8 (1.5, 6.6)	57	41 (71.9)	0.5 (0.3, 0.7)	0.426 (0.268, 0.678)	0.0001
Interaction								0.9276

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	27 (32.5)	NR (7.0, NE)	79	45 (57.0)	1.2 (0.5, 3.5)	0.362 (0.222, 0.591)	<0.0001
Docetaxel	56	31 (55.4)	2.1 (1.2, 7.7)	50	39 (78.0)	0.3 (0.3, 0.7)	0.355 (0.217, 0.583)	<0.0001
Irinotecan	116	70 (60.3)	2.1 (1.0, 2.8)	111	82 (73.9)	0.5 (0.5, 0.7)	0.483 (0.347, 0.673)	<0.0001
Interaction								0.3346

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
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Any TEAE: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	27 (42.9)	15.8 (2.2, NE)	57	36 (63.2)	0.5 (0.5, 3.5)	0.402 (0.240, 0.674)	0.0002
1	192	101 (52.6)	2.8 (2.0, 6.2)	183	130 (71.0)	0.5 (0.5, 0.7)	0.440 (0.337, 0.576)	<0.0001
Interaction								0.5949
Region #1								
Asia	201	117 (58.2)	2.1 (1.7, 3.4)	191	148 (77.5)	0.5 (0.4, 0.5)	0.386 (0.299, 0.499)	<0.0001
Europe/North America	54	11 (20.4)	NR (NE, NE)	49	18 (36.7)	3.3 (2.4, NE)	0.431 (0.202, 0.920)	0.0243
Interaction								0.8362

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

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Safety Analysis Set

Any TEAE: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	106 (60.2)	2.1 (1.4, 2.8)	168	132 (78.6)	0.5 (0.4, 0.5)	0.408 (0.313, 0.534)	<0.0001
Japan	25	11 (44.0)	4.4 (2.8, NE)	23	16 (69.6)	0.5 (0.3, 1.7)	0.217 (0.084, 0.561)	0.0004
Europe/North America	54	11 (20.4)	NR (NE, NE)	49	18 (36.7)	3.3 (2.4, NE)	0.431 (0.202, 0.920)	0.0243
Interaction								0.6298

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Race								
Asian and other	203	117 (57.6)	2.1 (2.0, 3.4)	198	151 (76.3)	0.5 (0.4, 0.5)	0.398 (0.309, 0.513)	<0.0001
White	52	11 (21.2)	NR (NE, NE)	42	15 (35.7)	3.3 (2.4, NE)	0.464 (0.212, 1.019)	0.0487
Interaction								0.7385

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	39 (48.8)	6.6 (2.2, NE)	60	39 (65.0)	0.7 (0.4, 1.4)	0.399 (0.252, 0.634)	<0.0001
vCPS < 10%	100	52 (52.0)	2.9 (1.5, 9.7)	119	83 (69.7)	0.5 (0.5, 0.9)	0.487 (0.342, 0.694)	<0.0001
Missing	75	37 (49.3)	2.8 (2.1, 13.8)	61	44 (72.1)	0.5 (0.3, 0.9)	0.388 (0.244, 0.615)	<0.0001
Interaction								0.7877

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	29 (18.5)	NR (11.0, NE)	149	5 (3.4)	NR (NE, NE)	4.319 (1.660, 11.236)	0.0011
>= 65 Years	98	8 (8.2)	NR (NE, NE)	91	6 (6.6)	NR (NE, NE)	0.995 (0.338, 2.926)	0.9922
Interaction								0.0325

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Gender								
Male	216	32 (14.8)	NR (NE, NE)	204	11 (5.4)	NR (NE, NE)	2.222 (1.110, 4.445)	0.0204
Female	39	5 (12.8)	NR (4.9, NE)	36	0 (0.0)	NR (NE, NE)	54752211.366 (0.000, NE)	0.0768
Interaction								0.9829

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	27 (14.4)	NR (NE, NE)	183	9 (4.9)	NR (NE, NE)	2.355 (1.099, 5.047)	0.0230
Non-Smoker	68	10 (14.7)	NR (11.0, NE)	57	2 (3.5)	NR (NE, NE)	3.411 (0.738, 15.752)	0.0952
Interaction								0.5958

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	8 (9.6)	NR (NE, NE)	79	2 (2.5)	NR (NE, NE)	3.484 (0.738, 16.453)	0.0922
Docetaxel	56	5 (8.9)	NR (NE, NE)	50	1 (2.0)	NR (NE, NE)	3.683 (0.426, 31.829)	0.2040
Irinotecan	116	24 (20.7)	NR (11.0, NE)	111	8 (7.2)	NR (NE, NE)	1.970 (0.868, 4.470)	0.0986
Interaction								0.8045

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	10 (15.9)	NR (14.9, NE)	57	0 (0.0)	NR (NE, NE)	22644564.354 (0.000, NE)	0.0102
1	192	27 (14.1)	NR (NE, NE)	183	11 (6.0)	NR (NE, NE)	1.901 (0.936, 3.861)	0.0703
Interaction								0.9852

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #1								
Asia	201	34 (16.9)	NR (NE, NE)	191	10 (5.2)	NR (NE, NE)	2.539 (1.245, 5.178)	0.0079
Europe/North America	54	3 (5.6)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	2.296 (0.237, 22.219)	0.4605
Interaction								0.9664

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	32 (18.2)	NR (14.9, NE)	168	10 (6.0)	NR (NE, NE)	2.395 (1.168, 4.913)	0.0138
Japan	25	2 (8.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	64906194.937 (0.000, NE)	0.2144
Europe/North America	54	3 (5.6)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	2.296 (0.237, 22.219)	0.4605
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	34 (16.7)	NR (NE, NE)	198	10 (5.1)	NR (NE, NE)	2.622 (1.286, 5.349)	0.0058
White	52	3 (5.8)	NR (NE, NE)	42	1 (2.4)	NR (NE, NE)	2.057 (0.213, 19.896)	0.5245
Interaction								0.8662

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	16 (20.0)	NR (14.9, NE)	60	5 (8.3)	NR (NE, NE)	1.719 (0.623, 4.747)	0.2889
vCPS < 10%	100	11 (11.0)	NR (11.0, NE)	119	3 (2.5)	NR (NE, NE)	3.577 (0.986, 12.970)	0.0387
Missing	75	10 (13.3)	NR (NE, NE)	61	3 (4.9)	NR (NE, NE)	2.429 (0.666, 8.861)	0.1642
Interaction								0.6886

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Investigations / PT - Blood alkaline phosphatase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	14 (8.9)	NR (NE, NE)	149	3 (2.0)	NR (NE, NE)	3.748 (1.071, 13.118)	0.0265
>= 65 Years	98	3 (3.1)	NR (NE, NE)	91	2 (2.2)	NR (NE, NE)	1.271 (0.211, 7.656)	0.7930
Interaction								0.3146

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Investigations / PT - Blood alkaline phosphatase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Gender								
Male	216	16 (7.4)	NR (NE, NE)	204	5 (2.5)	NR (NE, NE)	2.669 (0.974, 7.314)	0.0468
Female	39	1 (2.6)	NR (NE, NE)	36	0 (0.0)	NR (NE, NE)	15114368.536 (0.000, NE)	0.5351
Interaction								0.9894

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Blood alkaline phosphatase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	16 (8.6)	NR (NE, NE)	183	4 (2.2)	NR (NE, NE)	3.315 (1.103, 9.966)	0.0235
Non-Smoker	68	1 (1.5)	NR (NE, NE)	57	1 (1.8)	NR (NE, NE)	0.868 (0.054, 13.879)	0.9200
Interaction								0.3255

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Investigations / PT - Blood alkaline phosphatase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ICC Options								
Paclitaxel	83	4 (4.8)	NR (NE, NE)	79	2 (2.5)	NR (NE, NE)	1.656 (0.301, 9.117)	0.5581
Docetaxel	56	4 (7.1)	NR (NE, NE)	50	0 (0.0)	NR (NE, NE)	23406417.934 (0.000, NE)	0.0807
Irinotecan	116	9 (7.8)	NR (NE, NE)	111	3 (2.7)	NR (NE, NE)	2.545 (0.683, 9.479)	0.1485
Interaction								0.9776

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Investigations / PT - Blood alkaline phosphatase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	4 (6.3)	NR (NE, NE)	57	0 (0.0)	NR (NE, NE)	20169752.646 (0.000, NE)	0.1181
1	192	13 (6.8)	NR (NE, NE)	183	5 (2.7)	NR (NE, NE)	2.271 (0.807, 6.388)	0.1093
Interaction								0.9902

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Investigations / PT - Blood alkaline phosphatase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Region #1								
Asia	201	16 (8.0)	NR (NE, NE)	191	4 (2.1)	NR (NE, NE)	3.313 (1.103, 9.955)	0.0235
Europe/North America	54	1 (1.9)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	0.735 (0.045, 11.895)	0.8279
Interaction								0.3733

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Blood alkaline phosphatase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	14 (8.0)	NR (NE, NE)	168	4 (2.4)	NR (NE, NE)	2.999 (0.983, 9.147)	0.0422
Japan	25	2 (8.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	59628177.664 (0.000, NE)	0.2639
Europe/North America	54	1 (1.9)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	0.735 (0.045, 11.895)	0.8279
Interaction								0.7242

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Investigations / PT - Blood alkaline phosphatase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	16 (7.9)	NR (NE, NE)	198	5 (2.5)	NR (NE, NE)	2.748 (1.002, 7.535)	0.0403
White	52	1 (1.9)	NR (NE, NE)	42	0 (0.0)	NR (NE, NE)	50251318.474 (0.000, NE)	0.4561
Interaction								0.9926

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Investigations / PT - Blood alkaline phosphatase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	4 (5.0)	NR (NE, NE)	60	1 (1.7)	NR (NE, NE)	2.523 (0.276, 23.072)	0.3966
vCPS < 10%	100	9 (9.0)	NR (NE, NE)	119	3 (2.5)	NR (NE, NE)	3.073 (0.827, 11.420)	0.0775
Missing	75	4 (5.3)	NR (NE, NE)	61	1 (1.6)	NR (NE, NE)	3.078 (0.344, 27.567)	0.2890
Interaction								0.9789

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Investigations / PT - Blood creatine phosphokinase MB increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	6 (3.8)	--	149	1 (0.7)	--	--	--
>= 65 Years	98	5 (5.1)	--	91	0 (0.0)	--	--	--
Interaction								--
Gender								
Male	216	11 (5.1)	NR (NE, NE)	204	1 (0.5)	NR (NE, NE)	7.964 (1.019, 62.270)	0.0193
Female	39	0 (0.0)	NR (NE, NE)	36	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9995

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Investigations / PT - Blood creatine phosphokinase MB increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	6 (3.2)	--	183	1 (0.5)	--	--	--
Non-Smoker	68	5 (7.4)	--	57	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Investigations / PT - Blood creatine phosphokinase MB increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ICC Options								
Paclitaxel	83	2 (2.4)	--	79	0 (0.0)	--	--	--
Docetaxel	56	1 (1.8)	--	50	0 (0.0)	--	--	--
Irinotecan	116	8 (6.9)	--	111	1 (0.9)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Investigations / PT - Blood creatine phosphokinase MB increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	3 (4.8)	--	57	0 (0.0)	--	--	--
1	192	8 (4.2)	--	183	1 (0.5)	--	--	--
Interaction								--
Region #1								
Asia	201	11 (5.5)	NR (NE, NE)	191	1 (0.5)	NR (NE, NE)	7.811 (0.997, 61.192)	0.0211
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9994

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Investigations / PT - Blood creatine phosphokinase MB increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	10 (5.7)	NR (NE, NE)	168	1 (0.6)	NR (NE, NE)	7.309 (0.924, 57.782)	0.0279
Japan	25	1 (4.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	50648531.709 (0.000, NE)	0.4533
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Investigations / PT - Blood creatine phosphokinase MB increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	11 (5.4)	NR (NE, NE)	198	1 (0.5)	NR (NE, NE)	8.078 (1.031, 63.260)	0.0184
White	52	0 (0.0)	NR (NE, NE)	42	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9994

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Investigations / PT - Blood creatine phosphokinase MB increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	1 (1.3)	--	60	0 (0.0)	--	--	--
vCPS < 10%	100	4 (4.0)	--	119	1 (0.8)	--	--	--
Missing	75	6 (8.0)	--	61	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Blood creatine phosphokinase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	7 (4.5)	--	149	0 (0.0)	--	--	--
>= 65 Years	98	3 (3.1)	--	91	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Investigations / PT - Blood creatine phosphokinase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Gender								
Male	216	10 (4.6)	NR (NE, NE)	204	0 (0.0)	NR (NE, NE)	25050718.901 (0.000, NE)	0.0066
Female	39	0 (0.0)	NR (NE, NE)	36	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9980

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Investigations / PT - Blood creatine phosphokinase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Smoking Status								
Former/Current Smoker	187	7 (3.7)	--	183	0 (0.0)	--	--	--
Non-Smoker	68	3 (4.4)	--	57	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Blood creatine phosphokinase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ICC Options								
Paclitaxel	83	2 (2.4)	--	79	0 (0.0)	--	--	--
Docetaxel	56	1 (1.8)	--	50	0 (0.0)	--	--	--
Irinotecan	116	7 (6.0)	--	111	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Investigations / PT - Blood creatine phosphokinase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	3 (4.8)	--	57	0 (0.0)	--	--	--
1	192	7 (3.6)	--	183	0 (0.0)	--	--	--
Interaction								--
Region #1								
Asia	201	9 (4.5)	--	191	0 (0.0)	--	--	--
Europe/North America	54	1 (1.9)	--	49	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Investigations / PT - Blood creatine phosphokinase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	8 (4.5)	--	168	0 (0.0)	--	--	--
Japan	25	1 (4.0)	--	23	0 (0.0)	--	--	--
Europe/North America	54	1 (1.9)	--	49	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Blood creatine phosphokinase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	9 (4.4)	--	198	0 (0.0)	--	--	--
White	52	1 (1.9)	--	42	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Investigations / PT - Blood creatine phosphokinase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Baseline PD-L1 Status								
vCPS >= 10%	80	3 (3.8)	--	60	0 (0.0)	--	--	--
vCPS < 10%	100	4 (4.0)	--	119	0 (0.0)	--	--	--
Missing	75	3 (4.0)	--	61	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	8 (5.1)	NR (18.6, NE)	149	10 (6.7)	NR (NE, NE)	0.579 (0.219, 1.528)	0.2627
>= 65 Years	98	4 (4.1)	NR (NE, NE)	91	12 (13.2)	NR (NE, NE)	0.273 (0.088, 0.851)	0.0164
Interaction								0.2425
Gender								
Male	216	9 (4.2)	NR (NE, NE)	204	19 (9.3)	NR (NE, NE)	0.349 (0.152, 0.801)	0.0092
Female	39	3 (7.7)	NR (NE, NE)	36	3 (8.3)	NR (NE, NE)	0.824 (0.165, 4.110)	0.8133
Interaction								0.3302

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	9 (4.8)	NR (NE, NE)	183	15 (8.2)	NR (NE, NE)	0.523 (0.228, 1.200)	0.1185
Non-Smoker	68	3 (4.4)	NR (18.6, NE)	57	7 (12.3)	NR (NE, NE)	0.281 (0.072, 1.099)	0.0520
Interaction								0.5995

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	1 (1.2)	NR (NE, NE)	79	4 (5.1)	NR (NE, NE)	0.232 (0.026, 2.074)	0.1520
Docetaxel	56	2 (3.6)	NR (NE, NE)	50	6 (12.0)	NR (NE, NE)	0.262 (0.053, 1.305)	0.0777
Irinotecan	116	9 (7.8)	NR (18.6, NE)	111	12 (10.8)	NR (NE, NE)	0.496 (0.199, 1.234)	0.1236
Interaction								0.5351

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	2 (3.2)	NR (NE, NE)	57	6 (10.5)	NR (NE, NE)	0.241 (0.048, 1.210)	0.0613
1	192	10 (5.2)	NR (NE, NE)	183	16 (8.7)	NR (NE, NE)	0.495 (0.221, 1.108)	0.0805
Interaction								0.4581
Region #1								
Asia	201	10 (5.0)	NR (NE, NE)	191	18 (9.4)	NR (NE, NE)	0.412 (0.187, 0.911)	0.0236
Europe/North America	54	2 (3.7)	NR (NE, NE)	49	4 (8.2)	NR (NE, NE)	0.428 (0.078, 2.337)	0.3104
Interaction								0.9542

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	10 (5.7)	NR (NE, NE)	168	16 (9.5)	NR (NE, NE)	0.461 (0.205, 1.034)	0.0541
Japan	25	0 (0.0)	NR (NE, NE)	23	2 (8.7)	NR (NE, NE)	0.000 (0.000, NE)	0.1361
Europe/North America	54	2 (3.7)	NR (NE, NE)	49	4 (8.2)	NR (NE, NE)	0.428 (0.078, 2.337)	0.3104
Interaction								0.9820

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	203	10 (4.9)	NR (NE, NE)	198	19 (9.6)	NR (NE, NE)	0.404 (0.184, 0.885)	0.0191
White	52	2 (3.8)	NR (NE, NE)	42	3 (7.1)	NR (NE, NE)	0.510 (0.085, 3.055)	0.4497
Interaction								0.8874

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
Adverse events were classified based on MedDRA v23.0.
System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.
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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	2 (2.5)	NR (NE, NE)	60	4 (6.7)	NR (NE, NE)	0.342 (0.062, 1.869)	0.1936
vCPS < 10%	100	6 (6.0)	NR (NE, NE)	119	14 (11.8)	NR (NE, NE)	0.444 (0.170, 1.159)	0.0872
Missing	75	4 (5.3)	NR (18.6, NE)	61	4 (6.6)	NR (NE, NE)	0.489 (0.107, 2.224)	0.3451
Interaction								0.7694

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	5 (3.2)	NR (NE, NE)	149	57 (38.3)	NR (2.4, NE)	0.063 (0.025, 0.157)	<0.0001
>= 65 Years	98	1 (1.0)	NR (NE, NE)	91	37 (40.7)	NR (2.1, NE)	0.019 (0.003, 0.142)	<0.0001
Interaction								0.2876
Gender								
Male	216	4 (1.9)	NR (NE, NE)	204	83 (40.7)	NR (2.4, NE)	0.033 (0.012, 0.091)	<0.0001
Female	39	2 (5.1)	NR (NE, NE)	36	11 (30.6)	NR (NE, NE)	0.147 (0.033, 0.666)	0.0036
Interaction								0.1264

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	3 (1.6)	NR (NE, NE)	183	71 (38.8)	NR (2.8, NE)	0.030 (0.009, 0.096)	<0.0001
Non-Smoker	68	3 (4.4)	NR (NE, NE)	57	23 (40.4)	NR (1.2, NE)	0.091 (0.027, 0.304)	<0.0001
Interaction								0.2272

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	1 (1.2)	NR (NE, NE)	79	30 (38.0)	NR (2.4, NE)	0.025 (0.003, 0.181)	<0.0001
Docetaxel	56	0 (0.0)	NR (NE, NE)	50	25 (50.0)	2.8 (0.3, NE)	0.000 (0.000, NE)	<0.0001
Irinotecan	116	5 (4.3)	NR (NE, NE)	111	39 (35.1)	NR (2.1, NE)	0.098 (0.038, 0.249)	<0.0001
Interaction								0.4743

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	2 (3.2)	NR (NE, NE)	57	22 (38.6)	NR (1.3, NE)	0.063 (0.015, 0.268)	<0.0001
1	192	4 (2.1)	NR (NE, NE)	183	72 (39.3)	NR (2.8, NE)	0.040 (0.015, 0.110)	<0.0001
Interaction								0.6081
Region #1								
Asia	201	5 (2.5)	NR (NE, NE)	191	89 (46.6)	2.8 (1.2, NE)	0.038 (0.015, 0.094)	<0.0001
Europe/North America	54	1 (1.9)	NR (NE, NE)	49	5 (10.2)	NR (NE, NE)	0.159 (0.019, 1.364)	0.0543
Interaction								0.2091

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	5 (2.8)	NR (NE, NE)	168	76 (45.2)	2.8 (1.2, NE)	0.045 (0.018, 0.112)	<0.0001
Japan	25	0 (0.0)	NR (NE, NE)	23	13 (56.5)	0.8 (0.5, NE)	0.000 (0.000, NE)	<0.0001
Europe/North America	54	1 (1.9)	NR (NE, NE)	49	5 (10.2)	NR (NE, NE)	0.159 (0.019, 1.364)	0.0543
Interaction								0.5440

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	5 (2.5)	NR (NE, NE)	198	90 (45.5)	3.0 (1.2, NE)	0.039 (0.016, 0.097)	<0.0001
White	52	1 (1.9)	NR (NE, NE)	42	4 (9.5)	NR (NE, NE)	0.173 (0.019, 1.554)	0.0756
Interaction								0.1953

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	2 (2.5)	NR (NE, NE)	60	27 (45.0)	2.8 (1.0, NE)	0.036 (0.008, 0.152)	<0.0001
vCPS < 10%	100	2 (2.0)	NR (NE, NE)	119	43 (36.1)	NR (NE, NE)	0.043 (0.010, 0.180)	<0.0001
Missing	75	2 (2.7)	NR (NE, NE)	61	24 (39.3)	NR (1.0, NE)	0.057 (0.013, 0.242)	<0.0001
Interaction								0.9672

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	6 (3.8)	NR (NE, NE)	149	63 (42.3)	NR (0.9, NE)	0.066 (0.028, 0.153)	<0.0001
>= 65 Years	98	3 (3.1)	NR (NE, NE)	91	35 (38.5)	NR (1.5, NE)	0.064 (0.020, 0.210)	<0.0001
Interaction								0.8870
Gender								
Male	216	7 (3.2)	NR (NE, NE)	204	85 (41.7)	NR (NE, NE)	0.058 (0.027, 0.126)	<0.0001
Female	39	2 (5.1)	NR (NE, NE)	36	13 (36.1)	NR (0.5, NE)	0.120 (0.027, 0.532)	0.0007
Interaction								0.4631

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	5 (2.7)	NR (NE, NE)	183	69 (37.7)	NR (NE, NE)	0.054 (0.022, 0.134)	<0.0001
Non-Smoker	68	4 (5.9)	NR (NE, NE)	57	29 (50.9)	1.2 (0.5, NE)	0.086 (0.030, 0.246)	<0.0001
Interaction								0.5484

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	0 (0.0)	NR (NE, NE)	79	21 (26.6)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Docetaxel	56	4 (7.1)	NR (NE, NE)	50	27 (54.0)	0.8 (0.3, NE)	0.091 (0.031, 0.262)	<0.0001
Irinotecan	116	5 (4.3)	NR (NE, NE)	111	50 (45.0)	NR (0.9, NE)	0.068 (0.027, 0.171)	<0.0001
Interaction								0.9718

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	3 (4.8)	NR (NE, NE)	57	25 (43.9)	NR (0.8, NE)	0.079 (0.024, 0.265)	<0.0001
1	192	6 (3.1)	NR (NE, NE)	183	73 (39.9)	NR (NE, NE)	0.061 (0.026, 0.140)	<0.0001
Interaction								0.6383
Region #1								
Asia	201	9 (4.5)	NR (NE, NE)	191	96 (50.3)	1.2 (0.7, NE)	0.061 (0.031, 0.122)	<0.0001
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	2 (4.1)	NR (NE, NE)	0.000 (0.000, NE)	0.1344
Interaction								0.9818

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	8 (4.5)	NR (NE, NE)	168	84 (50.0)	1.2 (0.7, NE)	0.061 (0.029, 0.127)	<0.0001
Japan	25	1 (4.0)	NR (NE, NE)	23	12 (52.2)	0.8 (0.5, NE)	0.060 (0.008, 0.464)	0.0002
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	2 (4.1)	NR (NE, NE)	0.000 (0.000, NE)	0.1344
Interaction								0.9891

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	9 (4.4)	NR (NE, NE)	198	97 (49.0)	NR (0.7, NE)	0.063 (0.032, 0.126)	<0.0001
White	52	0 (0.0)	NR (NE, NE)	42	1 (2.4)	NR (NE, NE)	0.000 (0.000, NE)	0.2611
Interaction								0.9828

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	5 (6.3)	NR (NE, NE)	60	21 (35.0)	NR (1.5, NE)	0.131 (0.049, 0.349)	<0.0001
vCPS < 10%	100	3 (3.0)	NR (NE, NE)	119	47 (39.5)	NR (NE, NE)	0.057 (0.018, 0.185)	<0.0001
Missing	75	1 (1.3)	NR (NE, NE)	61	30 (49.2)	NR (0.5, NE)	0.021 (0.003, 0.157)	<0.0001
Interaction								0.1995

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	75 (47.8)	4.9 (2.1, 13.8)	149	87 (58.4)	1.2 (0.7, 2.2)	0.576 (0.420, 0.791)	0.0005
>= 65 Years	98	41 (41.8)	8.6 (3.4, NE)	91	54 (59.3)	1.5 (0.7, 5.7)	0.455 (0.299, 0.691)	0.0001
Interaction								0.4836
Gender								
Male	216	98 (45.4)	8.3 (3.4, 13.8)	204	121 (59.3)	1.2 (0.7, 2.2)	0.516 (0.393, 0.678)	<0.0001
Female	39	18 (46.2)	2.8 (1.5, NE)	36	20 (55.6)	1.2 (0.5, NE)	0.650 (0.341, 1.237)	0.1800
Interaction								0.7038

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	87 (46.5)	5.5 (2.9, 13.8)	183	110 (60.1)	1.2 (0.7, 2.2)	0.526 (0.395, 0.702)	<0.0001
Non-Smoker	68	29 (42.6)	8.6 (2.3, NE)	57	31 (54.4)	1.2 (0.5, 5.7)	0.554 (0.331, 0.929)	0.0218
Interaction								0.9247

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	28 (33.7)	NR (8.3, NE)	79	36 (45.6)	4.8 (2.3, NE)	0.607 (0.366, 1.007)	0.0491
Docetaxel	56	31 (55.4)	3.7 (1.4, 9.0)	50	31 (62.0)	1.2 (0.5, 3.7)	0.549 (0.326, 0.926)	0.0198
Irinotecan	116	57 (49.1)	3.3 (2.1, 14.0)	111	74 (66.7)	0.7 (0.5, 1.1)	0.416 (0.291, 0.595)	<0.0001
Interaction								0.3375

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	20 (31.7)	14.0 (8.6, NE)	57	32 (56.1)	3.7 (0.7, 6.6)	0.351 (0.196, 0.631)	0.0002
1	192	96 (50.0)	3.4 (2.1, 7.7)	183	109 (59.6)	1.2 (0.7, 2.0)	0.583 (0.441, 0.772)	0.0001
Interaction								0.1423
Region #1								
Asia	201	95 (47.3)	5.5 (2.8, 13.8)	191	120 (62.8)	0.9 (0.6, 1.3)	0.478 (0.363, 0.631)	<0.0001
Europe/North America	54	21 (38.9)	9.0 (4.2, NE)	49	21 (42.9)	4.2 (2.8, 6.6)	0.736 (0.397, 1.365)	0.3252
Interaction								0.1046

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	89 (50.6)	3.4 (2.1, 8.3)	168	109 (64.9)	0.7 (0.5, 1.2)	0.495 (0.371, 0.659)	<0.0001
Japan	25	6 (24.0)	NR (10.2, NE)	23	11 (47.8)	NR (0.7, NE)	0.258 (0.082, 0.817)	0.0122
Europe/North America	54	21 (38.9)	9.0 (4.2, NE)	49	21 (42.9)	4.2 (2.8, 6.6)	0.736 (0.397, 1.365)	0.3252
Interaction								0.1959

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	96 (47.3)	5.5 (2.8, 13.8)	198	121 (61.1)	1.0 (0.7, 1.4)	0.506 (0.384, 0.666)	<0.0001
White	52	20 (38.5)	9.0 (4.2, NE)	42	20 (47.6)	3.7 (1.9, 6.6)	0.634 (0.337, 1.193)	0.1506
Interaction								0.3377

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	30 (37.5)	13.8 (4.1, NE)	60	37 (61.7)	1.1 (0.5, 2.3)	0.341 (0.205, 0.567)	<0.0001
vCPS < 10%	100	50 (50.0)	4.9 (2.1, 9.0)	119	66 (55.5)	1.9 (0.8, 4.2)	0.700 (0.483, 1.014)	0.0558
Missing	75	36 (48.0)	4.2 (2.3, 13.8)	61	38 (62.3)	1.2 (0.5, 3.5)	0.537 (0.338, 0.854)	0.0069
Interaction								0.0653

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	30 (19.1)	NR (14.0, NE)	149	52 (34.9)	6.6 (3.7, NE)	0.391 (0.246, 0.620)	<0.0001
>= 65 Years	98	10 (10.2)	NR (NE, NE)	91	32 (35.2)	5.7 (3.4, NE)	0.206 (0.100, 0.424)	<0.0001
Interaction								0.1526
Gender								
Male	216	34 (15.7)	NR (NE, NE)	204	74 (36.3)	5.7 (3.7, NE)	0.304 (0.200, 0.461)	<0.0001
Female	39	6 (15.4)	NR (NE, NE)	36	10 (27.8)	NR (2.8, NE)	0.422 (0.150, 1.193)	0.0932
Interaction								0.5457

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	35 (18.7)	NR (NE, NE)	183	71 (38.8)	5.7 (3.2, NE)	0.335 (0.221, 0.508)	<0.0001
Non-Smoker	68	5 (7.4)	NR (NE, NE)	57	13 (22.8)	NR (3.4, NE)	0.240 (0.085, 0.683)	0.0037
Interaction								0.5694

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	15 (18.1)	NR (NE, NE)	79	23 (29.1)	6.6 (5.7, NE)	0.511 (0.265, 0.985)	0.0406
Docetaxel	56	12 (21.4)	NR (9.0, NE)	50	16 (32.0)	NR (3.2, NE)	0.478 (0.221, 1.033)	0.0534
Irinotecan	116	13 (11.2)	NR (NE, NE)	111	45 (40.5)	3.4 (2.0, NE)	0.168 (0.088, 0.322)	<0.0001
Interaction								0.0214

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	9 (14.3)	NR (14.0, NE)	57	21 (36.8)	6.6 (3.7, NE)	0.247 (0.108, 0.565)	0.0003
1	192	31 (16.1)	NR (NE, NE)	183	63 (34.4)	5.7 (3.4, NE)	0.343 (0.222, 0.531)	<0.0001
Interaction								0.6236
Region #1								
Asia	201	29 (14.4)	NR (NE, NE)	191	65 (34.0)	NR (3.5, NE)	0.306 (0.196, 0.479)	<0.0001
Europe/North America	54	11 (20.4)	NR (9.0, NE)	49	19 (38.8)	5.7 (2.8, NE)	0.375 (0.175, 0.802)	0.0084
Interaction								0.3892

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	28 (15.9)	NR (NE, NE)	168	60 (35.7)	NR (3.4, NE)	0.320 (0.202, 0.505)	<0.0001
Japan	25	1 (4.0)	NR (NE, NE)	23	5 (21.7)	NR (NE, NE)	0.179 (0.021, 1.537)	0.0740
Europe/North America	54	11 (20.4)	NR (9.0, NE)	49	19 (38.8)	5.7 (2.8, NE)	0.375 (0.175, 0.802)	0.0084
Interaction								0.5186

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	29 (14.3)	NR (NE, NE)	198	66 (33.3)	NR (5.7, NE)	0.310 (0.199, 0.485)	<0.0001
White	52	11 (21.2)	NR (9.0, NE)	42	18 (42.9)	4.2 (2.6, NE)	0.348 (0.162, 0.749)	0.0047
Interaction								0.5598

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	12 (15.0)	NR (14.0, NE)	60	23 (38.3)	5.7 (2.9, NE)	0.254 (0.124, 0.522)	<0.0001
vCPS < 10%	100	21 (21.0)	NR (9.0, NE)	119	40 (33.6)	5.7 (3.7, NE)	0.465 (0.273, 0.795)	0.0040
Missing	75	7 (9.3)	NR (NE, NE)	61	21 (34.4)	NR (3.5, NE)	0.214 (0.091, 0.507)	0.0001
Interaction								0.1288

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Metabolism and nutrition disorders / PT - Hyponatraemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	22 (14.0)	NR (14.5, NE)	149	19 (12.8)	NR (NE, NE)	0.809 (0.429, 1.528)	0.5114
>= 65 Years	98	10 (10.2)	NR (13.8, NE)	91	14 (15.4)	NR (6.9, NE)	0.462 (0.195, 1.097)	0.0726
Interaction								0.2693
Gender								
Male	216	28 (13.0)	NR (17.2, NE)	204	26 (12.7)	NR (NE, NE)	0.715 (0.409, 1.249)	0.2343
Female	39	4 (10.3)	NR (NE, NE)	36	7 (19.4)	NR (NE, NE)	0.492 (0.144, 1.685)	0.2448
Interaction								0.3699

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Metabolism and nutrition disorders / PT - Hyponatraemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	24 (12.8)	NR (NE, NE)	183	21 (11.5)	NR (NE, NE)	0.824 (0.450, 1.511)	0.5306
Non-Smoker	68	8 (11.8)	17.2 (17.2, NE)	57	12 (21.1)	NR (4.8, NE)	0.384 (0.147, 1.002)	0.0418
Interaction								0.2182

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders / PT - Hyponatraemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	3 (3.6)	NR (NE, NE)	79	3 (3.8)	NR (NE, NE)	0.860 (0.172, 4.291)	0.8540
Docetaxel	56	9 (16.1)	NR (9.0, NE)	50	5 (10.0)	NR (NE, NE)	1.040 (0.327, 3.301)	0.9472
Irinotecan	116	20 (17.2)	17.2 (13.8, NE)	111	25 (22.5)	NR (3.9, NE)	0.491 (0.262, 0.922)	0.0229
Interaction								0.4057

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders / PT - Hyponatraemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	5 (7.9)	NR (14.5, NE)	57	5 (8.8)	NR (NE, NE)	0.528 (0.138, 2.024)	0.3443
1	192	27 (14.1)	NR (17.2, NE)	183	28 (15.3)	NR (6.9, NE)	0.687 (0.397, 1.187)	0.1732
Interaction								0.9610
Region #1								
Asia	201	30 (14.9)	NR (17.2, NE)	191	32 (16.8)	NR (NE, NE)	0.614 (0.364, 1.036)	0.0640
Europe/North America	54	2 (3.7)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	1.552 (0.139, 17.293)	0.7178
Interaction								0.4323

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders / PT - Hyponatraemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	28 (15.9)	NR (14.5, NE)	168	30 (17.9)	NR (6.9, NE)	0.616 (0.359, 1.058)	0.0748
Japan	25	2 (8.0)	NR (10.6, NE)	23	2 (8.7)	NR (NE, NE)	0.589 (0.073, 4.782)	0.6172
Europe/North America	54	2 (3.7)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	1.552 (0.139, 17.293)	0.7178
Interaction								0.7342

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
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Any TEAE: SOC - Metabolism and nutrition disorders / PT - Hyponatraemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	203	31 (15.3)	NR (17.2, NE)	198	32 (16.2)	NR (NE, NE)	0.663 (0.395, 1.112)	0.1151
White	52	1 (1.9)	NR (NE, NE)	42	1 (2.4)	NR (4.8, NE)	0.644 (0.040, 10.446)	0.7552
Interaction								0.9464

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
Adverse events were classified based on MedDRA v23.0.
System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.
Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.
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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.
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Any TEAE: SOC - Metabolism and nutrition disorders / PT - Hyponatraemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	7 (8.8)	NR (14.5, NE)	60	7 (11.7)	NR (NE, NE)	0.481 (0.158, 1.461)	0.1858
vCPS < 10%	100	15 (15.0)	NR (NE, NE)	119	17 (14.3)	NR (NE, NE)	0.882 (0.438, 1.779)	0.7251
Missing	75	10 (13.3)	NR (13.8, NE)	61	9 (14.8)	NR (6.9, NE)	0.634 (0.244, 1.653)	0.3456
Interaction								0.6961

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Musculoskeletal and connective tissue disorders / PT - Myalgia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	5 (3.2)	NR (NE, NE)	149	7 (4.7)	NR (NE, NE)	0.663 (0.210, 2.090)	0.4794
>= 65 Years	98	1 (1.0)	NR (NE, NE)	91	7 (7.7)	NR (NE, NE)	0.106 (0.013, 0.883)	0.0125
Interaction								0.1685
Gender								
Male	216	6 (2.8)	NR (NE, NE)	204	12 (5.9)	NR (NE, NE)	0.428 (0.159, 1.151)	0.0830
Female	39	0 (0.0)	NR (NE, NE)	36	2 (5.6)	NR (NE, NE)	0.000 (0.000, NE)	0.1382
Interaction								0.9922

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Musculoskeletal and connective tissue disorders / PT - Myalgia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	6 (3.2)	NR (NE, NE)	183	14 (7.7)	NR (NE, NE)	0.377 (0.144, 0.990)	0.0393
Non-Smoker	68	0 (0.0)	NR (NE, NE)	57	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9996

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Musculoskeletal and connective tissue disorders / PT - Myalgia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ICC Options								
Paclitaxel	83	4 (4.8)	NR (NE, NE)	79	11 (13.9)	NR (NE, NE)	0.302 (0.095, 0.959)	0.0309
Docetaxel	56	0 (0.0)	NR (NE, NE)	50	3 (6.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0631
Irinotecan	116	2 (1.7)	NR (NE, NE)	111	0 (0.0)	NR (NE, NE)	28387187.662 (0.000, NE)	0.1661
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Musculoskeletal and connective tissue disorders / PT - Myalgia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	1 (1.6)	NR (NE, NE)	57	2 (3.5)	NR (NE, NE)	0.444 (0.040, 4.901)	0.4962
1	192	5 (2.6)	NR (NE, NE)	183	12 (6.6)	NR (NE, NE)	0.352 (0.122, 1.014)	0.0432
Interaction								0.9263

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Musculoskeletal and connective tissue disorders / PT - Myalgia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #1								
Asia	201	5 (2.5)	NR (NE, NE)	191	14 (7.3)	NR (NE, NE)	0.300 (0.107, 0.845)	0.0157
Europe/North America	54	1 (1.9)	NR (NE, NE)	49	0 (0.0)	NR (NE, NE)	26442990.647 (0.000, NE)	0.3458
Interaction								0.9915

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Musculoskeletal and connective tissue disorders / PT - Myalgia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Region #2								
Asia (excluding Japan)	176	5 (2.8)	NR (NE, NE)	168	11 (6.5)	NR (NE, NE)	0.383 (0.131, 1.119)	0.0683
Japan	25	0 (0.0)	NR (NE, NE)	23	3 (13.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0648
Europe/North America	54	1 (1.9)	NR (NE, NE)	49	0 (0.0)	NR (NE, NE)	26442990.647 (0.000, NE)	0.3458
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Musculoskeletal and connective tissue disorders / PT - Myalgia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	203	5 (2.5)	NR (NE, NE)	198	14 (7.1)	NR (NE, NE)	0.310 (0.110, 0.871)	0.0189
White	52	1 (1.9)	NR (NE, NE)	42	0 (0.0)	NR (NE, NE)	23828168.338 (0.000, NE)	0.3746
Interaction								0.9877

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Musculoskeletal and connective tissue disorders / PT - Myalgia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Baseline PD-L1 Status								
vCPS >= 10%	80	3 (3.8)	--	60	4 (6.7)	--	--	--
vCPS < 10%	100	2 (2.0)	--	119	6 (5.0)	--	--	--
Missing	75	1 (1.3)	--	61	4 (6.6)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Neoplasms benign, malignant and unspecified (incl cysts and polyps)

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	11 (7.0)	NR (NE, NE)	149	5 (3.4)	NR (NE, NE)	1.688 (0.582, 4.895)	0.3300
>= 65 Years	98	12 (12.2)	NR (NE, NE)	91	3 (3.3)	NR (NE, NE)	3.564 (1.004, 12.649)	0.0357
Interaction								0.4263
Gender								
Male	216	18 (8.3)	NR (NE, NE)	204	6 (2.9)	NR (NE, NE)	2.336 (0.921, 5.923)	0.0657
Female	39	5 (12.8)	NR (NE, NE)	36	2 (5.6)	NR (NE, NE)	2.421 (0.470, 12.481)	0.2750
Interaction								0.9625

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	16 (8.6)	NR (NE, NE)	183	5 (2.7)	NR (NE, NE)	2.616 (0.952, 7.188)	0.0529
Non-Smoker	68	7 (10.3)	NR (NE, NE)	57	3 (5.3)	NR (NE, NE)	1.886 (0.487, 7.306)	0.3504
Interaction								0.6602

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Any TEAE: SOC - Neoplasms benign, malignant and unspecified (incl cysts and polyps)

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	9 (10.8)	NR (NE, NE)	79	3 (3.8)	NR (NE, NE)	2.890 (0.782, 10.685)	0.0953
Docetaxel	56	5 (8.9)	NR (NE, NE)	50	1 (2.0)	NR (NE, NE)	4.017 (0.468, 34.460)	0.1700
Irinotecan	116	9 (7.8)	NR (NE, NE)	111	4 (3.6)	NR (NE, NE)	1.505 (0.452, 5.007)	0.5022
Interaction								0.7540

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Neoplasms benign, malignant and unspecified (incl cysts and polyps)

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	4 (6.3)	NR (NE, NE)	57	2 (3.5)	NR (NE, NE)	1.801 (0.330, 9.832)	0.4909
1	192	19 (9.9)	NR (NE, NE)	183	6 (3.3)	NR (NE, NE)	2.529 (1.003, 6.373)	0.0417
Interaction								0.6320
Region #1								
Asia	201	14 (7.0)	NR (NE, NE)	191	6 (3.1)	NR (NE, NE)	1.737 (0.660, 4.570)	0.2574
Europe/North America	54	9 (16.7)	NR (NE, NE)	49	2 (4.1)	NR (NE, NE)	4.225 (0.913, 19.556)	0.0448
Interaction								0.3779

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Neoplasms benign, malignant and unspecified (incl cysts and polyps)

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	10 (5.7)	NR (NE, NE)	168	5 (3.0)	NR (NE, NE)	1.450 (0.488, 4.303)	0.5012
Japan	25	4 (16.0)	NR (NE, NE)	23	1 (4.3)	NR (4.3, NE)	3.227 (0.354, 29.446)	0.2731
Europe/North America	54	9 (16.7)	NR (NE, NE)	49	2 (4.1)	NR (NE, NE)	4.225 (0.913, 19.556)	0.0448
Interaction								0.5624

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Neoplasms benign, malignant and unspecified (incl cysts and polyps)

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	203	14 (6.9)	NR (NE, NE)	198	6 (3.0)	NR (NE, NE)	1.797 (0.683, 4.727)	0.2284
White	52	9 (17.3)	NR (NE, NE)	42	2 (4.8)	NR (NE, NE)	3.737 (0.807, 17.296)	0.0701
Interaction								0.4748

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Neoplasms benign, malignant and unspecified (incl cysts and polyps)

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	9 (11.3)	NR (NE, NE)	60	1 (1.7)	NR (NE, NE)	6.120 (0.774, 48.373)	0.0499
vCPS < 10%	100	7 (7.0)	NR (NE, NE)	119	4 (3.4)	NR (NE, NE)	1.759 (0.512, 6.044)	0.3639
Missing	75	7 (9.3)	NR (NE, NE)	61	3 (4.9)	NR (NE, NE)	1.485 (0.369, 5.977)	0.5755
Interaction								0.6012

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	18 (11.5)	NR (17.8, NE)	149	35 (23.5)	9.7 (9.7, NE)	0.360 (0.199, 0.649)	0.0004
>= 65 Years	98	13 (13.3)	NR (NE, NE)	91	28 (30.8)	7.4 (5.3, NE)	0.277 (0.140, 0.548)	<0.0001
Interaction								0.7081
Gender								
Male	216	21 (9.7)	NR (NE, NE)	204	50 (24.5)	9.7 (7.4, NE)	0.262 (0.153, 0.446)	<0.0001
Female	39	10 (25.6)	NR (3.5, NE)	36	13 (36.1)	NR (2.2, NE)	0.557 (0.241, 1.290)	0.1648
Interaction								0.1512

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	21 (11.2)	NR (NE, NE)	183	47 (25.7)	7.4 (5.3, NE)	0.313 (0.185, 0.531)	<0.0001
Non-Smoker	68	10 (14.7)	17.8 (8.3, NE)	57	16 (28.1)	NR (2.2, NE)	0.353 (0.157, 0.796)	0.0089
Interaction								0.6125

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	13 (15.7)	NR (NE, NE)	79	36 (45.6)	2.8 (1.4, NE)	0.230 (0.121, 0.439)	<0.0001
Docetaxel	56	8 (14.3)	NR (17.8, NE)	50	7 (14.0)	NR (NE, NE)	0.808 (0.290, 2.252)	0.6831
Irinotecan	116	10 (8.6)	NR (NE, NE)	111	20 (18.0)	7.4 (5.3, NE)	0.293 (0.130, 0.662)	0.0019
Interaction								0.1022

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	3 (4.8)	NR (NE, NE)	57	21 (36.8)	7.4 (2.8, NE)	0.079 (0.023, 0.273)	<0.0001
1	192	28 (14.6)	NR (17.8, NE)	183	42 (23.0)	9.7 (5.3, NE)	0.451 (0.275, 0.740)	0.0012
Interaction								0.0075
Region #1								
Asia	201	16 (8.0)	NR (NE, NE)	191	44 (23.0)	9.7 (5.3, NE)	0.233 (0.129, 0.422)	<0.0001
Europe/North America	54	15 (27.8)	NR (6.2, NE)	49	19 (38.8)	7.4 (1.4, NE)	0.496 (0.244, 1.005)	0.0468
Interaction								0.0567

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	15 (8.5)	NR (NE, NE)	168	35 (20.8)	9.7 (5.3, NE)	0.286 (0.153, 0.534)	<0.0001
Japan	25	1 (4.0)	NR (NE, NE)	23	9 (39.1)	2.8 (1.0, NE)	0.060 (0.007, 0.486)	0.0005
Europe/North America	54	15 (27.8)	NR (6.2, NE)	49	19 (38.8)	7.4 (1.4, NE)	0.496 (0.244, 1.005)	0.0468
Interaction								0.0689

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	16 (7.9)	NR (NE, NE)	198	45 (22.7)	9.7 (5.3, NE)	0.235 (0.130, 0.425)	<0.0001
White	52	15 (28.8)	NR (6.2, NE)	42	18 (42.9)	7.4 (1.0, NE)	0.452 (0.221, 0.922)	0.0249
Interaction								0.0999

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	9 (11.3)	NR (NE, NE)	60	12 (20.0)	9.7 (9.7, NE)	0.375 (0.152, 0.924)	0.0270
vCPS < 10%	100	17 (17.0)	17.8 (8.3, NE)	119	29 (24.4)	NR (7.4, NE)	0.501 (0.270, 0.930)	0.0255
Missing	75	5 (6.7)	NR (NE, NE)	61	22 (36.1)	5.3 (2.8, NE)	0.124 (0.046, 0.332)	<0.0001
Interaction								0.0259

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders / PT - Dizziness

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	4 (2.5)	NR (NE, NE)	149	13 (8.7)	NR (NE, NE)	0.244 (0.079, 0.755)	0.0082
>= 65 Years	98	7 (7.1)	NR (NE, NE)	91	6 (6.6)	NR (NE, NE)	0.827 (0.270, 2.533)	0.7382
Interaction								0.1018
Gender								
Male	216	7 (3.2)	NR (NE, NE)	204	14 (6.9)	NR (NE, NE)	0.387 (0.154, 0.973)	0.0365
Female	39	4 (10.3)	NR (8.3, NE)	36	5 (13.9)	NR (NE, NE)	0.583 (0.153, 2.213)	0.4226
Interaction								0.5151

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders / PT - Dizziness

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	6 (3.2)	NR (NE, NE)	183	13 (7.1)	NR (NE, NE)	0.371 (0.139, 0.988)	0.0391
Non-Smoker	68	5 (7.4)	NR (NE, NE)	57	6 (10.5)	NR (NE, NE)	0.507 (0.150, 1.719)	0.2670
Interaction								0.5457

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders / PT - Dizziness

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	6 (7.2)	NR (NE, NE)	79	5 (6.3)	NR (NE, NE)	0.946 (0.284, 3.150)	0.9281
Docetaxel	56	2 (3.6)	NR (NE, NE)	50	2 (4.0)	NR (NE, NE)	0.669 (0.093, 4.800)	0.6872
Irinotecan	116	3 (2.6)	NR (NE, NE)	111	12 (10.8)	NR (NE, NE)	0.167 (0.046, 0.616)	0.0027
Interaction								0.1399

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders / PT - Dizziness

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	2 (3.2)	NR (NE, NE)	57	5 (8.8)	NR (NE, NE)	0.267 (0.050, 1.414)	0.0975
1	192	9 (4.7)	NR (NE, NE)	183	14 (7.7)	NR (NE, NE)	0.489 (0.208, 1.149)	0.0941
Interaction								0.5666
Region #1								
Asia	201	4 (2.0)	NR (NE, NE)	191	16 (8.4)	NR (NE, NE)	0.196 (0.064, 0.597)	0.0015
Europe/North America	54	7 (13.0)	NR (8.3, NE)	49	3 (6.1)	NR (NE, NE)	1.744 (0.446, 6.810)	0.4179
Interaction								0.0088

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders / PT - Dizziness

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	4 (2.3)	NR (NE, NE)	168	15 (8.9)	NR (NE, NE)	0.216 (0.071, 0.662)	0.0033
Japan	25	0 (0.0)	NR (NE, NE)	23	1 (4.3)	NR (2.4, NE)	0.000 (0.000, NE)	0.1573
Europe/North America	54	7 (13.0)	NR (8.3, NE)	49	3 (6.1)	NR (NE, NE)	1.744 (0.446, 6.810)	0.4179
Interaction								0.0410

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders / PT - Dizziness

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	4 (2.0)	NR (NE, NE)	198	16 (8.1)	NR (NE, NE)	0.202 (0.066, 0.615)	0.0019
White	52	7 (13.5)	NR (8.3, NE)	42	3 (7.1)	NR (NE, NE)	1.542 (0.395, 6.015)	0.5296
Interaction								0.0147

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders / PT - Dizziness

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	6 (7.5)	NR (NE, NE)	60	2 (3.3)	NR (NE, NE)	1.850 (0.368, 9.292)	0.4483
vCPS < 10%	100	4 (4.0)	NR (NE, NE)	119	12 (10.1)	NR (NE, NE)	0.302 (0.096, 0.953)	0.0309
Missing	75	1 (1.3)	NR (NE, NE)	61	5 (8.2)	NR (NE, NE)	0.132 (0.015, 1.150)	0.0321
Interaction								0.1147

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Nervous system disorders / PT - Peripheral sensory neuropathy

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	1 (0.6)	NR (NE, NE)	149	10 (6.7)	NR (9.7, NE)	0.069 (0.009, 0.552)	0.0012
>= 65 Years	98	1 (1.0)	NR (NE, NE)	91	13 (14.3)	NR (NE, NE)	0.058 (0.008, 0.445)	0.0002
Interaction								0.8510
Gender								
Male	216	0 (0.0)	NR (NE, NE)	204	19 (9.3)	NR (9.7, NE)	0.000 (0.000, NE)	<0.0001
Female	39	2 (5.1)	NR (NE, NE)	36	4 (11.1)	NR (NE, NE)	0.389 (0.071, 2.149)	0.2622
Interaction								0.9885

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Safety Analysis Set
Any TEAE: SOC - Nervous system disorders / PT - Peripheral sensory neuropathy

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	2 (1.1)	NR (NE, NE)	183	19 (10.4)	NR (9.7, NE)	0.070 (0.016, 0.307)	<0.0001
Non-Smoker	68	0 (0.0)	NR (NE, NE)	57	4 (7.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0262
Interaction								0.9913

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Nervous system disorders / PT - Peripheral sensory neuropathy

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ICC Options								
Paclitaxel	83	1 (1.2)	NR (NE, NE)	79	19 (24.1)	9.7 (9.7, NE)	0.036 (0.005, 0.270)	<0.0001
Docetaxel	56	0 (0.0)	NR (NE, NE)	50	3 (6.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0608
Irinotecan	116	1 (0.9)	NR (NE, NE)	111	1 (0.9)	NR (NE, NE)	0.950 (0.059, 15.190)	0.9711
Interaction								0.2412

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders / PT - Peripheral sensory neuropathy

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	0 (0.0)	NR (NE, NE)	57	8 (14.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0014
1	192	2 (1.0)	NR (NE, NE)	183	15 (8.2)	NR (9.7, NE)	0.082 (0.018, 0.374)	<0.0001
Interaction								0.9908
Region #1								
Asia	201	0 (0.0)	NR (NE, NE)	191	14 (7.3)	NR (9.7, NE)	0.000 (0.000, NE)	<0.0001
Europe/North America	54	2 (3.7)	NR (NE, NE)	49	9 (18.4)	NR (NE, NE)	0.176 (0.038, 0.815)	0.0122
Interaction								0.9888

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Nervous system disorders / PT - Peripheral sensory neuropathy

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	0 (0.0)	NR (NE, NE)	168	7 (4.2)	NR (9.7, NE)	0.000 (0.000, NE)	0.0003
Japan	25	0 (0.0)	NR (NE, NE)	23	7 (30.4)	NR (1.0, NE)	0.000 (0.000, NE)	0.0015
Europe/North America	54	2 (3.7)	NR (NE, NE)	49	9 (18.4)	NR (NE, NE)	0.176 (0.038, 0.815)	0.0122
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Nervous system disorders / PT - Peripheral sensory neuropathy

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	0 (0.0)	NR (NE, NE)	198	15 (7.6)	NR (9.7, NE)	0.000 (0.000, NE)	<0.0001
White	52	2 (3.8)	NR (NE, NE)	42	8 (19.0)	NR (NE, NE)	0.175 (0.037, 0.827)	0.0130
Interaction								0.9888

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders / PT - Peripheral sensory neuropathy

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	2 (2.5)	NR (NE, NE)	60	3 (5.0)	NR (9.7, NE)	0.333 (0.053, 2.112)	0.2235
vCPS < 10%	100	0 (0.0)	NR (NE, NE)	119	11 (9.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0010
Missing	75	0 (0.0)	NR (NE, NE)	61	9 (14.8)	NR (3.5, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Skin and subcutaneous tissue disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	35 (22.3)	NR (NE, NE)	149	38 (25.5)	NR (NE, NE)	0.760 (0.478, 1.209)	0.2437
>= 65 Years	98	24 (24.5)	NR (10.3, NE)	91	29 (31.9)	5.3 (5.1, NE)	0.567 (0.325, 0.989)	0.0425
Interaction								0.7528
Gender								
Male	216	47 (21.8)	NR (10.7, NE)	204	49 (24.0)	NR (5.3, NE)	0.740 (0.493, 1.111)	0.1439
Female	39	12 (30.8)	NR (2.6, NE)	36	18 (50.0)	1.9 (0.9, NE)	0.421 (0.199, 0.888)	0.0192
Interaction								0.2806

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Skin and subcutaneous tissue disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	43 (23.0)	NR (10.7, NE)	183	53 (29.0)	NR (5.3, NE)	0.630 (0.418, 0.951)	0.0259
Non-Smoker	68	16 (23.5)	NR (5.1, NE)	57	14 (24.6)	NR (3.0, NE)	0.789 (0.383, 1.625)	0.5180
Interaction								0.4894

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Skin and subcutaneous tissue disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	23 (27.7)	NR (NE, NE)	79	37 (46.8)	3.0 (1.3, NE)	0.517 (0.307, 0.873)	0.0116
Docetaxel	56	14 (25.0)	10.3 (7.0, NE)	50	12 (24.0)	NR (NE, NE)	0.783 (0.358, 1.712)	0.5374
Irinotecan	116	22 (19.0)	NR (NE, NE)	111	18 (16.2)	NR (5.3, NE)	0.898 (0.474, 1.703)	0.7419
Interaction								0.2912

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Skin and subcutaneous tissue disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	18 (28.6)	NR (7.0, NE)	57	21 (36.8)	NR (3.0, NE)	0.598 (0.317, 1.131)	0.1091
1	192	41 (21.4)	NR (10.7, NE)	183	46 (25.1)	NR (5.1, NE)	0.701 (0.457, 1.075)	0.1006
Interaction								0.7271
Region #1								
Asia	201	45 (22.4)	NR (10.7, NE)	191	49 (25.7)	NR (NE, NE)	0.680 (0.450, 1.027)	0.0646
Europe/North America	54	14 (25.9)	NR (NE, NE)	49	18 (36.7)	5.3 (2.4, NE)	0.647 (0.321, 1.303)	0.2182
Interaction								0.8704

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Safety Analysis Set

Any TEAE: SOC - Skin and subcutaneous tissue disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	39 (22.2)	NR (10.7, NE)	168	36 (21.4)	NR (NE, NE)	0.837 (0.528, 1.325)	0.4457
Japan	25	6 (24.0)	NR (10.3, NE)	23	13 (56.5)	0.7 (0.5, NE)	0.222 (0.078, 0.629)	0.0020
Europe/North America	54	14 (25.9)	NR (NE, NE)	49	18 (36.7)	5.3 (2.4, NE)	0.647 (0.321, 1.303)	0.2182
Interaction								0.0734

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Safety Analysis Set

Any TEAE: SOC - Skin and subcutaneous tissue disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	45 (22.2)	NR (10.7, NE)	198	53 (26.8)	NR (5.1, NE)	0.639 (0.426, 0.959)	0.0288
White	52	14 (26.9)	NR (NE, NE)	42	14 (33.3)	NR (2.4, NE)	0.755 (0.359, 1.586)	0.4560
Interaction								0.7661

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Skin and subcutaneous tissue disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	16 (20.0)	NR (10.3, NE)	60	17 (28.3)	NR (5.1, NE)	0.493 (0.246, 0.987)	0.0410
vCPS < 10%	100	32 (32.0)	NR (5.1, NE)	119	33 (27.7)	NR (5.3, NE)	1.091 (0.669, 1.781)	0.7260
Missing	75	11 (14.7)	NR (9.6, NE)	61	17 (27.9)	NR (NE, NE)	0.374 (0.170, 0.822)	0.0107
Interaction								0.0576

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Skin and subcutaneous tissue disorders / PT - Alopecia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	0 (0.0)	NR (NE, NE)	149	24 (16.1)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
>= 65 Years	98	0 (0.0)	NR (NE, NE)	91	18 (19.8)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9999
Gender								
Male	216	0 (0.0)	NR (NE, NE)	204	29 (14.2)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Female	39	0 (0.0)	NR (NE, NE)	36	13 (36.1)	NR (1.9, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9997

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Skin and subcutaneous tissue disorders / PT - Alopecia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Smoking Status								
Former/Current Smoker	187	0 (0.0)	NR (NE, NE)	183	34 (18.6)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Non-Smoker	68	0 (0.0)	NR (NE, NE)	57	8 (14.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0009
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
Adverse events were classified based on MedDRA v23.0.
System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.
Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.
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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Skin and subcutaneous tissue disorders / PT - Alopecia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ICC Options								
Paclitaxel	83	0 (0.0)	NR (NE, NE)	79	24 (30.4)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Docetaxel	56	0 (0.0)	NR (NE, NE)	50	10 (20.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0002
Irinotecan	116	0 (0.0)	NR (NE, NE)	111	8 (7.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0027
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Skin and subcutaneous tissue disorders / PT - Alopecia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	0 (0.0)	NR (NE, NE)	57	16 (28.1)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
1	192	0 (0.0)	NR (NE, NE)	183	26 (14.2)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9998
Region #1								
Asia	201	0 (0.0)	NR (NE, NE)	191	31 (16.2)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	11 (22.4)	NR (NE, NE)	0.000 (0.000, NE)	0.0002
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Skin and subcutaneous tissue disorders / PT - Alopecia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	0 (0.0)	NR (NE, NE)	168	20 (11.9)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Japan	25	0 (0.0)	NR (NE, NE)	23	11 (47.8)	NR (0.7, NE)	0.000 (0.000, NE)	<0.0001
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	11 (22.4)	NR (NE, NE)	0.000 (0.000, NE)	0.0002
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Skin and subcutaneous tissue disorders / PT - Alopecia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	0 (0.0)	NR (NE, NE)	198	33 (16.7)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
White	52	0 (0.0)	NR (NE, NE)	42	9 (21.4)	NR (NE, NE)	0.000 (0.000, NE)	0.0003
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Skin and subcutaneous tissue disorders / PT - Alopecia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	0 (0.0)	NR (NE, NE)	60	10 (16.7)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
vCPS < 10%	100	0 (0.0)	NR (NE, NE)	119	23 (19.3)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Missing	75	0 (0.0)	NR (NE, NE)	61	9 (14.8)	NR (NE, NE)	0.000 (0.000, NE)	0.0003
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	27 (35.1)	NR (4.3, NE)	70	40 (57.1)	1.4 (0.9, 5.6)	0.473 (0.289, 0.774)	0.0020
>= 65 Years	62	17 (27.4)	NR (NE, NE)	59	32 (54.2)	1.5 (0.9, NE)	0.368 (0.201, 0.674)	0.0006
Interaction								0.5472
Gender								
Male	118	40 (33.9)	NR (8.9, NE)	106	62 (58.5)	1.4 (1.0, 4.1)	0.431 (0.288, 0.645)	<0.0001
Female	21	4 (19.0)	NR (NE, NE)	23	10 (43.5)	NR (0.5, NE)	0.377 (0.118, 1.203)	0.0797
Interaction								0.6613

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	33 (31.7)	NR (8.9, NE)	101	55 (54.5)	2.0 (1.0, 5.6)	0.440 (0.284, 0.680)	0.0001
Non-Smoker	35	11 (31.4)	NR (2.1, NE)	28	17 (60.7)	1.2 (0.5, NE)	0.395 (0.183, 0.853)	0.0129
Interaction								0.7840
ICC Options								
Paclitaxel	83	23 (27.7)	NR (NE, NE)	79	35 (44.3)	4.7 (1.5, NE)	0.534 (0.314, 0.907)	0.0173
Docetaxel	56	21 (37.5)	NR (3.4, NE)	50	37 (74.0)	0.9 (0.3, 1.3)	0.294 (0.168, 0.515)	<0.0001
Interaction								0.1737

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	7 (16.3)	NR (NE, NE)	37	17 (45.9)	5.6 (1.7, NE)	0.296 (0.122, 0.718)	0.0037
1	96	37 (38.5)	NR (3.4, NE)	92	55 (59.8)	1.0 (0.5, 4.1)	0.456 (0.298, 0.697)	0.0002
Interaction								0.3752
Region #1								
Asia	103	33 (32.0)	NR (NE, NE)	99	54 (54.5)	1.4 (1.0, NE)	0.446 (0.288, 0.692)	0.0002
Europe/North America	36	11 (30.6)	NR (8.9, NE)	30	18 (60.0)	1.5 (0.5, 5.6)	0.386 (0.180, 0.828)	0.0102
Interaction								0.8971

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	32 (41.0)	NR (2.1, NE)	76	48 (63.2)	1.0 (0.5, 2.0)	0.478 (0.303, 0.752)	0.0008
Japan	25	1 (4.0)	NR (NE, NE)	23	6 (26.1)	NR (2.8, NE)	0.122 (0.015, 1.026)	0.0203
Europe/North America	36	11 (30.6)	NR (8.9, NE)	30	18 (60.0)	1.5 (0.5, 5.6)	0.386 (0.180, 0.828)	0.0102
Interaction								0.4757

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	34 (32.4)	NR (NE, NE)	106	56 (52.8)	1.7 (1.0, NE)	0.476 (0.309, 0.732)	0.0004
White	34	10 (29.4)	NR (8.9, NE)	23	16 (69.6)	1.0 (0.5, 5.6)	0.304 (0.137, 0.677)	0.0017
Interaction								0.4371

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	14 (31.1)	NR (3.4, NE)	34	20 (58.8)	1.1 (0.5, NE)	0.375 (0.187, 0.749)	0.0036
vCPS < 10%	53	18 (34.0)	NR (4.3, NE)	54	35 (64.8)	1.0 (0.5, 2.2)	0.362 (0.203, 0.647)	0.0003
Missing	41	12 (29.3)	NR (6.9, NE)	41	17 (41.5)	4.7 (1.4, NE)	0.612 (0.290, 1.291)	0.1814
Interaction								0.5408

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	22 (28.6)	NR (8.3, NE)	70	31 (44.3)	5.6 (1.4, NE)	0.531 (0.306, 0.920)	0.0211
>= 65 Years	62	15 (24.2)	NR (NE, NE)	59	21 (35.6)	5.1 (4.1, NE)	0.518 (0.262, 1.025)	0.0529
Interaction								0.9541
Gender								
Male	118	33 (28.0)	NR (NE, NE)	106	45 (42.5)	5.1 (2.0, NE)	0.516 (0.327, 0.814)	0.0036
Female	21	4 (19.0)	NR (NE, NE)	23	7 (30.4)	NR (0.5, NE)	0.555 (0.162, 1.897)	0.3323
Interaction								0.8959

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	29 (27.9)	NR (NE, NE)	101	44 (43.6)	5.1 (1.4, NE)	0.493 (0.307, 0.795)	0.0028
Non-Smoker	35	8 (22.9)	NR (4.3, NE)	28	8 (28.6)	NR (2.1, NE)	0.727 (0.272, 1.943)	0.5216
Interaction								0.5586
ICC Options								
Paclitaxel	83	20 (24.1)	NR (NE, NE)	79	26 (32.9)	NR (4.1, NE)	0.668 (0.372, 1.198)	0.1702
Docetaxel	56	17 (30.4)	NR (8.3, NE)	50	26 (52.0)	2.0 (1.0, NE)	0.353 (0.185, 0.673)	0.0009
Interaction								0.2919

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Any TEAE: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	4 (9.3)	NR (NE, NE)	37	8 (21.6)	NR (5.6, NE)	0.388 (0.116, 1.296)	0.1096
1	96	33 (34.4)	NR (8.3, NE)	92	44 (47.8)	4.1 (1.1, NE)	0.530 (0.334, 0.840)	0.0056
Interaction								0.6173
Region #1								
Asia	103	26 (25.2)	NR (NE, NE)	99	40 (40.4)	NR (2.0, NE)	0.487 (0.295, 0.803)	0.0037
Europe/North America	36	11 (30.6)	NR (8.9, NE)	30	12 (40.0)	5.6 (1.0, NE)	0.645 (0.281, 1.479)	0.2922
Interaction								0.4809

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	25 (32.1)	NR (8.3, NE)	76	36 (47.4)	2.0 (1.1, NE)	0.514 (0.306, 0.862)	0.0097
Japan	25	1 (4.0)	NR (NE, NE)	23	4 (17.4)	NR (2.8, NE)	0.194 (0.021, 1.743)	0.1014
Europe/North America	36	11 (30.6)	NR (8.9, NE)	30	12 (40.0)	5.6 (1.0, NE)	0.645 (0.281, 1.479)	0.2922
Interaction								0.5378

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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Any TEAE: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	27 (25.7)	NR (NE, NE)	106	41 (38.7)	NR (2.1, NE)	0.533 (0.326, 0.871)	0.0101
White	34	10 (29.4)	NR (8.9, NE)	23	11 (47.8)	5.1 (0.5, NE)	0.485 (0.204, 1.155)	0.0914
Interaction								0.9725

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Any TEAE: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	14 (31.1)	NR (8.3, NE)	34	17 (50.0)	4.1 (0.8, NE)	0.457 (0.223, 0.937)	0.0278
vCPS < 10%	53	16 (30.2)	NR (8.9, NE)	54	23 (42.6)	5.6 (1.1, NE)	0.560 (0.292, 1.071)	0.0743
Missing	41	7 (17.1)	NR (NE, NE)	41	12 (29.3)	NR (5.1, NE)	0.521 (0.205, 1.327)	0.1579
Interaction								0.8882

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	77	3 (3.9)	NR (NE, NE)	70	7 (10.0)	NR (NE, NE)	0.361 (0.093, 1.396)	0.1227
>= 65 Years	62	1 (1.6)	NR (NE, NE)	59	5 (8.5)	NR (6.3, NE)	0.145 (0.016, 1.282)	0.0465
Interaction								0.5525
Gender								
Male	118	4 (3.4)	NR (NE, NE)	106	11 (10.4)	NR (NE, NE)	0.301 (0.096, 0.946)	0.0289
Female	21	0 (0.0)	NR (NE, NE)	23	1 (4.3)	NR (6.3, NE)	0.000 (0.000, NE)	0.1573
Interaction								0.9940

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	2 (1.9)	--	101	7 (6.9)	--	--	--
Non-Smoker	35	2 (5.7)	--	28	5 (17.9)	--	--	--
Interaction								--
ICC Options								
Paclitaxel	83	1 (1.2)	NR (NE, NE)	79	2 (2.5)	NR (NE, NE)	0.466 (0.042, 5.137)	0.5228
Docetaxel	56	3 (5.4)	NR (NE, NE)	50	10 (20.0)	NR (6.3, NE)	0.223 (0.061, 0.814)	0.0126
Interaction								0.6435

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	43	2 (4.7)	NR (NE, NE)	37	4 (10.8)	NR (NE, NE)	0.413 (0.076, 2.258)	0.2912
1	96	2 (2.1)	NR (NE, NE)	92	8 (8.7)	NR (NE, NE)	0.202 (0.042, 0.960)	0.0261
Interaction								0.6072
Region #1								
Asia	103	4 (3.9)	NR (NE, NE)	99	11 (11.1)	NR (NE, NE)	0.308 (0.098, 0.970)	0.0329
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	1 (3.3)	NR (NE, NE)	0.000 (0.000, NE)	0.2733
Interaction								0.9923

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	4 (5.1)	NR (NE, NE)	76	11 (14.5)	NR (NE, NE)	0.312 (0.099, 0.982)	0.0347
Japan	25	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	1 (3.3)	NR (NE, NE)	0.000 (0.000, NE)	0.2733
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
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Any TEAE: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	4 (3.8)	NR (NE, NE)	106	11 (10.4)	NR (NE, NE)	0.326 (0.103, 1.028)	0.0438
White	34	0 (0.0)	NR (NE, NE)	23	1 (4.3)	NR (NE, NE)	0.000 (0.000, NE)	0.2240
Interaction								0.9921

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
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Any TEAE: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	1 (2.2)	--	34	5 (14.7)	--	--	--
vCPS < 10%	53	1 (1.9)	--	54	6 (11.1)	--	--	--
Missing	41	2 (4.9)	--	41	1 (2.4)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	77	1 (1.3)	NR (NE, NE)	70	8 (11.4)	NR (NE, NE)	0.107 (0.013, 0.852)	0.0098
>= 65 Years	62	1 (1.6)	NR (NE, NE)	59	13 (22.0)	NR (4.7, NE)	0.060 (0.008, 0.465)	0.0003
Interaction								0.7412
Gender								
Male	118	2 (1.7)	NR (NE, NE)	106	18 (17.0)	NR (NE, NE)	0.087 (0.020, 0.375)	<0.0001
Female	21	0 (0.0)	NR (NE, NE)	23	3 (13.0)	NR (NE, NE)	0.000 (0.000, NE)	0.1022
Interaction								0.9901

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

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Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	1 (1.0)	NR (NE, NE)	101	13 (12.9)	NR (NE, NE)	0.065 (0.009, 0.502)	0.0005
Non-Smoker	35	1 (2.9)	NR (NE, NE)	28	8 (28.6)	NR (2.2, NE)	0.090 (0.011, 0.717)	0.0041
Interaction								0.8583
ICC Options								
Paclitaxel	83	0 (0.0)	NR (NE, NE)	79	12 (15.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0001
Docetaxel	56	2 (3.6)	NR (NE, NE)	50	9 (18.0)	NR (NE, NE)	0.184 (0.040, 0.852)	0.0142
Interaction								0.9911

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	43	2 (4.7)	NR (NE, NE)	37	7 (18.9)	NR (NE, NE)	0.232 (0.048, 1.115)	0.0453
1	96	0 (0.0)	NR (NE, NE)	92	14 (15.2)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9903
Region #1								
Asia	103	2 (1.9)	NR (NE, NE)	99	9 (9.1)	NR (NE, NE)	0.204 (0.044, 0.946)	0.0239
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	12 (40.0)	4.7 (1.5, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9910

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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Any TEAE: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	2 (2.6)	NR (NE, NE)	76	9 (11.8)	NR (NE, NE)	0.205 (0.044, 0.947)	0.0238
Japan	25	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	12 (40.0)	4.7 (1.5, NE)	0.000 (0.000, NE)	<0.0001
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	2 (1.9)	NR (NE, NE)	106	10 (9.4)	NR (NE, NE)	0.193 (0.042, 0.880)	0.0173
White	34	0 (0.0)	NR (NE, NE)	23	11 (47.8)	4.7 (1.0, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9886

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
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Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	0 (0.0)	NR (NE, NE)	34	3 (8.8)	NR (NE, NE)	0.000 (0.000, NE)	0.0436
vCPS < 10%	53	1 (1.9)	NR (NE, NE)	54	14 (25.9)	NR (NE, NE)	0.060 (0.008, 0.460)	0.0002
Missing	41	1 (2.4)	NR (NE, NE)	41	4 (9.8)	NR (4.7, NE)	0.226 (0.025, 2.038)	0.1457
Interaction								0.6493

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	14 (18.2)	16.5 (9.0, NE)	70	1 (1.4)	NR (NE, NE)	10.051 (1.313, 76.931)	0.0058
>= 65 Years	62	10 (16.1)	NR (10.6, NE)	59	0 (0.0)	NR (NE, NE)	24962242.942 (0.000, NE)	0.0095
Interaction								0.9928

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Gender								
Male	118	20 (16.9)	NR (11.6, NE)	106	1 (0.9)	NR (NE, NE)	13.045 (1.737, 97.990)	0.0012
Female	21	4 (19.0)	9.0 (2.3, NE)	23	0 (0.0)	NR (NE, NE)	101665480.426 (0.000, NE)	0.0290
Interaction								0.9926

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	15 (14.4)	NR (16.5, NE)	101	1 (1.0)	NR (NE, NE)	11.509 (1.506, 87.938)	0.0028
Non-Smoker	35	9 (25.7)	9.0 (4.2, NE)	28	0 (0.0)	NR (NE, NE)	62507366.254 (0.000, NE)	0.0132
Interaction								0.9926

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	18 (21.7)	16.5 (9.0, NE)	79	1 (1.3)	NR (NE, NE)	13.922 (1.841, 105.255)	0.0008
Docetaxel	56	6 (10.7)	NR (11.6, NE)	50	0 (0.0)	NR (NE, NE)	18523395.133 (0.000, NE)	0.0710
Interaction								0.9913

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	10 (23.3)	11.6 (8.3, NE)	37	0 (0.0)	NR (NE, NE)	56936179.249 (0.000, NE)	0.0164
1	96	14 (14.6)	NR (16.5, NE)	92	1 (1.1)	NR (NE, NE)	11.388 (1.493, 86.857)	0.0029
Interaction								0.9902

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #1								
Asia	103	19 (18.4)	16.5 (10.6, NE)	99	1 (1.0)	NR (NE, NE)	11.998 (1.593, 90.340)	0.0021
Europe/North America	36	5 (13.9)	NR (NE, NE)	30	0 (0.0)	NR (NE, NE)	27971823.757 (0.000, NE)	0.0296
Interaction								0.9918

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	12 (15.4)	NR (16.5, NE)	76	1 (1.3)	NR (NE, NE)	8.955 (1.157, 69.308)	0.0107
Japan	25	7 (28.0)	11.6 (4.6, NE)	23	0 (0.0)	NR (NE, NE)	49166268.174 (0.000, NE)	0.0771
Europe/North America	36	5 (13.9)	NR (NE, NE)	30	0 (0.0)	NR (NE, NE)	27971823.757 (0.000, NE)	0.0296
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	19 (18.1)	16.5 (10.6, NE)	106	1 (0.9)	NR (NE, NE)	12.769 (1.695, 96.180)	0.0014
White	34	5 (14.7)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	23616334.015 (0.000, NE)	0.0482
Interaction								0.9927

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	6 (13.3)	NR (9.0, NE)	34	1 (2.9)	NR (NE, NE)	2.930 (0.348, 24.669)	0.3003
vCPS < 10%	53	10 (18.9)	NR (16.5, NE)	54	0 (0.0)	NR (NE, NE)	28203570.659 (0.000, NE)	0.0032
Missing	41	8 (19.5)	NR (4.6, NE)	41	0 (0.0)	NR (NE, NE)	76459732.468 (0.000, NE)	0.0102
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	77	11 (14.3)	NR (4.9, NE)	70	0 (0.0)	NR (NE, NE)	22765671.292 (0.000, NE)	0.0061
>= 65 Years	62	6 (9.7)	NR (NE, NE)	59	0 (0.0)	NR (NE, NE)	26076844.154 (0.000, NE)	0.0311
Interaction								0.9998

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Gender								
Male	118	14 (11.9)	NR (16.5, NE)	106	0 (0.0)	NR (NE, NE)	22487951.927 (0.000, NE)	0.0024
Female	21	3 (14.3)	NR (2.3, NE)	23	0 (0.0)	NR (NE, NE)	92609463.771 (0.000, NE)	0.0744
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	12 (11.5)	NR (16.5, NE)	101	0 (0.0)	NR (NE, NE)	23958115.109 (0.000, NE)	0.0032
Non-Smoker	35	5 (14.3)	NR (4.2, NE)	28	0 (0.0)	NR (NE, NE)	58036047.775 (0.000, NE)	0.0689
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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Table 14.3.1.2.2.2.1.b.s:
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Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ICC Options								
Paclitaxel	83	13 (15.7)	NR (10.6, NE)	79	0 (0.0)	NR (NE, NE)	24970640.163 (0.000, NE)	0.0020
Docetaxel	56	4 (7.1)	NR (NE, NE)	50	0 (0.0)	NR (NE, NE)	19015915.978 (0.000, NE)	0.1234
Interaction								0.9998

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	43	7 (16.3)	NR (10.6, NE)	37	0 (0.0)	NR (NE, NE)	21158112.681 (0.000, NE)	0.0374
1	96	10 (10.4)	NR (16.5, NE)	92	0 (0.0)	NR (NE, NE)	23910491.194 (0.000, NE)	0.0057
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Region #1								
Asia	103	13 (12.6)	NR (16.5, NE)	99	0 (0.0)	NR (NE, NE)	22075038.129 (0.000, NE)	0.0032
Europe/North America	36	4 (11.1)	NR (4.9, NE)	30	0 (0.0)	NR (NE, NE)	68856680.081 (0.000, NE)	0.0661
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Region #2								
Asia (excluding Japan)	78	9 (11.5)	--	76	0 (0.0)	--	--	--
Japan	25	4 (16.0)	--	23	0 (0.0)	--	--	--
Europe/North America	36	4 (11.1)	--	30	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	105	13 (12.4)	NR (16.5, NE)	106	0 (0.0)	NR (NE, NE)	23301963.057 (0.000, NE)	0.0023
White	34	4 (11.8)	NR (4.9, NE)	23	0 (0.0)	NR (NE, NE)	59592827.402 (0.000, NE)	0.0928
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
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Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Baseline PD-L1 Status								
vCPS >= 10%	45	3 (6.7)	--	34	0 (0.0)	--	--	--
vCPS < 10%	53	8 (15.1)	--	54	0 (0.0)	--	--	--
Missing	41	6 (14.6)	--	41	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Gastrointestinal disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	47 (61.0)	2.0 (0.9, 5.9)	70	40 (57.1)	1.2 (0.7, 2.6)	0.807 (0.527, 1.237)	0.3199
>= 65 Years	62	41 (66.1)	2.4 (1.4, 3.4)	59	39 (66.1)	1.1 (0.4, 2.1)	0.627 (0.398, 0.988)	0.0407
Interaction								0.6382
Gender								
Male	118	75 (63.6)	2.4 (1.4, 3.4)	106	62 (58.5)	1.2 (0.7, 2.6)	0.770 (0.546, 1.086)	0.1316
Female	21	13 (61.9)	2.1 (0.3, 6.2)	23	17 (73.9)	1.0 (0.1, 2.1)	0.512 (0.242, 1.081)	0.0709
Interaction								0.3505

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Gastrointestinal disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	70 (67.3)	2.0 (1.2, 3.1)	101	61 (60.4)	1.1 (0.4, 2.3)	0.783 (0.552, 1.111)	0.1643
Non-Smoker	35	18 (51.4)	2.9 (0.8, NE)	28	18 (64.3)	1.2 (0.5, 5.1)	0.538 (0.273, 1.061)	0.0684
Interaction								0.4328
ICC Options								
Paclitaxel	83	53 (63.9)	2.0 (1.2, 3.4)	79	50 (63.3)	1.1 (0.5, 2.3)	0.724 (0.489, 1.073)	0.1031
Docetaxel	56	35 (62.5)	2.9 (0.8, 7.2)	50	29 (58.0)	1.1 (0.3, 6.1)	0.709 (0.427, 1.178)	0.1776
Interaction								0.9383

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Gastrointestinal disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	23 (53.5)	5.9 (2.0, 9.8)	37	24 (64.9)	1.3 (0.4, 5.1)	0.486 (0.267, 0.883)	0.0148
1	96	65 (67.7)	1.4 (0.8, 2.9)	92	55 (59.8)	1.1 (0.5, 2.3)	0.847 (0.588, 1.220)	0.3661
Interaction								0.1380
Region #1								
Asia	103	61 (59.2)	3.0 (1.8, 4.1)	99	56 (56.6)	1.1 (0.5, 2.3)	0.687 (0.474, 0.995)	0.0441
Europe/North America	36	27 (75.0)	1.2 (0.3, 2.5)	30	23 (76.7)	1.1 (0.4, 2.3)	0.778 (0.439, 1.380)	0.3812
Interaction								0.5059

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Gastrointestinal disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	50 (64.1)	2.2 (1.2, 3.4)	76	41 (53.9)	1.2 (0.4, NE)	0.802 (0.526, 1.221)	0.2983
Japan	25	11 (44.0)	9.8 (1.5, NE)	23	15 (65.2)	1.1 (0.3, NE)	0.422 (0.187, 0.953)	0.0317
Europe/North America	36	27 (75.0)	1.2 (0.3, 2.5)	30	23 (76.7)	1.1 (0.4, 2.3)	0.778 (0.439, 1.380)	0.3812
Interaction								0.1968

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Gastrointestinal disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	63 (60.0)	2.9 (1.8, 3.7)	106	61 (57.5)	1.1 (0.6, 2.3)	0.698 (0.487, 1.001)	0.0478
White	34	25 (73.5)	1.2 (0.3, 2.5)	23	18 (78.3)	1.2 (0.2, 2.3)	0.706 (0.378, 1.321)	0.2631
Interaction								0.7754

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Gastrointestinal disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	34 (75.6)	1.9 (0.6, 3.3)	34	25 (73.5)	0.4 (0.2, 1.9)	0.591 (0.346, 1.009)	0.0486
vCPS < 10%	53	37 (69.8)	1.5 (0.8, 3.7)	54	32 (59.3)	1.5 (0.7, 2.6)	0.882 (0.541, 1.439)	0.6130
Missing	41	17 (41.5)	4.1 (2.5, NE)	41	22 (53.7)	1.0 (0.3, NE)	0.562 (0.297, 1.063)	0.0698
Interaction								0.2368

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Gastrointestinal disorders / PT - Abdominal pain upper

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	77	2 (2.6)	--	70	4 (5.7)	--	--	--
>= 65 Years	62	2 (3.2)	--	59	6 (10.2)	--	--	--
Interaction								--
Gender								
Male	118	4 (3.4)	NR (NE, NE)	106	6 (5.7)	NR (NE, NE)	0.512 (0.142, 1.838)	0.2955
Female	21	0 (0.0)	NR (NE, NE)	23	4 (17.4)	NR (NE, NE)	0.000 (0.000, NE)	0.0478
Interaction								0.9926

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Gastrointestinal disorders / PT - Abdominal pain upper

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	2 (1.9)	--	101	5 (5.0)	--	--	--
Non-Smoker	35	2 (5.7)	--	28	5 (17.9)	--	--	--
Interaction								--
ICC Options								
Paclitaxel	83	1 (1.2)	--	79	7 (8.9)	--	--	--
Docetaxel	56	3 (5.4)	--	50	3 (6.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Gastrointestinal disorders / PT - Abdominal pain upper

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	43	0 (0.0)	--	37	5 (13.5)	--	--	--
1	96	4 (4.2)	--	92	5 (5.4)	--	--	--
Interaction								--
Region #1								
Asia	103	3 (2.9)	--	99	6 (6.1)	--	--	--
Europe/North America	36	1 (2.8)	--	30	4 (13.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Gastrointestinal disorders / PT - Abdominal pain upper

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Region #2								
Asia (excluding Japan)	78	3 (3.8)	--	76	6 (7.9)	--	--	--
Japan	25	0 (0.0)	--	23	0 (0.0)	--	--	--
Europe/North America	36	1 (2.8)	--	30	4 (13.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Gastrointestinal disorders / PT - Abdominal pain upper

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	105	3 (2.9)	--	106	6 (5.7)	--	--	--
White	34	1 (2.9)	--	23	4 (17.4)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Gastrointestinal disorders / PT - Abdominal pain upper

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	2 (4.4)	--	34	5 (14.7)	--	--	--
vCPS < 10%	53	1 (1.9)	--	54	3 (5.6)	--	--	--
Missing	41	1 (2.4)	--	41	2 (4.9)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - General disorders and administration site conditions

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	34 (44.2)	8.5 (2.5, NE)	70	39 (55.7)	1.7 (1.0, 3.0)	0.536 (0.333, 0.865)	0.0089
>= 65 Years	62	39 (62.9)	3.5 (1.3, 7.6)	59	38 (64.4)	1.0 (0.5, 2.6)	0.626 (0.391, 1.003)	0.0465
Interaction								0.4943
Gender								
Male	118	62 (52.5)	6.9 (2.7, 8.6)	106	61 (57.5)	1.3 (0.9, 2.6)	0.587 (0.406, 0.849)	0.0039
Female	21	11 (52.4)	2.2 (0.3, NE)	23	16 (69.6)	1.8 (0.3, 2.7)	0.595 (0.269, 1.317)	0.1908
Interaction								0.9571

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - General disorders and administration site conditions

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	56 (53.8)	3.6 (2.2, 8.6)	101	62 (61.4)	1.3 (0.9, 2.3)	0.571 (0.392, 0.831)	0.0028
Non-Smoker	35	17 (48.6)	7.7 (2.1, NE)	28	15 (53.6)	1.9 (0.4, NE)	0.594 (0.283, 1.247)	0.1611
Interaction								0.7519
ICC Options								
Paclitaxel	83	46 (55.4)	3.5 (1.9, 9.9)	79	49 (62.0)	1.7 (0.8, 2.6)	0.614 (0.403, 0.936)	0.0211
Docetaxel	56	27 (48.2)	5.5 (2.9, 8.6)	50	28 (56.0)	1.3 (0.8, NE)	0.548 (0.315, 0.951)	0.0281
Interaction								0.8051

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - General disorders and administration site conditions

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	22 (51.2)	7.7 (2.7, 9.9)	37	20 (54.1)	2.6 (1.0, NE)	0.589 (0.308, 1.126)	0.1037
1	96	51 (53.1)	3.5 (2.0, 10.3)	92	57 (62.0)	1.2 (0.6, 1.9)	0.562 (0.379, 0.833)	0.0033
Interaction								0.6300
Region #1								
Asia	103	47 (45.6)	7.7 (3.6, 11.0)	99	55 (55.6)	1.6 (0.9, 3.0)	0.525 (0.348, 0.791)	0.0016
Europe/North America	36	26 (72.2)	2.2 (0.7, 3.5)	30	22 (73.3)	1.0 (0.4, 2.7)	0.670 (0.372, 1.209)	0.1753
Interaction								0.2847

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - General disorders and administration site conditions

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	34 (43.6)	7.7 (3.4, 12.7)	76	41 (53.9)	1.6 (0.9, NE)	0.545 (0.338, 0.878)	0.0107
Japan	25	13 (52.0)	6.9 (1.9, NE)	23	14 (60.9)	1.7 (0.4, NE)	0.432 (0.187, 1.000)	0.0431
Europe/North America	36	26 (72.2)	2.2 (0.7, 3.5)	30	22 (73.3)	1.0 (0.4, 2.7)	0.670 (0.372, 1.209)	0.1753
Interaction								0.5521

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - General disorders and administration site conditions

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	47 (44.8)	7.7 (3.6, 11.0)	106	59 (55.7)	1.7 (0.9, 2.7)	0.511 (0.341, 0.766)	0.0009
White	34	26 (76.5)	1.7 (0.5, 2.8)	23	18 (78.3)	0.9 (0.2, 1.9)	0.655 (0.352, 1.217)	0.1715
Interaction								0.3574

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - General disorders and administration site conditions

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	29 (64.4)	2.9 (1.2, 7.0)	34	23 (67.6)	1.0 (0.2, 2.5)	0.590 (0.337, 1.032)	0.0590
vCPS < 10%	53	30 (56.6)	7.7 (1.2, 11.0)	54	30 (55.6)	2.1 (0.9, 3.0)	0.669 (0.390, 1.147)	0.1380
Missing	41	14 (34.1)	9.9 (2.5, NE)	41	24 (58.5)	1.1 (0.8, NE)	0.413 (0.208, 0.818)	0.0084
Interaction								0.3455

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Infections and infestations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	27 (35.1)	10.5 (3.8, NE)	70	23 (32.9)	8.0 (3.4, NE)	0.870 (0.494, 1.531)	0.6280
>= 65 Years	62	16 (25.8)	11.5 (5.6, NE)	59	24 (40.7)	3.1 (2.6, NE)	0.420 (0.212, 0.829)	0.0099
Interaction								0.1704
Gender								
Male	118	39 (33.1)	10.5 (5.3, NE)	106	38 (35.8)	8.0 (3.1, NE)	0.708 (0.447, 1.121)	0.1380
Female	21	4 (19.0)	NR (2.1, NE)	23	9 (39.1)	3.1 (2.4, NE)	0.341 (0.091, 1.274)	0.0935
Interaction								0.2952

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Infections and infestations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	32 (30.8)	11.5 (5.6, NE)	101	39 (38.6)	5.3 (2.8, NE)	0.585 (0.360, 0.948)	0.0275
Non-Smoker	35	11 (31.4)	10.5 (2.8, NE)	28	8 (28.6)	4.9 (3.1, NE)	0.952 (0.375, 2.415)	0.9176
Interaction								0.3283
ICC Options								
Paclitaxel	83	25 (30.1)	13.8 (5.3, NE)	79	25 (31.6)	8.0 (3.3, NE)	0.766 (0.431, 1.359)	0.3591
Docetaxel	56	18 (32.1)	9.5 (3.2, NE)	50	22 (44.0)	3.1 (1.4, NE)	0.479 (0.251, 0.914)	0.0223
Interaction								0.3722

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Infections and infestations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	10 (23.3)	13.8 (7.3, NE)	37	10 (27.0)	8.0 (4.9, NE)	0.574 (0.223, 1.473)	0.2417
1	96	33 (34.4)	5.6 (3.8, NE)	92	37 (40.2)	3.1 (2.4, NE)	0.645 (0.399, 1.043)	0.0708
Interaction								0.8703
Region #1								
Asia	103	33 (32.0)	10.5 (5.3, NE)	99	35 (35.4)	NR (2.8, NE)	0.639 (0.390, 1.046)	0.0719
Europe/North America	36	10 (27.8)	NR (7.3, NE)	30	12 (40.0)	4.9 (2.8, NE)	0.653 (0.278, 1.530)	0.3226
Interaction								0.8936

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Infections and infestations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	25 (32.1)	9.5 (4.9, NE)	76	27 (35.5)	NR (2.4, NE)	0.635 (0.364, 1.107)	0.1057
Japan	25	8 (32.0)	11.5 (5.6, NE)	23	8 (34.8)	NR (3.0, NE)	0.633 (0.219, 1.834)	0.3952
Europe/North America	36	10 (27.8)	NR (7.3, NE)	30	12 (40.0)	4.9 (2.8, NE)	0.653 (0.278, 1.530)	0.3226
Interaction								0.9594

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Infections and infestations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	34 (32.4)	10.5 (5.3, NE)	106	37 (34.9)	NR (2.8, NE)	0.668 (0.412, 1.083)	0.0984
White	34	9 (26.5)	NR (7.3, NE)	23	10 (43.5)	4.9 (2.8, NE)	0.594 (0.239, 1.476)	0.2568
Interaction								0.8711

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Infections and infestations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	11 (24.4)	13.8 (5.3, NE)	34	15 (44.1)	2.8 (2.2, NE)	0.298 (0.127, 0.699)	0.0033
vCPS < 10%	53	23 (43.4)	5.6 (2.8, NE)	54	22 (40.7)	4.9 (3.0, NE)	0.856 (0.470, 1.558)	0.6091
Missing	41	9 (22.0)	11.5 (3.2, NE)	41	10 (24.4)	NR (NE, NE)	0.731 (0.288, 1.854)	0.5057
Interaction								0.1829

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	30 (39.0)	NR (2.2, NE)	70	47 (67.1)	0.5 (0.4, 1.2)	0.362 (0.226, 0.579)	<0.0001
>= 65 Years	62	28 (45.2)	7.7 (2.8, 15.8)	59	37 (62.7)	1.0 (0.3, 3.0)	0.383 (0.227, 0.646)	0.0002
Interaction								0.6404
Gender								
Male	118	51 (43.2)	7.7 (2.9, NE)	106	73 (68.9)	0.5 (0.4, 1.2)	0.360 (0.248, 0.522)	<0.0001
Female	21	7 (33.3)	NR (2.1, NE)	23	11 (47.8)	NR (0.3, NE)	0.493 (0.190, 1.279)	0.1329
Interaction								0.6001

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	45 (43.3)	7.6 (2.8, NE)	101	66 (65.3)	0.7 (0.5, 1.4)	0.383 (0.259, 0.568)	<0.0001
Non-Smoker	35	13 (37.1)	9.2 (2.1, NE)	28	18 (64.3)	0.5 (0.3, NE)	0.356 (0.170, 0.745)	0.0032
Interaction								0.8213
ICC Options								
Paclitaxel	83	27 (32.5)	NR (7.0, NE)	79	45 (57.0)	1.2 (0.5, 3.5)	0.362 (0.222, 0.591)	<0.0001
Docetaxel	56	31 (55.4)	2.1 (1.2, 7.7)	50	39 (78.0)	0.3 (0.3, 0.7)	0.355 (0.217, 0.583)	<0.0001
Interaction								0.9336

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	13 (30.2)	15.8 (9.2, NE)	37	22 (59.5)	0.7 (0.3, NE)	0.307 (0.149, 0.630)	0.0005
1	96	45 (46.9)	4.4 (2.1, 9.7)	92	62 (67.4)	0.5 (0.4, 1.2)	0.408 (0.275, 0.607)	<0.0001
Interaction								0.3754
Region #1								
Asia	103	52 (50.5)	3.5 (2.1, 9.2)	99	74 (74.7)	0.5 (0.3, 0.5)	0.339 (0.233, 0.492)	<0.0001
Europe/North America	36	6 (16.7)	NR (NE, NE)	30	10 (33.3)	NR (3.0, NE)	0.412 (0.149, 1.139)	0.0757
Interaction								0.8052

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	41 (52.6)	2.8 (2.0, 7.7)	76	58 (76.3)	0.4 (0.3, 0.7)	0.368 (0.243, 0.559)	<0.0001
Japan	25	11 (44.0)	4.4 (2.8, NE)	23	16 (69.6)	0.5 (0.3, 1.7)	0.217 (0.084, 0.561)	0.0004
Europe/North America	36	6 (16.7)	NR (NE, NE)	30	10 (33.3)	NR (3.0, NE)	0.412 (0.149, 1.139)	0.0757
Interaction								0.8696

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	52 (49.5)	3.5 (2.1, 9.2)	106	77 (72.6)	0.5 (0.3, 0.7)	0.354 (0.244, 0.512)	<0.0001
White	34	6 (17.6)	NR (NE, NE)	23	7 (30.4)	NR (3.0, NE)	0.498 (0.166, 1.489)	0.1990
Interaction								0.6183

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	18 (40.0)	7.6 (3.1, NE)	34	22 (64.7)	0.6 (0.3, 1.5)	0.370 (0.196, 0.699)	0.0012
vCPS < 10%	53	22 (41.5)	9.7 (2.1, NE)	54	34 (63.0)	0.6 (0.3, 3.3)	0.410 (0.236, 0.713)	0.0008
Missing	41	18 (43.9)	9.2 (2.1, NE)	41	28 (68.3)	0.5 (0.3, 1.7)	0.359 (0.190, 0.677)	0.0007
Interaction								0.9639

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	77	8 (10.4)	--	70	1 (1.4)	--	--	--
>= 65 Years	62	5 (8.1)	--	59	2 (3.4)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
Adverse events were classified based on MedDRA v23.0.
System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.
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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Gender								
Male	118	10 (8.5)	NR (NE, NE)	106	3 (2.8)	NR (NE, NE)	2.729 (0.748, 9.961)	0.1118
Female	21	3 (14.3)	NR (2.8, NE)	23	0 (0.0)	NR (NE, NE)	74428493.556 (0.000, NE)	0.1010
Interaction								0.9933

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	10 (9.6)	NR (NE, NE)	101	2 (2.0)	NR (NE, NE)	4.156 (0.905, 19.089)	0.0464
Non-Smoker	35	3 (8.6)	NR (NE, NE)	28	1 (3.6)	NR (NE, NE)	2.217 (0.230, 21.341)	0.4794
Interaction								0.6609
ICC Options								
Paclitaxel	83	8 (9.6)	NR (NE, NE)	79	2 (2.5)	NR (NE, NE)	3.484 (0.738, 16.453)	0.0922
Docetaxel	56	5 (8.9)	NR (NE, NE)	50	1 (2.0)	NR (NE, NE)	3.683 (0.426, 31.829)	0.2040
Interaction								0.9165

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	4 (9.3)	NR (NE, NE)	37	0 (0.0)	NR (NE, NE)	22891617.579 (0.000, NE)	0.0846
1	96	9 (9.4)	NR (NE, NE)	92	3 (3.3)	NR (NE, NE)	2.590 (0.697, 9.622)	0.1391
Interaction								0.9909

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Region #1								
Asia	103	10 (9.7)	NR (NE, NE)	99	3 (3.0)	NR (NE, NE)	2.833 (0.776, 10.342)	0.0981
Europe/North America	36	3 (8.3)	NR (NE, NE)	30	0 (0.0)	NR (NE, NE)	61821321.059 (0.000, NE)	0.1359
Interaction								0.9920

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	8 (10.3)	NR (NE, NE)	76	3 (3.9)	NR (NE, NE)	2.307 (0.609, 8.743)	0.2031
Japan	25	2 (8.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	64906194.937 (0.000, NE)	0.2144
Europe/North America	36	3 (8.3)	NR (NE, NE)	30	0 (0.0)	NR (NE, NE)	61821321.059 (0.000, NE)	0.1359
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	10 (9.5)	NR (NE, NE)	106	3 (2.8)	NR (NE, NE)	2.987 (0.818, 10.906)	0.0809
White	34	3 (8.8)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	54573131.189 (0.000, NE)	0.1700
Interaction								0.9929

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	5 (11.1)	--	34	1 (2.9)	--	--	--
vCPS < 10%	53	3 (5.7)	--	54	1 (1.9)	--	--	--
Missing	41	5 (12.2)	--	41	1 (2.4)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	77	2 (2.6)	--	70	3 (4.3)	--	--	--
>= 65 Years	62	1 (1.6)	--	59	7 (11.9)	--	--	--
Interaction								--
Gender								
Male	118	2 (1.7)	NR (NE, NE)	106	9 (8.5)	NR (NE, NE)	0.186 (0.040, 0.860)	0.0153
Female	21	1 (4.8)	NR (NE, NE)	23	1 (4.3)	NR (NE, NE)	1.047 (0.065, 16.744)	0.9743
Interaction								0.2665

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Smoking Status								
Former/Current Smoker	104	3 (2.9)	NR (NE, NE)	101	9 (8.9)	NR (NE, NE)	0.302 (0.082, 1.118)	0.0558
Non-Smoker	35	0 (0.0)	NR (NE, NE)	28	1 (3.6)	NR (NE, NE)	0.000 (0.000, NE)	0.2618
Interaction								0.9930
ICC Options								
Paclitaxel	83	1 (1.2)	--	79	4 (5.1)	--	--	--
Docetaxel	56	2 (3.6)	--	50	6 (12.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	1 (2.3)	--	37	3 (8.1)	--	--	--
1	96	2 (2.1)	--	92	7 (7.6)	--	--	--
Interaction								--
Region #1								
Asia	103	2 (1.9)	--	99	6 (6.1)	--	--	--
Europe/North America	36	1 (2.8)	--	30	4 (13.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

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Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Region #2								
Asia (excluding Japan)	78	2 (2.6)	--	76	4 (5.3)	--	--	--
Japan	25	0 (0.0)	--	23	2 (8.7)	--	--	--
Europe/North America	36	1 (2.8)	--	30	4 (13.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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Any TEAE: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	2 (1.9)	--	106	7 (6.6)	--	--	--
White	34	1 (2.9)	--	23	3 (13.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Baseline PD-L1 Status								
vCPS >= 10%	45	1 (2.2)	--	34	2 (5.9)	--	--	--
vCPS < 10%	53	2 (3.8)	--	54	6 (11.1)	--	--	--
Missing	41	0 (0.0)	--	41	2 (4.9)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	77	1 (1.3)	NR (NE, NE)	70	34 (48.6)	2.4 (0.5, NE)	0.019 (0.003, 0.138)	<0.0001
>= 65 Years	62	0 (0.0)	NR (NE, NE)	59	21 (35.6)	NR (2.8, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9857
Gender								
Male	118	0 (0.0)	NR (NE, NE)	106	48 (45.3)	3.0 (1.0, NE)	0.000 (0.000, NE)	<0.0001
Female	21	1 (4.8)	NR (NE, NE)	23	7 (30.4)	NR (0.5, NE)	0.137 (0.017, 1.114)	0.0288
Interaction								0.9846

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	1 (1.0)	NR (NE, NE)	101	44 (43.6)	3.0 (1.2, NE)	0.016 (0.002, 0.116)	<0.0001
Non-Smoker	35	0 (0.0)	NR (NE, NE)	28	11 (39.3)	NR (0.5, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9888
ICC Options								
Paclitaxel	83	1 (1.2)	NR (NE, NE)	79	30 (38.0)	NR (2.4, NE)	0.025 (0.003, 0.181)	<0.0001
Docetaxel	56	0 (0.0)	NR (NE, NE)	50	25 (50.0)	2.8 (0.3, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9860

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	1 (2.3)	NR (NE, NE)	37	18 (48.6)	2.4 (0.5, NE)	0.036 (0.005, 0.273)	<0.0001
1	96	0 (0.0)	NR (NE, NE)	92	37 (40.2)	NR (1.4, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9873
Region #1								
Asia	103	0 (0.0)	NR (NE, NE)	99	52 (52.5)	1.2 (0.5, NE)	0.000 (0.000, NE)	<0.0001
Europe/North America	36	1 (2.8)	NR (NE, NE)	30	3 (10.0)	NR (NE, NE)	0.270 (0.028, 2.598)	0.2223
Interaction								0.9869

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	0 (0.0)	NR (NE, NE)	76	39 (51.3)	1.4 (0.5, NE)	0.000 (0.000, NE)	<0.0001
Japan	25	0 (0.0)	NR (NE, NE)	23	13 (56.5)	0.8 (0.5, NE)	0.000 (0.000, NE)	<0.0001
Europe/North America	36	1 (2.8)	NR (NE, NE)	30	3 (10.0)	NR (NE, NE)	0.270 (0.028, 2.598)	0.2223
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	0 (0.0)	NR (NE, NE)	106	53 (50.0)	2.4 (0.7, NE)	0.000 (0.000, NE)	<0.0001
White	34	1 (2.9)	NR (NE, NE)	23	2 (8.7)	NR (NE, NE)	0.337 (0.031, 3.712)	0.3476
Interaction								0.9859

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Baseline PD-L1 Status								
vCPS >= 10%	45	0 (0.0)	NR (NE, NE)	34	16 (47.1)	3.0 (0.7, NE)	0.000 (0.000, NE)	<0.0001
vCPS < 10%	53	1 (1.9)	NR (NE, NE)	54	19 (35.2)	NR (2.4, NE)	0.042 (0.006, 0.318)	<0.0001
Missing	41	0 (0.0)	NR (NE, NE)	41	20 (48.8)	1.2 (0.5, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	77	1 (1.3)	NR (NE, NE)	70	32 (45.7)	NR (0.5, NE)	0.022 (0.003, 0.160)	<0.0001
>= 65 Years	62	3 (4.8)	NR (NE, NE)	59	16 (27.1)	NR (NE, NE)	0.154 (0.045, 0.530)	0.0006
Interaction								0.1101
Gender								
Male	118	2 (1.7)	NR (NE, NE)	106	42 (39.6)	NR (NE, NE)	0.034 (0.008, 0.140)	<0.0001
Female	21	2 (9.5)	NR (NE, NE)	23	6 (26.1)	NR (NE, NE)	0.336 (0.068, 1.666)	0.1554
Interaction								0.0406

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	2 (1.9)	NR (NE, NE)	101	37 (36.6)	NR (NE, NE)	0.042 (0.010, 0.175)	<0.0001
Non-Smoker	35	2 (5.7)	NR (NE, NE)	28	11 (39.3)	NR (0.5, NE)	0.121 (0.027, 0.548)	0.0009
Interaction								0.3418
ICC Options								
Paclitaxel	83	0 (0.0)	NR (NE, NE)	79	21 (26.6)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Docetaxel	56	4 (7.1)	NR (NE, NE)	50	27 (54.0)	0.8 (0.3, NE)	0.091 (0.031, 0.262)	<0.0001
Interaction								0.9852

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	43	2 (4.7)	NR (NE, NE)	37	14 (37.8)	NR (0.8, NE)	0.097 (0.022, 0.430)	0.0001
1	96	2 (2.1)	NR (NE, NE)	92	34 (37.0)	NR (NE, NE)	0.046 (0.011, 0.193)	<0.0001
Interaction								0.4331
Region #1								
Asia	103	4 (3.9)	NR (NE, NE)	99	47 (47.5)	NR (0.5, NE)	0.060 (0.022, 0.168)	<0.0001
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	1 (3.3)	NR (NE, NE)	0.000 (0.000, NE)	0.2733
Interaction								0.9910

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	3 (3.8)	NR (NE, NE)	76	35 (46.1)	NR (0.5, NE)	0.061 (0.018, 0.199)	<0.0001
Japan	25	1 (4.0)	NR (NE, NE)	23	12 (52.2)	0.8 (0.5, NE)	0.060 (0.008, 0.464)	0.0002
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	1 (3.3)	NR (NE, NE)	0.000 (0.000, NE)	0.2733
Interaction								0.9996

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	4 (3.8)	NR (NE, NE)	106	48 (45.3)	NR (0.5, NE)	0.063 (0.023, 0.175)	<0.0001
White	34	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9986

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	2 (4.4)	NR (NE, NE)	34	10 (29.4)	NR (NE, NE)	0.131 (0.029, 0.601)	0.0019
vCPS < 10%	53	2 (3.8)	NR (NE, NE)	54	18 (33.3)	NR (NE, NE)	0.084 (0.019, 0.370)	<0.0001
Missing	41	0 (0.0)	NR (NE, NE)	41	20 (48.8)	NR (0.3, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9476

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	36 (46.8)	4.9 (2.0, NE)	70	38 (54.3)	1.9 (1.0, 6.6)	0.681 (0.428, 1.085)	0.0987
>= 65 Years	62	23 (37.1)	9.0 (4.1, NE)	59	29 (49.2)	3.5 (1.2, NE)	0.519 (0.292, 0.924)	0.0224
Interaction								0.6081
Gender								
Male	118	52 (44.1)	8.6 (3.6, 13.8)	106	56 (52.8)	2.6 (1.3, 5.7)	0.629 (0.427, 0.928)	0.0170
Female	21	7 (33.3)	NR (1.0, NE)	23	11 (47.8)	2.8 (0.3, NE)	0.608 (0.235, 1.572)	0.2931
Interaction								0.6282

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	48 (46.2)	8.3 (2.3, NE)	101	53 (52.5)	2.6 (1.2, 6.6)	0.705 (0.474, 1.050)	0.0803
Non-Smoker	35	11 (31.4)	9.0 (3.6, NE)	28	14 (50.0)	4.8 (0.5, NE)	0.375 (0.160, 0.879)	0.0179
Interaction								0.3235
ICC Options								
Paclitaxel	83	28 (33.7)	NR (8.3, NE)	79	36 (45.6)	4.8 (2.3, NE)	0.607 (0.366, 1.007)	0.0491
Docetaxel	56	31 (55.4)	3.7 (1.4, 9.0)	50	31 (62.0)	1.2 (0.5, 3.7)	0.549 (0.326, 0.926)	0.0198
Interaction								0.9603

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	11 (25.6)	NR (8.6, NE)	37	20 (54.1)	4.8 (0.7, 6.6)	0.272 (0.124, 0.599)	0.0005
1	96	48 (50.0)	3.6 (2.0, 9.0)	92	47 (51.1)	2.3 (1.2, NE)	0.808 (0.537, 1.216)	0.2981
Interaction								0.0312
Region #1								
Asia	103	44 (42.7)	9.0 (3.4, NE)	99	55 (55.6)	1.4 (0.7, 5.7)	0.551 (0.367, 0.826)	0.0030
Europe/North America	36	15 (41.7)	8.6 (1.4, NE)	30	12 (40.0)	4.8 (2.8, NE)	0.880 (0.399, 1.945)	0.7504
Interaction								0.1177

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	38 (48.7)	3.7 (2.0, NE)	76	44 (57.9)	1.2 (0.6, 3.5)	0.634 (0.409, 0.984)	0.0376
Japan	25	6 (24.0)	NR (10.2, NE)	23	11 (47.8)	NR (0.7, NE)	0.258 (0.082, 0.817)	0.0122
Europe/North America	36	15 (41.7)	8.6 (1.4, NE)	30	12 (40.0)	4.8 (2.8, NE)	0.880 (0.399, 1.945)	0.7504
Interaction								0.1618

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	45 (42.9)	9.0 (3.4, NE)	106	56 (52.8)	1.7 (1.2, 5.7)	0.599 (0.401, 0.896)	0.0104
White	34	14 (41.2)	8.6 (1.4, NE)	23	11 (47.8)	4.8 (2.6, NE)	0.707 (0.310, 1.613)	0.4018
Interaction								0.4176

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	16 (35.6)	13.8 (4.1, NE)	34	22 (64.7)	1.0 (0.3, NE)	0.312 (0.157, 0.619)	0.0003
vCPS < 10%	53	29 (54.7)	3.7 (1.4, 9.0)	54	22 (40.7)	4.8 (2.6, NE)	1.189 (0.676, 2.090)	0.5439
Missing	41	14 (34.1)	NR (2.3, NE)	41	23 (56.1)	1.4 (0.6, NE)	0.499 (0.256, 0.972)	0.0349
Interaction								0.0031

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	77	20 (26.0)	NR (9.0, NE)	70	19 (27.1)	NR (3.7, NE)	0.787 (0.418, 1.483)	0.4549
>= 65 Years	62	7 (11.3)	NR (NE, NE)	59	20 (33.9)	5.7 (3.5, NE)	0.245 (0.101, 0.597)	0.0008
Interaction								0.0395
Gender								
Male	118	25 (21.2)	NR (NE, NE)	106	33 (31.1)	6.6 (5.7, NE)	0.532 (0.313, 0.902)	0.0169
Female	21	2 (9.5)	NR (NE, NE)	23	6 (26.1)	NR (2.8, NE)	0.350 (0.071, 1.735)	0.1785
Interaction								0.4678

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Smoking Status								
Former/Current Smoker	104	25 (24.0)	NR (9.0, NE)	101	35 (34.7)	6.6 (3.5, NE)	0.538 (0.319, 0.907)	0.0177
Non-Smoker	35	2 (5.7)	NR (NE, NE)	28	4 (14.3)	NR (5.7, NE)	0.338 (0.062, 1.855)	0.1903
Interaction								0.6140
ICC Options								
Paclitaxel	83	15 (18.1)	NR (NE, NE)	79	23 (29.1)	6.6 (5.7, NE)	0.511 (0.265, 0.985)	0.0406
Docetaxel	56	12 (21.4)	NR (9.0, NE)	50	16 (32.0)	NR (3.2, NE)	0.478 (0.221, 1.033)	0.0534
Interaction								0.9690

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	6 (14.0)	NR (NE, NE)	37	12 (32.4)	6.6 (3.7, NE)	0.293 (0.106, 0.808)	0.0121
1	96	21 (21.9)	NR (9.0, NE)	92	27 (29.3)	NR (3.5, NE)	0.627 (0.353, 1.114)	0.1059
Interaction								0.2695
Region #1								
Asia	103	18 (17.5)	NR (NE, NE)	99	28 (28.3)	NR (5.7, NE)	0.499 (0.274, 0.907)	0.0196
Europe/North America	36	9 (25.0)	NR (4.9, NE)	30	11 (36.7)	5.7 (2.8, NE)	0.520 (0.207, 1.304)	0.1547
Interaction								0.6428

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	17 (21.8)	NR (9.0, NE)	76	23 (30.3)	NR (5.7, NE)	0.595 (0.316, 1.118)	0.1010
Japan	25	1 (4.0)	NR (NE, NE)	23	5 (21.7)	NR (NE, NE)	0.179 (0.021, 1.537)	0.0740
Europe/North America	36	9 (25.0)	NR (4.9, NE)	30	11 (36.7)	5.7 (2.8, NE)	0.520 (0.207, 1.304)	0.1547
Interaction								0.3958

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	18 (17.1)	NR (NE, NE)	106	29 (27.4)	NR (5.7, NE)	0.507 (0.280, 0.918)	0.0219
White	34	9 (26.5)	NR (4.9, NE)	23	10 (43.5)	6.6 (2.6, NE)	0.470 (0.184, 1.200)	0.1046
Interaction								0.8833

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	7 (15.6)	NR (NE, NE)	34	13 (38.2)	6.6 (0.7, NE)	0.299 (0.118, 0.758)	0.0068
vCPS < 10%	53	18 (34.0)	9.0 (3.9, NE)	54	14 (25.9)	NR (3.7, NE)	1.099 (0.540, 2.240)	0.7929
Missing	41	2 (4.9)	NR (NE, NE)	41	12 (29.3)	NR (3.5, NE)	0.144 (0.032, 0.645)	0.0032
Interaction								0.0060

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Musculoskeletal and connective tissue disorders / PT - Myalgia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	77	3 (3.9)	NR (NE, NE)	70	7 (10.0)	NR (NE, NE)	0.374 (0.097, 1.448)	0.1370
>= 65 Years	62	1 (1.6)	NR (NE, NE)	59	7 (11.9)	NR (NE, NE)	0.111 (0.013, 0.915)	0.0141
Interaction								0.3906
Gender								
Male	118	4 (3.4)	NR (NE, NE)	106	12 (11.3)	NR (NE, NE)	0.268 (0.086, 0.835)	0.0146
Female	21	0 (0.0)	NR (NE, NE)	23	2 (8.7)	NR (NE, NE)	0.000 (0.000, NE)	0.1718
Interaction								0.9932

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Musculoskeletal and connective tissue disorders / PT - Myalgia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	4 (3.8)	NR (NE, NE)	101	14 (13.9)	NR (NE, NE)	0.243 (0.079, 0.745)	0.0072
Non-Smoker	35	0 (0.0)	NR (NE, NE)	28	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9995
ICC Options								
Paclitaxel	83	4 (4.8)	NR (NE, NE)	79	11 (13.9)	NR (NE, NE)	0.302 (0.095, 0.959)	0.0309
Docetaxel	56	0 (0.0)	NR (NE, NE)	50	3 (6.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0631
Interaction								0.9899

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Musculoskeletal and connective tissue disorders / PT - Myalgia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	0 (0.0)	NR (NE, NE)	37	2 (5.4)	NR (NE, NE)	0.000 (0.000, NE)	0.1248
1	96	4 (4.2)	NR (NE, NE)	92	12 (13.0)	NR (NE, NE)	0.282 (0.090, 0.881)	0.0198
Interaction								0.9909
Region #1								
Asia	103	4 (3.9)	NR (NE, NE)	99	14 (14.1)	NR (NE, NE)	0.241 (0.079, 0.737)	0.0066
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9995

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Musculoskeletal and connective tissue disorders / PT - Myalgia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	4 (5.1)	NR (NE, NE)	76	11 (14.5)	NR (NE, NE)	0.313 (0.099, 0.989)	0.0357
Japan	25	0 (0.0)	NR (NE, NE)	23	3 (13.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0648
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Musculoskeletal and connective tissue disorders / PT - Myalgia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	105	4 (3.8)	NR (NE, NE)	106	14 (13.2)	NR (NE, NE)	0.255 (0.083, 0.780)	0.0096
White	34	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9995

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
Adverse events were classified based on MedDRA v23.0.
System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.
Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.
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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Musculoskeletal and connective tissue disorders / PT - Myalgia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Baseline PD-L1 Status								
vCPS >= 10%	45	2 (4.4)	--	34	4 (11.8)	--	--	--
vCPS < 10%	53	2 (3.8)	--	54	6 (11.1)	--	--	--
Missing	41	0 (0.0)	--	41	4 (9.8)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Neoplasms benign, malignant and unspecified (incl cysts and polyps)

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	5 (6.5)	NR (NE, NE)	70	2 (2.9)	NR (NE, NE)	2.263 (0.439, 11.663)	0.3157
>= 65 Years	62	9 (14.5)	NR (NE, NE)	59	2 (3.4)	NR (NE, NE)	4.233 (0.914, 19.613)	0.0446
Interaction								0.5608
Gender								
Male	118	11 (9.3)	NR (NE, NE)	106	2 (1.9)	NR (NE, NE)	4.722 (1.046, 21.315)	0.0259
Female	21	3 (14.3)	NR (NE, NE)	23	2 (8.7)	NR (NE, NE)	1.795 (0.300, 10.757)	0.5158
Interaction								0.3976

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Neoplasms benign, malignant and unspecified (incl cysts and polyps)

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	11 (10.6)	NR (NE, NE)	101	3 (3.0)	NR (NE, NE)	3.407 (0.949, 12.229)	0.0455
Non-Smoker	35	3 (8.6)	NR (NE, NE)	28	1 (3.6)	NR (NE, NE)	2.447 (0.254, 23.540)	0.4231
Interaction								0.7977
ICC Options								
Paclitaxel	83	9 (10.8)	NR (NE, NE)	79	3 (3.8)	NR (NE, NE)	2.890 (0.782, 10.685)	0.0953
Docetaxel	56	5 (8.9)	NR (NE, NE)	50	1 (2.0)	NR (NE, NE)	4.017 (0.468, 34.460)	0.1700
Interaction								0.7889

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Neoplasms benign, malignant and unspecified (incl cysts and polyps)

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	3 (7.0)	NR (NE, NE)	37	1 (2.7)	NR (NE, NE)	2.716 (0.282, 26.118)	0.3674
1	96	11 (11.5)	NR (NE, NE)	92	3 (3.3)	NR (NE, NE)	3.405 (0.949, 12.216)	0.0453
Interaction								0.8306
Region #1								
Asia	103	8 (7.8)	NR (NE, NE)	99	2 (2.0)	NR (NE, NE)	3.577 (0.758, 16.878)	0.0854
Europe/North America	36	6 (16.7)	NR (NE, NE)	30	2 (6.7)	NR (NE, NE)	2.816 (0.568, 13.971)	0.1856
Interaction								0.8181

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Neoplasms benign, malignant and unspecified (incl cysts and polyps)

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	4 (5.1)	--	76	1 (1.3)	--	--	--
Japan	25	4 (16.0)	--	23	1 (4.3)	--	--	--
Europe/North America	36	6 (16.7)	--	30	2 (6.7)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Neoplasms benign, malignant and unspecified (incl cysts and polyps)

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	8 (7.6)	NR (NE, NE)	106	2 (1.9)	NR (NE, NE)	3.771 (0.799, 17.795)	0.0716
White	34	6 (17.6)	NR (NE, NE)	23	2 (8.7)	NR (NE, NE)	2.302 (0.464, 11.423)	0.2939
Interaction								0.6518

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Neoplasms benign, malignant and unspecified (incl cysts and polyps)

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Baseline PD-L1 Status								
vCPS >= 10%	45	6 (13.3)	--	34	1 (2.9)	--	--	--
vCPS < 10%	53	4 (7.5)	--	54	1 (1.9)	--	--	--
Missing	41	4 (9.8)	--	41	2 (4.9)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Nervous system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	13 (16.9)	NR (17.8, NE)	70	23 (32.9)	9.7 (3.5, NE)	0.375 (0.186, 0.758)	0.0044
>= 65 Years	62	8 (12.9)	NR (NE, NE)	59	20 (33.9)	NR (2.4, NE)	0.267 (0.115, 0.616)	0.0009
Interaction								0.4878
Gender								
Male	118	16 (13.6)	NR (17.8, NE)	106	32 (30.2)	9.7 (3.5, NE)	0.305 (0.164, 0.570)	<0.0001
Female	21	5 (23.8)	NR (3.5, NE)	23	11 (47.8)	2.4 (0.8, NE)	0.400 (0.138, 1.160)	0.0787
Interaction								0.7581

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Nervous system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	14 (13.5)	NR (NE, NE)	101	32 (31.7)	9.7 (3.5, NE)	0.316 (0.167, 0.597)	0.0002
Non-Smoker	35	7 (20.0)	17.8 (6.2, NE)	28	11 (39.3)	NR (0.9, NE)	0.362 (0.139, 0.940)	0.0293
Interaction								0.7893
ICC Options								
Paclitaxel	83	13 (15.7)	NR (NE, NE)	79	36 (45.6)	2.8 (1.4, NE)	0.230 (0.121, 0.439)	<0.0001
Docetaxel	56	8 (14.3)	NR (17.8, NE)	50	7 (14.0)	NR (NE, NE)	0.808 (0.290, 2.252)	0.6831
Interaction								0.0378

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Nervous system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	2 (4.7)	NR (NE, NE)	37	16 (43.2)	NR (1.0, NE)	0.077 (0.018, 0.338)	<0.0001
1	96	19 (19.8)	NR (17.8, NE)	92	27 (29.3)	9.7 (3.5, NE)	0.504 (0.278, 0.915)	0.0213
Interaction								0.0088
Region #1								
Asia	103	12 (11.7)	NR (17.8, NE)	99	28 (28.3)	9.7 (3.5, NE)	0.288 (0.144, 0.574)	0.0002
Europe/North America	36	9 (25.0)	NR (3.5, NE)	30	15 (50.0)	2.4 (0.5, NE)	0.337 (0.142, 0.798)	0.0093
Interaction								0.7077

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Nervous system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	11 (14.1)	NR (17.8, NE)	76	19 (25.0)	9.7 (9.7, NE)	0.419 (0.197, 0.890)	0.0196
Japan	25	1 (4.0)	NR (NE, NE)	23	9 (39.1)	2.8 (1.0, NE)	0.060 (0.007, 0.486)	0.0005
Europe/North America	36	9 (25.0)	NR (3.5, NE)	30	15 (50.0)	2.4 (0.5, NE)	0.337 (0.142, 0.798)	0.0093
Interaction								0.1916

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Nervous system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	12 (11.4)	NR (17.8, NE)	106	29 (27.4)	9.7 (3.5, NE)	0.295 (0.148, 0.588)	0.0002
White	34	9 (26.5)	NR (3.5, NE)	23	14 (60.9)	0.7 (0.4, NE)	0.263 (0.110, 0.632)	0.0013
Interaction								0.8673

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Nervous system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	8 (17.8)	NR (NE, NE)	34	9 (26.5)	9.7 (2.7, NE)	0.466 (0.175, 1.238)	0.1168
vCPS < 10%	53	11 (20.8)	17.8 (17.8, NE)	54	17 (31.5)	NR (2.4, NE)	0.489 (0.223, 1.069)	0.0665
Missing	41	2 (4.9)	NR (NE, NE)	41	17 (41.5)	3.5 (1.0, NE)	0.083 (0.019, 0.364)	<0.0001
Interaction								0.0676

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Nervous system disorders / PT - Peripheral sensory neuropathy

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	0 (0.0)	NR (NE, NE)	70	10 (14.3)	NR (9.7, NE)	0.000 (0.000, NE)	0.0002
>= 65 Years	62	1 (1.6)	NR (NE, NE)	59	12 (20.3)	NR (NE, NE)	0.067 (0.009, 0.518)	0.0006
Interaction								0.9924
Gender								
Male	118	0 (0.0)	NR (NE, NE)	106	18 (17.0)	NR (9.7, NE)	0.000 (0.000, NE)	<0.0001
Female	21	1 (4.8)	NR (2.5, NE)	23	4 (17.4)	NR (2.4, NE)	0.234 (0.026, 2.109)	0.1589
Interaction								0.9894

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Nervous system disorders / PT - Peripheral sensory neuropathy

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	1 (1.0)	NR (NE, NE)	101	18 (17.8)	9.7 (9.7, NE)	0.036 (0.005, 0.278)	<0.0001
Non-Smoker	35	0 (0.0)	NR (NE, NE)	28	4 (14.3)	NR (NE, NE)	0.000 (0.000, NE)	0.0199
Interaction								0.9923
ICC Options								
Paclitaxel	83	1 (1.2)	NR (NE, NE)	79	19 (24.1)	9.7 (9.7, NE)	0.036 (0.005, 0.270)	<0.0001
Docetaxel	56	0 (0.0)	NR (NE, NE)	50	3 (6.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0608
Interaction								0.9927

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Nervous system disorders / PT - Peripheral sensory neuropathy

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	0 (0.0)	NR (NE, NE)	37	8 (21.6)	NR (NE, NE)	0.000 (0.000, NE)	0.0010
1	96	1 (1.0)	NR (NE, NE)	92	14 (15.2)	9.7 (9.7, NE)	0.045 (0.006, 0.353)	<0.0001
Interaction								0.9905
Region #1								
Asia	103	0 (0.0)	NR (NE, NE)	99	14 (14.1)	NR (9.7, NE)	0.000 (0.000, NE)	<0.0001
Europe/North America	36	1 (2.8)	NR (NE, NE)	30	8 (26.7)	NR (NE, NE)	0.088 (0.011, 0.709)	0.0040
Interaction								0.9921

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Nervous system disorders / PT - Peripheral sensory neuropathy

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	0 (0.0)	--	76	7 (9.2)	--	--	--
Japan	25	0 (0.0)	--	23	7 (30.4)	--	--	--
Europe/North America	36	1 (2.8)	--	30	8 (26.7)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Nervous system disorders / PT - Peripheral sensory neuropathy

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	0 (0.0)	NR (NE, NE)	106	15 (14.2)	NR (9.7, NE)	0.000 (0.000, NE)	<0.0001
White	34	1 (2.9)	NR (NE, NE)	23	7 (30.4)	NR (2.4, NE)	0.081 (0.010, 0.657)	0.0026
Interaction								0.9892

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Nervous system disorders / PT - Peripheral sensory neuropathy

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	1 (2.2)	NR (NE, NE)	34	3 (8.8)	NR (9.7, NE)	0.183 (0.019, 1.804)	0.1047
vCPS < 10%	53	0 (0.0)	NR (NE, NE)	54	10 (18.5)	NR (NE, NE)	0.000 (0.000, NE)	0.0006
Missing	41	0 (0.0)	NR (NE, NE)	41	9 (22.0)	NR (3.5, NE)	0.000 (0.000, NE)	0.0004
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Skin and subcutaneous tissue disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	20 (26.0)	NR (7.0, NE)	70	26 (37.1)	NR (1.4, NE)	0.616 (0.343, 1.106)	0.0996
>= 65 Years	62	17 (27.4)	NR (9.6, NE)	59	23 (39.0)	5.1 (1.9, NE)	0.557 (0.294, 1.057)	0.0686
Interaction								0.9758
Gender								
Male	118	33 (28.0)	NR (9.6, NE)	106	34 (32.1)	NR (5.1, NE)	0.748 (0.461, 1.213)	0.2354
Female	21	4 (19.0)	NR (2.2, NE)	23	15 (65.2)	1.4 (0.7, 1.9)	0.196 (0.064, 0.596)	0.0014
Interaction								0.0392

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Skin and subcutaneous tissue disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	27 (26.0)	NR (9.6, NE)	101	38 (37.6)	NR (2.4, NE)	0.558 (0.338, 0.920)	0.0198
Non-Smoker	35	10 (28.6)	NR (2.1, NE)	28	11 (39.3)	NR (1.9, NE)	0.679 (0.288, 1.600)	0.3700
Interaction								0.7015
ICC Options								
Paclitaxel	83	23 (27.7)	NR (NE, NE)	79	37 (46.8)	3.0 (1.3, NE)	0.517 (0.307, 0.873)	0.0116
Docetaxel	56	14 (25.0)	10.3 (7.0, NE)	50	12 (24.0)	NR (NE, NE)	0.783 (0.358, 1.712)	0.5374
Interaction								0.2789

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Skin and subcutaneous tissue disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	13 (30.2)	NR (7.0, NE)	37	17 (45.9)	NR (0.7, NE)	0.492 (0.237, 1.021)	0.0509
1	96	24 (25.0)	NR (9.6, NE)	92	32 (34.8)	NR (1.9, NE)	0.623 (0.365, 1.062)	0.0784
Interaction								0.5912
Region #1								
Asia	103	29 (28.2)	NR (9.6, NE)	99	37 (37.4)	NR (1.9, NE)	0.605 (0.370, 0.989)	0.0420
Europe/North America	36	8 (22.2)	NR (NE, NE)	30	12 (40.0)	NR (1.4, NE)	0.523 (0.214, 1.281)	0.1487
Interaction								0.7909

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Skin and subcutaneous tissue disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	23 (29.5)	NR (7.0, NE)	76	24 (31.6)	NR (5.1, NE)	0.822 (0.462, 1.461)	0.5014
Japan	25	6 (24.0)	NR (10.3, NE)	23	13 (56.5)	0.7 (0.5, NE)	0.222 (0.078, 0.629)	0.0020
Europe/North America	36	8 (22.2)	NR (NE, NE)	30	12 (40.0)	NR (1.4, NE)	0.523 (0.214, 1.281)	0.1487
Interaction								0.0940

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Skin and subcutaneous tissue disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	29 (27.6)	NR (9.6, NE)	106	41 (38.7)	5.1 (1.9, NE)	0.569 (0.351, 0.920)	0.0194
White	34	8 (23.5)	NR (NE, NE)	23	8 (34.8)	NR (1.4, NE)	0.660 (0.248, 1.761)	0.4036
Interaction								0.7993

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Skin and subcutaneous tissue disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	10 (22.2)	10.3 (10.3, NE)	34	14 (41.2)	5.1 (1.6, NE)	0.428 (0.189, 0.968)	0.0350
vCPS < 10%	53	22 (41.5)	7.0 (2.1, NE)	54	20 (37.0)	NR (1.4, NE)	1.076 (0.584, 1.980)	0.8143
Missing	41	5 (12.2)	NR (9.6, NE)	41	15 (36.6)	NR (1.9, NE)	0.218 (0.072, 0.658)	0.0029
Interaction								0.0393

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Skin and subcutaneous tissue disorders / PT - Alopecia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	0 (0.0)	NR (NE, NE)	70	18 (25.7)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
>= 65 Years	62	0 (0.0)	NR (NE, NE)	59	16 (27.1)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								1.0000
Gender								
Male	118	0 (0.0)	NR (NE, NE)	106	22 (20.8)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Female	21	0 (0.0)	NR (NE, NE)	23	12 (52.2)	1.9 (0.9, NE)	0.000 (0.000, NE)	0.0002
Interaction								0.9997

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Skin and subcutaneous tissue disorders / PT - Alopecia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	0 (0.0)	NR (NE, NE)	101	27 (26.7)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Non-Smoker	35	0 (0.0)	NR (NE, NE)	28	7 (25.0)	NR (1.9, NE)	0.000 (0.000, NE)	0.0011
Interaction								0.9999
ICC Options								
Paclitaxel	83	0 (0.0)	NR (NE, NE)	79	24 (30.4)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Docetaxel	56	0 (0.0)	NR (NE, NE)	50	10 (20.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0002
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

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Any TEAE: SOC - Skin and subcutaneous tissue disorders / PT - Alopecia

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Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	0 (0.0)	NR (NE, NE)	37	13 (35.1)	NR (1.0, NE)	0.000 (0.000, NE)	<0.0001
1	96	0 (0.0)	NR (NE, NE)	92	21 (22.8)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9998
Region #1								
Asia	103	0 (0.0)	NR (NE, NE)	99	25 (25.3)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	9 (30.0)	NR (2.4, NE)	0.000 (0.000, NE)	0.0005
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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Any TEAE: SOC - Skin and subcutaneous tissue disorders / PT - Alopecia

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Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	0 (0.0)	NR (NE, NE)	76	14 (18.4)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Japan	25	0 (0.0)	NR (NE, NE)	23	11 (47.8)	NR (0.7, NE)	0.000 (0.000, NE)	<0.0001
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	9 (30.0)	NR (2.4, NE)	0.000 (0.000, NE)	0.0005
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

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Any TEAE: SOC - Skin and subcutaneous tissue disorders / PT - Alopecia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	0 (0.0)	NR (NE, NE)	106	27 (25.5)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
White	34	0 (0.0)	NR (NE, NE)	23	7 (30.4)	NR (2.4, NE)	0.000 (0.000, NE)	0.0007
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Skin and subcutaneous tissue disorders / PT - Alopecia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	0 (0.0)	NR (NE, NE)	34	10 (29.4)	NR (1.9, NE)	0.000 (0.000, NE)	<0.0001
vCPS < 10%	53	0 (0.0)	NR (NE, NE)	54	16 (29.6)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Missing	41	0 (0.0)	NR (NE, NE)	41	8 (19.5)	NR (NE, NE)	0.000 (0.000, NE)	0.0024
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	14 (8.9)	NR (17.5, NE)	149	34 (22.8)	NR (NE, NE)	0.275 (0.144, 0.524)	<0.0001
>= 65 Years	98	4 (4.1)	NR (NE, NE)	91	22 (24.2)	9.2 (NE, NE)	0.121 (0.039, 0.374)	<0.0001
Interaction								0.1671
Gender								
Male	216	17 (7.9)	NR (NE, NE)	204	49 (24.0)	NR (9.2, NE)	0.235 (0.133, 0.416)	<0.0001
Female	39	1 (2.6)	NR (NE, NE)	36	7 (19.4)	NR (NE, NE)	0.120 (0.015, 0.978)	0.0173
Interaction								0.4398

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	15 (8.0)	NR (NE, NE)	183	41 (22.4)	NR (9.2, NE)	0.257 (0.139, 0.475)	<0.0001
Non-Smoker	68	3 (4.4)	NR (NE, NE)	57	15 (26.3)	NR (NE, NE)	0.128 (0.036, 0.448)	0.0002
Interaction								0.2770

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	4 (4.8)	NR (NE, NE)	79	12 (15.2)	NR (NE, NE)	0.280 (0.090, 0.870)	0.0186
Docetaxel	56	9 (16.1)	NR (7.6, NE)	50	19 (38.0)	NR (1.3, NE)	0.301 (0.134, 0.676)	0.0018
Irinotecan	116	5 (4.3)	NR (17.5, NE)	111	25 (22.5)	NR (9.2, NE)	0.113 (0.039, 0.329)	<0.0001
Interaction								0.5256

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	2 (3.2)	NR (17.5, NE)	57	11 (19.3)	NR (9.2, NE)	0.059 (0.008, 0.464)	0.0003
1	192	16 (8.3)	NR (NE, NE)	183	45 (24.6)	NR (NE, NE)	0.268 (0.151, 0.476)	<0.0001
Interaction								0.3689
Region #1								
Asia	201	15 (7.5)	NR (NE, NE)	191	44 (23.0)	NR (NE, NE)	0.233 (0.127, 0.429)	<0.0001
Europe/North America	54	3 (5.6)	NR (NE, NE)	49	12 (24.5)	NR (9.2, NE)	0.179 (0.050, 0.642)	0.0031
Interaction								0.7568

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	14 (8.0)	NR (NE, NE)	168	39 (23.2)	NR (NE, NE)	0.246 (0.130, 0.465)	<0.0001
Japan	25	1 (4.0)	NR (NE, NE)	23	5 (21.7)	NR (2.8, NE)	0.146 (0.017, 1.262)	0.0427
Europe/North America	54	3 (5.6)	NR (NE, NE)	49	12 (24.5)	NR (9.2, NE)	0.179 (0.050, 0.642)	0.0031
Interaction								0.8103

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	15 (7.4)	NR (NE, NE)	198	45 (22.7)	NR (NE, NE)	0.236 (0.129, 0.433)	<0.0001
White	52	3 (5.8)	NR (NE, NE)	42	11 (26.2)	NR (9.2, NE)	0.173 (0.048, 0.625)	0.0025
Interaction								0.6975

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	7 (8.8)	NR (17.5, NE)	60	16 (26.7)	NR (NE, NE)	0.205 (0.079, 0.530)	0.0003
vCPS < 10%	100	9 (9.0)	NR (NE, NE)	119	32 (26.9)	NR (9.2, NE)	0.252 (0.119, 0.533)	0.0001
Missing	75	2 (2.7)	NR (NE, NE)	61	8 (13.1)	NR (NE, NE)	0.181 (0.038, 0.857)	0.0155
Interaction								0.8183

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	12 (7.6)	NR (NE, NE)	149	17 (11.4)	NR (NE, NE)	0.493 (0.229, 1.061)	0.0647
>= 65 Years	98	3 (3.1)	NR (NE, NE)	91	9 (9.9)	9.2 (9.2, NE)	0.218 (0.055, 0.871)	0.0193
Interaction								0.3119
Gender								
Male	216	14 (6.5)	NR (NE, NE)	204	22 (10.8)	NR (9.2, NE)	0.439 (0.219, 0.880)	0.0171
Female	39	1 (2.6)	NR (NE, NE)	36	4 (11.1)	NR (NE, NE)	0.219 (0.024, 1.958)	0.1354
Interaction								0.4661

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	12 (6.4)	NR (NE, NE)	183	19 (10.4)	NR (9.2, NE)	0.451 (0.212, 0.957)	0.0333
Non-Smoker	68	3 (4.4)	NR (NE, NE)	57	7 (12.3)	NR (NE, NE)	0.290 (0.074, 1.137)	0.0593
Interaction								0.5440

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	4 (4.8)	NR (NE, NE)	79	6 (7.6)	NR (NE, NE)	0.580 (0.164, 2.058)	0.3932
Docetaxel	56	6 (10.7)	NR (NE, NE)	50	4 (8.0)	NR (NE, NE)	1.130 (0.317, 4.034)	0.8505
Irinotecan	116	5 (4.3)	NR (17.5, NE)	111	16 (14.4)	NR (9.2, NE)	0.170 (0.055, 0.523)	0.0005
Interaction								0.1267

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	1 (1.6)	NR (17.5, NE)	57	3 (5.3)	NR (9.2, NE)	0.000 (0.000, NE)	0.0169
1	192	14 (7.3)	NR (NE, NE)	183	23 (12.6)	NR (NE, NE)	0.473 (0.242, 0.924)	0.0248
Interaction								0.5946
Region #1								
Asia	201	12 (6.0)	NR (NE, NE)	191	20 (10.5)	NR (NE, NE)	0.435 (0.208, 0.906)	0.0223
Europe/North America	54	3 (5.6)	NR (NE, NE)	49	6 (12.2)	NR (9.2, NE)	0.362 (0.088, 1.480)	0.1411
Interaction								0.9220

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	11 (6.3)	NR (NE, NE)	168	17 (10.1)	NR (NE, NE)	0.473 (0.217, 1.031)	0.0541
Japan	25	1 (4.0)	NR (NE, NE)	23	3 (13.0)	NR (2.8, NE)	0.253 (0.026, 2.451)	0.2007
Europe/North America	54	3 (5.6)	NR (NE, NE)	49	6 (12.2)	NR (9.2, NE)	0.362 (0.088, 1.480)	0.1411
Interaction								0.8200

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	12 (5.9)	NR (NE, NE)	198	21 (10.6)	NR (NE, NE)	0.429 (0.207, 0.888)	0.0190
White	52	3 (5.8)	NR (NE, NE)	42	5 (11.9)	NR (9.2, NE)	0.385 (0.090, 1.643)	0.1815
Interaction								0.9979

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	6 (7.5)	NR (17.5, NE)	60	5 (8.3)	NR (NE, NE)	0.610 (0.182, 2.044)	0.4180
vCPS < 10%	100	7 (7.0)	NR (NE, NE)	119	18 (15.1)	NR (9.2, NE)	0.372 (0.154, 0.900)	0.0225
Missing	75	2 (2.7)	NR (NE, NE)	61	3 (4.9)	NR (NE, NE)	0.478 (0.079, 2.892)	0.4111
Interaction								0.7603

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	0 (0.0)	--	149	6 (4.0)	--	--	--
>= 65 Years	98	0 (0.0)	--	91	5 (5.5)	--	--	--
Interaction								--
Gender								
Male	216	0 (0.0)	NR (NE, NE)	204	10 (4.9)	NR (NE, NE)	0.000 (0.000, NE)	0.0006
Female	39	0 (0.0)	NR (NE, NE)	36	1 (2.8)	NR (NE, NE)	0.000 (0.000, NE)	0.2980
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	0 (0.0)	--	183	8 (4.4)	--	--	--
Non-Smoker	68	0 (0.0)	--	57	3 (5.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ICC Options								
Paclitaxel	83	0 (0.0)	--	79	0 (0.0)	--	--	--
Docetaxel	56	0 (0.0)	--	50	8 (16.0)	--	--	--
Irinotecan	116	0 (0.0)	--	111	3 (2.7)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	0 (0.0)	--	57	2 (3.5)	--	--	--
1	192	0 (0.0)	--	183	9 (4.9)	--	--	--
Interaction								--
Region #1								
Asia	201	0 (0.0)	--	191	9 (4.7)	--	--	--
Europe/North America	54	0 (0.0)	--	49	2 (4.1)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	0 (0.0)	--	168	7 (4.2)	--	--	--
Japan	25	0 (0.0)	--	23	2 (8.7)	--	--	--
Europe/North America	54	0 (0.0)	--	49	2 (4.1)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	203	0 (0.0)	--	198	9 (4.5)	--	--	--
White	52	0 (0.0)	--	42	2 (4.8)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Baseline PD-L1 Status								
vCPS >= 10%	80	0 (0.0)	--	60	4 (6.7)	--	--	--
vCPS < 10%	100	0 (0.0)	--	119	3 (2.5)	--	--	--
Missing	75	0 (0.0)	--	61	4 (6.6)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	0 (0.0)	NR (NE, NE)	149	11 (7.4)	NR (NE, NE)	0.000 (0.000, NE)	0.0005
>= 65 Years	98	0 (0.0)	NR (NE, NE)	91	6 (6.6)	NR (NE, NE)	0.000 (0.000, NE)	0.0095
Interaction								1.0000
Gender								
Male	216	0 (0.0)	NR (NE, NE)	204	16 (7.8)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Female	39	0 (0.0)	NR (NE, NE)	36	1 (2.8)	NR (NE, NE)	0.000 (0.000, NE)	0.3042
Interaction								0.9998

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	0 (0.0)	NR (NE, NE)	183	11 (6.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0006
Non-Smoker	68	0 (0.0)	NR (NE, NE)	57	6 (10.5)	NR (NE, NE)	0.000 (0.000, NE)	0.0066
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	0 (0.0)	--	79	1 (1.3)	--	--	--
Docetaxel	56	0 (0.0)	--	50	7 (14.0)	--	--	--
Irinotecan	116	0 (0.0)	--	111	9 (8.1)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	0 (0.0)	NR (NE, NE)	57	4 (7.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0330
1	192	0 (0.0)	NR (NE, NE)	183	13 (7.1)	NR (NE, NE)	0.000 (0.000, NE)	0.0002
Interaction								1.0000
Region #1								
Asia	201	0 (0.0)	NR (NE, NE)	191	16 (8.4)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	0.000 (0.000, NE)	0.2888
Interaction								0.9997

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	0 (0.0)	NR (NE, NE)	168	16 (9.5)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Japan	25	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	0.000 (0.000, NE)	0.2888
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	203	0 (0.0)	NR (NE, NE)	198	16 (8.1)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
White	52	0 (0.0)	NR (NE, NE)	42	1 (2.4)	NR (NE, NE)	0.000 (0.000, NE)	0.2601
Interaction								0.9997

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Baseline PD-L1 Status								
vCPS >= 10%	80	0 (0.0)	NR (NE, NE)	60	6 (10.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0033
vCPS < 10%	100	0 (0.0)	NR (NE, NE)	119	10 (8.4)	NR (NE, NE)	0.000 (0.000, NE)	0.0030
Missing	75	0 (0.0)	NR (NE, NE)	61	1 (1.6)	NR (NE, NE)	0.000 (0.000, NE)	0.2668
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	1 (0.6)	--	149	8 (5.4)	--	--	--
>= 65 Years	98	0 (0.0)	--	91	8 (8.8)	--	--	--
Interaction								--
Gender								
Male	216	1 (0.5)	NR (NE, NE)	204	14 (6.9)	NR (NE, NE)	0.056 (0.007, 0.436)	0.0002
Female	39	0 (0.0)	NR (NE, NE)	36	2 (5.6)	NR (NE, NE)	0.000 (0.000, NE)	0.1435
Interaction								0.9917

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	1 (0.5)	NR (NE, NE)	183	11 (6.0)	NR (NE, NE)	0.071 (0.009, 0.563)	0.0013
Non-Smoker	68	0 (0.0)	NR (NE, NE)	57	5 (8.8)	NR (NE, NE)	0.000 (0.000, NE)	0.0130
Interaction								0.9927

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	0 (0.0)	--	79	5 (6.3)	--	--	--
Docetaxel	56	1 (1.8)	--	50	7 (14.0)	--	--	--
Irinotecan	116	0 (0.0)	--	111	4 (3.6)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	1 (1.6)	NR (NE, NE)	57	4 (7.0)	NR (NE, NE)	0.180 (0.020, 1.653)	0.0894
1	192	0 (0.0)	NR (NE, NE)	183	12 (6.6)	NR (NE, NE)	0.000 (0.000, NE)	0.0003
Interaction								0.9915
Region #1								
Asia	201	1 (0.5)	NR (NE, NE)	191	11 (5.8)	NR (NE, NE)	0.068 (0.009, 0.546)	0.0011
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	5 (10.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0152
Interaction								0.9903

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	1 (0.6)	NR (NE, NE)	168	11 (6.5)	NR (NE, NE)	0.068 (0.008, 0.543)	0.0011
Japan	25	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	5 (10.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0152
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	1 (0.5)	NR (NE, NE)	198	11 (5.6)	NR (NE, NE)	0.070 (0.009, 0.559)	0.0013
White	52	0 (0.0)	NR (NE, NE)	42	5 (11.9)	NR (NE, NE)	0.000 (0.000, NE)	0.0096
Interaction								0.9913

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	0 (0.0)	NR (NE, NE)	60	3 (5.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0416
vCPS < 10%	100	1 (1.0)	NR (NE, NE)	119	10 (8.4)	NR (NE, NE)	0.094 (0.012, 0.756)	0.0065
Missing	75	0 (0.0)	NR (NE, NE)	61	3 (4.9)	NR (NE, NE)	0.000 (0.000, NE)	0.0530
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	25 (15.9)	NR (20.9, NE)	149	28 (18.8)	NR (8.9, NE)	0.605 (0.348, 1.050)	0.0710
>= 65 Years	98	13 (13.3)	NR (NE, NE)	91	17 (18.7)	NR (6.1, NE)	0.569 (0.273, 1.186)	0.1268
Interaction								0.7217
Gender								
Male	216	35 (16.2)	NR (20.9, NE)	204	38 (18.6)	NR (8.9, NE)	0.647 (0.404, 1.034)	0.0663
Female	39	3 (7.7)	NR (NE, NE)	36	7 (19.4)	NR (NE, NE)	0.346 (0.089, 1.342)	0.1077
Interaction								0.2830

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	28 (15.0)	NR (NE, NE)	183	34 (18.6)	NR (8.9, NE)	0.617 (0.372, 1.025)	0.0595
Non-Smoker	68	10 (14.7)	NR (20.9, NE)	57	11 (19.3)	NR (NE, NE)	0.538 (0.220, 1.314)	0.1670
Interaction								0.8965

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	10 (12.0)	NR (NE, NE)	79	9 (11.4)	NR (8.9, NE)	0.909 (0.367, 2.254)	0.8372
Docetaxel	56	8 (14.3)	NR (9.7, NE)	50	5 (10.0)	NR (6.1, NE)	1.075 (0.344, 3.359)	0.9010
Irinotecan	116	20 (17.2)	NR (20.9, NE)	111	31 (27.9)	NR (NE, NE)	0.411 (0.229, 0.738)	0.0021
Interaction								0.1329

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	5 (7.9)	NR (NE, NE)	57	9 (15.8)	NR (8.9, NE)	0.381 (0.126, 1.154)	0.0764
1	192	33 (17.2)	NR (20.9, NE)	183	36 (19.7)	NR (NE, NE)	0.649 (0.400, 1.051)	0.0764
Interaction								0.3806
Region #1								
Asia	201	28 (13.9)	NR (20.9, NE)	191	31 (16.2)	NR (NE, NE)	0.639 (0.378, 1.078)	0.0905
Europe/North America	54	10 (18.5)	NR (NE, NE)	49	14 (28.6)	8.9 (6.1, NE)	0.525 (0.232, 1.190)	0.1164
Interaction								0.7557

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	26 (14.8)	NR (20.9, NE)	168	28 (16.7)	NR (NE, NE)	0.652 (0.377, 1.127)	0.1223
Japan	25	2 (8.0)	NR (NE, NE)	23	3 (13.0)	NR (2.4, NE)	0.525 (0.087, 3.174)	0.4757
Europe/North America	54	10 (18.5)	NR (NE, NE)	49	14 (28.6)	8.9 (6.1, NE)	0.525 (0.232, 1.190)	0.1164
Interaction								0.8871

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	29 (14.3)	NR (20.9, NE)	198	32 (16.2)	NR (NE, NE)	0.664 (0.397, 1.110)	0.1157
White	52	9 (17.3)	NR (NE, NE)	42	13 (31.0)	8.9 (6.1, NE)	0.440 (0.187, 1.037)	0.0536
Interaction								0.4657

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	12 (15.0)	NR (NE, NE)	60	16 (26.7)	NR (8.9, NE)	0.334 (0.155, 0.718)	0.0033
vCPS < 10%	100	17 (17.0)	NR (NE, NE)	119	24 (20.2)	NR (6.1, NE)	0.716 (0.383, 1.338)	0.2924
Missing	75	9 (12.0)	NR (20.9, NE)	61	5 (8.2)	NR (NE, NE)	1.159 (0.377, 3.563)	0.7969
Interaction								0.1922

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	2 (1.3)	--	149	7 (4.7)	--	--	--
>= 65 Years	98	1 (1.0)	--	91	8 (8.8)	--	--	--
Interaction								--
Gender								
Male	216	3 (1.4)	NR (NE, NE)	204	13 (6.4)	NR (NE, NE)	0.191 (0.054, 0.674)	0.0041
Female	39	0 (0.0)	NR (NE, NE)	36	2 (5.6)	NR (NE, NE)	0.000 (0.000, NE)	0.1408
Interaction								0.9900

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	3 (1.6)	NR (NE, NE)	183	11 (6.0)	NR (NE, NE)	0.232 (0.064, 0.834)	0.0147
Non-Smoker	68	0 (0.0)	NR (NE, NE)	57	4 (7.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0283
Interaction								0.9912

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	1 (1.2)	NR (NE, NE)	79	2 (2.5)	NR (NE, NE)	0.459 (0.042, 5.063)	0.5143
Docetaxel	56	0 (0.0)	NR (NE, NE)	50	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Irinotecan	116	2 (1.7)	NR (NE, NE)	111	13 (11.7)	NR (NE, NE)	0.123 (0.028, 0.549)	0.0011
Interaction								0.6502

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	0 (0.0)	NR (NE, NE)	57	2 (3.5)	NR (NE, NE)	0.000 (0.000, NE)	0.1351
1	192	3 (1.6)	NR (NE, NE)	183	13 (7.1)	NR (NE, NE)	0.192 (0.055, 0.676)	0.0042
Interaction								0.9921
Region #1								
Asia	201	3 (1.5)	NR (NE, NE)	191	11 (5.8)	NR (NE, NE)	0.224 (0.062, 0.807)	0.0123
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	4 (8.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0310
Interaction								0.9920

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	3 (1.7)	NR (NE, NE)	168	11 (6.5)	NR (NE, NE)	0.222 (0.062, 0.801)	0.0118
Japan	25	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	4 (8.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0310
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	3 (1.5)	NR (NE, NE)	198	11 (5.6)	NR (NE, NE)	0.232 (0.064, 0.834)	0.0148
White	52	0 (0.0)	NR (NE, NE)	42	4 (9.5)	NR (NE, NE)	0.000 (0.000, NE)	0.0215
Interaction								0.9923

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	1 (1.3)	NR (NE, NE)	60	5 (8.3)	NR (NE, NE)	0.117 (0.014, 1.012)	0.0199
vCPS < 10%	100	2 (2.0)	NR (NE, NE)	119	10 (8.4)	NR (NE, NE)	0.218 (0.048, 0.996)	0.0307
Missing	75	0 (0.0)	NR (NE, NE)	61	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9231

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	9 (5.7)	NR (NE, NE)	149	13 (8.7)	NR (NE, NE)	0.457 (0.187, 1.113)	0.0774
>= 65 Years	98	6 (6.1)	NR (NE, NE)	91	12 (13.2)	NR (NE, NE)	0.315 (0.113, 0.875)	0.0202
Interaction								0.6517
Gender								
Male	216	13 (6.0)	NR (NE, NE)	204	19 (9.3)	NR (NE, NE)	0.423 (0.200, 0.896)	0.0207
Female	39	2 (5.1)	NR (NE, NE)	36	6 (16.7)	NR (2.6, NE)	0.238 (0.047, 1.198)	0.0596
Interaction								0.5163

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	8 (4.3)	NR (NE, NE)	183	17 (9.3)	NR (NE, NE)	0.281 (0.110, 0.715)	0.0045
Non-Smoker	68	7 (10.3)	NR (NE, NE)	57	8 (14.0)	NR (3.7, NE)	0.522 (0.185, 1.470)	0.2112
Interaction								0.4298

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	7 (8.4)	NR (NE, NE)	79	6 (7.6)	NR (NE, NE)	0.834 (0.268, 2.601)	0.7546
Docetaxel	56	4 (7.1)	NR (13.3, NE)	50	5 (10.0)	NR (3.7, NE)	0.539 (0.141, 2.060)	0.3594
Irinotecan	116	4 (3.4)	NR (NE, NE)	111	14 (12.6)	NR (NE, NE)	0.193 (0.062, 0.603)	0.0018
Interaction								0.0993

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	2 (3.2)	NR (NE, NE)	57	4 (7.0)	NR (5.7, NE)	0.156 (0.017, 1.416)	0.0594
1	192	13 (6.8)	NR (NE, NE)	183	21 (11.5)	NR (NE, NE)	0.426 (0.209, 0.865)	0.0153
Interaction								0.7768
Region #1								
Asia	201	10 (5.0)	NR (NE, NE)	191	14 (7.3)	NR (NE, NE)	0.441 (0.186, 1.044)	0.0564
Europe/North America	54	5 (9.3)	NR (NE, NE)	49	11 (22.4)	NR (5.6, NE)	0.348 (0.121, 1.007)	0.0415
Interaction								0.7355

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	8 (4.5)	NR (NE, NE)	168	14 (8.3)	NR (NE, NE)	0.347 (0.137, 0.882)	0.0207
Japan	25	2 (8.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	58857345.823 (0.000, NE)	0.2435
Europe/North America	54	5 (9.3)	NR (NE, NE)	49	11 (22.4)	NR (5.6, NE)	0.348 (0.121, 1.007)	0.0415
Interaction								0.9996

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	10 (4.9)	NR (NE, NE)	198	16 (8.1)	NR (NE, NE)	0.384 (0.165, 0.891)	0.0213
White	52	5 (9.6)	NR (NE, NE)	42	9 (21.4)	NR (5.6, NE)	0.386 (0.129, 1.156)	0.0773
Interaction								0.9325

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	5 (6.3)	NR (NE, NE)	60	8 (13.3)	NR (NE, NE)	0.318 (0.101, 0.998)	0.0393
vCPS < 10%	100	4 (4.0)	NR (13.3, NE)	119	16 (13.4)	NR (5.7, NE)	0.118 (0.027, 0.515)	0.0007
Missing	75	6 (8.0)	NR (NE, NE)	61	1 (1.6)	NR (NE, NE)	4.314 (0.517, 35.993)	0.1409
Interaction								0.0668

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	15 (9.6)	NR (NE, NE)	149	16 (10.7)	NR (NE, NE)	0.680 (0.330, 1.403)	0.2940
>= 65 Years	98	5 (5.1)	NR (13.7, NE)	91	15 (16.5)	9.2 (9.2, NE)	0.165 (0.054, 0.503)	0.0005
Interaction								0.0997
Gender								
Male	216	19 (8.8)	NR (NE, NE)	204	27 (13.2)	NR (9.2, NE)	0.460 (0.247, 0.854)	0.0119
Female	39	1 (2.6)	NR (7.3, NE)	36	4 (11.1)	NR (NE, NE)	0.166 (0.018, 1.533)	0.0748
Interaction								0.4387

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	16 (8.6)	NR (NE, NE)	183	26 (14.2)	NR (9.2, NE)	0.401 (0.206, 0.782)	0.0056
Non-Smoker	68	4 (5.9)	NR (NE, NE)	57	5 (8.8)	NR (4.9, NE)	0.497 (0.130, 1.896)	0.2972
Interaction								0.7793

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	9 (10.8)	NR (NE, NE)	79	10 (12.7)	NR (NE, NE)	0.699 (0.279, 1.751)	0.4422
Docetaxel	56	3 (5.4)	NR (NE, NE)	50	7 (14.0)	NR (NE, NE)	0.313 (0.081, 1.215)	0.0762
Irinotecan	116	8 (6.9)	NR (15.8, NE)	111	14 (12.6)	NR (9.2, NE)	0.296 (0.110, 0.795)	0.0109
Interaction								0.5446

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	3 (4.8)	NR (15.8, NE)	57	6 (10.5)	NR (9.2, NE)	0.204 (0.040, 1.043)	0.0367
1	192	17 (8.9)	NR (NE, NE)	183	25 (13.7)	NR (NE, NE)	0.489 (0.260, 0.921)	0.0239
Interaction								0.5901
Region #1								
Asia	201	14 (7.0)	NR (NE, NE)	191	20 (10.5)	NR (NE, NE)	0.468 (0.228, 0.959)	0.0340
Europe/North America	54	6 (11.1)	NR (NE, NE)	49	11 (22.4)	9.2 (4.9, NE)	0.400 (0.146, 1.096)	0.0656
Interaction								0.9737

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	14 (8.0)	NR (NE, NE)	168	16 (9.5)	NR (NE, NE)	0.579 (0.273, 1.228)	0.1500
Japan	25	0 (0.0)	NR (NE, NE)	23	4 (17.4)	NR (NE, NE)	0.000 (0.000, NE)	0.0336
Europe/North America	54	6 (11.1)	NR (NE, NE)	49	11 (22.4)	9.2 (4.9, NE)	0.400 (0.146, 1.096)	0.0656
Interaction								0.9214

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	15 (7.4)	NR (NE, NE)	198	21 (10.6)	NR (NE, NE)	0.502 (0.251, 1.005)	0.0475
White	52	5 (9.6)	NR (NE, NE)	42	10 (23.8)	9.2 (4.9, NE)	0.322 (0.109, 0.951)	0.0310
Interaction								0.6382

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	3 (3.8)	NR (15.8, NE)	60	7 (11.7)	NR (NE, NE)	0.210 (0.052, 0.845)	0.0168
vCPS < 10%	100	15 (15.0)	NR (10.8, NE)	119	18 (15.1)	NR (9.2, NE)	0.782 (0.389, 1.572)	0.4889
Missing	75	2 (2.7)	NR (13.7, NE)	61	6 (9.8)	NR (NE, NE)	0.119 (0.014, 0.991)	0.0187
Interaction								0.1056

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations / PT - Pneumonia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	10 (6.4)	NR (NE, NE)	149	6 (4.0)	NR (NE, NE)	1.144 (0.404, 3.235)	0.8003
>= 65 Years	98	2 (2.0)	NR (NE, NE)	91	11 (12.1)	NR (NE, NE)	0.097 (0.019, 0.490)	0.0008
Interaction								0.0181
Gender								
Male	216	12 (5.6)	NR (NE, NE)	204	15 (7.4)	NR (NE, NE)	0.521 (0.235, 1.153)	0.1018
Female	39	0 (0.0)	NR (NE, NE)	36	2 (5.6)	NR (NE, NE)	0.000 (0.000, NE)	0.1082
Interaction								0.9906

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations / PT - Pneumonia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	8 (4.3)	NR (NE, NE)	183	14 (7.7)	NR (NE, NE)	0.359 (0.141, 0.913)	0.0252
Non-Smoker	68	4 (5.9)	NR (NE, NE)	57	3 (5.3)	NR (NE, NE)	0.876 (0.191, 4.015)	0.8645
Interaction								0.3586

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations / PT - Pneumonia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	4 (4.8)	NR (NE, NE)	79	6 (7.6)	NR (NE, NE)	0.506 (0.137, 1.863)	0.2970
Docetaxel	56	3 (5.4)	NR (NE, NE)	50	5 (10.0)	NR (NE, NE)	0.435 (0.104, 1.829)	0.2427
Irinotecan	116	5 (4.3)	NR (15.8, NE)	111	6 (5.4)	NR (NE, NE)	0.434 (0.117, 1.606)	0.2004
Interaction								0.9778

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations / PT - Pneumonia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	1 (1.6)	NR (15.8, NE)	57	2 (3.5)	NR (NE, NE)	0.000 (0.000, NE)	0.1342
1	192	11 (5.7)	NR (NE, NE)	183	15 (8.2)	NR (NE, NE)	0.512 (0.231, 1.134)	0.0933
Interaction								0.7305
Region #1								
Asia	201	11 (5.5)	NR (NE, NE)	191	13 (6.8)	NR (NE, NE)	0.564 (0.244, 1.299)	0.1730
Europe/North America	54	1 (1.9)	NR (NE, NE)	49	4 (8.2)	NR (NE, NE)	0.184 (0.021, 1.653)	0.0898
Interaction								0.3869

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations / PT - Pneumonia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	11 (6.3)	NR (NE, NE)	168	10 (6.0)	NR (NE, NE)	0.718 (0.295, 1.745)	0.4626
Japan	25	0 (0.0)	NR (NE, NE)	23	3 (13.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0704
Europe/North America	54	1 (1.9)	NR (NE, NE)	49	4 (8.2)	NR (NE, NE)	0.184 (0.021, 1.653)	0.0898
Interaction								0.5590

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations / PT - Pneumonia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	11 (5.4)	NR (NE, NE)	198	14 (7.1)	NR (NE, NE)	0.540 (0.237, 1.227)	0.1357
White	52	1 (1.9)	NR (NE, NE)	42	3 (7.1)	NR (NE, NE)	0.214 (0.022, 2.066)	0.1425
Interaction								0.4976

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations / PT - Pneumonia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	3 (3.8)	NR (15.8, NE)	60	3 (5.0)	NR (NE, NE)	0.457 (0.086, 2.417)	0.3463
vCPS < 10%	100	8 (8.0)	NR (NE, NE)	119	10 (8.4)	NR (NE, NE)	0.721 (0.280, 1.858)	0.4963
Missing	75	1 (1.3)	NR (NE, NE)	61	4 (6.6)	NR (NE, NE)	0.176 (0.019, 1.591)	0.0817
Interaction								0.3916

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	17 (10.8)	NR (NE, NE)	149	50 (33.6)	NR (4.1, NE)	0.219 (0.123, 0.388)	<0.0001
>= 65 Years	98	8 (8.2)	NR (NE, NE)	91	40 (44.0)	NR (1.2, NE)	0.118 (0.053, 0.264)	<0.0001
Interaction								0.1868
Gender								
Male	216	22 (10.2)	NR (NE, NE)	204	82 (40.2)	NR (2.1, NE)	0.162 (0.099, 0.267)	<0.0001
Female	39	3 (7.7)	NR (NE, NE)	36	8 (22.2)	NR (NE, NE)	0.277 (0.073, 1.055)	0.0442
Interaction								0.5012

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	17 (9.1)	NR (NE, NE)	183	68 (37.2)	NR (4.1, NE)	0.153 (0.087, 0.269)	<0.0001
Non-Smoker	68	8 (11.8)	NR (NE, NE)	57	22 (38.6)	NR (1.0, NE)	0.237 (0.105, 0.535)	0.0002
Interaction								0.5806

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	6 (7.2)	NR (NE, NE)	79	24 (30.4)	NR (4.1, NE)	0.185 (0.075, 0.455)	<0.0001
Docetaxel	56	6 (10.7)	NR (13.8, NE)	50	27 (54.0)	1.0 (0.3, NE)	0.108 (0.041, 0.285)	<0.0001
Irinotecan	116	13 (11.2)	NR (13.8, NE)	111	39 (35.1)	NR (2.1, NE)	0.208 (0.108, 0.403)	<0.0001
Interaction								0.3916

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	4 (6.3)	NR (NE, NE)	57	19 (33.3)	NR (2.4, NE)	0.105 (0.031, 0.362)	<0.0001
1	192	21 (10.9)	NR (NE, NE)	183	71 (38.8)	NR (2.1, NE)	0.193 (0.117, 0.318)	<0.0001
Interaction								0.4456
Region #1								
Asia	201	21 (10.4)	NR (NE, NE)	191	81 (42.4)	4.1 (2.0, NE)	0.149 (0.090, 0.249)	<0.0001
Europe/North America	54	4 (7.4)	NR (NE, NE)	49	9 (18.4)	NR (NE, NE)	0.345 (0.106, 1.126)	0.0640
Interaction								0.2326

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	19 (10.8)	NR (NE, NE)	168	71 (42.3)	4.1 (1.4, NE)	0.155 (0.090, 0.265)	<0.0001
Japan	25	2 (8.0)	NR (NE, NE)	23	10 (43.5)	NR (0.5, NE)	0.125 (0.026, 0.593)	0.0018
Europe/North America	54	4 (7.4)	NR (NE, NE)	49	9 (18.4)	NR (NE, NE)	0.345 (0.106, 1.126)	0.0640
Interaction								0.4162

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	21 (10.3)	NR (NE, NE)	198	84 (42.4)	4.1 (2.0, NE)	0.149 (0.090, 0.247)	<0.0001
White	52	4 (7.7)	NR (NE, NE)	42	6 (14.3)	NR (NE, NE)	0.465 (0.131, 1.660)	0.2259
Interaction								0.1143

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	7 (8.8)	NR (NE, NE)	60	22 (36.7)	4.1 (2.0, NE)	0.138 (0.057, 0.334)	<0.0001
vCPS < 10%	100	8 (8.0)	NR (13.8, NE)	119	48 (40.3)	NR (1.4, NE)	0.134 (0.061, 0.298)	<0.0001
Missing	75	10 (13.3)	NR (13.8, NE)	61	20 (32.8)	NR (NE, NE)	0.283 (0.127, 0.627)	0.0008
Interaction								0.3618

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	5 (3.2)	NR (NE, NE)	149	7 (4.7)	NR (NE, NE)	0.610 (0.193, 1.928)	0.3941
>= 65 Years	98	1 (1.0)	NR (NE, NE)	91	11 (12.1)	NR (NE, NE)	0.074 (0.010, 0.576)	0.0012
Interaction								0.0847
Gender								
Male	216	5 (2.3)	NR (NE, NE)	204	15 (7.4)	NR (NE, NE)	0.278 (0.101, 0.769)	0.0083
Female	39	1 (2.6)	NR (NE, NE)	36	3 (8.3)	NR (NE, NE)	0.247 (0.025, 2.434)	0.1969
Interaction								0.9868

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	5 (2.7)	NR (NE, NE)	183	13 (7.1)	NR (NE, NE)	0.334 (0.119, 0.942)	0.0291
Non-Smoker	68	1 (1.5)	NR (NE, NE)	57	5 (8.8)	NR (NE, NE)	0.145 (0.017, 1.246)	0.0414
Interaction								0.5258

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	0 (0.0)	NR (NE, NE)	79	3 (3.8)	NR (NE, NE)	0.000 (0.000, NE)	0.0734
Docetaxel	56	2 (3.6)	NR (NE, NE)	50	6 (12.0)	NR (NE, NE)	0.264 (0.053, 1.315)	0.0786
Irinotecan	116	4 (3.4)	NR (NE, NE)	111	9 (8.1)	NR (NE, NE)	0.325 (0.097, 1.086)	0.0556
Interaction								0.9435

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	1 (1.6)	NR (NE, NE)	57	6 (10.5)	NR (NE, NE)	0.125 (0.015, 1.051)	0.0237
1	192	5 (2.6)	NR (NE, NE)	183	12 (6.6)	NR (NE, NE)	0.356 (0.125, 1.015)	0.0431
Interaction								0.4178
Region #1								
Asia	201	5 (2.5)	NR (NE, NE)	191	15 (7.9)	NR (NE, NE)	0.267 (0.096, 0.741)	0.0065
Europe/North America	54	1 (1.9)	NR (NE, NE)	49	3 (6.1)	NR (NE, NE)	0.288 (0.030, 2.768)	0.2492
Interaction								0.9891

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	5 (2.8)	NR (NE, NE)	168	13 (7.7)	NR (NE, NE)	0.305 (0.108, 0.861)	0.0177
Japan	25	0 (0.0)	NR (NE, NE)	23	2 (8.7)	NR (NE, NE)	0.000 (0.000, NE)	0.1361
Europe/North America	54	1 (1.9)	NR (NE, NE)	49	3 (6.1)	NR (NE, NE)	0.288 (0.030, 2.768)	0.2492
Interaction								0.9912

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	5 (2.5)	NR (NE, NE)	198	16 (8.1)	NR (NE, NE)	0.259 (0.094, 0.712)	0.0048
White	52	1 (1.9)	NR (NE, NE)	42	2 (4.8)	NR (NE, NE)	0.386 (0.035, 4.257)	0.4180
Interaction								0.8151

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	0 (0.0)	NR (NE, NE)	60	3 (5.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0355
vCPS < 10%	100	4 (4.0)	NR (NE, NE)	119	12 (10.1)	NR (NE, NE)	0.348 (0.112, 1.082)	0.0556
Missing	75	2 (2.7)	NR (NE, NE)	61	3 (4.9)	NR (NE, NE)	0.452 (0.074, 2.774)	0.3797
Interaction								0.9571

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	0 (0.0)	NR (NE, NE)	149	36 (24.2)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
>= 65 Years	98	0 (0.0)	NR (NE, NE)	91	27 (29.7)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9999
Gender								
Male	216	0 (0.0)	NR (NE, NE)	204	57 (27.9)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Female	39	0 (0.0)	NR (NE, NE)	36	6 (16.7)	NR (NE, NE)	0.000 (0.000, NE)	0.0089
Interaction								0.9998

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	0 (0.0)	NR (NE, NE)	183	50 (27.3)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Non-Smoker	68	0 (0.0)	NR (NE, NE)	57	13 (22.8)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	0 (0.0)	NR (NE, NE)	79	19 (24.1)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Docetaxel	56	0 (0.0)	NR (NE, NE)	50	19 (38.0)	NR (1.0, NE)	0.000 (0.000, NE)	<0.0001
Irinotecan	116	0 (0.0)	NR (NE, NE)	111	25 (22.5)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	0 (0.0)	NR (NE, NE)	57	14 (24.6)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
1	192	0 (0.0)	NR (NE, NE)	183	49 (26.8)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9999
Region #1								
Asia	201	0 (0.0)	NR (NE, NE)	191	58 (30.4)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	5 (10.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0137
Interaction								0.9995

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	0 (0.0)	NR (NE, NE)	168	49 (29.2)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Japan	25	0 (0.0)	NR (NE, NE)	23	9 (39.1)	NR (0.5, NE)	0.000 (0.000, NE)	0.0005
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	5 (10.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0137
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	0 (0.0)	NR (NE, NE)	198	59 (29.8)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
White	52	0 (0.0)	NR (NE, NE)	42	4 (9.5)	NR (NE, NE)	0.000 (0.000, NE)	0.0187
Interaction								0.9994

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	0 (0.0)	NR (NE, NE)	60	15 (25.0)	NR (4.1, NE)	0.000 (0.000, NE)	<0.0001
vCPS < 10%	100	0 (0.0)	NR (NE, NE)	119	34 (28.6)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Missing	75	0 (0.0)	NR (NE, NE)	61	14 (23.0)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	1 (0.6)	NR (NE, NE)	149	30 (20.1)	NR (NE, NE)	0.027 (0.004, 0.198)	<0.0001
>= 65 Years	98	0 (0.0)	NR (NE, NE)	91	18 (19.8)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9863
Gender								
Male	216	1 (0.5)	NR (NE, NE)	204	42 (20.6)	NR (NE, NE)	0.020 (0.003, 0.144)	<0.0001
Female	39	0 (0.0)	NR (NE, NE)	36	6 (16.7)	NR (NE, NE)	0.000 (0.000, NE)	0.0084
Interaction								0.9876

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	0 (0.0)	NR (NE, NE)	183	34 (18.6)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Non-Smoker	68	1 (1.5)	NR (NE, NE)	57	14 (24.6)	NR (NE, NE)	0.050 (0.006, 0.378)	<0.0001
Interaction								0.9874

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	0 (0.0)	NR (NE, NE)	79	8 (10.1)	NR (NE, NE)	0.000 (0.000, NE)	0.0029
Docetaxel	56	0 (0.0)	NR (NE, NE)	50	20 (40.0)	NR (1.0, NE)	0.000 (0.000, NE)	<0.0001
Irinotecan	116	1 (0.9)	NR (NE, NE)	111	20 (18.0)	NR (NE, NE)	0.040 (0.005, 0.300)	<0.0001
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	0 (0.0)	NR (NE, NE)	57	12 (21.1)	NR (NE, NE)	0.000 (0.000, NE)	0.0001
1	192	1 (0.5)	NR (NE, NE)	183	36 (19.7)	NR (NE, NE)	0.023 (0.003, 0.170)	<0.0001
Interaction								0.9890
Region #1								
Asia	201	1 (0.5)	NR (NE, NE)	191	46 (24.1)	NR (NE, NE)	0.018 (0.002, 0.130)	<0.0001
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	2 (4.1)	NR (NE, NE)	0.000 (0.000, NE)	0.1324
Interaction								0.9884

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	1 (0.6)	NR (NE, NE)	168	37 (22.0)	NR (NE, NE)	0.022 (0.003, 0.164)	<0.0001
Japan	25	0 (0.0)	NR (NE, NE)	23	9 (39.1)	NR (0.5, NE)	0.000 (0.000, NE)	0.0005
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	2 (4.1)	NR (NE, NE)	0.000 (0.000, NE)	0.1324
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	1 (0.5)	NR (NE, NE)	198	47 (23.7)	NR (NE, NE)	0.018 (0.002, 0.131)	<0.0001
White	52	0 (0.0)	NR (NE, NE)	42	1 (2.4)	NR (NE, NE)	0.000 (0.000, NE)	0.2611
Interaction								0.9892

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	1 (1.3)	NR (NE, NE)	60	9 (15.0)	NR (NE, NE)	0.067 (0.008, 0.534)	0.0008
vCPS < 10%	100	0 (0.0)	NR (NE, NE)	119	25 (21.0)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Missing	75	0 (0.0)	NR (NE, NE)	61	14 (23.0)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	15 (9.6)	NR (14.5, NE)	149	15 (10.1)	NR (9.6, NE)	0.599 (0.282, 1.273)	0.1780
>= 65 Years	98	11 (11.2)	NR (NE, NE)	91	16 (17.6)	NR (NE, NE)	0.458 (0.204, 1.030)	0.0528
Interaction								0.3923
Gender								
Male	216	23 (10.6)	NR (NE, NE)	204	23 (11.3)	NR (9.6, NE)	0.603 (0.328, 1.111)	0.1012
Female	39	3 (7.7)	NR (NE, NE)	36	8 (22.2)	NR (3.1, NE)	0.281 (0.073, 1.073)	0.0478
Interaction								0.2085

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	21 (11.2)	NR (14.5, NE)	183	20 (10.9)	NR (9.6, NE)	0.669 (0.351, 1.276)	0.2194
Non-Smoker	68	5 (7.4)	NR (NE, NE)	57	11 (19.3)	NR (4.8, NE)	0.258 (0.086, 0.775)	0.0099
Interaction								0.1145

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	8 (9.6)	NR (NE, NE)	79	5 (6.3)	NR (NE, NE)	1.243 (0.394, 3.926)	0.7100
Docetaxel	56	10 (17.9)	10.2 (6.9, NE)	50	8 (16.0)	9.6 (4.9, NE)	0.645 (0.242, 1.724)	0.3783
Irinotecan	116	8 (6.9)	NR (14.5, NE)	111	18 (16.2)	NR (NE, NE)	0.244 (0.096, 0.625)	0.0015
Interaction								0.0592

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	6 (9.5)	NR (13.8, NE)	57	8 (14.0)	NR (9.6, NE)	0.321 (0.095, 1.087)	0.0554
1	192	20 (10.4)	NR (NE, NE)	183	23 (12.6)	NR (NE, NE)	0.607 (0.328, 1.125)	0.1092
Interaction								0.7019
Region #1								
Asia	201	23 (11.4)	NR (NE, NE)	191	24 (12.6)	NR (9.6, NE)	0.564 (0.307, 1.037)	0.0618
Europe/North America	54	3 (5.6)	NR (NE, NE)	49	7 (14.3)	NR (NE, NE)	0.350 (0.090, 1.359)	0.1126
Interaction								0.4724

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	17 (9.7)	NR (NE, NE)	168	22 (13.1)	NR (9.6, NE)	0.465 (0.237, 0.912)	0.0227
Japan	25	6 (24.0)	13.8 (4.1, NE)	23	2 (8.7)	NR (NE, NE)	1.558 (0.290, 8.369)	0.6023
Europe/North America	54	3 (5.6)	NR (NE, NE)	49	7 (14.3)	NR (NE, NE)	0.350 (0.090, 1.359)	0.1126
Interaction								0.2632

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	23 (11.3)	NR (NE, NE)	198	24 (12.1)	NR (9.6, NE)	0.582 (0.317, 1.071)	0.0784
White	52	3 (5.8)	NR (NE, NE)	42	7 (16.7)	NR (4.8, NE)	0.309 (0.080, 1.200)	0.0728
Interaction								0.3557

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	7 (8.8)	NR (13.8, NE)	60	9 (15.0)	NR (4.9, NE)	0.279 (0.091, 0.855)	0.0177
vCPS < 10%	100	10 (10.0)	NR (NE, NE)	119	15 (12.6)	NR (NE, NE)	0.599 (0.266, 1.346)	0.2095
Missing	75	9 (12.0)	NR (13.8, NE)	61	7 (11.5)	9.6 (NE, NE)	0.777 (0.276, 2.194)	0.6332
Interaction								0.5132

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	2 (1.3)	--	149	6 (4.0)	--	--	--
>= 65 Years	98	0 (0.0)	--	91	4 (4.4)	--	--	--
Interaction								--
Gender								
Male	216	2 (0.9)	NR (NE, NE)	204	9 (4.4)	NR (NE, NE)	0.089 (0.011, 0.703)	0.0039
Female	39	0 (0.0)	NR (NE, NE)	36	1 (2.8)	NR (NE, NE)	0.000 (0.000, NE)	0.2980
Interaction								0.9924

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	2 (1.1)	NR (NE, NE)	183	9 (4.9)	NR (NE, NE)	0.097 (0.012, 0.765)	0.0060
Non-Smoker	68	0 (0.0)	NR (NE, NE)	57	1 (1.8)	NR (NE, NE)	0.000 (0.000, NE)	0.1649
Interaction								0.9936

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	1 (1.2)	--	79	2 (2.5)	--	--	--
Docetaxel	56	1 (1.8)	--	50	2 (4.0)	--	--	--
Irinotecan	116	0 (0.0)	--	111	6 (5.4)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	1 (1.6)	NR (14.0, NE)	57	1 (1.8)	NR (NE, NE)	0.000 (0.000, NE)	0.2963
1	192	1 (0.5)	NR (NE, NE)	183	9 (4.9)	NR (NE, NE)	0.088 (0.011, 0.698)	0.0038
Interaction								0.2724
Region #1								
Asia	201	1 (0.5)	--	191	6 (3.1)	--	--	--
Europe/North America	54	1 (1.9)	--	49	4 (8.2)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
TEAE >= Grade 3: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Region #2								
Asia (excluding Japan)	176	1 (0.6)	--	168	5 (3.0)	--	--	--
Japan	25	0 (0.0)	--	23	1 (4.3)	--	--	--
Europe/North America	54	1 (1.9)	--	49	4 (8.2)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	203	1 (0.5)	--	198	6 (3.0)	--	--	--
White	52	1 (1.9)	--	42	4 (9.5)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	1 (1.3)	--	60	4 (6.7)	--	--	--
vCPS < 10%	100	1 (1.0)	--	119	3 (2.5)	--	--	--
Missing	75	0 (0.0)	--	61	3 (4.9)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-aesocpt-sub.sas 20AUG2024 03:24 t-14-03-01-02-02-03-01-s-aesocpt-sub-g3-safety-fa.rtf

Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	10 (13.0)	NR (NE, NE)	70	18 (25.7)	NR (NE, NE)	0.397 (0.182, 0.864)	0.0155
>= 65 Years	62	3 (4.8)	NR (NE, NE)	59	13 (22.0)	NR (NE, NE)	0.195 (0.056, 0.686)	0.0044
Interaction								0.2690
Gender								
Male	118	12 (10.2)	NR (NE, NE)	106	26 (24.5)	NR (NE, NE)	0.335 (0.168, 0.666)	0.0010
Female	21	1 (4.8)	NR (NE, NE)	23	5 (21.7)	NR (NE, NE)	0.209 (0.024, 1.791)	0.1115
Interaction								0.5835

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Smoking Status								
Former/Current Smoker	104	10 (9.6)	NR (NE, NE)	101	25 (24.8)	NR (NE, NE)	0.322 (0.154, 0.673)	0.0014
Non-Smoker	35	3 (8.6)	NR (4.3, NE)	28	6 (21.4)	NR (NE, NE)	0.303 (0.074, 1.232)	0.0774
Interaction								0.9704
ICC Options								
Paclitaxel	83	4 (4.8)	NR (NE, NE)	79	12 (15.2)	NR (NE, NE)	0.280 (0.090, 0.870)	0.0186
Docetaxel	56	9 (16.1)	NR (7.6, NE)	50	19 (38.0)	NR (1.3, NE)	0.301 (0.134, 0.676)	0.0018
Interaction								0.9102

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	1 (2.3)	NR (NE, NE)	37	8 (21.6)	NR (NE, NE)	0.085 (0.010, 0.686)	0.0033
1	96	12 (12.5)	NR (NE, NE)	92	23 (25.0)	NR (NE, NE)	0.412 (0.205, 0.830)	0.0102
Interaction								0.1724
Region #1								
Asia	103	11 (10.7)	NR (NE, NE)	99	23 (23.2)	NR (NE, NE)	0.369 (0.179, 0.762)	0.0048
Europe/North America	36	2 (5.6)	NR (NE, NE)	30	8 (26.7)	NR (NE, NE)	0.181 (0.038, 0.853)	0.0148
Interaction								0.3963

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	10 (12.8)	NR (NE, NE)	76	18 (23.7)	NR (NE, NE)	0.439 (0.201, 0.957)	0.0323
Japan	25	1 (4.0)	NR (NE, NE)	23	5 (21.7)	NR (2.8, NE)	0.146 (0.017, 1.262)	0.0427
Europe/North America	36	2 (5.6)	NR (NE, NE)	30	8 (26.7)	NR (NE, NE)	0.181 (0.038, 0.853)	0.0148
Interaction								0.4322

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	11 (10.5)	NR (NE, NE)	106	24 (22.6)	NR (NE, NE)	0.376 (0.183, 0.771)	0.0053
White	34	2 (5.9)	NR (NE, NE)	23	7 (30.4)	NR (1.0, NE)	0.165 (0.034, 0.795)	0.0103
Interaction								0.3295

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	4 (8.9)	NR (NE, NE)	34	8 (23.5)	NR (NE, NE)	0.310 (0.093, 1.032)	0.0429
vCPS < 10%	53	7 (13.2)	NR (NE, NE)	54	17 (31.5)	NR (NE, NE)	0.302 (0.123, 0.742)	0.0056
Missing	41	2 (4.9)	NR (NE, NE)	41	6 (14.6)	NR (NE, NE)	0.307 (0.062, 1.527)	0.1262
Interaction								0.9877

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	0 (0.0)	--	70	4 (5.7)	--	--	--
>= 65 Years	62	0 (0.0)	--	59	4 (6.8)	--	--	--
Interaction								--
Gender								
Male	118	0 (0.0)	--	106	7 (6.6)	--	--	--
Female	21	0 (0.0)	--	23	1 (4.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

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Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Smoking Status								
Former/Current Smoker	104	0 (0.0)	--	101	7 (6.9)	--	--	--
Non-Smoker	35	0 (0.0)	--	28	1 (3.6)	--	--	--
Interaction								--
ICC Options								
Paclitaxel	83	0 (0.0)	--	79	0 (0.0)	--	--	--
Docetaxel	56	0 (0.0)	--	50	8 (16.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	43	0 (0.0)	--	37	2 (5.4)	--	--	--
1	96	0 (0.0)	--	92	6 (6.5)	--	--	--
Interaction								--
Region #1								
Asia	103	0 (0.0)	--	99	7 (7.1)	--	--	--
Europe/North America	36	0 (0.0)	--	30	1 (3.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Region #2								
Asia (excluding Japan)	78	0 (0.0)	--	76	5 (6.6)	--	--	--
Japan	25	0 (0.0)	--	23	2 (8.7)	--	--	--
Europe/North America	36	0 (0.0)	--	30	1 (3.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	0 (0.0)	--	106	7 (6.6)	--	--	--
White	34	0 (0.0)	--	23	1 (4.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Baseline PD-L1 Status								
vCPS >= 10%	45	0 (0.0)	--	34	2 (5.9)	--	--	--
vCPS < 10%	53	0 (0.0)	--	54	2 (3.7)	--	--	--
Missing	41	0 (0.0)	--	41	4 (9.8)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	77	0 (0.0)	--	70	5 (7.1)	--	--	--
>= 65 Years	62	0 (0.0)	--	59	3 (5.1)	--	--	--
Interaction								--
Gender								
Male	118	0 (0.0)	--	106	8 (7.5)	--	--	--
Female	21	0 (0.0)	--	23	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	0 (0.0)	--	101	6 (5.9)	--	--	--
Non-Smoker	35	0 (0.0)	--	28	2 (7.1)	--	--	--
Interaction								--
ICC Options								
Paclitaxel	83	0 (0.0)	--	79	1 (1.3)	--	--	--
Docetaxel	56	0 (0.0)	--	50	7 (14.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	43	0 (0.0)	--	37	4 (10.8)	--	--	--
1	96	0 (0.0)	--	92	4 (4.3)	--	--	--
Interaction								--
Region #1								
Asia	103	0 (0.0)	--	99	7 (7.1)	--	--	--
Europe/North America	36	0 (0.0)	--	30	1 (3.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Region #2								
Asia (excluding Japan)	78	0 (0.0)	--	76	7 (9.2)	--	--	--
Japan	25	0 (0.0)	--	23	0 (0.0)	--	--	--
Europe/North America	36	0 (0.0)	--	30	1 (3.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	0 (0.0)	--	106	7 (6.6)	--	--	--
White	34	0 (0.0)	--	23	1 (4.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	0 (0.0)	--	34	2 (5.9)	--	--	--
vCPS < 10%	53	0 (0.0)	--	54	5 (9.3)	--	--	--
Missing	41	0 (0.0)	--	41	1 (2.4)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	1 (1.3)	--	70	5 (7.1)	--	--	--
>= 65 Years	62	0 (0.0)	--	59	7 (11.9)	--	--	--
Interaction								--
Gender								
Male	118	1 (0.8)	NR (NE, NE)	106	10 (9.4)	NR (NE, NE)	0.074 (0.009, 0.589)	0.0015
Female	21	0 (0.0)	NR (NE, NE)	23	2 (8.7)	NR (NE, NE)	0.000 (0.000, NE)	0.1820
Interaction								0.9924

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	1 (1.0)	NR (NE, NE)	101	9 (8.9)	NR (NE, NE)	0.086 (0.011, 0.695)	0.0041
Non-Smoker	35	0 (0.0)	NR (NE, NE)	28	3 (10.7)	NR (NE, NE)	0.000 (0.000, NE)	0.0492
Interaction								0.9936
ICC Options								
Paclitaxel	83	0 (0.0)	--	79	5 (6.3)	--	--	--
Docetaxel	56	1 (1.8)	--	50	7 (14.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	43	1 (2.3)	--	37	3 (8.1)	--	--	--
1	96	0 (0.0)	--	92	9 (9.8)	--	--	--
Interaction								--
Region #1								
Asia	103	1 (1.0)	--	99	7 (7.1)	--	--	--
Europe/North America	36	0 (0.0)	--	30	5 (16.7)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Region #2								
Asia (excluding Japan)	78	1 (1.3)	--	76	7 (9.2)	--	--	--
Japan	25	0 (0.0)	--	23	0 (0.0)	--	--	--
Europe/North America	36	0 (0.0)	--	30	5 (16.7)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	1 (1.0)	--	106	7 (6.6)	--	--	--
White	34	0 (0.0)	--	23	5 (21.7)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	0 (0.0)	--	34	2 (5.9)	--	--	--
vCPS < 10%	53	1 (1.9)	--	54	8 (14.8)	--	--	--
Missing	41	0 (0.0)	--	41	2 (4.9)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	7 (9.1)	NR (13.8, NE)	70	28 (40.0)	4.1 (1.4, NE)	0.140 (0.058, 0.343)	<0.0001
>= 65 Years	62	5 (8.1)	NR (NE, NE)	59	23 (39.0)	NR (1.1, NE)	0.157 (0.059, 0.415)	<0.0001
Interaction								0.8947
Gender								
Male	118	11 (9.3)	NR (NE, NE)	106	47 (44.3)	4.1 (1.2, NE)	0.135 (0.068, 0.269)	<0.0001
Female	21	1 (4.8)	NR (3.1, NE)	23	4 (17.4)	NR (NE, NE)	0.246 (0.027, 2.203)	0.1721
Interaction								0.6687

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	11 (10.6)	NR (NE, NE)	101	42 (41.6)	NR (1.4, NE)	0.164 (0.082, 0.329)	<0.0001
Non-Smoker	35	1 (2.9)	NR (NE, NE)	28	9 (32.1)	NR (0.5, NE)	0.080 (0.010, 0.632)	0.0018
Interaction								0.3719
ICC Options								
Paclitaxel	83	6 (7.2)	NR (NE, NE)	79	24 (30.4)	NR (4.1, NE)	0.185 (0.075, 0.455)	<0.0001
Docetaxel	56	6 (10.7)	NR (13.8, NE)	50	27 (54.0)	1.0 (0.3, NE)	0.108 (0.041, 0.285)	<0.0001
Interaction								0.4684

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	4 (9.3)	NR (13.8, NE)	37	14 (37.8)	NR (1.1, NE)	0.137 (0.039, 0.484)	0.0003
1	96	8 (8.3)	NR (NE, NE)	92	37 (40.2)	NR (1.2, NE)	0.153 (0.071, 0.331)	<0.0001
Interaction								0.8679
Region #1								
Asia	103	10 (9.7)	NR (NE, NE)	99	45 (45.5)	4.1 (1.1, NE)	0.129 (0.062, 0.266)	<0.0001
Europe/North America	36	2 (5.6)	NR (NE, NE)	30	6 (20.0)	NR (NE, NE)	0.240 (0.048, 1.195)	0.0571
Interaction								0.4986

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	8 (10.3)	NR (NE, NE)	76	35 (46.1)	4.1 (1.1, NE)	0.133 (0.059, 0.303)	<0.0001
Japan	25	2 (8.0)	NR (NE, NE)	23	10 (43.5)	NR (0.5, NE)	0.125 (0.026, 0.593)	0.0018
Europe/North America	36	2 (5.6)	NR (NE, NE)	30	6 (20.0)	NR (NE, NE)	0.240 (0.048, 1.195)	0.0571
Interaction								0.7642

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	10 (9.5)	NR (NE, NE)	106	48 (45.3)	4.1 (1.1, NE)	0.128 (0.062, 0.263)	<0.0001
White	34	2 (5.9)	NR (NE, NE)	23	3 (13.0)	NR (NE, NE)	0.399 (0.066, 2.406)	0.2945
Interaction								0.2453

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	3 (6.7)	NR (NE, NE)	34	10 (29.4)	NR (4.1, NE)	0.163 (0.044, 0.604)	0.0021
vCPS < 10%	53	4 (7.5)	NR (13.8, NE)	54	26 (48.1)	2.4 (0.5, NE)	0.081 (0.024, 0.268)	<0.0001
Missing	41	5 (12.2)	NR (NE, NE)	41	15 (36.6)	NR (1.2, NE)	0.267 (0.097, 0.736)	0.0053
Interaction								0.4390

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	77	2 (2.6)	--	70	3 (4.3)	--	--	--
>= 65 Years	62	0 (0.0)	--	59	6 (10.2)	--	--	--
Interaction								--
Gender								
Male	118	2 (1.7)	NR (NE, NE)	106	8 (7.5)	NR (NE, NE)	0.210 (0.044, 0.989)	0.0285
Female	21	0 (0.0)	NR (NE, NE)	23	1 (4.3)	NR (NE, NE)	0.000 (0.000, NE)	0.3393
Interaction								0.9926

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	2 (1.9)	NR (NE, NE)	101	8 (7.9)	NR (NE, NE)	0.229 (0.049, 1.079)	0.0403
Non-Smoker	35	0 (0.0)	NR (NE, NE)	28	1 (3.6)	NR (NE, NE)	0.000 (0.000, NE)	0.2618
Interaction								0.9938
ICC Options								
Paclitaxel	83	0 (0.0)	--	79	3 (3.8)	--	--	--
Docetaxel	56	2 (3.6)	--	50	6 (12.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	43	1 (2.3)	--	37	3 (8.1)	--	--	--
1	96	1 (1.0)	--	92	6 (6.5)	--	--	--
Interaction								--
Region #1								
Asia	103	2 (1.9)	--	99	6 (6.1)	--	--	--
Europe/North America	36	0 (0.0)	--	30	3 (10.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Region #2								
Asia (excluding Japan)	78	2 (2.6)	--	76	4 (5.3)	--	--	--
Japan	25	0 (0.0)	--	23	2 (8.7)	--	--	--
Europe/North America	36	0 (0.0)	--	30	3 (10.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	105	2 (1.9)	--	106	7 (6.6)	--	--	--
White	34	0 (0.0)	--	23	2 (8.7)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.
System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.
Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.
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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	0 (0.0)	--	34	1 (2.9)	--	--	--
vCPS < 10%	53	2 (3.8)	--	54	6 (11.1)	--	--	--
Missing	41	0 (0.0)	--	41	2 (4.9)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	77	0 (0.0)	NR (NE, NE)	70	23 (32.9)	NR (2.4, NE)	0.000 (0.000, NE)	<0.0001
>= 65 Years	62	0 (0.0)	NR (NE, NE)	59	15 (25.4)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9999
Gender								
Male	118	0 (0.0)	NR (NE, NE)	106	35 (33.0)	NR (4.1, NE)	0.000 (0.000, NE)	<0.0001
Female	21	0 (0.0)	NR (NE, NE)	23	3 (13.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0931
Interaction								0.9997

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Smoking Status								
Former/Current Smoker	104	0 (0.0)	NR (NE, NE)	101	32 (31.7)	NR (4.1, NE)	0.000 (0.000, NE)	<0.0001
Non-Smoker	35	0 (0.0)	NR (NE, NE)	28	6 (21.4)	NR (NE, NE)	0.000 (0.000, NE)	0.0040
Interaction								0.9998
ICC Options								
Paclitaxel	83	0 (0.0)	NR (NE, NE)	79	19 (24.1)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Docetaxel	56	0 (0.0)	NR (NE, NE)	50	19 (38.0)	NR (1.0, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9998

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	43	0 (0.0)	NR (NE, NE)	37	12 (32.4)	NR (2.4, NE)	0.000 (0.000, NE)	<0.0001
1	96	0 (0.0)	NR (NE, NE)	92	26 (28.3)	NR (4.1, NE)	0.000 (0.000, NE)	<0.0001
Interaction								1.0000
Region #1								
Asia	103	0 (0.0)	NR (NE, NE)	99	35 (35.4)	NR (4.1, NE)	0.000 (0.000, NE)	<0.0001
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	3 (10.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0537
Interaction								0.9995

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Region #2								
Asia (excluding Japan)	78	0 (0.0)	NR (NE, NE)	76	26 (34.2)	NR (2.4, NE)	0.000 (0.000, NE)	<0.0001
Japan	25	0 (0.0)	NR (NE, NE)	23	9 (39.1)	NR (0.5, NE)	0.000 (0.000, NE)	0.0005
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	3 (10.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0537
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	105	0 (0.0)	NR (NE, NE)	106	36 (34.0)	NR (4.1, NE)	0.000 (0.000, NE)	<0.0001
White	34	0 (0.0)	NR (NE, NE)	23	2 (8.7)	NR (NE, NE)	0.000 (0.000, NE)	0.0827
Interaction								0.9995

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.
System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.
Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.
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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	0 (0.0)	NR (NE, NE)	34	9 (26.5)	NR (4.1, NE)	0.000 (0.000, NE)	0.0001
vCPS < 10%	53	0 (0.0)	NR (NE, NE)	54	17 (31.5)	NR (2.4, NE)	0.000 (0.000, NE)	<0.0001
Missing	41	0 (0.0)	NR (NE, NE)	41	12 (29.3)	NR (NE, NE)	0.000 (0.000, NE)	0.0002
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	77	0 (0.0)	NR (NE, NE)	70	17 (24.3)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
>= 65 Years	62	0 (0.0)	NR (NE, NE)	59	11 (18.6)	NR (NE, NE)	0.000 (0.000, NE)	0.0004
Interaction								0.9999
Gender								
Male	118	0 (0.0)	NR (NE, NE)	106	25 (23.6)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Female	21	0 (0.0)	NR (NE, NE)	23	3 (13.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0904
Interaction								0.9998

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Smoking Status								
Former/Current Smoker	104	0 (0.0)	NR (NE, NE)	101	22 (21.8)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Non-Smoker	35	0 (0.0)	NR (NE, NE)	28	6 (21.4)	NR (NE, NE)	0.000 (0.000, NE)	0.0038
Interaction								1.0000
ICC Options								
Paclitaxel	83	0 (0.0)	NR (NE, NE)	79	8 (10.1)	NR (NE, NE)	0.000 (0.000, NE)	0.0029
Docetaxel	56	0 (0.0)	NR (NE, NE)	50	20 (40.0)	NR (1.0, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9994

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	0 (0.0)	NR (NE, NE)	37	10 (27.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0003
1	96	0 (0.0)	NR (NE, NE)	92	18 (19.6)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9999
Region #1								
Asia	103	0 (0.0)	NR (NE, NE)	99	27 (27.3)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	1 (3.3)	NR (NE, NE)	0.000 (0.000, NE)	0.2733
Interaction								0.9994

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	0 (0.0)	NR (NE, NE)	76	18 (23.7)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Japan	25	0 (0.0)	NR (NE, NE)	23	9 (39.1)	NR (0.5, NE)	0.000 (0.000, NE)	0.0005
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	1 (3.3)	NR (NE, NE)	0.000 (0.000, NE)	0.2733
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	105	0 (0.0)	NR (NE, NE)	106	28 (26.4)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
White	34	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9965

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.
System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.
Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.
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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	0 (0.0)	NR (NE, NE)	34	4 (11.8)	NR (NE, NE)	0.000 (0.000, NE)	0.0191
vCPS < 10%	53	0 (0.0)	NR (NE, NE)	54	13 (24.1)	NR (NE, NE)	0.000 (0.000, NE)	0.0001
Missing	41	0 (0.0)	NR (NE, NE)	41	11 (26.8)	NR (NE, NE)	0.000 (0.000, NE)	0.0004
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Vascular disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	6 (7.8)	--	70	0 (0.0)	--	--	--
>= 65 Years	62	2 (3.2)	--	59	0 (0.0)	--	--	--
Interaction								--
Gender								
Male	118	7 (5.9)	--	106	0 (0.0)	--	--	--
Female	21	1 (4.8)	--	23	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Vascular disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	7 (6.7)	--	101	0 (0.0)	--	--	--
Non-Smoker	35	1 (2.9)	--	28	0 (0.0)	--	--	--
Interaction								--
ICC Options								
Paclitaxel	83	5 (6.0)	--	79	0 (0.0)	--	--	--
Docetaxel	56	3 (5.4)	--	50	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Vascular disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	4 (9.3)	--	37	0 (0.0)	--	--	--
1	96	4 (4.2)	--	92	0 (0.0)	--	--	--
Interaction								--
Region #1								
Asia	103	5 (4.9)	--	99	0 (0.0)	--	--	--
Europe/North America	36	3 (8.3)	--	30	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Vascular disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	5 (6.4)	--	76	0 (0.0)	--	--	--
Japan	25	0 (0.0)	--	23	0 (0.0)	--	--	--
Europe/North America	36	3 (8.3)	--	30	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Vascular disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	5 (4.8)	--	106	0 (0.0)	--	--	--
White	34	3 (8.8)	--	23	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Vascular disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	4 (8.9)	--	34	0 (0.0)	--	--	--
vCPS < 10%	53	4 (7.5)	--	54	0 (0.0)	--	--	--
Missing	41	0 (0.0)	--	41	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	1 (0.6)	NR (NE, NE)	149	11 (7.4)	NR (NE, NE)	0.083 (0.011, 0.642)	0.0023
>= 65 Years	98	0 (0.0)	NR (NE, NE)	91	8 (8.8)	NR (NE, NE)	0.000 (0.000, NE)	0.0028
Interaction								0.9903
Gender								
Male	216	1 (0.5)	NR (NE, NE)	204	17 (8.3)	NR (NE, NE)	0.053 (0.007, 0.400)	<0.0001
Female	39	0 (0.0)	NR (NE, NE)	36	2 (5.6)	NR (NE, NE)	0.000 (0.000, NE)	0.1408
Interaction								0.9914

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	1 (0.5)	NR (NE, NE)	183	13 (7.1)	NR (NE, NE)	0.072 (0.009, 0.554)	0.0009
Non-Smoker	68	0 (0.0)	NR (NE, NE)	57	6 (10.5)	NR (NE, NE)	0.000 (0.000, NE)	0.0064
Interaction								0.9922

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	0 (0.0)	NR (NE, NE)	79	1 (1.3)	NR (NE, NE)	0.000 (0.000, NE)	0.3049
Docetaxel	56	1 (1.8)	NR (NE, NE)	50	9 (18.0)	NR (NE, NE)	0.093 (0.012, 0.732)	0.0043
Irinotecan	116	0 (0.0)	NR (NE, NE)	111	9 (8.1)	NR (NE, NE)	0.000 (0.000, NE)	0.0017
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	0 (0.0)	NR (NE, NE)	57	2 (3.5)	NR (NE, NE)	0.000 (0.000, NE)	0.1353
1	192	1 (0.5)	NR (NE, NE)	183	17 (9.3)	NR (NE, NE)	0.054 (0.007, 0.403)	<0.0001
Interaction								0.9933
Region #1								
Asia	201	1 (0.5)	NR (NE, NE)	191	18 (9.4)	NR (NE, NE)	0.051 (0.007, 0.380)	<0.0001
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	0.000 (0.000, NE)	0.2888
Interaction								0.9912

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	1 (0.6)	NR (NE, NE)	168	16 (9.5)	NR (NE, NE)	0.057 (0.008, 0.432)	0.0001
Japan	25	0 (0.0)	NR (NE, NE)	23	2 (8.7)	NR (NE, NE)	0.000 (0.000, NE)	0.1354
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	0.000 (0.000, NE)	0.2888
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	1 (0.5)	NR (NE, NE)	198	18 (9.1)	NR (NE, NE)	0.052 (0.007, 0.391)	<0.0001
White	52	0 (0.0)	NR (NE, NE)	42	1 (2.4)	NR (NE, NE)	0.000 (0.000, NE)	0.2601
Interaction								0.9911

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	0 (0.0)	--	60	5 (8.3)	--	--	--
vCPS < 10%	100	0 (0.0)	--	119	9 (7.6)	--	--	--
Missing	75	1 (1.3)	--	61	5 (8.2)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	18 (11.5)	NR (15.8, NE)	149	15 (10.1)	NR (NE, NE)	0.825 (0.408, 1.667)	0.5905
>= 65 Years	98	7 (7.1)	NR (13.8, NE)	91	16 (17.6)	9.2 (9.2, NE)	0.230 (0.088, 0.605)	0.0015
Interaction								0.0712
Gender								
Male	216	24 (11.1)	NR (NE, NE)	204	27 (13.2)	NR (9.2, NE)	0.567 (0.319, 1.010)	0.0513
Female	39	1 (2.6)	NR (7.3, NE)	36	4 (11.1)	NR (NE, NE)	0.166 (0.018, 1.533)	0.0748
Interaction								0.3115

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	19 (10.2)	NR (15.8, NE)	183	26 (14.2)	NR (9.2, NE)	0.464 (0.247, 0.872)	0.0146
Non-Smoker	68	6 (8.8)	NR (NE, NE)	57	5 (8.8)	NR (4.9, NE)	0.742 (0.220, 2.496)	0.6281
Interaction								0.5094

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	7 (8.4)	NR (NE, NE)	79	11 (13.9)	NR (NE, NE)	0.463 (0.173, 1.239)	0.1169
Docetaxel	56	7 (12.5)	NR (NE, NE)	50	7 (14.0)	NR (NE, NE)	0.700 (0.245, 2.004)	0.5040
Irinotecan	116	11 (9.5)	NR (13.8, NE)	111	13 (11.7)	NR (9.2, NE)	0.453 (0.187, 1.098)	0.0733
Interaction								0.8304

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Safety Analysis Set

Serious TEAE: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	4 (6.3)	NR (15.8, NE)	57	5 (8.8)	NR (9.2, NE)	0.343 (0.080, 1.473)	0.1332
1	192	21 (10.9)	NR (NE, NE)	183	26 (14.2)	NR (NE, NE)	0.553 (0.305, 1.003)	0.0480
Interaction								0.9636
Region #1								
Asia	201	21 (10.4)	NR (NE, NE)	191	20 (10.5)	NR (NE, NE)	0.679 (0.359, 1.285)	0.2311
Europe/North America	54	4 (7.4)	NR (NE, NE)	49	11 (22.4)	9.2 (4.9, NE)	0.258 (0.081, 0.823)	0.0140
Interaction								0.1915

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	20 (11.4)	NR (15.8, NE)	168	16 (9.5)	NR (NE, NE)	0.810 (0.409, 1.604)	0.5450
Japan	25	1 (4.0)	NR (6.8, NE)	23	4 (17.4)	NR (NE, NE)	0.148 (0.015, 1.457)	0.0666
Europe/North America	54	4 (7.4)	NR (NE, NE)	49	11 (22.4)	9.2 (4.9, NE)	0.258 (0.081, 0.823)	0.0140
Interaction								0.1341

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	22 (10.8)	NR (NE, NE)	198	21 (10.6)	NR (NE, NE)	0.710 (0.381, 1.323)	0.2781
White	52	3 (5.8)	NR (NE, NE)	42	10 (23.8)	9.2 (4.9, NE)	0.187 (0.051, 0.687)	0.0049
Interaction								0.0923

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Serious TEAE: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	5 (6.3)	NR (15.8, NE)	60	8 (13.3)	NR (NE, NE)	0.306 (0.096, 0.974)	0.0351
vCPS < 10%	100	15 (15.0)	NR (10.8, NE)	119	16 (13.4)	NR (9.2, NE)	0.828 (0.403, 1.700)	0.6063
Missing	75	5 (6.7)	NR (13.8, NE)	61	7 (11.5)	NR (NE, NE)	0.392 (0.114, 1.349)	0.1240
Interaction								0.2119

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

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Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
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Serious TEAE: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	1 (0.6)	--	149	7 (4.7)	--	--	--
>= 65 Years	98	0 (0.0)	--	91	6 (6.6)	--	--	--
Interaction								--
Gender								
Male	216	1 (0.5)	NR (NE, NE)	204	12 (5.9)	NR (NE, NE)	0.076 (0.010, 0.583)	0.0012
Female	39	0 (0.0)	NR (NE, NE)	36	1 (2.8)	NR (NE, NE)	0.000 (0.000, NE)	0.3042
Interaction								0.9928

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	1 (0.5)	--	183	8 (4.4)	--	--	--
Non-Smoker	68	0 (0.0)	--	57	5 (8.8)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

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Serious TEAE: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	1 (1.2)	--	79	0 (0.0)	--	--	--
Docetaxel	56	0 (0.0)	--	50	4 (8.0)	--	--	--
Irinotecan	116	0 (0.0)	--	111	9 (8.1)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Serious TEAE: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	1 (1.6)	NR (NE, NE)	57	3 (5.3)	NR (NE, NE)	0.296 (0.031, 2.847)	0.2626
1	192	0 (0.0)	NR (NE, NE)	183	10 (5.5)	NR (NE, NE)	0.000 (0.000, NE)	0.0010
Interaction								0.9920
Region #1								
Asia	201	1 (0.5)	NR (NE, NE)	191	13 (6.8)	NR (NE, NE)	0.071 (0.009, 0.540)	0.0007
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9993

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

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Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	1 (0.6)	NR (NE, NE)	168	13 (7.7)	NR (NE, NE)	0.071 (0.009, 0.540)	0.0007
Japan	25	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	1 (0.5)	NR (NE, NE)	198	13 (6.6)	NR (NE, NE)	0.073 (0.010, 0.555)	0.0009
White	52	0 (0.0)	NR (NE, NE)	42	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9993

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	0 (0.0)	--	60	3 (5.0)	--	--	--
vCPS < 10%	100	0 (0.0)	--	119	6 (5.0)	--	--	--
Missing	75	1 (1.3)	--	61	4 (6.6)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	0 (0.0)	--	149	6 (4.0)	--	--	--
>= 65 Years	98	0 (0.0)	--	91	4 (4.4)	--	--	--
Interaction								--
Gender								
Male	216	0 (0.0)	--	204	9 (4.4)	--	--	--
Female	39	0 (0.0)	--	36	1 (2.8)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	0 (0.0)	--	183	7 (3.8)	--	--	--
Non-Smoker	68	0 (0.0)	--	57	3 (5.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	0 (0.0)	--	79	0 (0.0)	--	--	--
Docetaxel	56	0 (0.0)	--	50	4 (8.0)	--	--	--
Irinotecan	116	0 (0.0)	--	111	6 (5.4)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	0 (0.0)	--	57	2 (3.5)	--	--	--
1	192	0 (0.0)	--	183	8 (4.4)	--	--	--
Interaction								--
Region #1								
Asia	201	0 (0.0)	NR (NE, NE)	191	10 (5.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0010
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9979

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	0 (0.0)	NR (NE, NE)	168	10 (6.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0010
Japan	25	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

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Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
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Serious TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	0 (0.0)	NR (NE, NE)	198	10 (5.1)	NR (NE, NE)	0.000 (0.000, NE)	0.0012
White	52	0 (0.0)	NR (NE, NE)	42	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9979

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	0 (0.0)	--	60	2 (3.3)	--	--	--
vCPS < 10%	100	0 (0.0)	--	119	6 (5.0)	--	--	--
Missing	75	0 (0.0)	--	61	2 (3.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

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Table 14.3.1.2.4.1.1.b.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	1 (1.3)	--	70	6 (8.6)	--	--	--
>= 65 Years	62	0 (0.0)	--	59	4 (6.8)	--	--	--
Interaction								--
Gender								
Male	118	1 (0.8)	NR (NE, NE)	106	9 (8.5)	NR (NE, NE)	0.096 (0.012, 0.761)	0.0056
Female	21	0 (0.0)	NR (NE, NE)	23	1 (4.3)	NR (NE, NE)	0.000 (0.000, NE)	0.3393
Interaction								0.9934

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.4.1.1.b.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	1 (1.0)	NR (NE, NE)	101	9 (8.9)	NR (NE, NE)	0.104 (0.013, 0.824)	0.0083
Non-Smoker	35	0 (0.0)	NR (NE, NE)	28	1 (3.6)	NR (NE, NE)	0.000 (0.000, NE)	0.2636
Interaction								0.9945
ICC Options								
Paclitaxel	83	0 (0.0)	NR (NE, NE)	79	1 (1.3)	NR (NE, NE)	0.000 (0.000, NE)	0.3049
Docetaxel	56	1 (1.8)	NR (NE, NE)	50	9 (18.0)	NR (NE, NE)	0.093 (0.012, 0.732)	0.0043
Interaction								0.9952

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-aesocpt-sub.sas 20AUG2024 03:24 t-14-03-01-02-04-01-01-b-s-aesocpt-sub-sae-safetys-fa.rtf

Table 14.3.1.2.4.1.1.b.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	0 (0.0)	NR (NE, NE)	37	1 (2.7)	NR (NE, NE)	0.000 (0.000, NE)	0.2810
1	96	1 (1.0)	NR (NE, NE)	92	9 (9.8)	NR (NE, NE)	0.103 (0.013, 0.810)	0.0076
Interaction								0.9943
Region #1								
Asia	103	1 (1.0)	NR (NE, NE)	99	9 (9.1)	NR (NE, NE)	0.103 (0.013, 0.815)	0.0078
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	1 (3.3)	NR (NE, NE)	0.000 (0.000, NE)	0.2733
Interaction								0.9945

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-aesocpt-sub.sas 20AUG2024 03:24 t-14-03-01-02-04-01-01-b-s-aesocpt-sub-sae-safetys-fa.rtf

Table 14.3.1.2.4.1.1.b.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	1 (1.3)	--	76	7 (9.2)	--	--	--
Japan	25	0 (0.0)	--	23	2 (8.7)	--	--	--
Europe/North America	36	0 (0.0)	--	30	1 (3.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-aesocpt-sub.sas 20AUG2024 03:24 t-14-03-01-02-04-01-01-b-s-aesocpt-sub-sae-safetys-fa.rtf

Table 14.3.1.2.4.1.1.b.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	1 (1.0)	NR (NE, NE)	106	9 (8.5)	NR (NE, NE)	0.109 (0.014, 0.858)	0.0099
White	34	0 (0.0)	NR (NE, NE)	23	1 (4.3)	NR (NE, NE)	0.000 (0.000, NE)	0.2240
Interaction								0.9944

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-aesocpt-sub.sas 20AUG2024 03:24 t-14-03-01-02-04-01-01-b-s-aesocpt-sub-sae-safetys-fa.rtf

Table 14.3.1.2.4.1.1.b.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	0 (0.0)	--	34	2 (5.9)	--	--	--
vCPS < 10%	53	0 (0.0)	--	54	4 (7.4)	--	--	--
Missing	41	1 (2.4)	--	41	4 (9.8)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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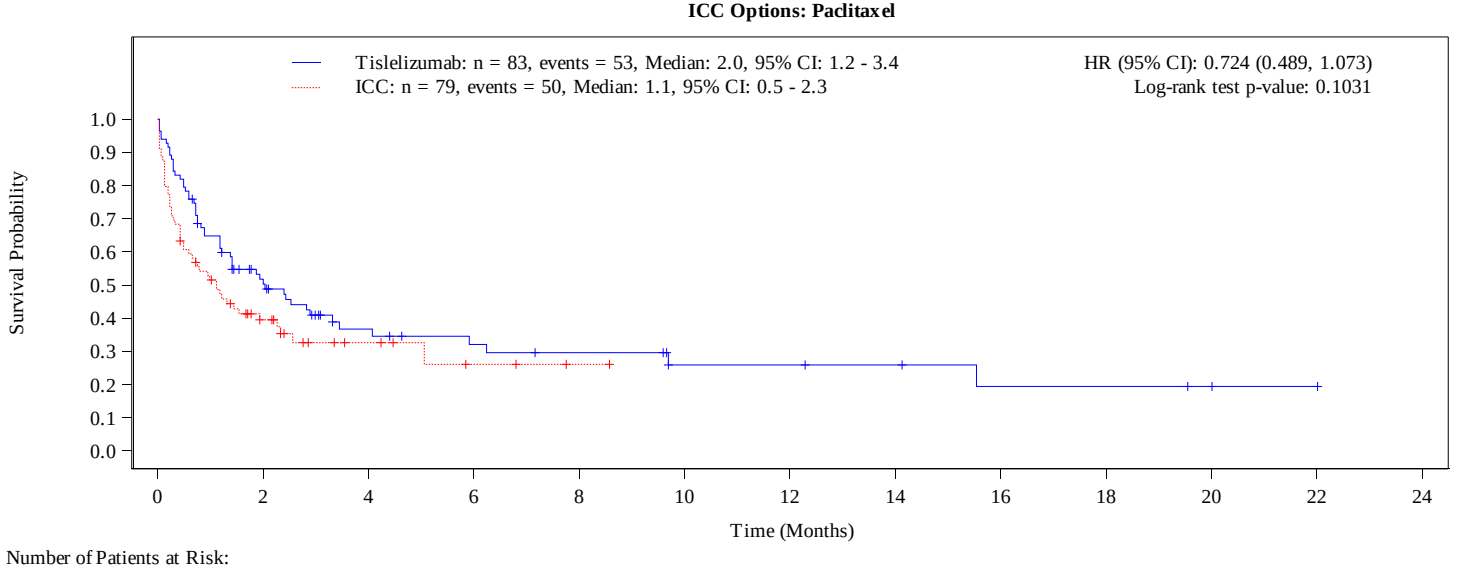
[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-aesocpt-sub.sas 20AUG2024 03:24 t-14-03-01-02-04-01-01-b-s-aesocpt-sub-sae-safetys-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders

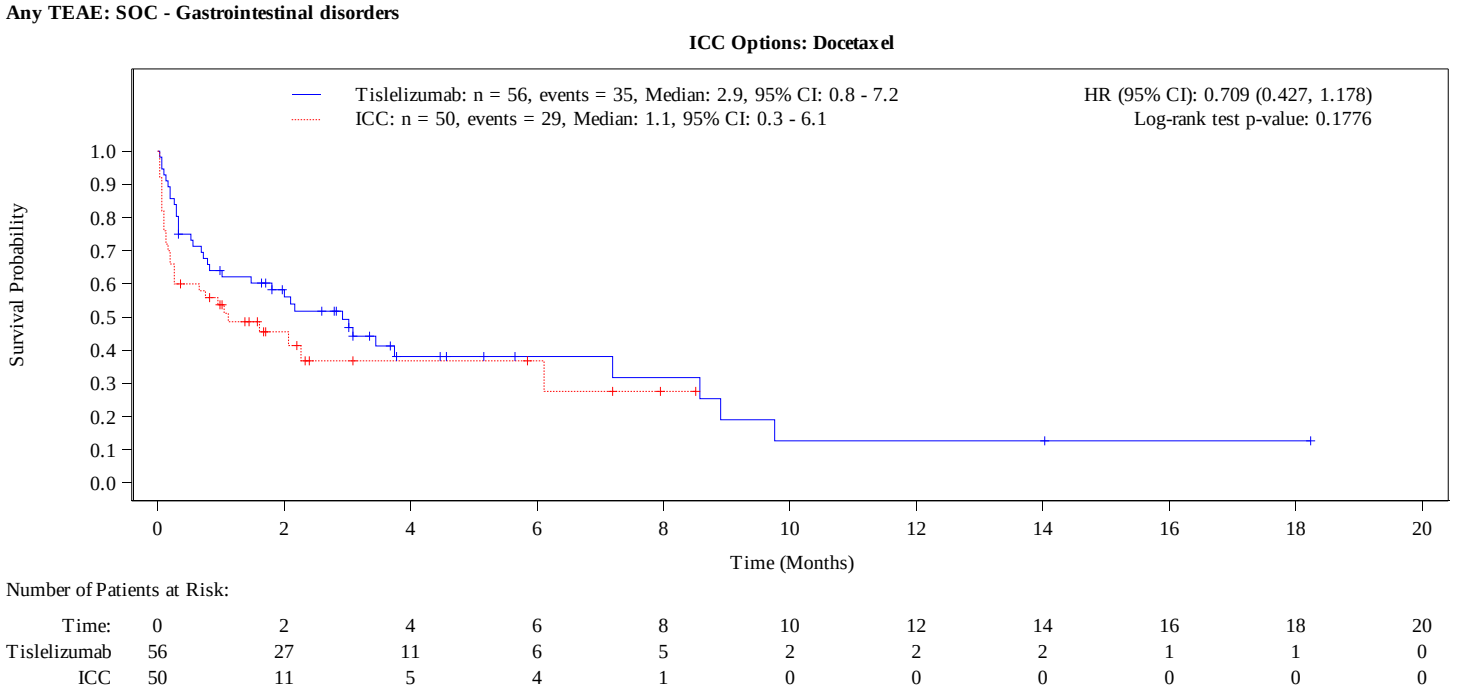


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24
Tislelizumab	83	35	17	13	10	6	6	5	3	3	2	1	0
ICC	79	21	8	3	1	0	0	0	0	0	0	0	0

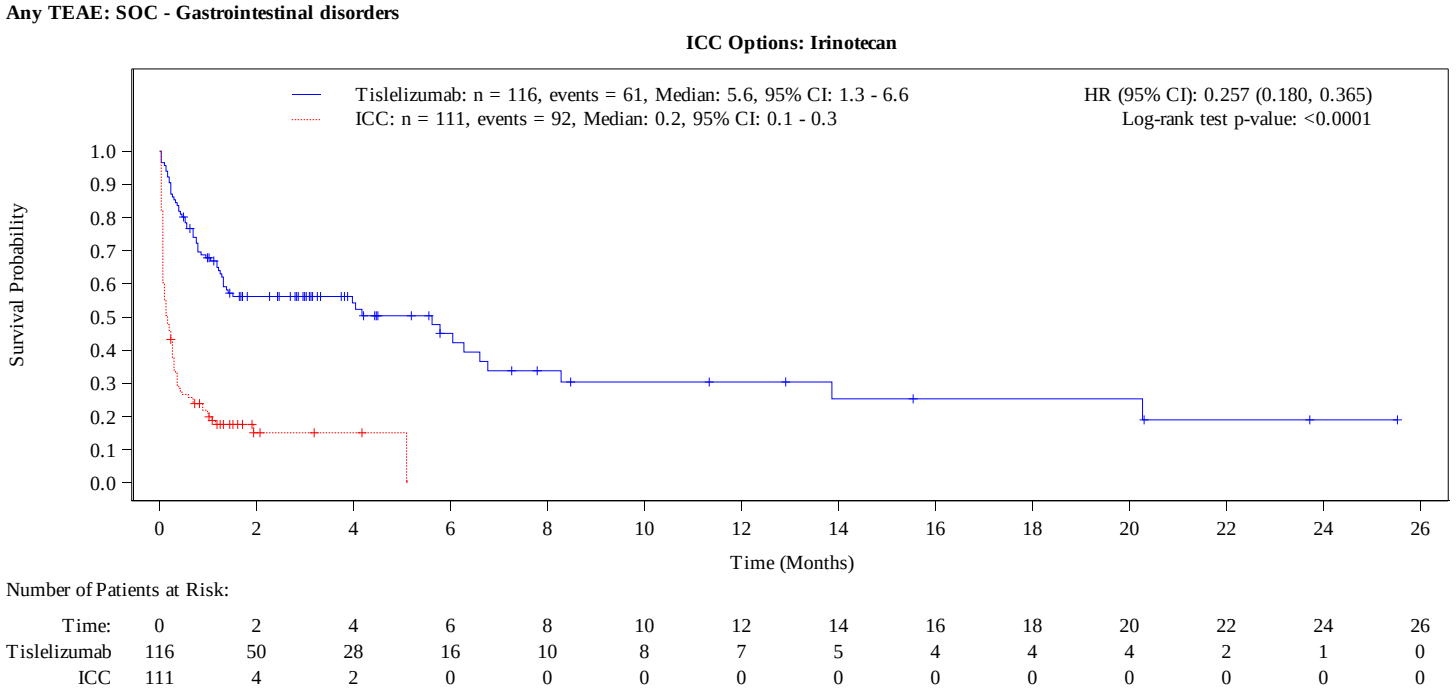
Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

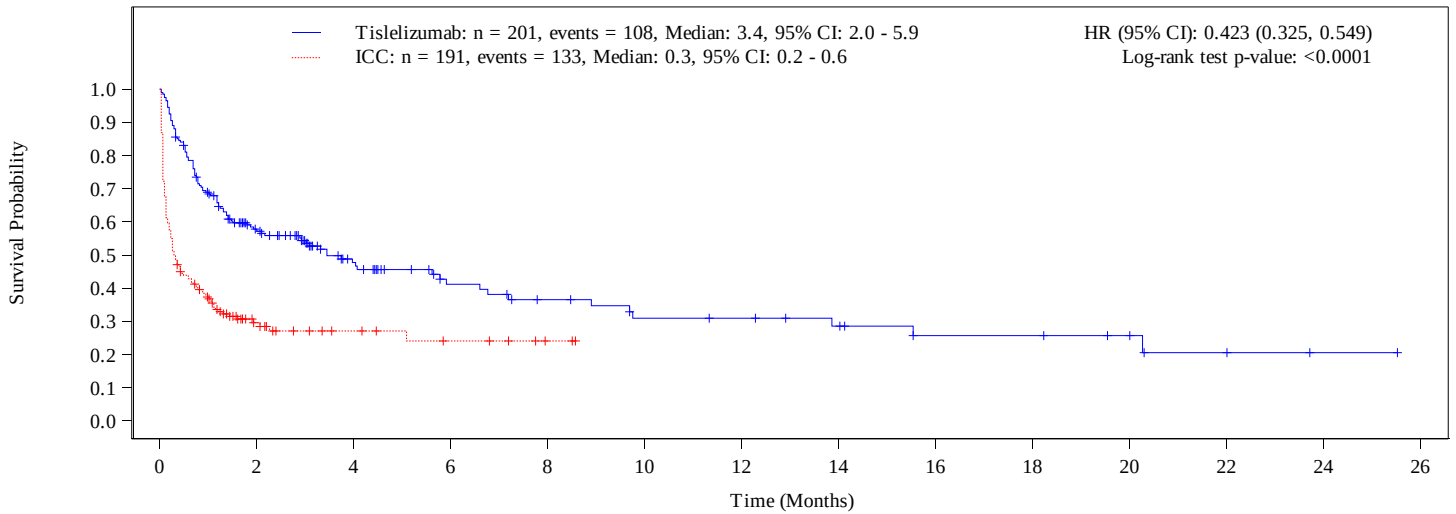


Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders

Region #1: Asia



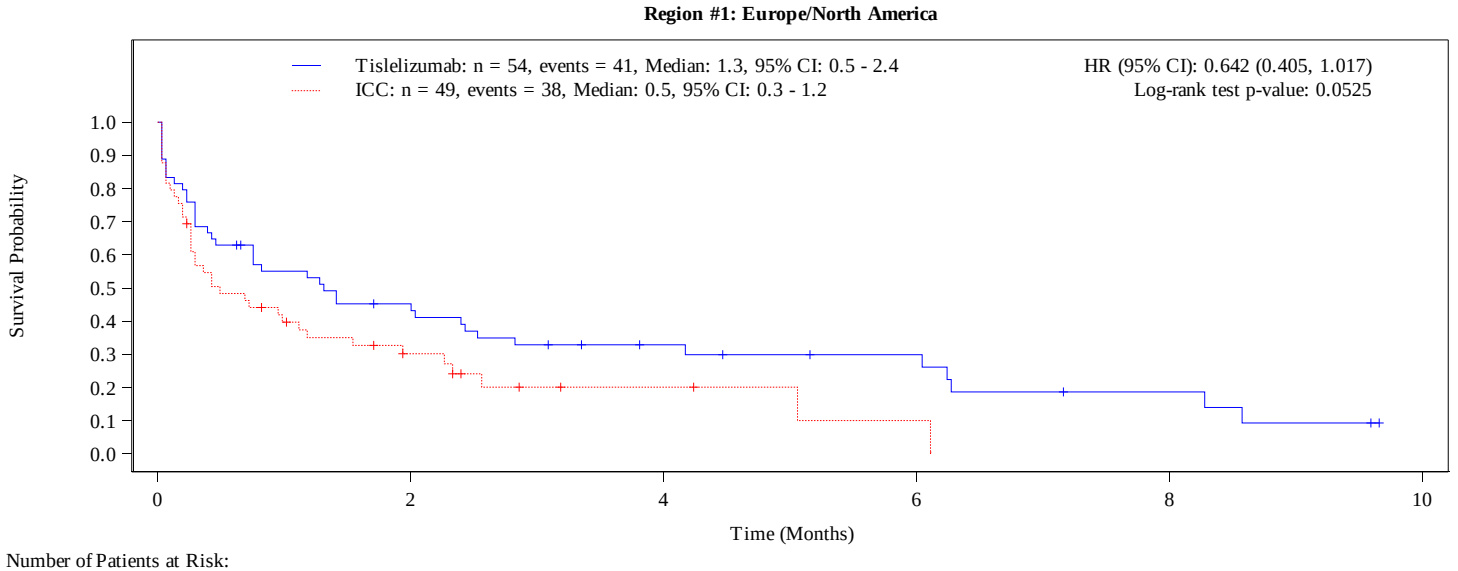
Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	201	90	45	27	21	16	15	12	8	8	6	3	1	0
ICC	191	26	12	6	2	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders



Number of Patients at Risk:

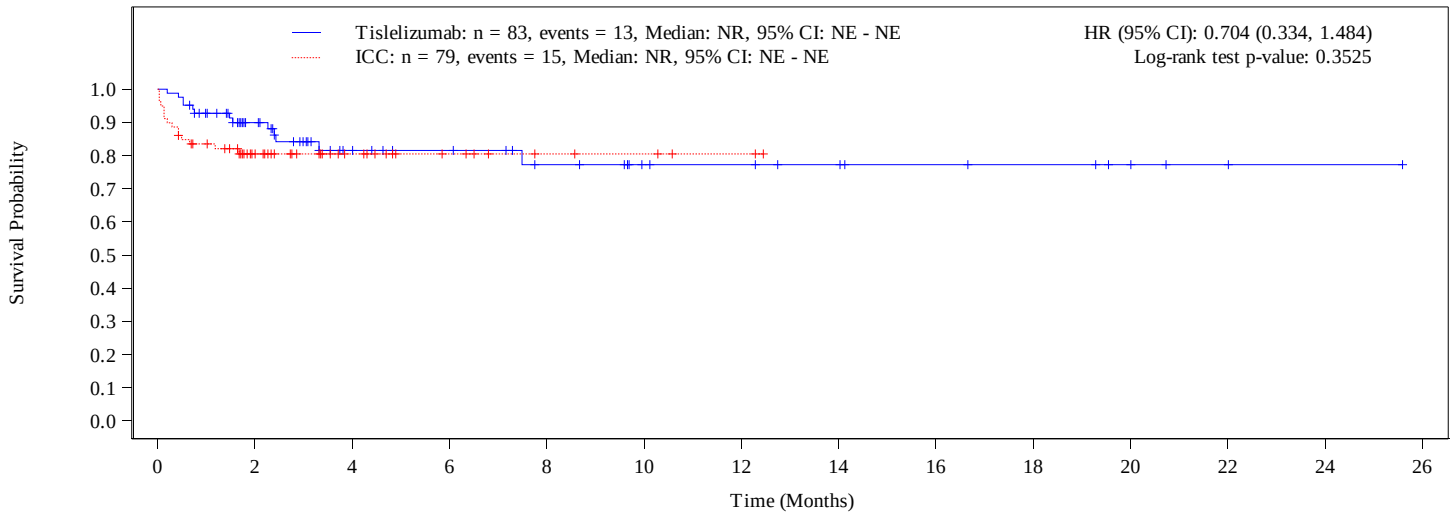
Time:	0	2	4	6	8	10
Tislelizumab	54	22	11	8	4	0
ICC	49	10	3	1	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Diarrhoea

ICC Options: Paclitaxel

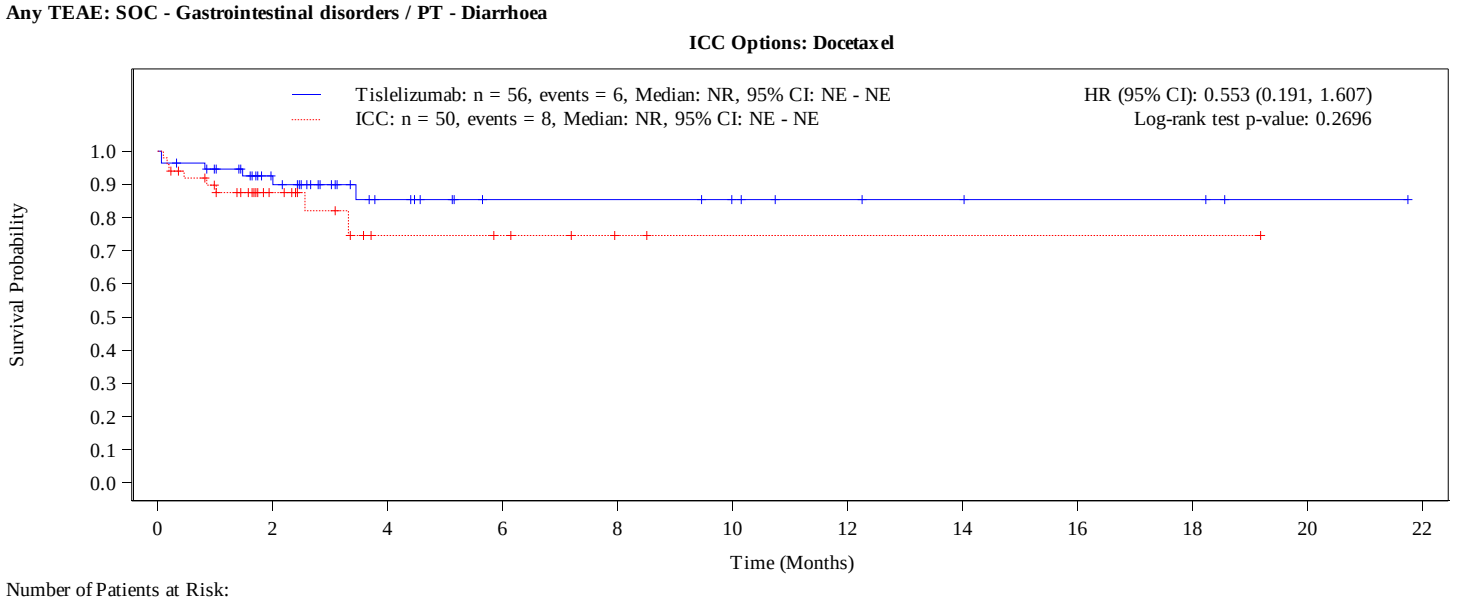


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	83	51	27	23	17	12	11	9	7	6	4	2	1	0
ICC	79	40	17	9	5	4	2	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



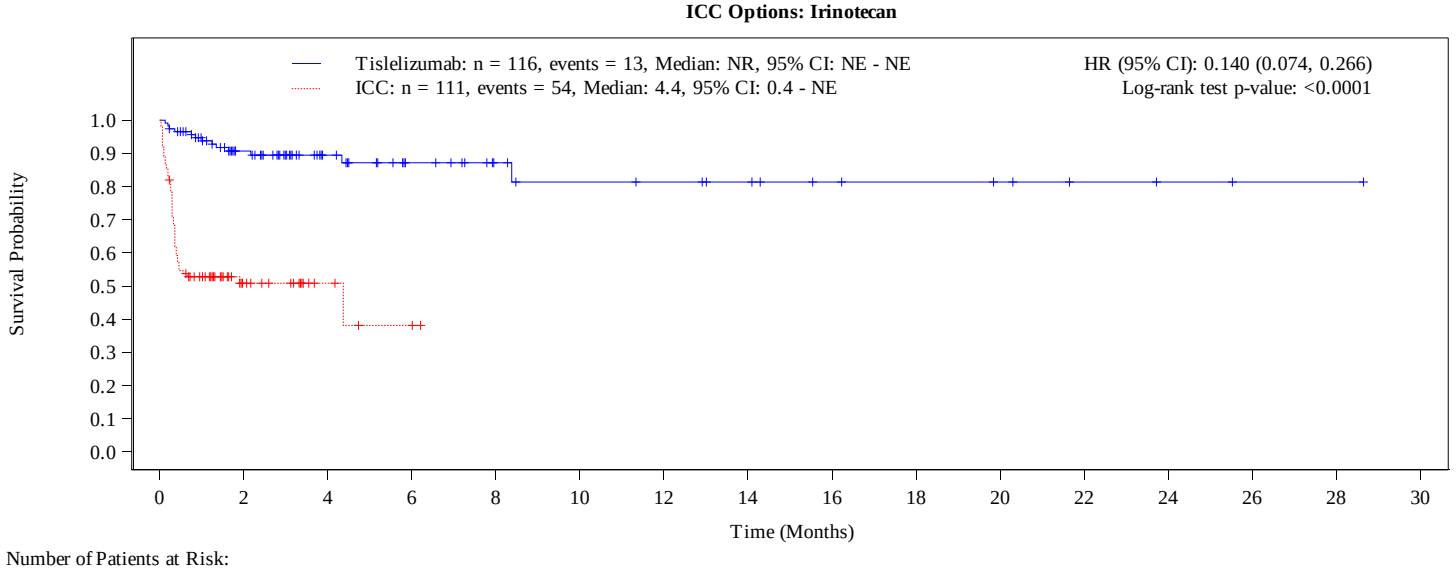
Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	56	35	17	9	9	7	5	4	3	3	1	0
ICC	50	20	7	5	2	1	1	1	1	1	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Diarrhoea



Number of Patients at Risk:

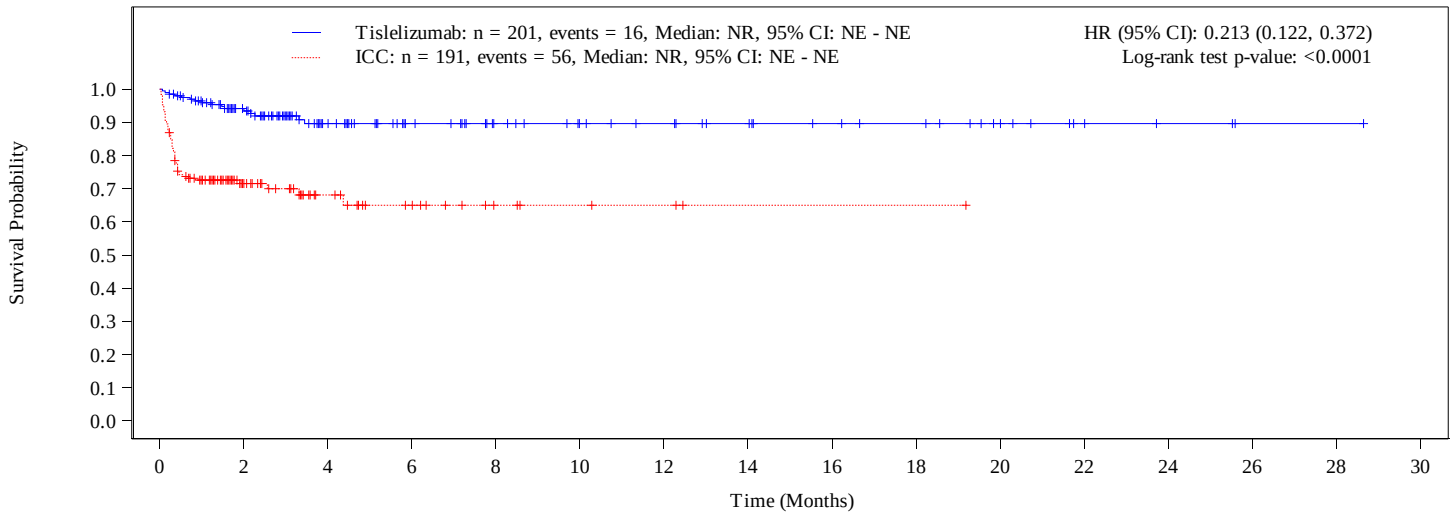
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	116	73	40	24	16	13	12	10	7	6	5	3	2	1	1	0
ICC	111	20	5	2	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Diarrhoea

Region #1: Asia



Number of Patients at Risk:

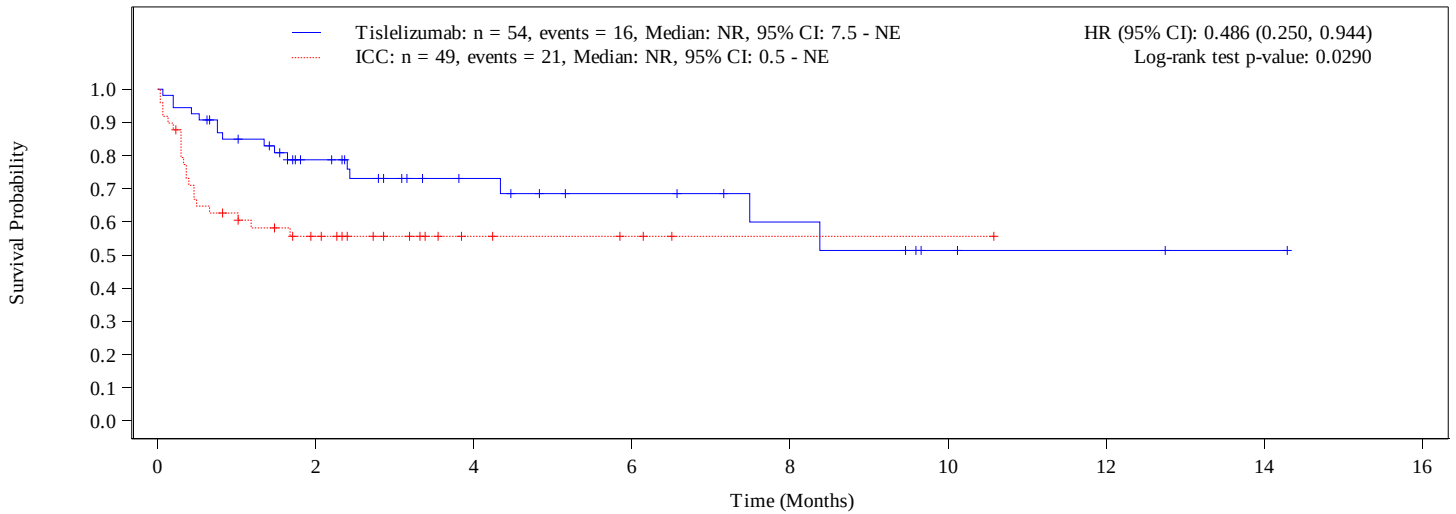
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	201	128	68	46	35	29	26	22	17	15	10	5	3	1	1	0
ICC	191	61	24	13	6	4	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Diarrhoea

Region #1: Europe/North America

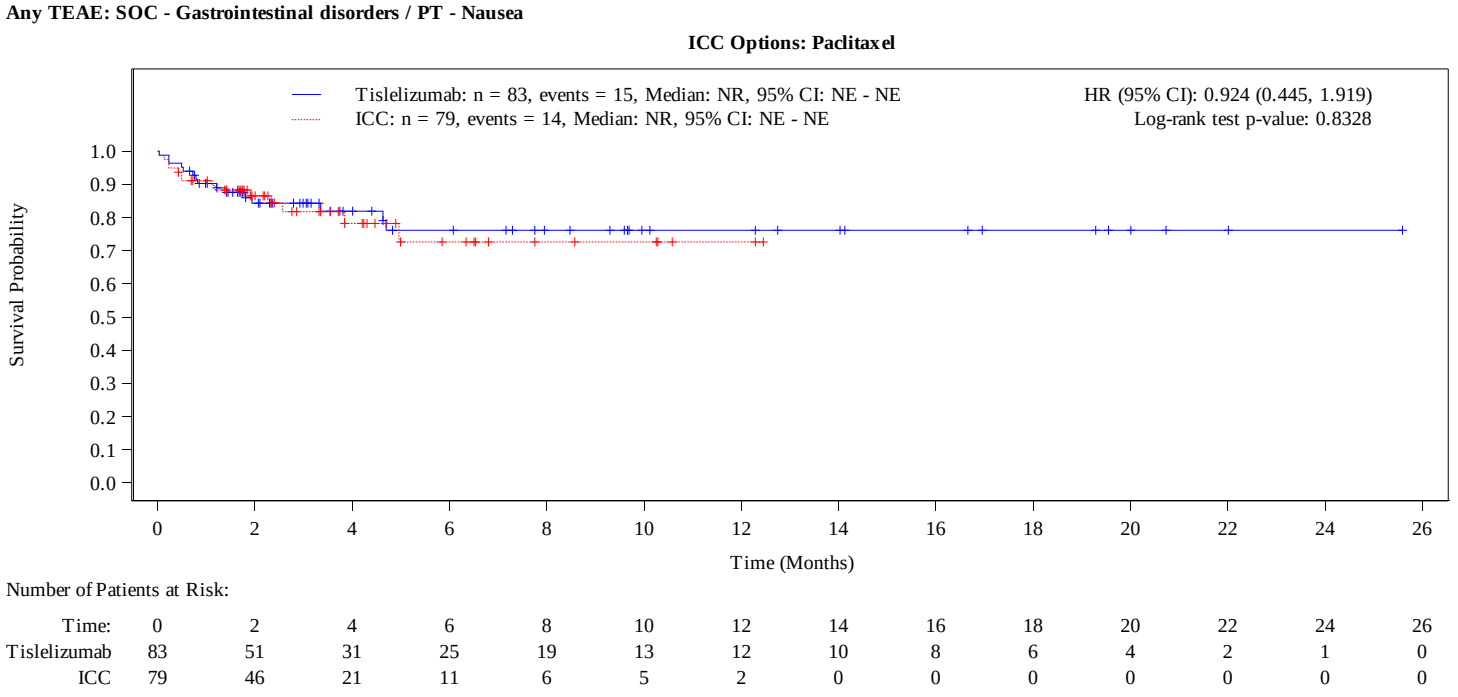


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16
Tislelizumab	54	31	16	10	7	3	2	1	0
ICC	49	19	5	3	1	1	0	0	0

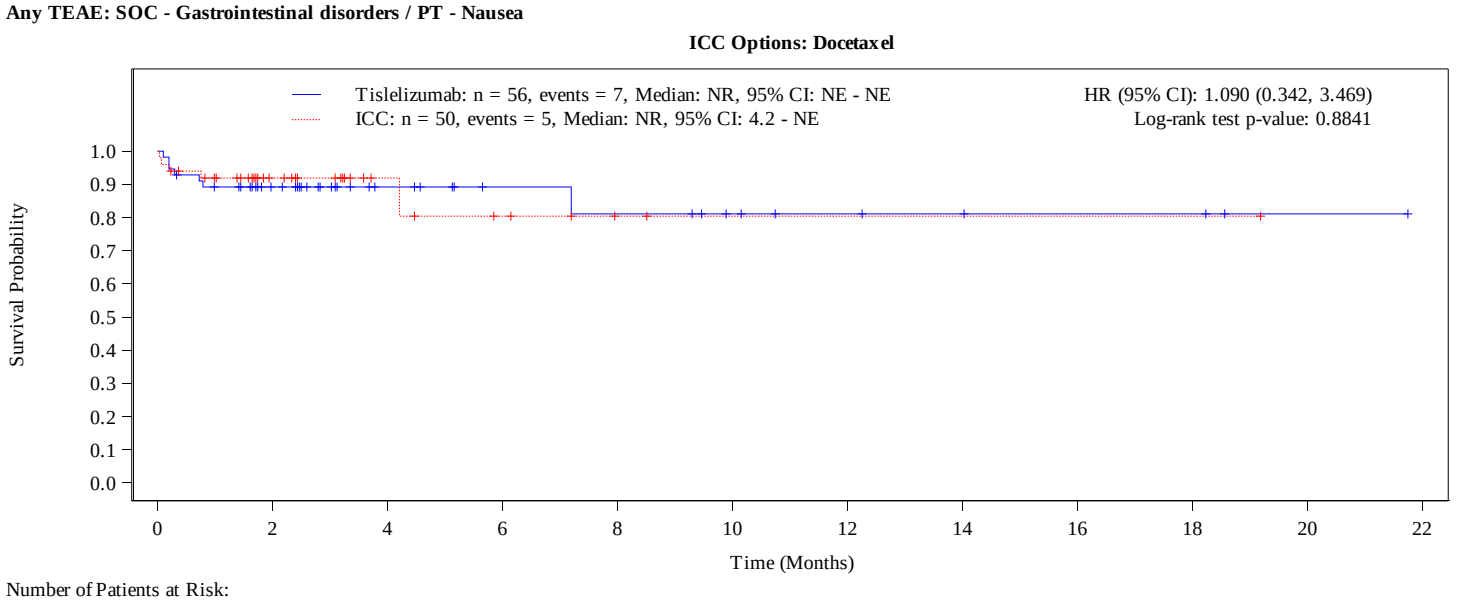
Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



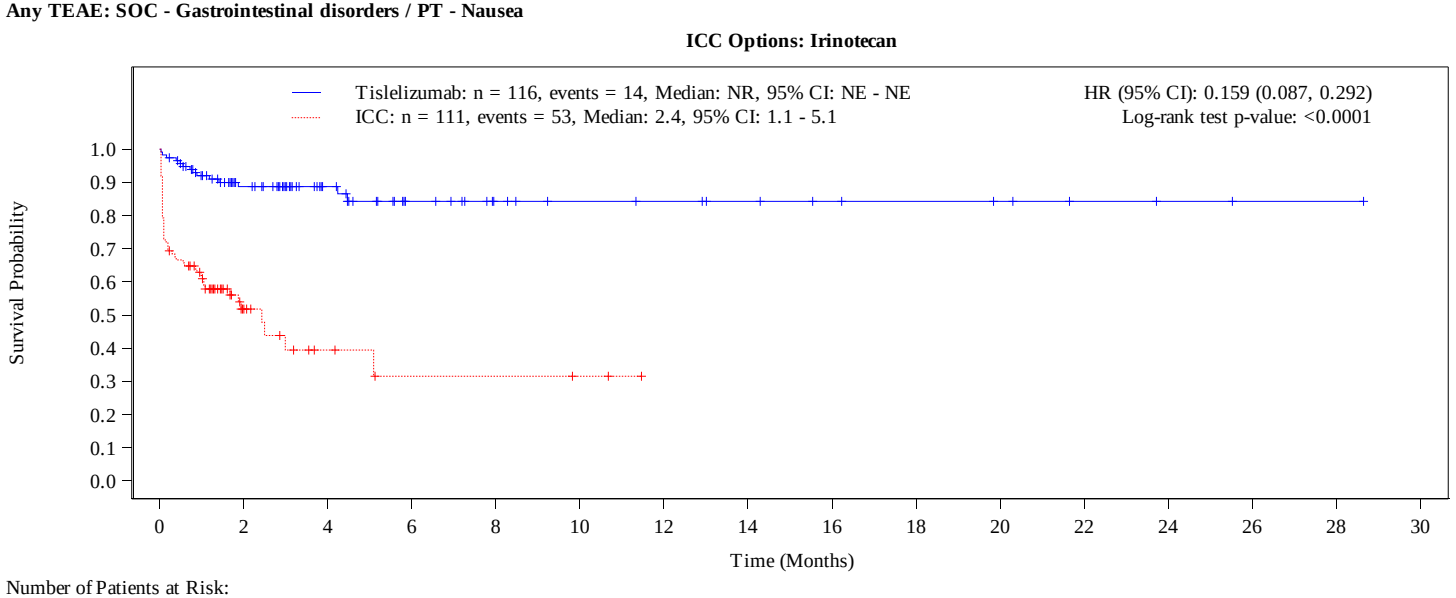
Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



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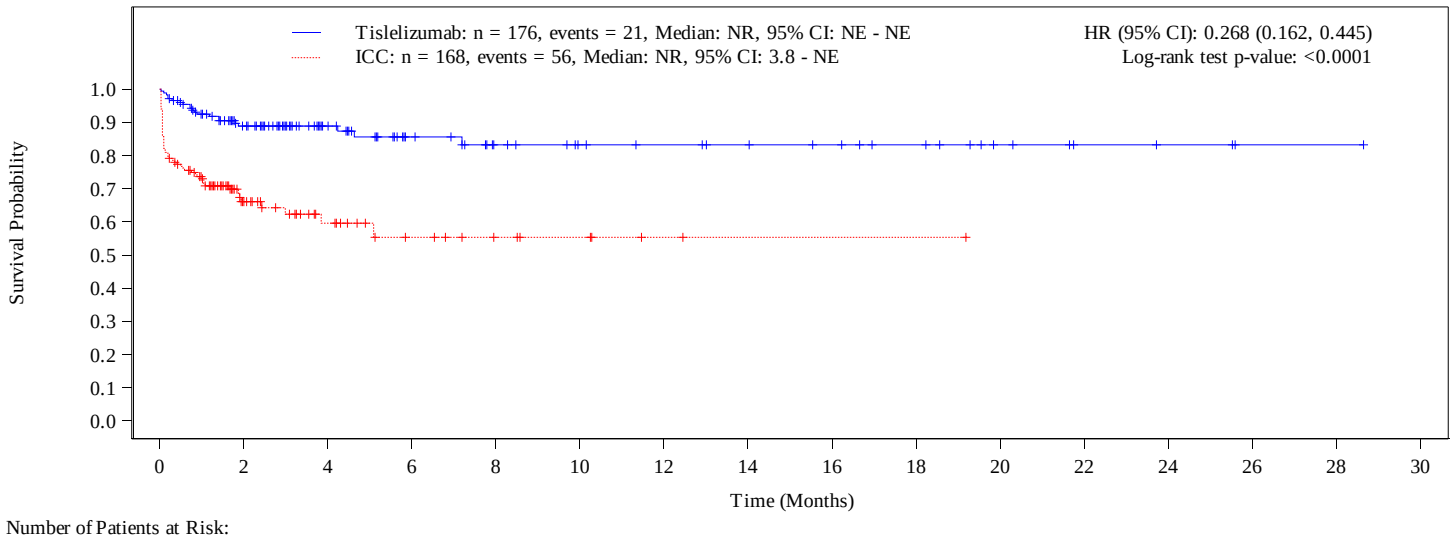
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Nausea

Region #2: Asia (excluding Japan)



Number of Patients at Risk:

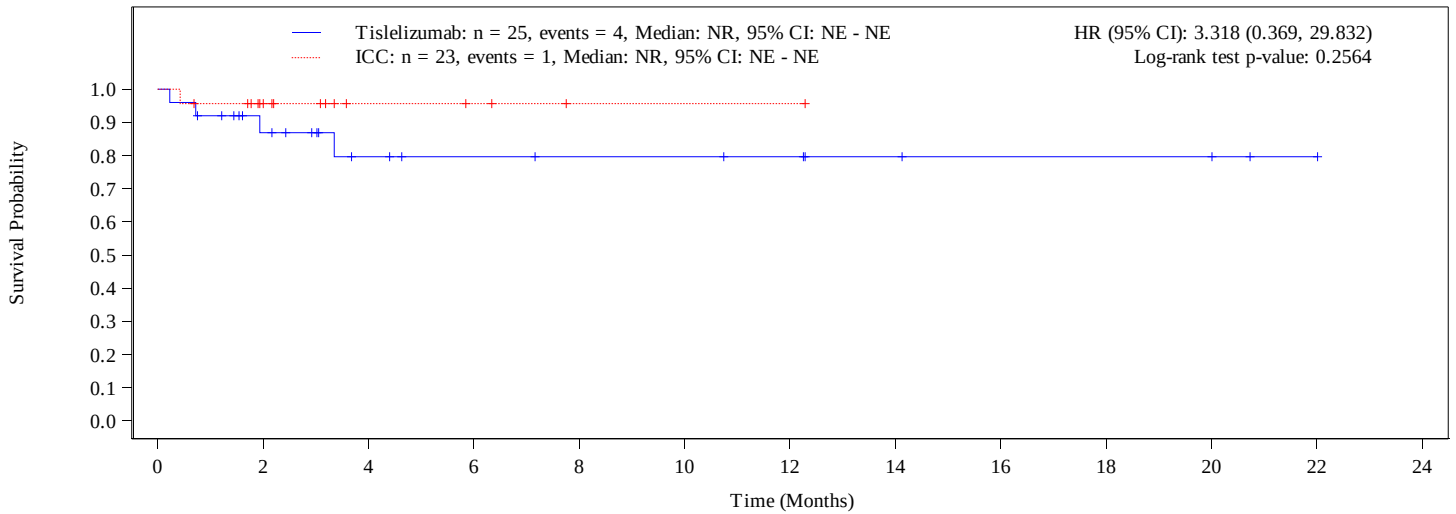
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	176	108	60	38	28	22	20	18	15	12	7	4	3	1	1	0
ICC	168	47	22	11	7	5	2	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Nausea

Region #2: Japan

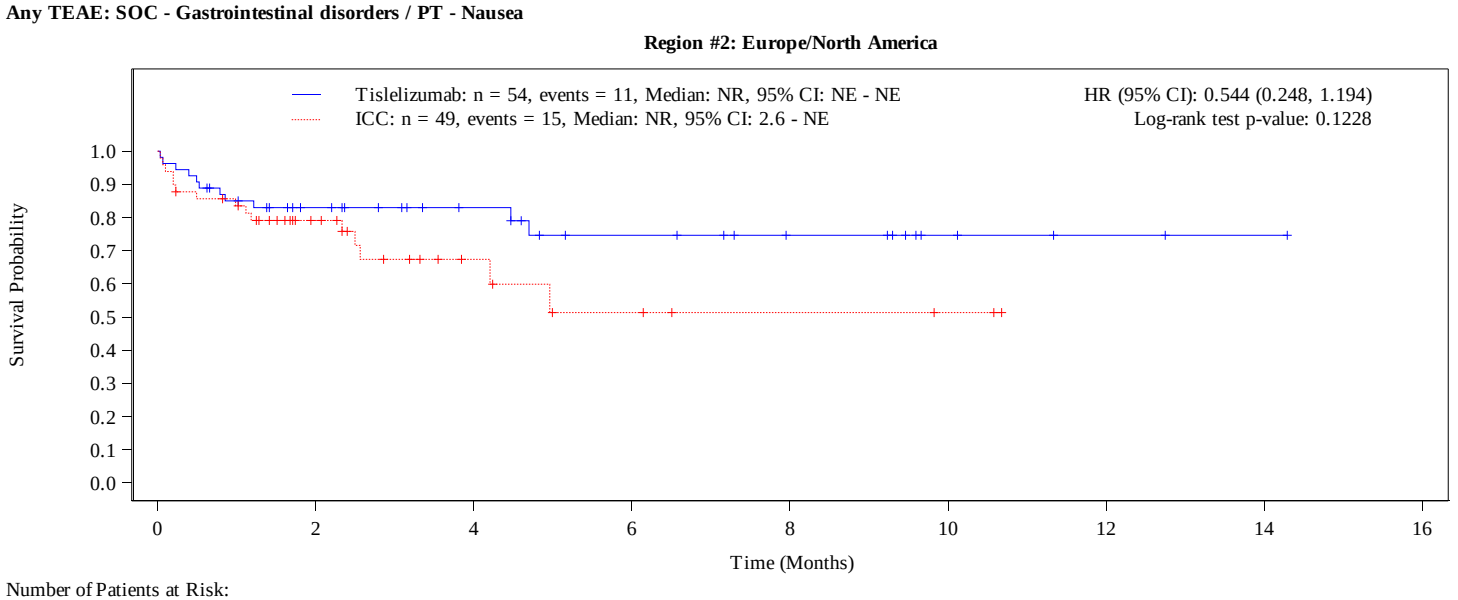


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24
Tislelizumab	25	17	10	8	7	7	6	4	3	3	3	1	0
ICC	23	12	4	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

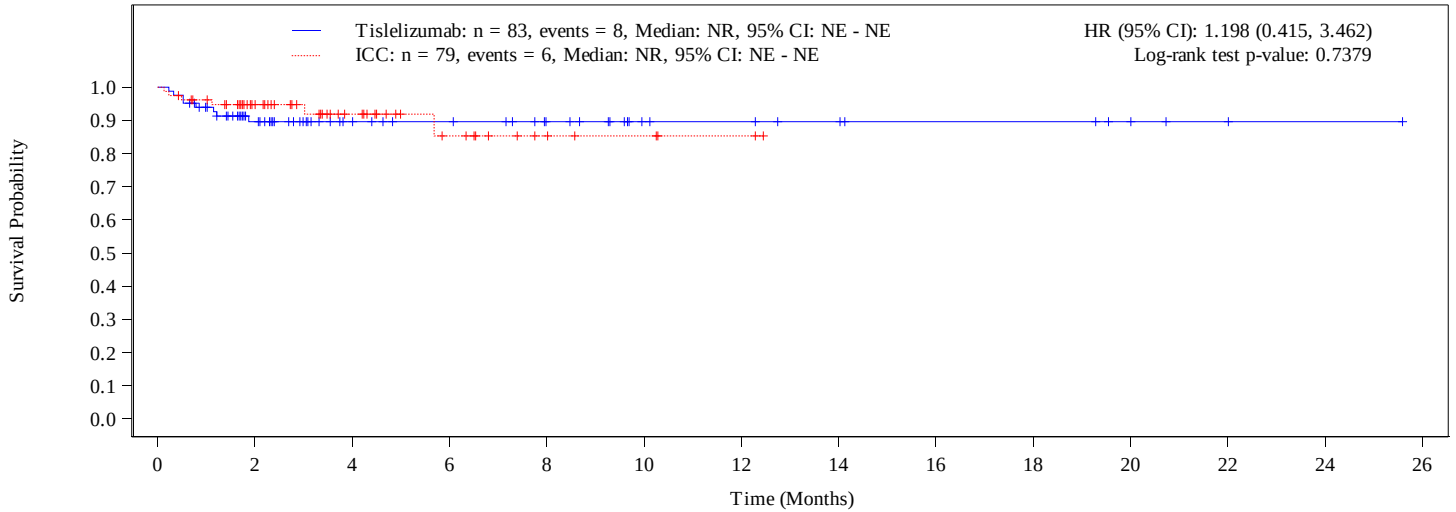


Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Vomiting

ICC Options: Paclitaxel

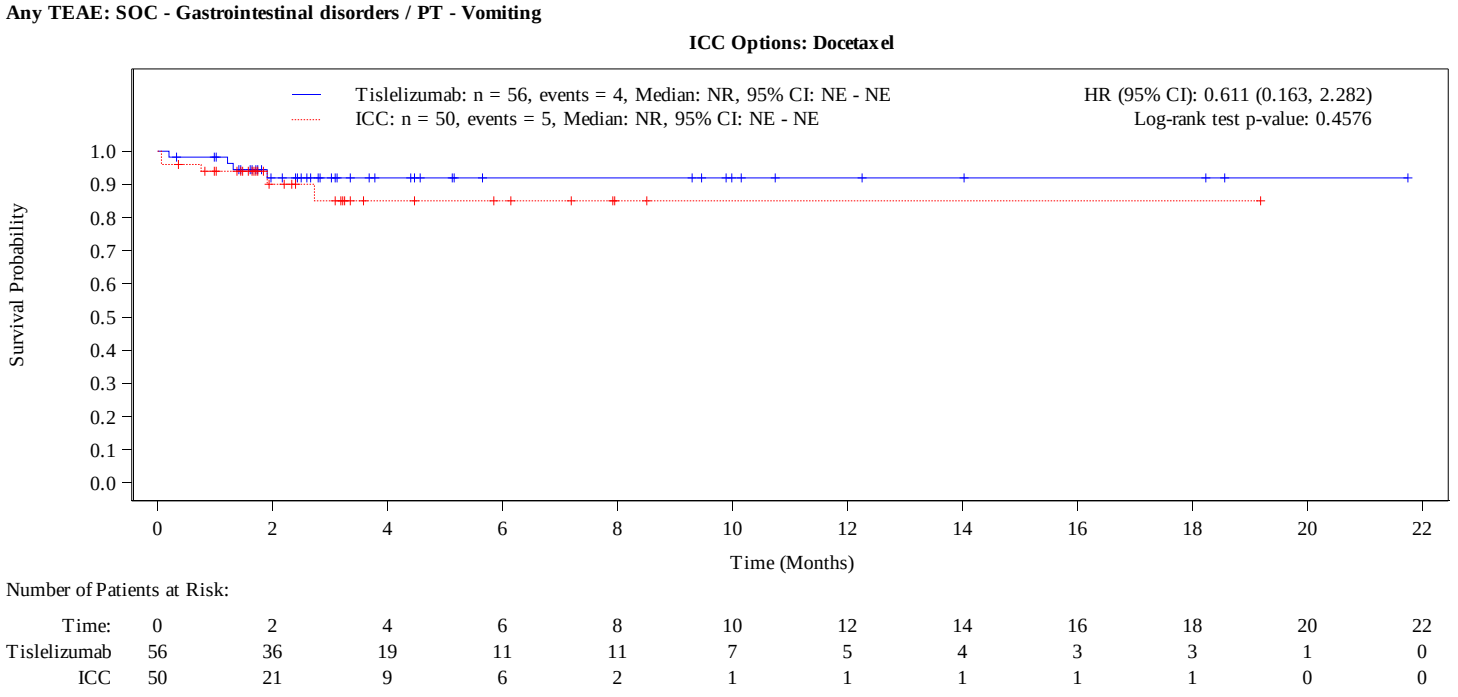


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	83	53	30	26	19	11	10	8	6	6	4	2	1	0
ICC	79	51	23	12	6	4	2	0	0	0	0	0	0	0

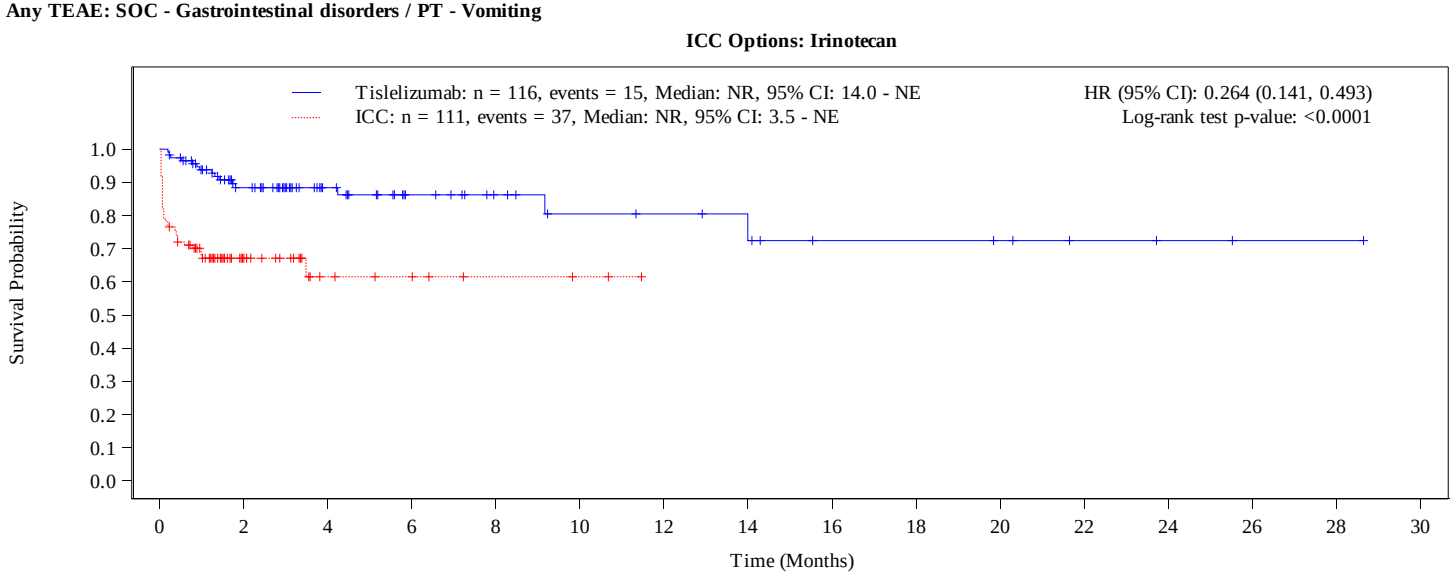
Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



Number of Patients at Risk:

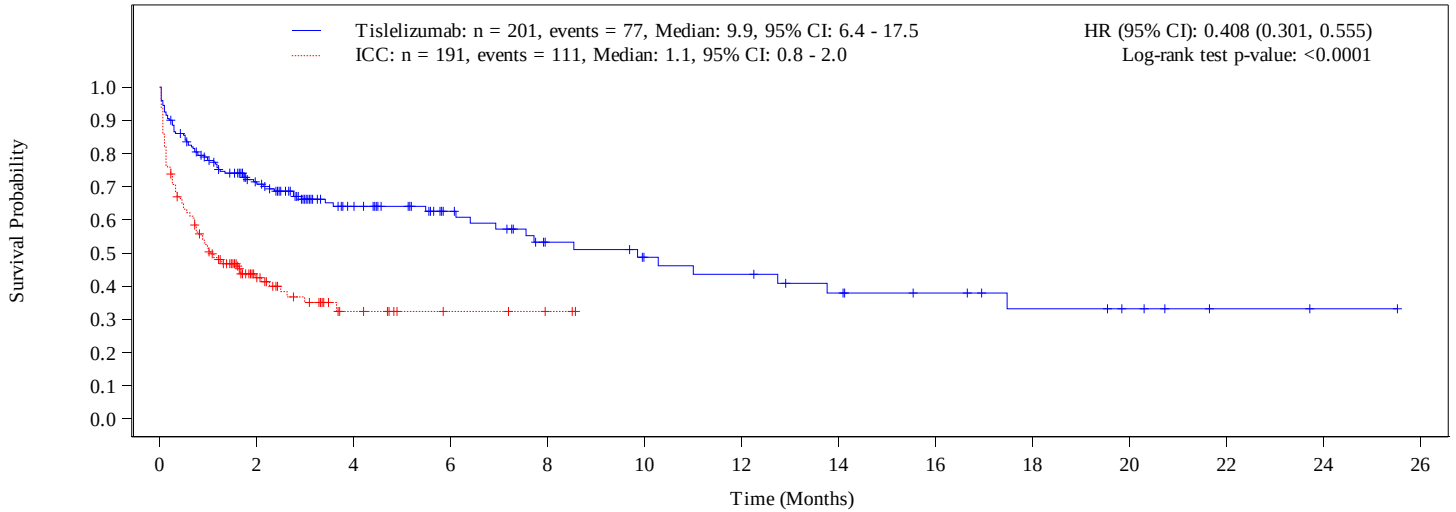
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	116	73	42	24	17	13	11	9	6	6	5	3	2	1	1	0
ICC	111	25	8	6	3	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions

Region #1: Asia



Number of Patients at Risk:

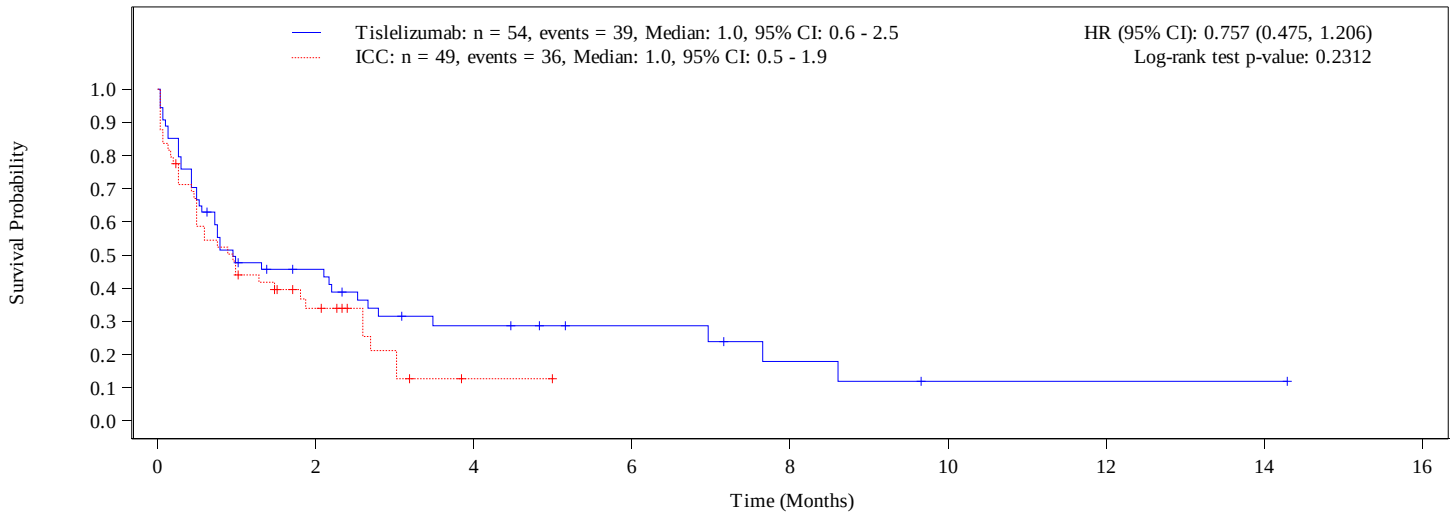
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	201	103	55	36	24	19	17	13	10	7	5	2	1	0
ICC	191	37	10	4	2	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions

Region #1: Europe/North America



Number of Patients at Risk:

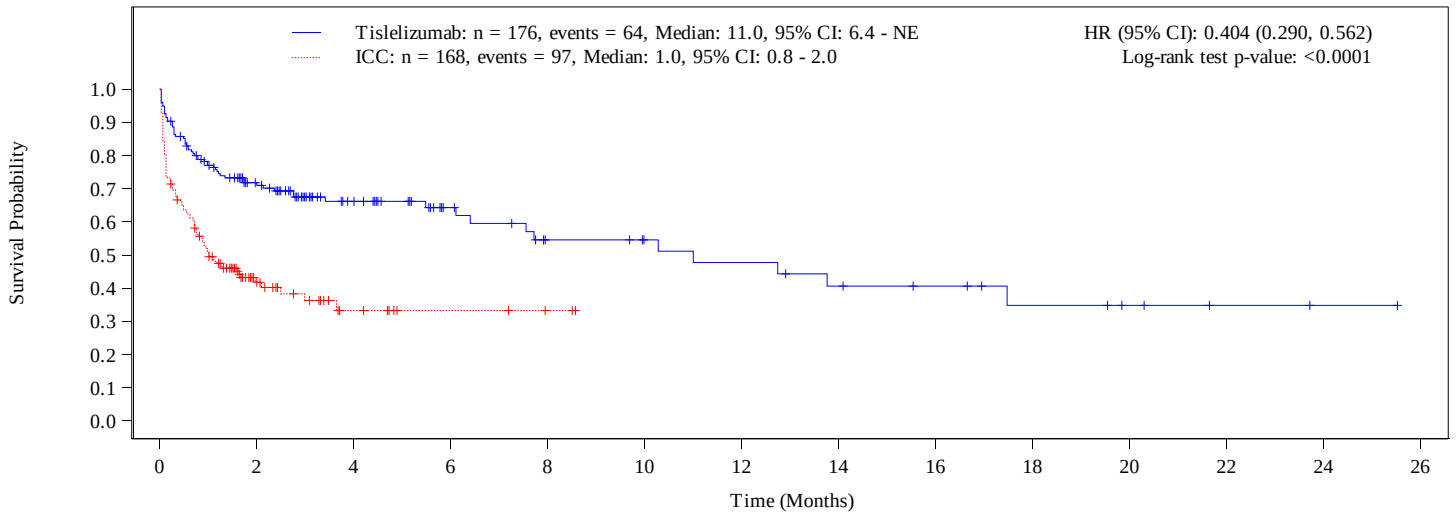
Time:	0	2	4	6	8	10	12	14	16
Tislelizumab	54	20	10	6	3	1	1	1	0
ICC	49	12	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions

Region #2: Asia (excluding Japan)

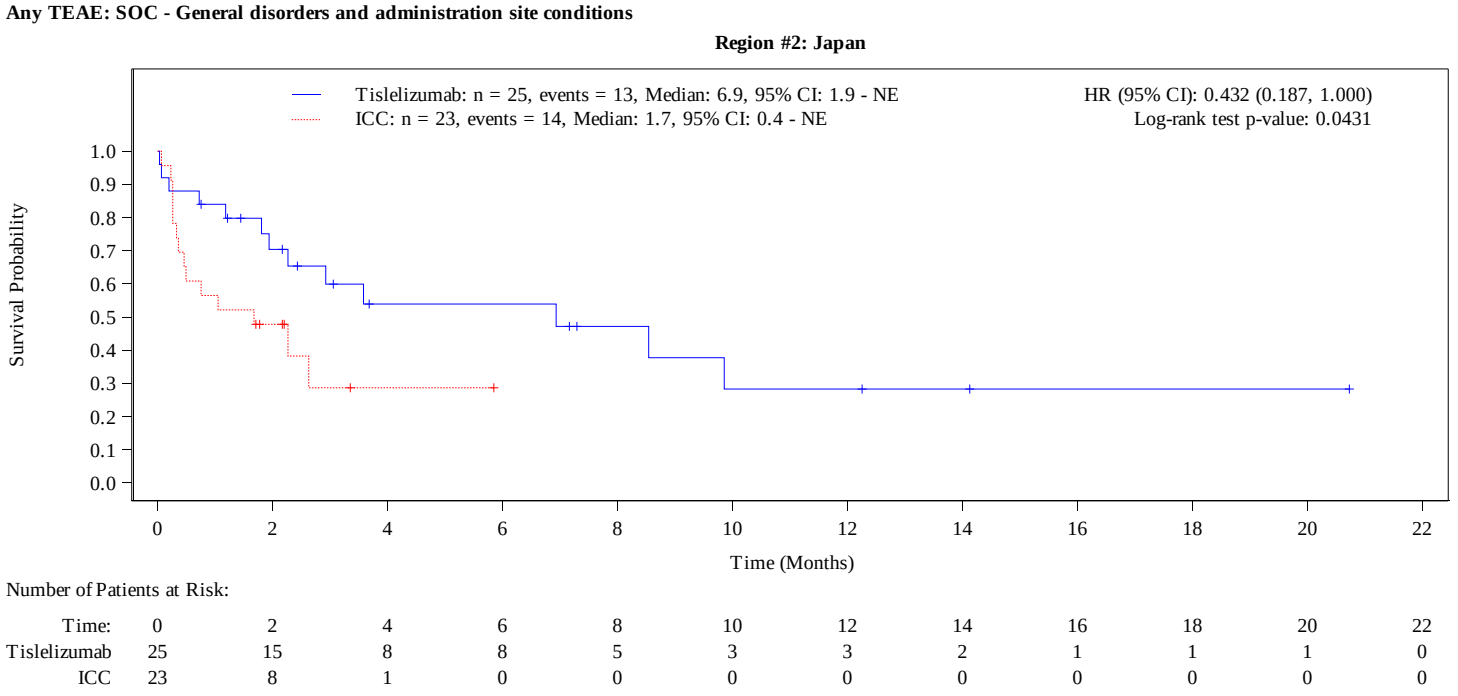


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	176	88	47	28	19	16	14	11	9	6	4	2	1	0
ICC	168	29	9	4	2	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

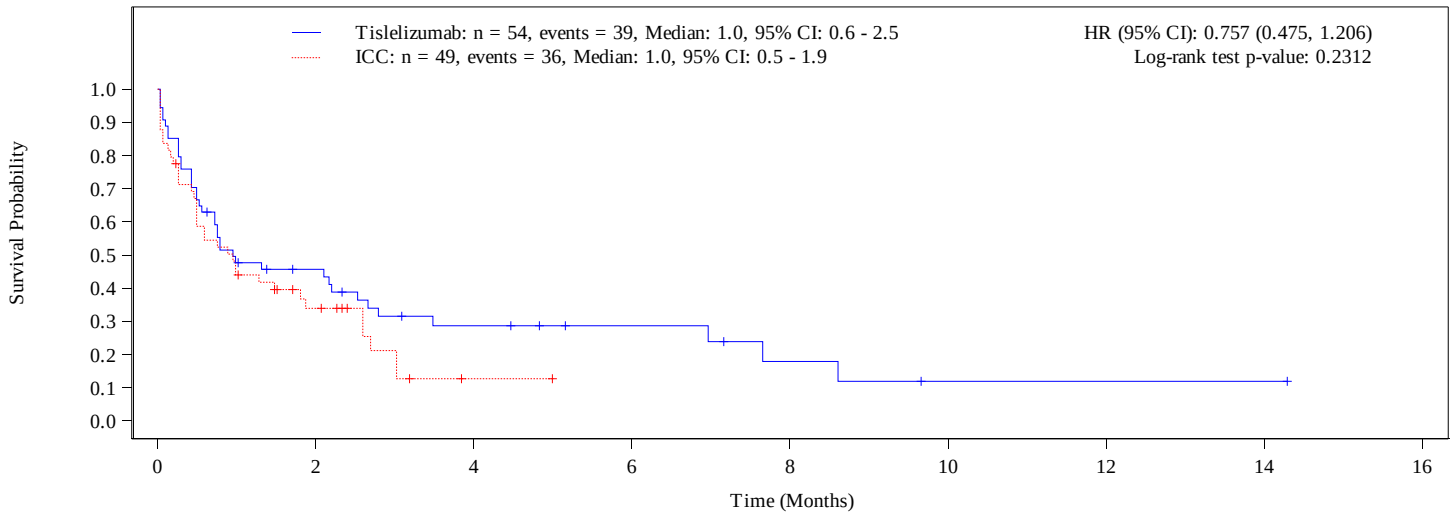


Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions

Region #2: Europe/North America



Number of Patients at Risk:

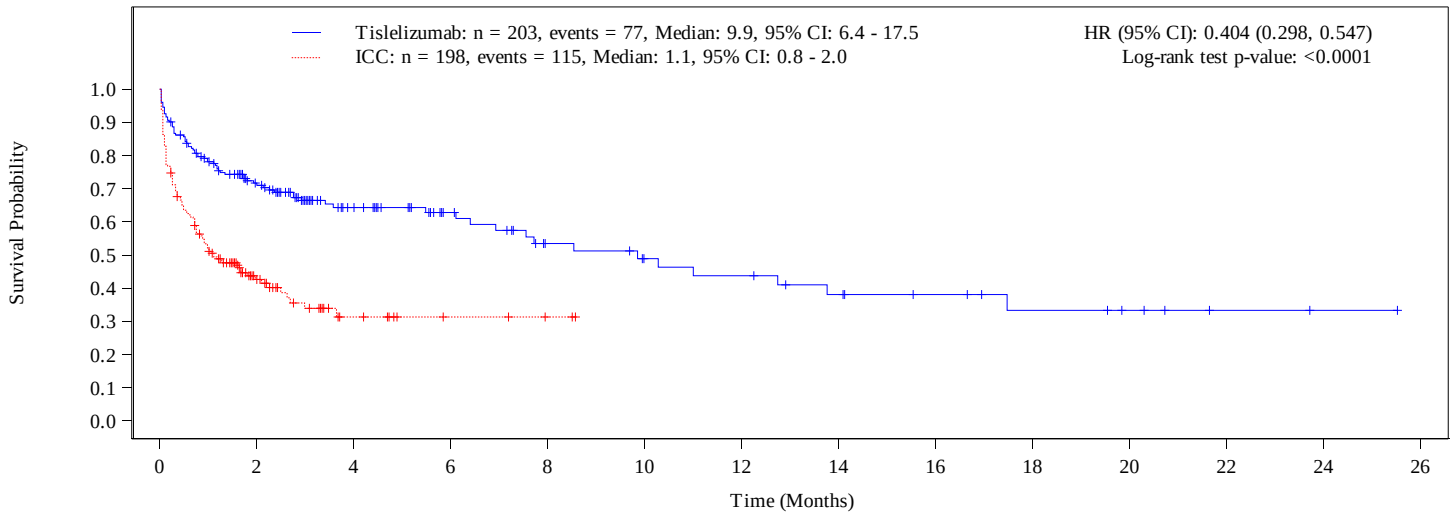
Time:	0	2	4	6	8	10	12	14	16
Tislelizumab	54	20	10	6	3	1	1	1	0
ICC	49	12	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions

Race: Asian and other



Number of Patients at Risk:

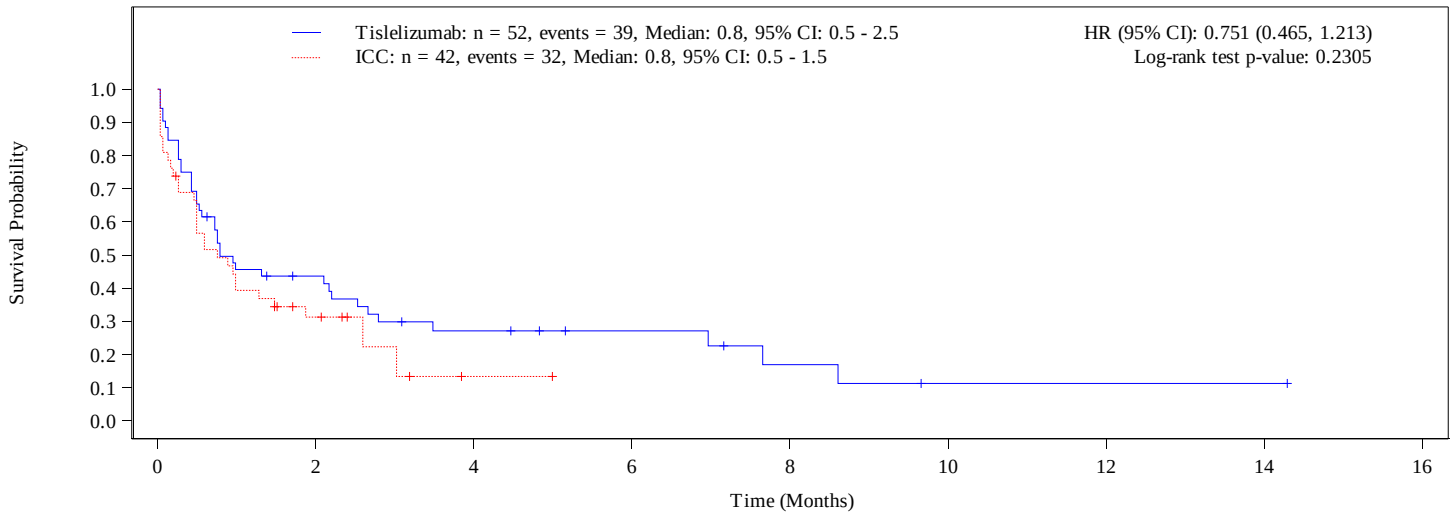
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	203	104	55	36	24	19	17	13	10	7	5	2	1	0
ICC	198	39	10	4	2	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions

Race: White

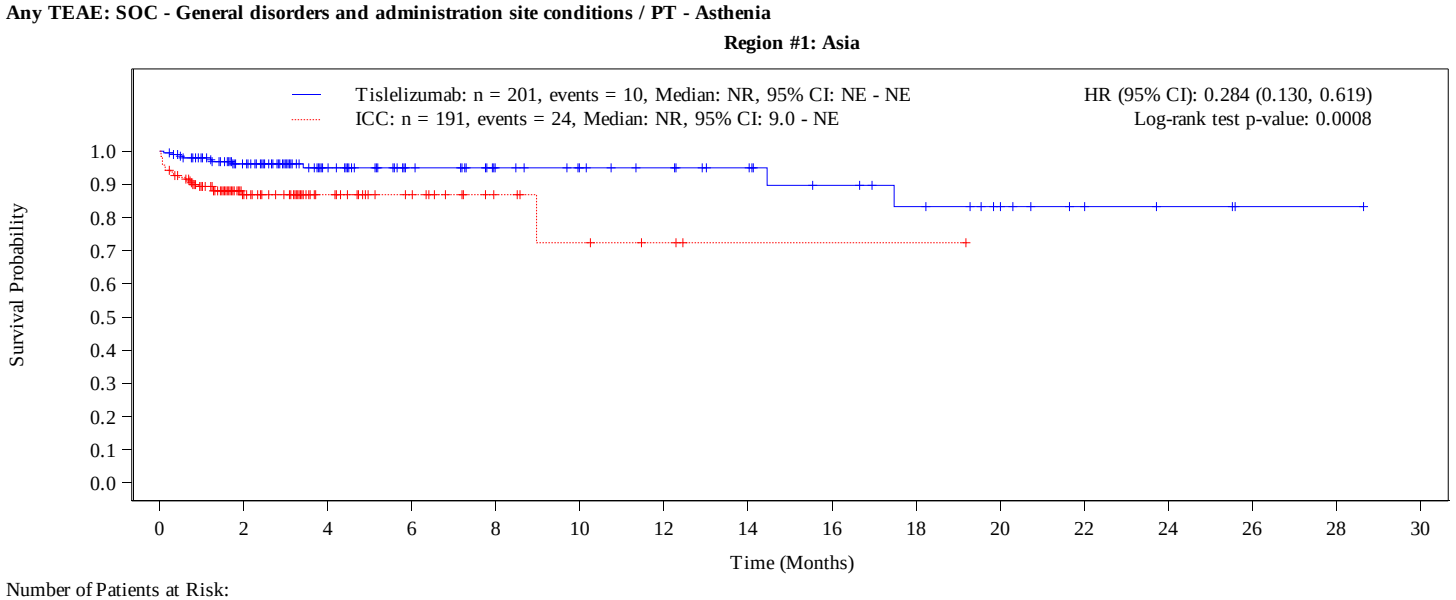


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16
Tislelizumab	52	19	10	6	3	1	1	1	0
ICC	42	10	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	201	131	71	46	35	29	26	22	16	13	9	5	3	1	1	0
ICC	191	74	31	17	8	5	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
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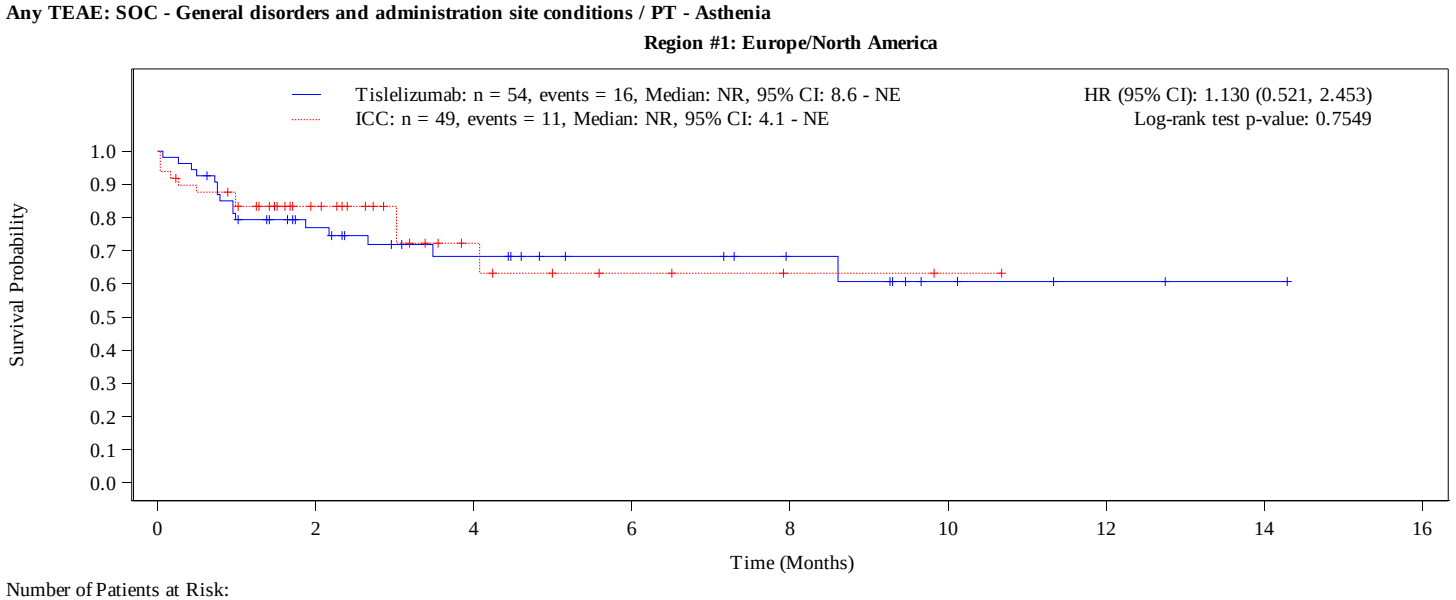
Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16
Tislelizumab	54	32	19	12	9	4	2	1	0
ICC	49	27	8	4	2	1	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
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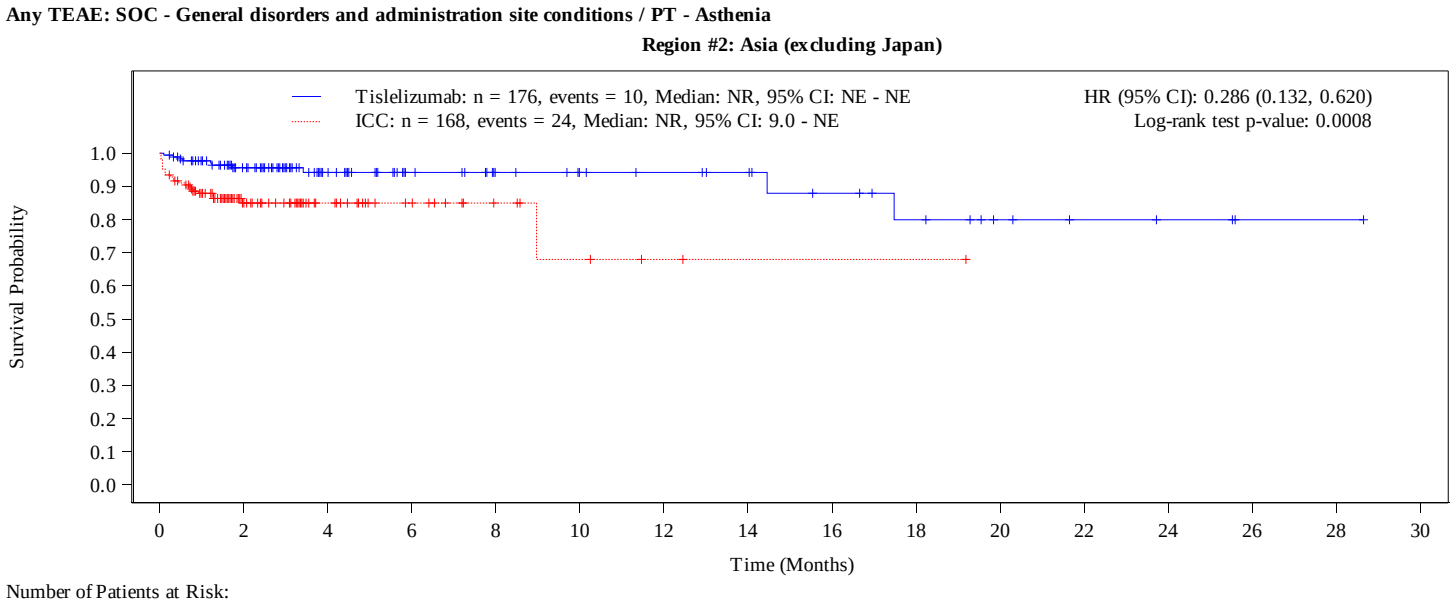
Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

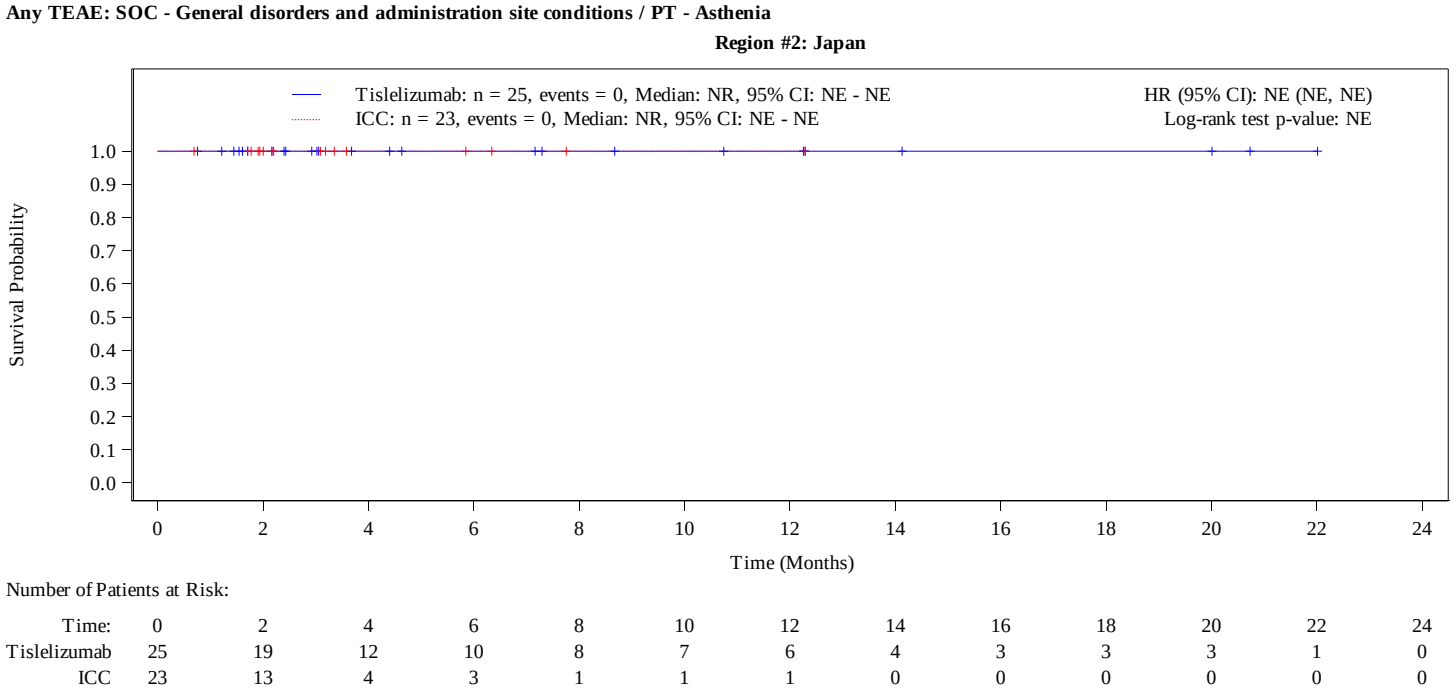


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	176	112	59	36	27	22	20	18	13	10	6	4	3	1	1	0
ICC	168	61	27	14	7	4	2	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

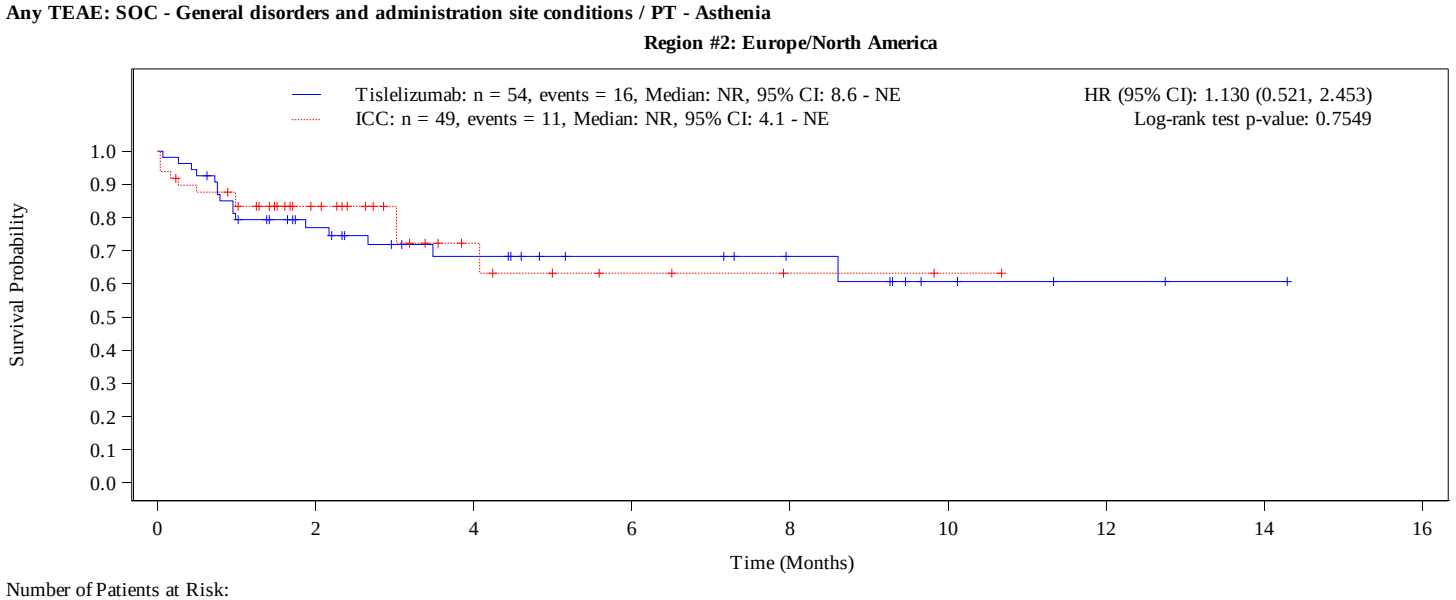


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24
Tislelizumab	25	19	12	10	8	7	6	4	3	3	3	1	0
ICC	23	13	4	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

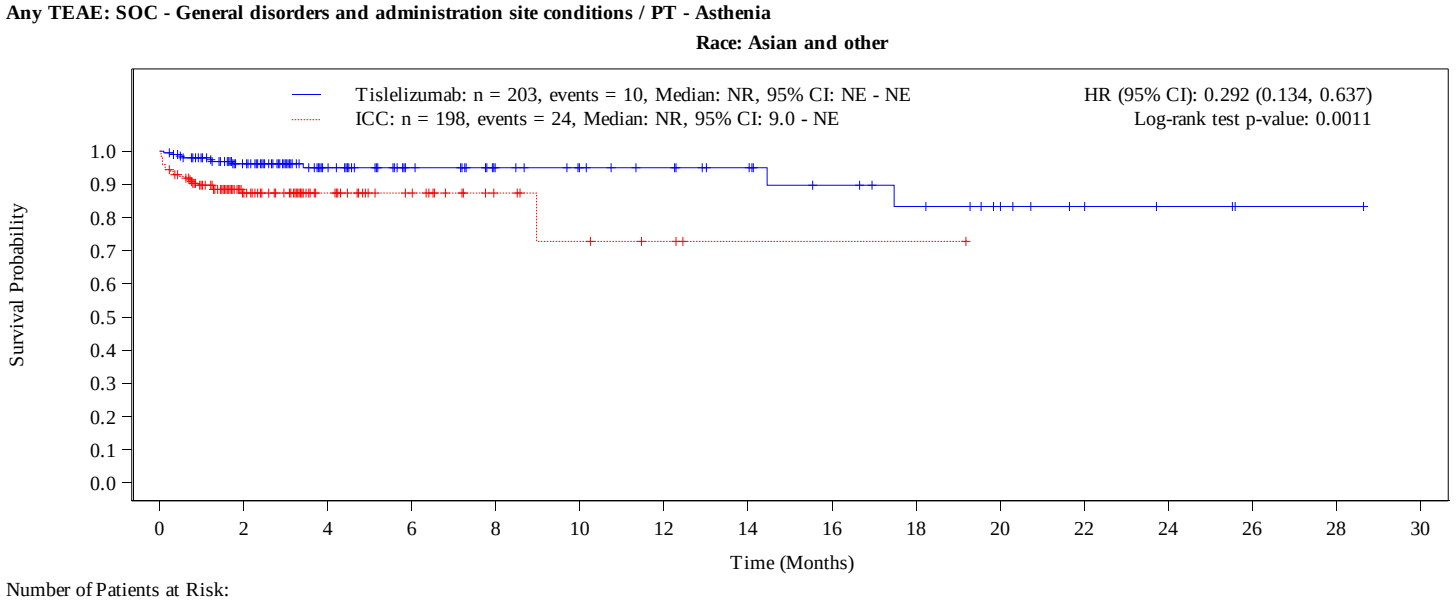


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16
Tislelizumab	54	32	19	12	9	4	2	1	0
ICC	49	27	8	4	2	1	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

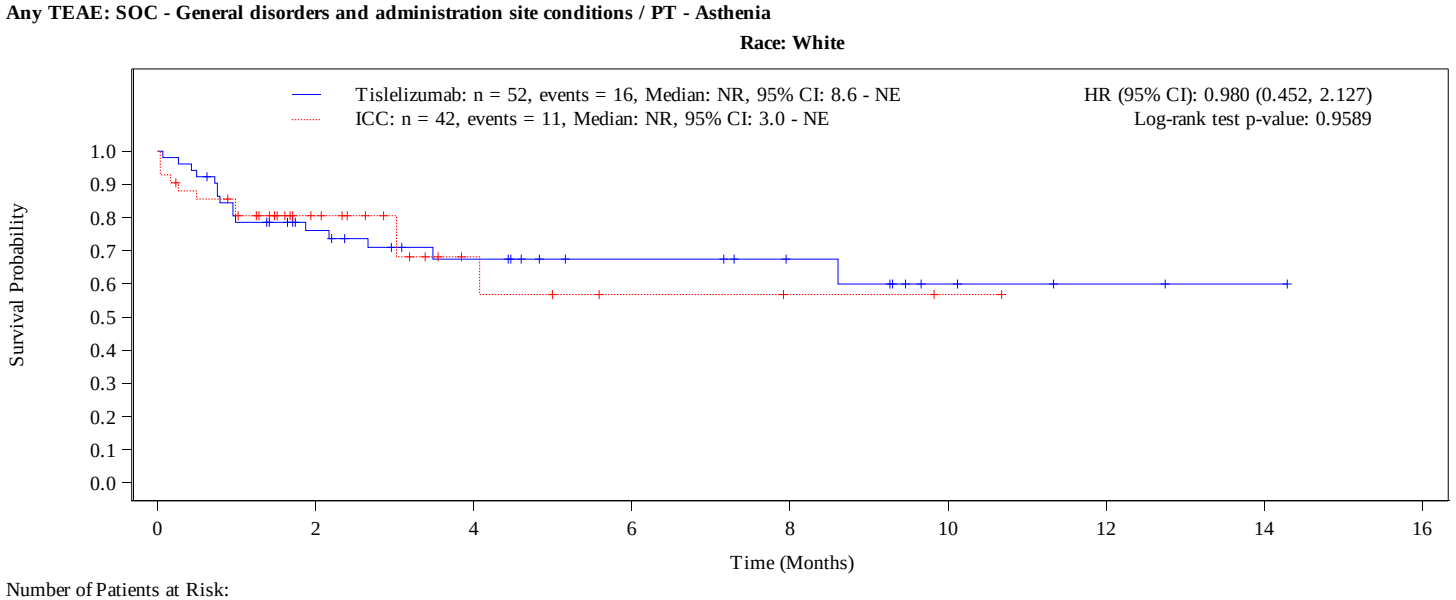


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	203	132	71	46	35	29	26	22	16	13	9	5	3	1	1	0
ICC	198	79	33	18	8	5	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



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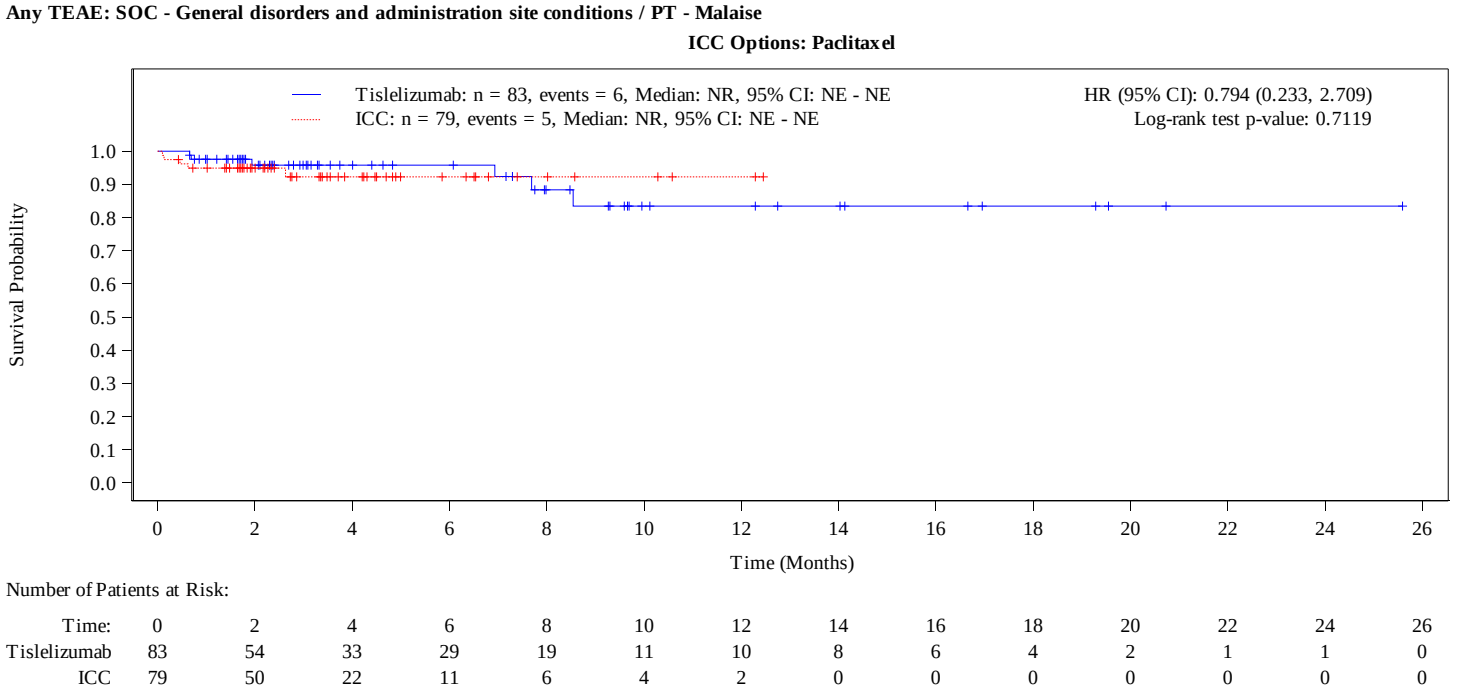
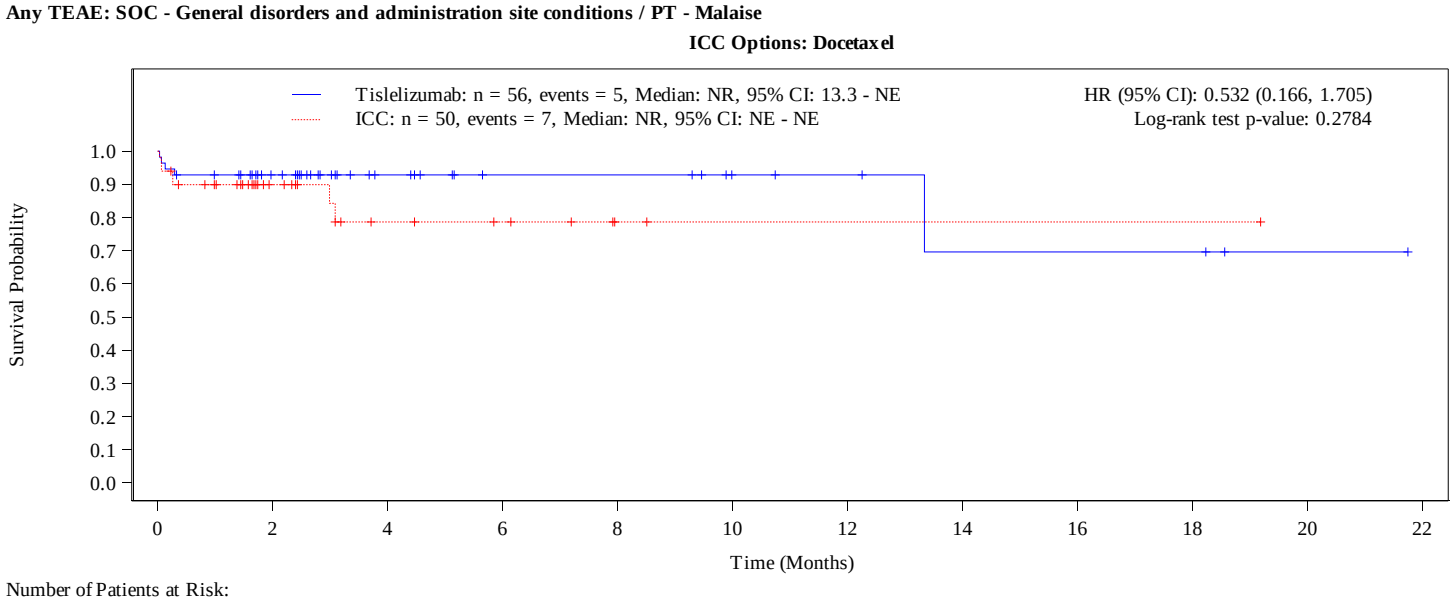
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

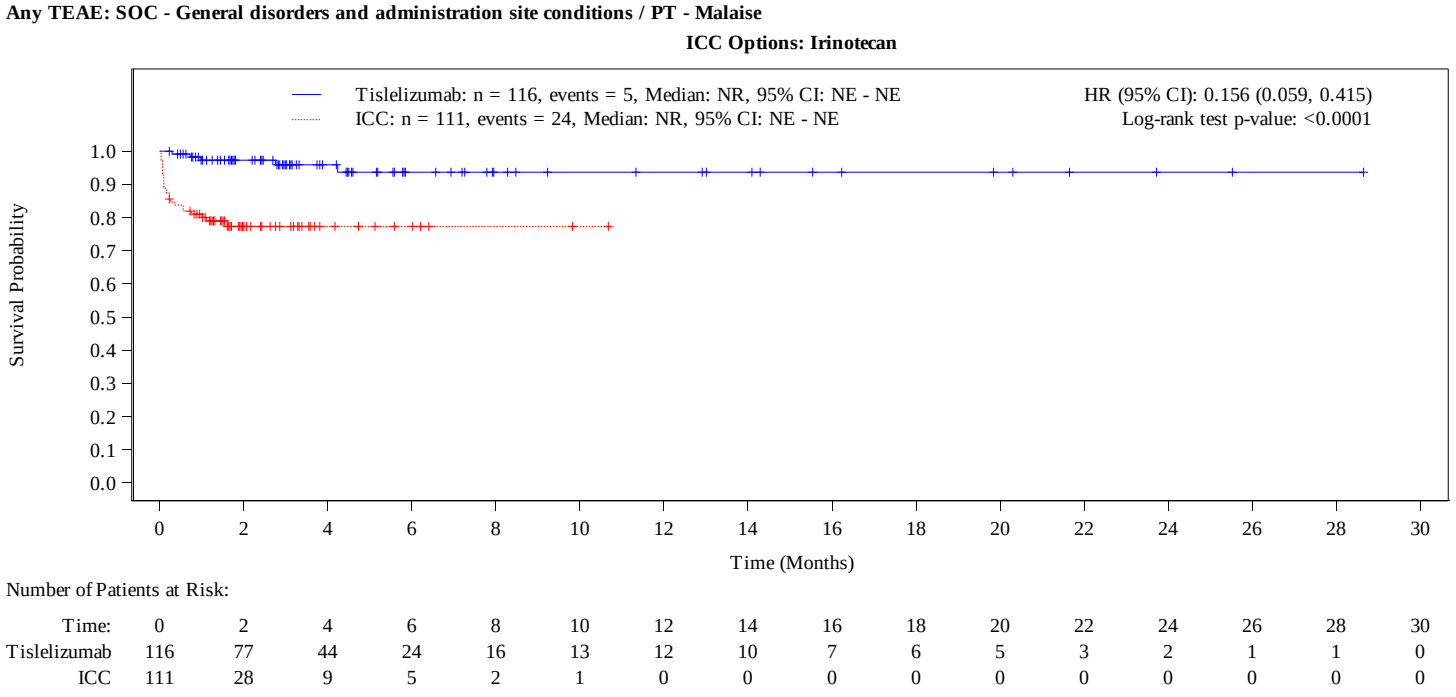


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	56	37	18	10	10	6	5	3	3	3	1	0
ICC	50	20	8	6	2	1	1	1	1	1	0	0

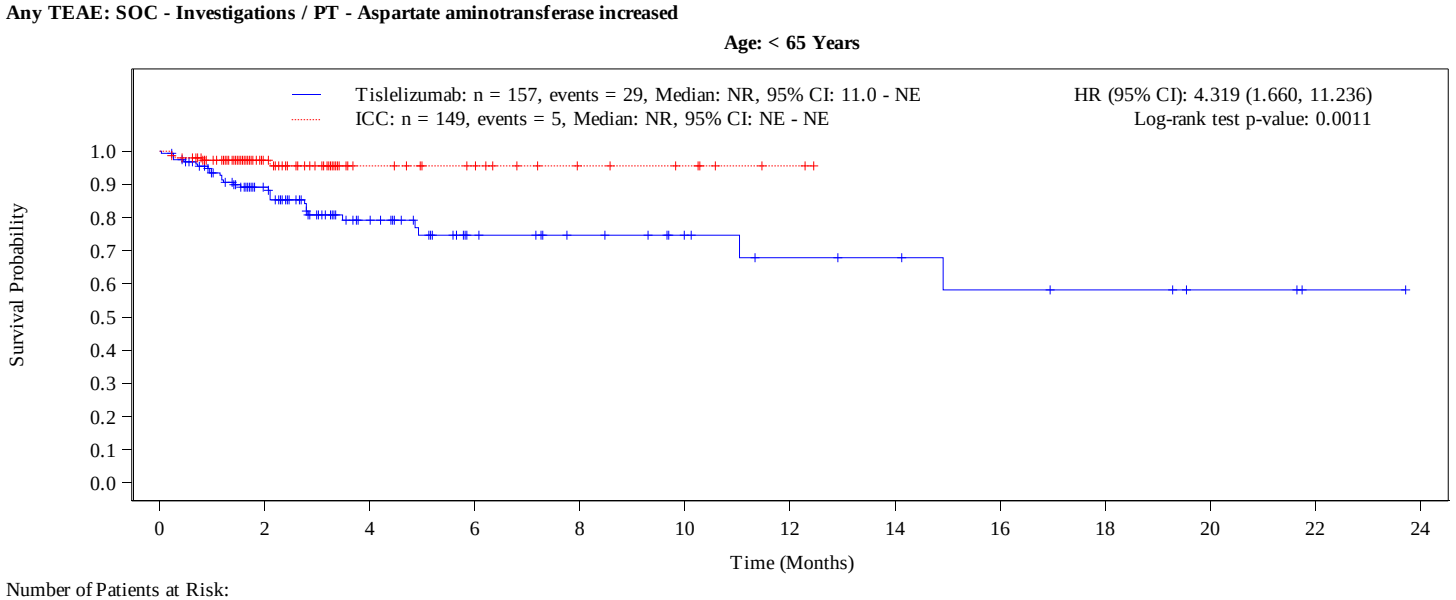
Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



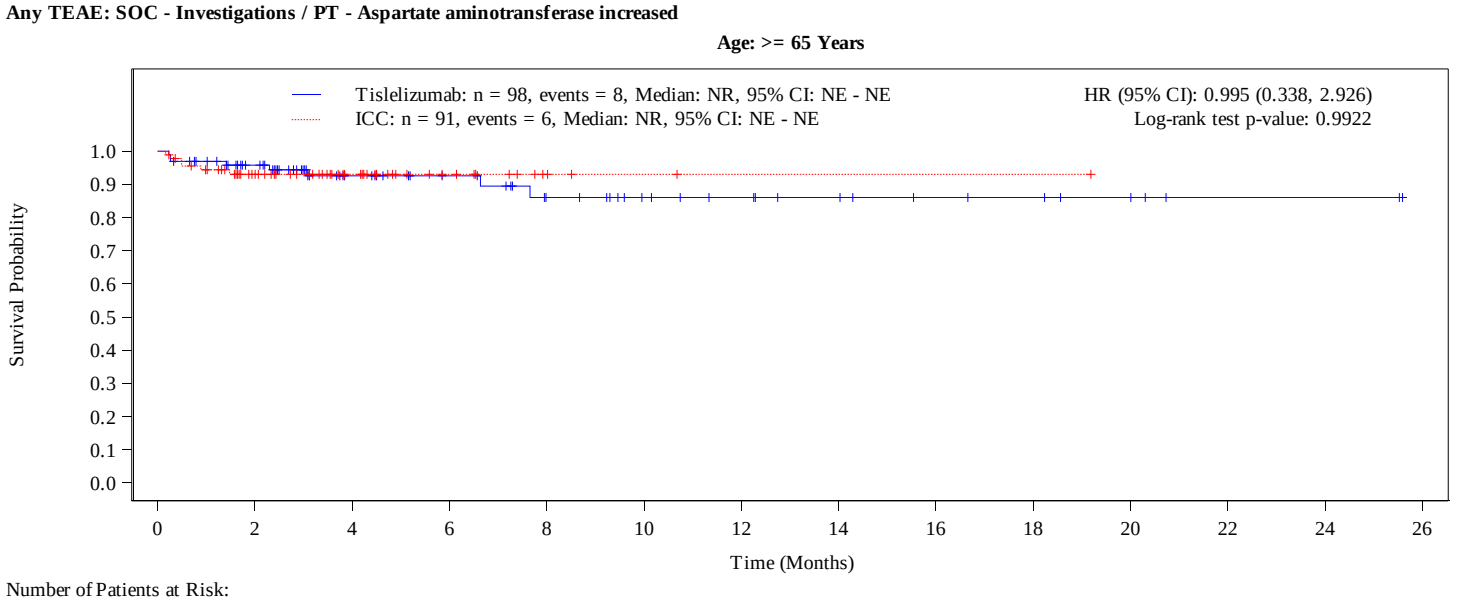
Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

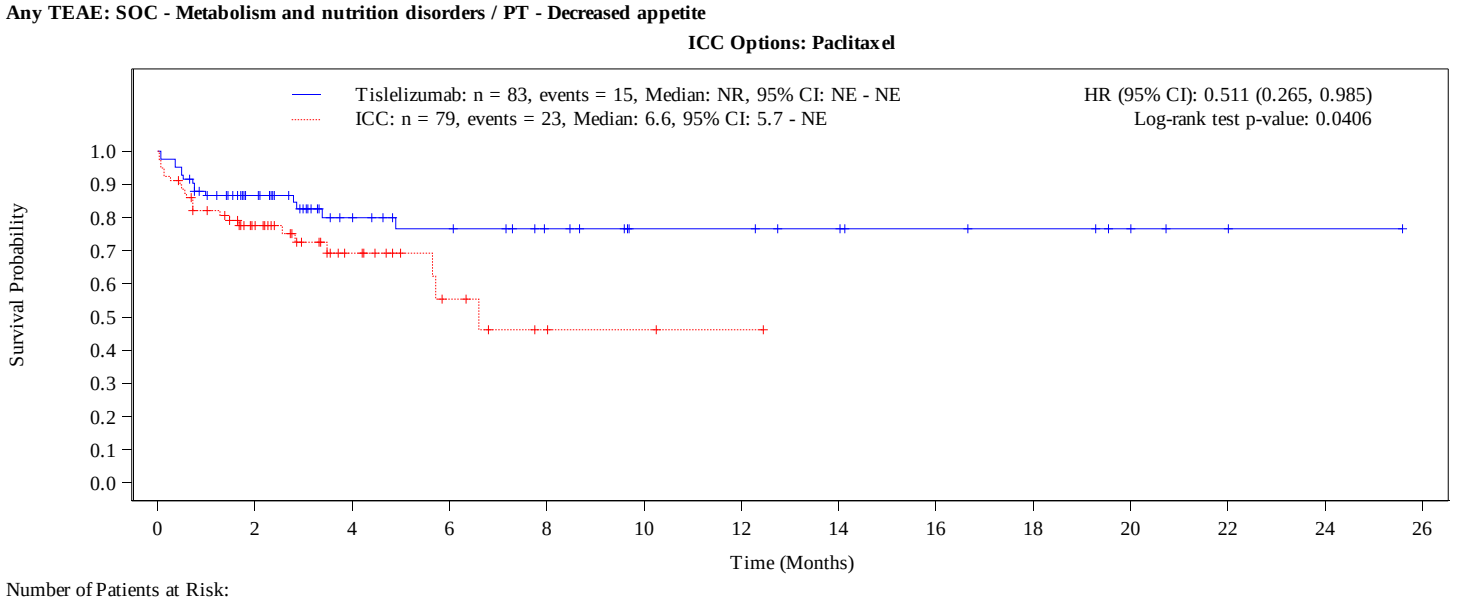


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	98	71	39	31	23	17	14	11	8	7	5	2	2	0
ICC	91	54	24	11	4	2	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



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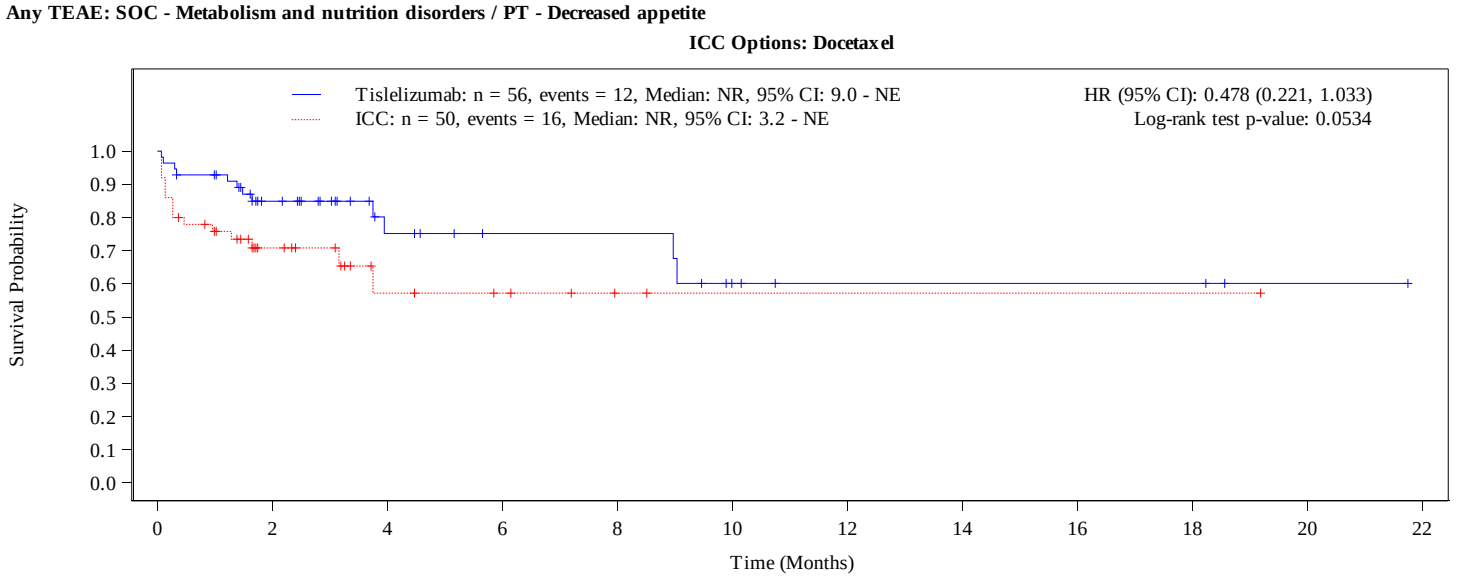
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

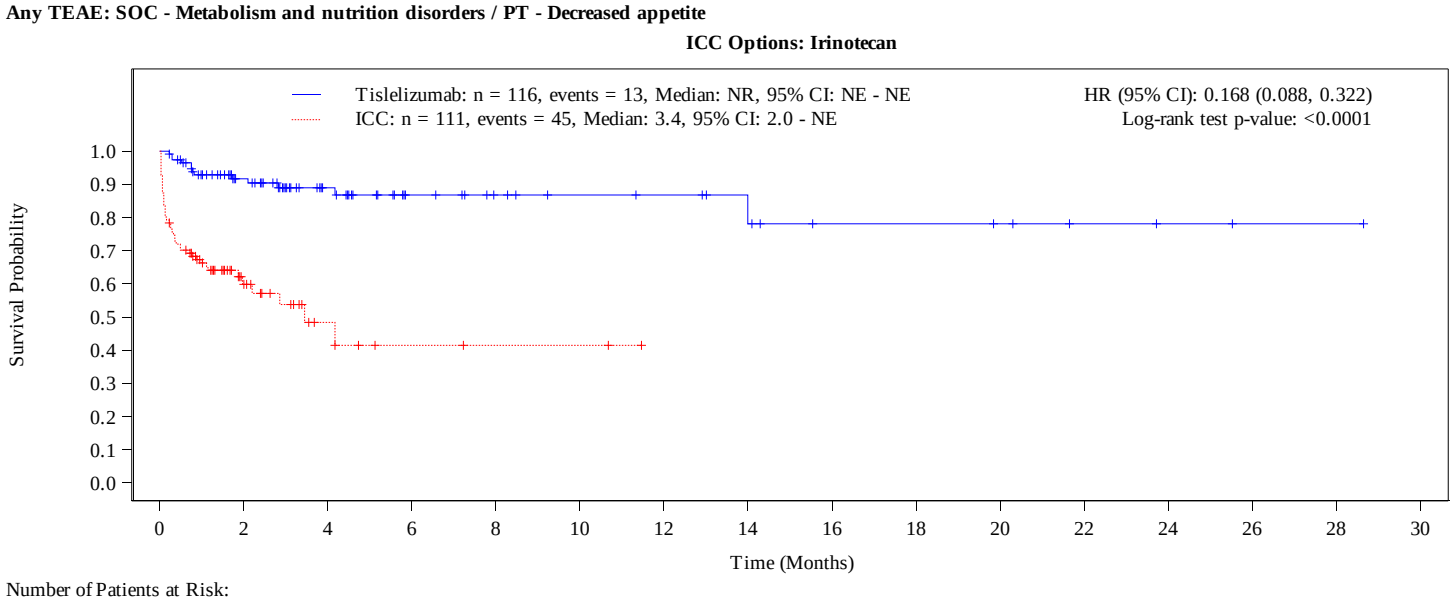


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	56	33	15	10	10	5	3	3	3	3	1	0
ICC	50	19	7	5	2	1	1	1	1	1	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



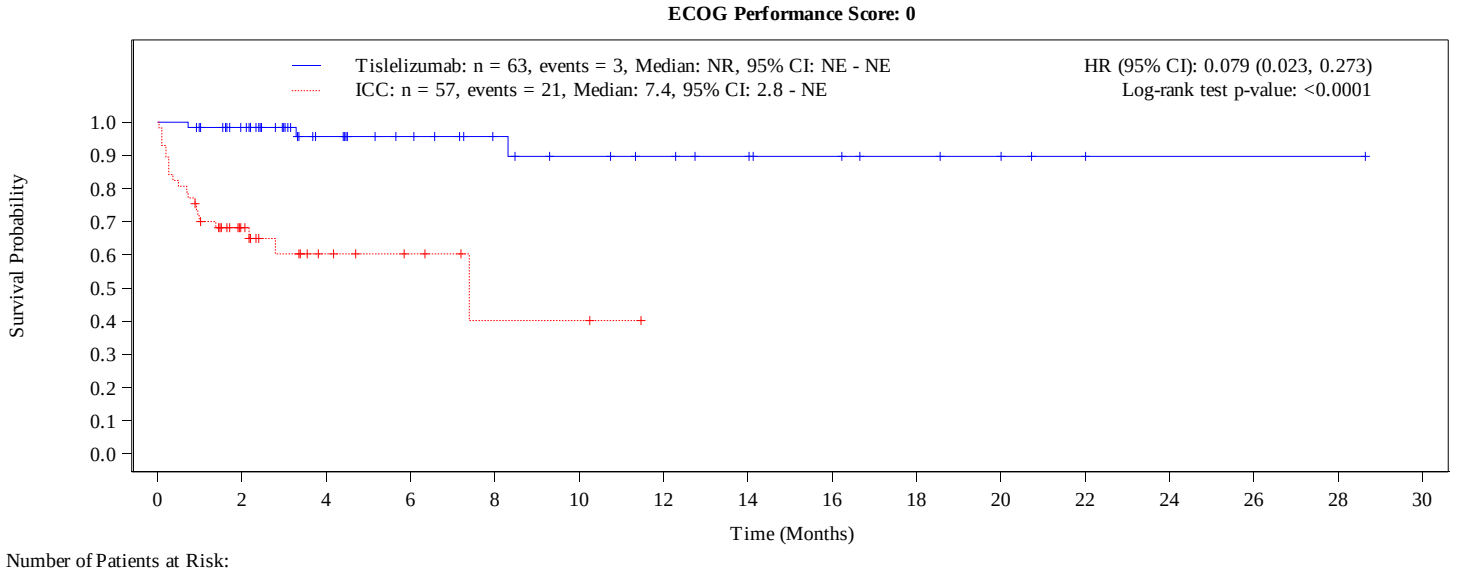
Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	116	73	41	22	16	13	12	9	6	6	5	3	2	1	1	0
ICC	111	26	7	3	2	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders

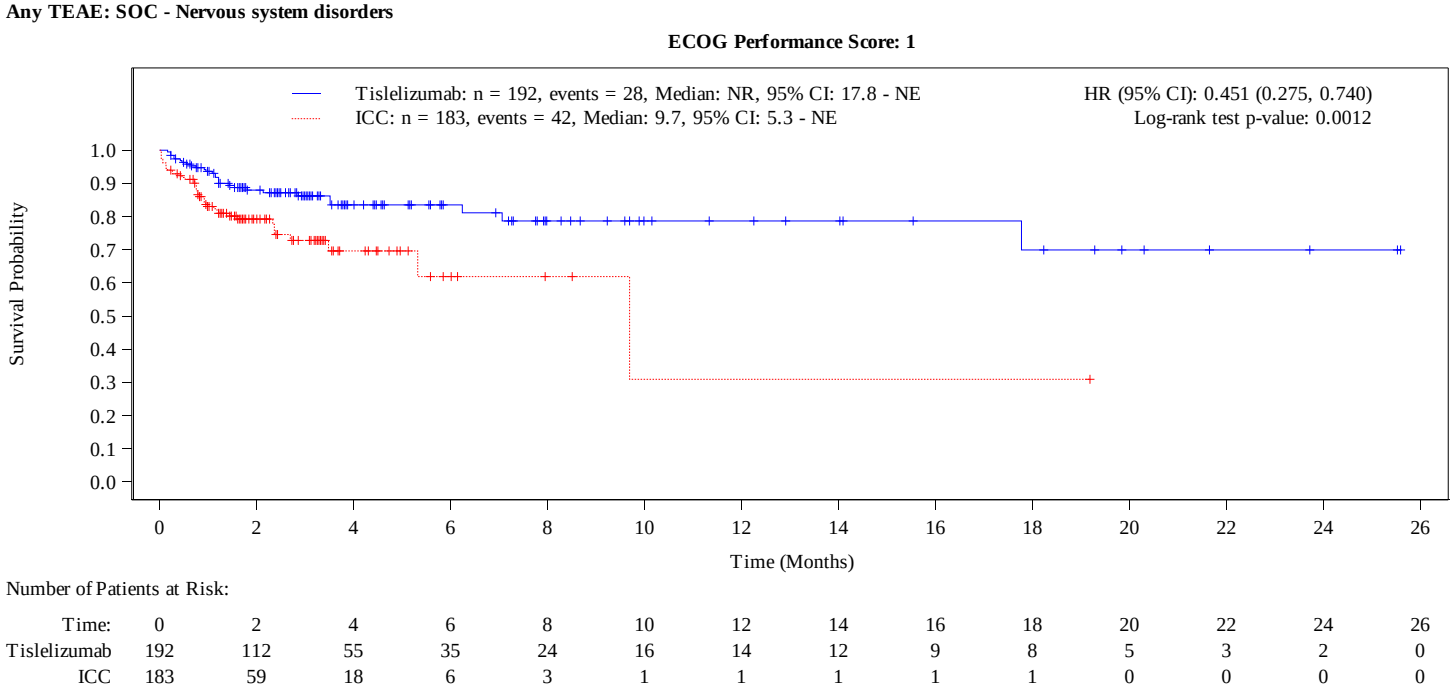


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	63	50	31	22	16	13	11	9	7	5	4	2	1	1	1	0
ICC	57	22	9	5	2	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
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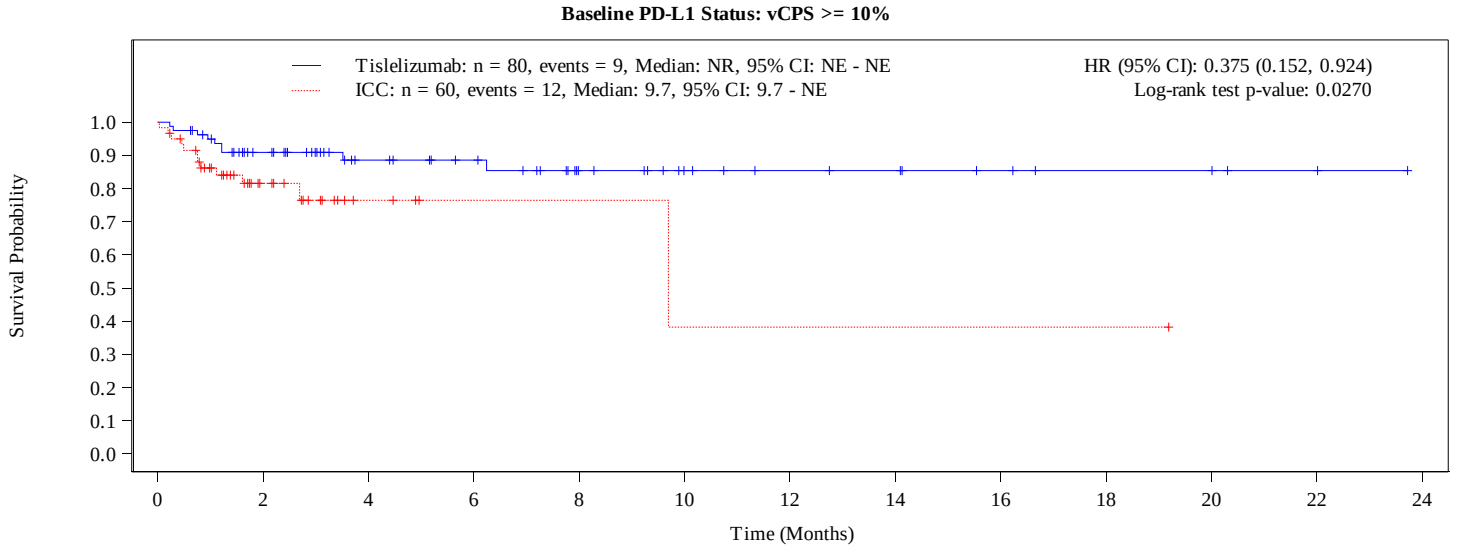
Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders



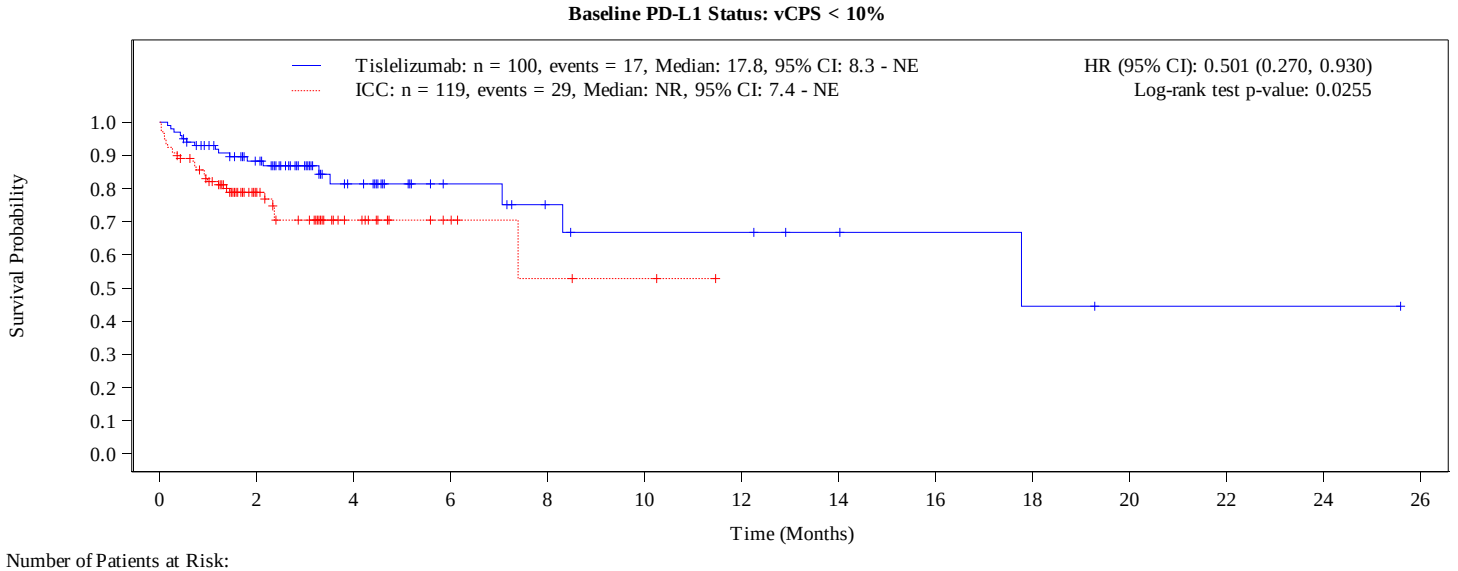
Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24
Tislelizumab	80	53	34	29	19	13	10	9	6	4	4	2	0
ICC	60	20	5	2	2	1	1	1	1	1	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders

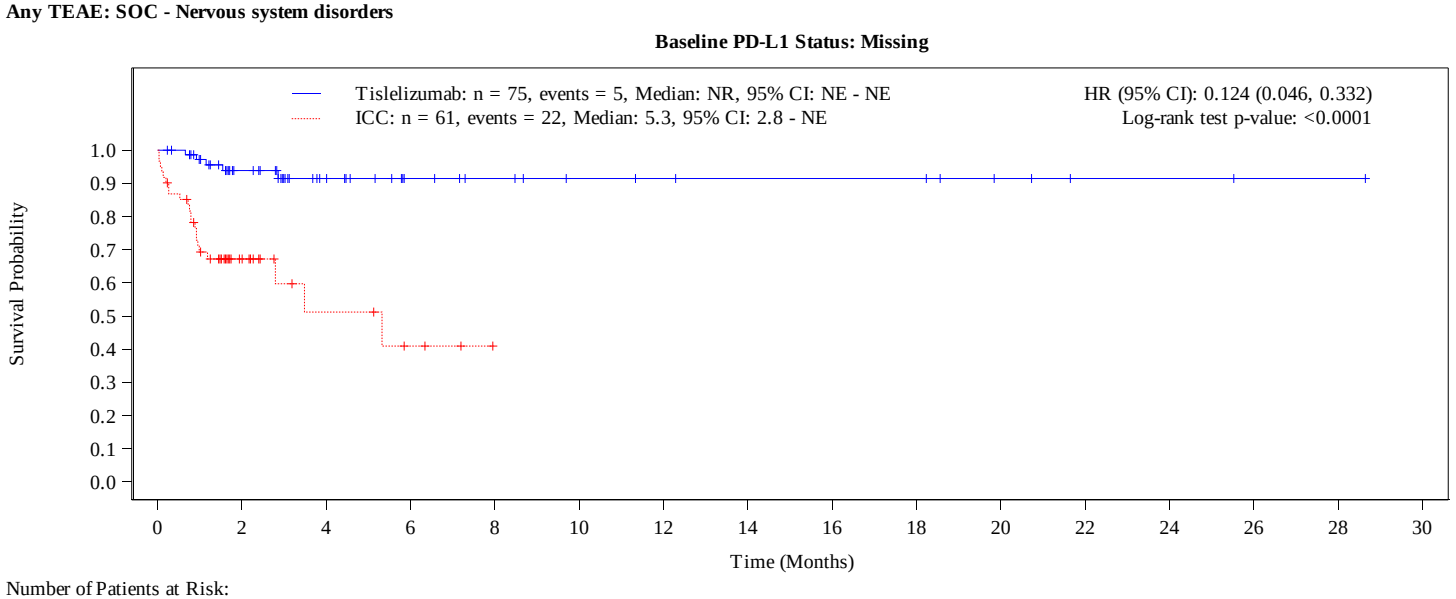


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	100	65	26	13	9	7	7	5	3	2	1	1	1	0
ICC	119	43	16	6	3	2	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



Number of Patients at Risk:

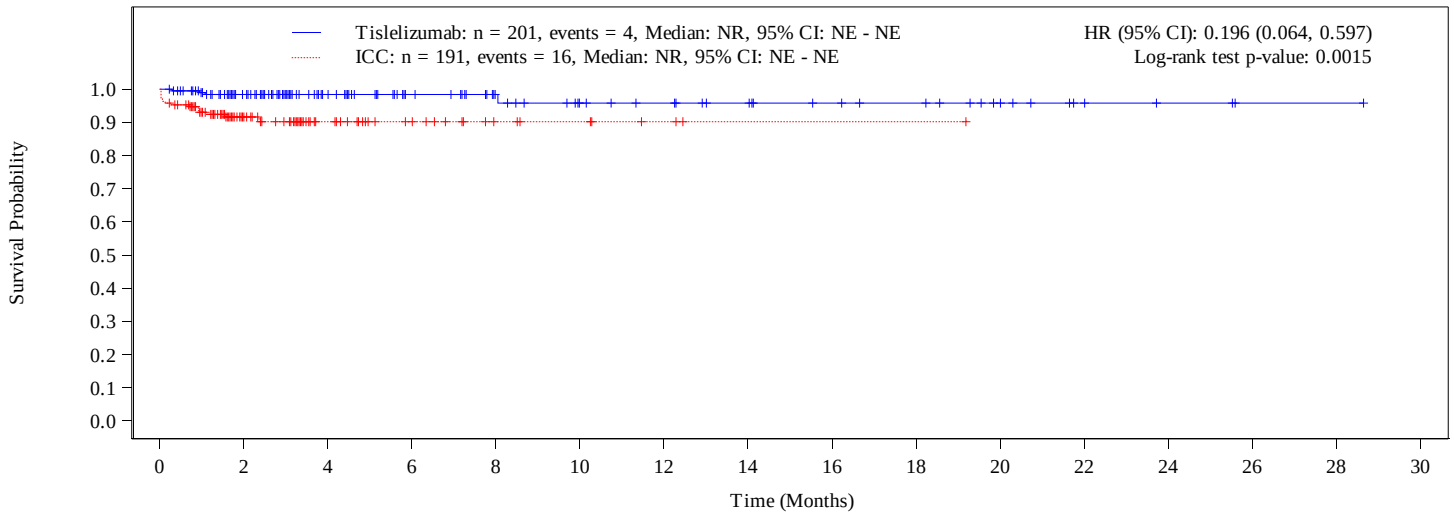
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	75	44	26	15	12	9	8	7	7	7	4	2	2	1	1	0
ICC	61	18	6	3	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders / PT - Dizziness

Region #1: Asia

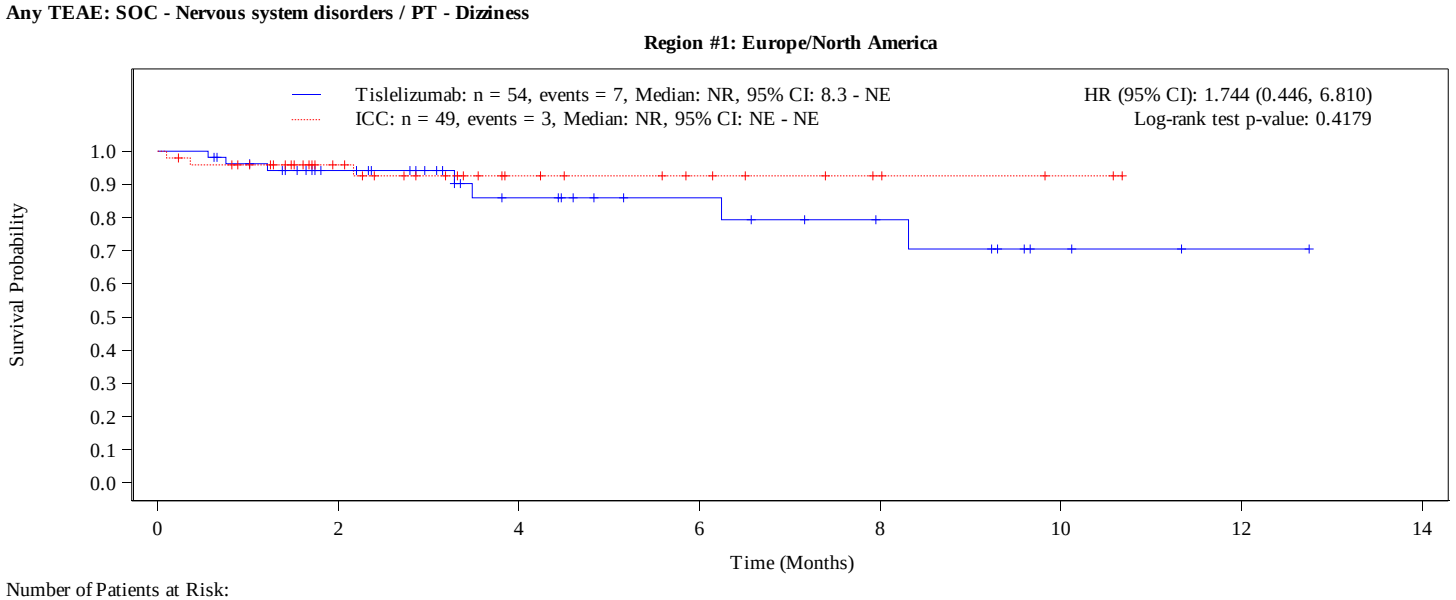


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	201	135	75	50	38	29	26	22	17	15	10	5	3	1	1	0
ICC	191	75	29	16	8	6	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

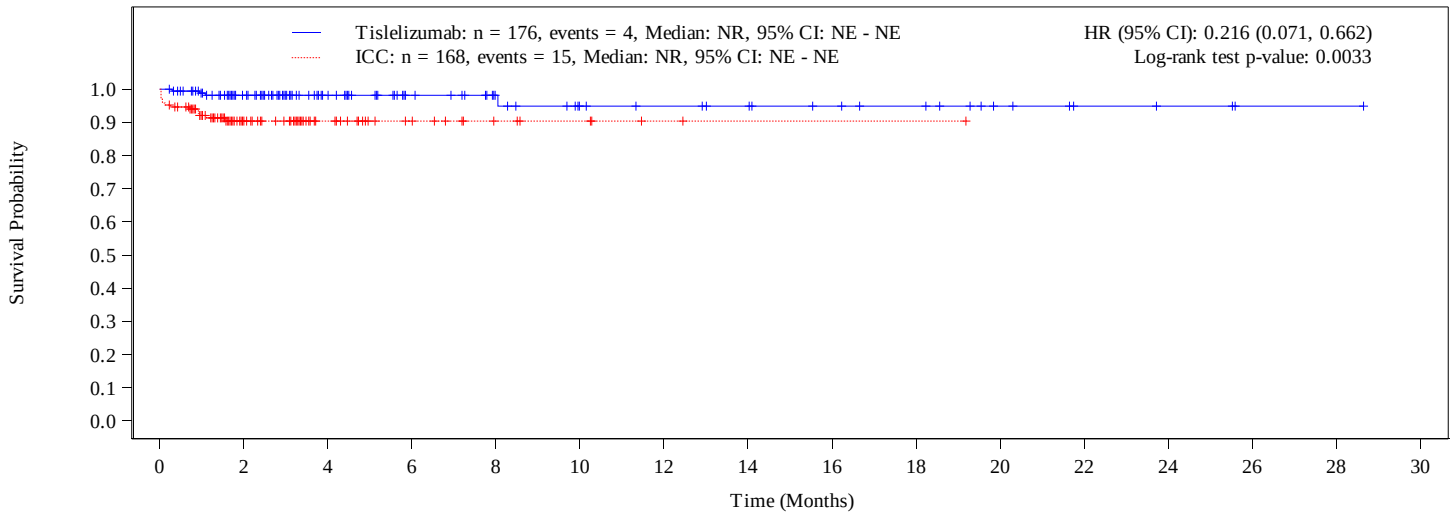


Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders / PT - Dizziness

Region #2: Asia (excluding Japan)



Number of Patients at Risk:

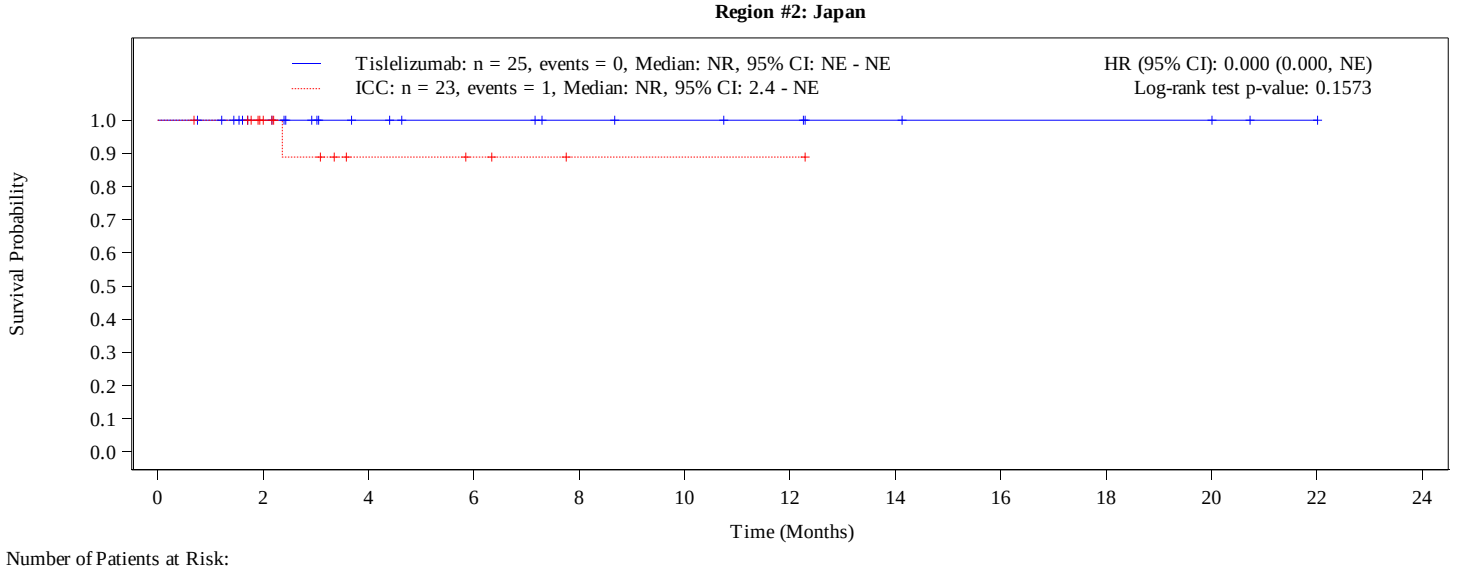
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	176	116	63	40	30	22	20	18	14	12	7	4	3	1	1	0
ICC	168	62	25	13	7	5	2	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders / PT - Dizziness

Region #2: Japan

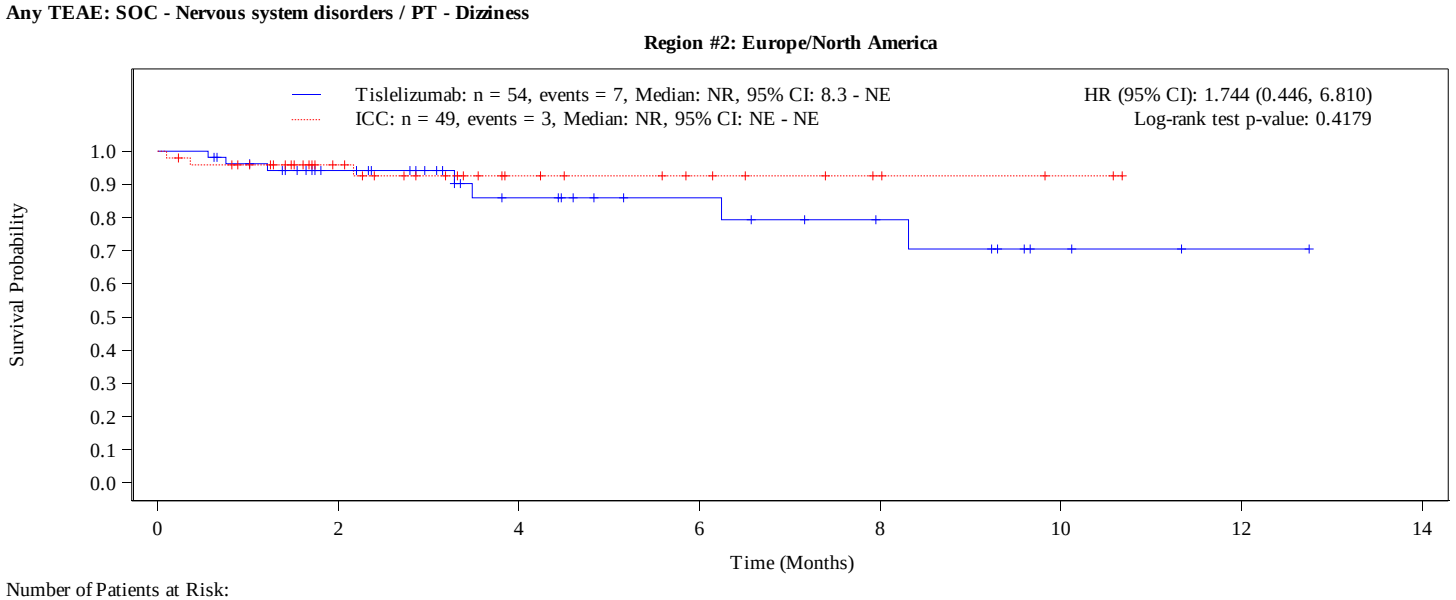


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24
Tislelizumab	25	19	12	10	8	7	6	4	3	3	3	1	0
ICC	23	13	4	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
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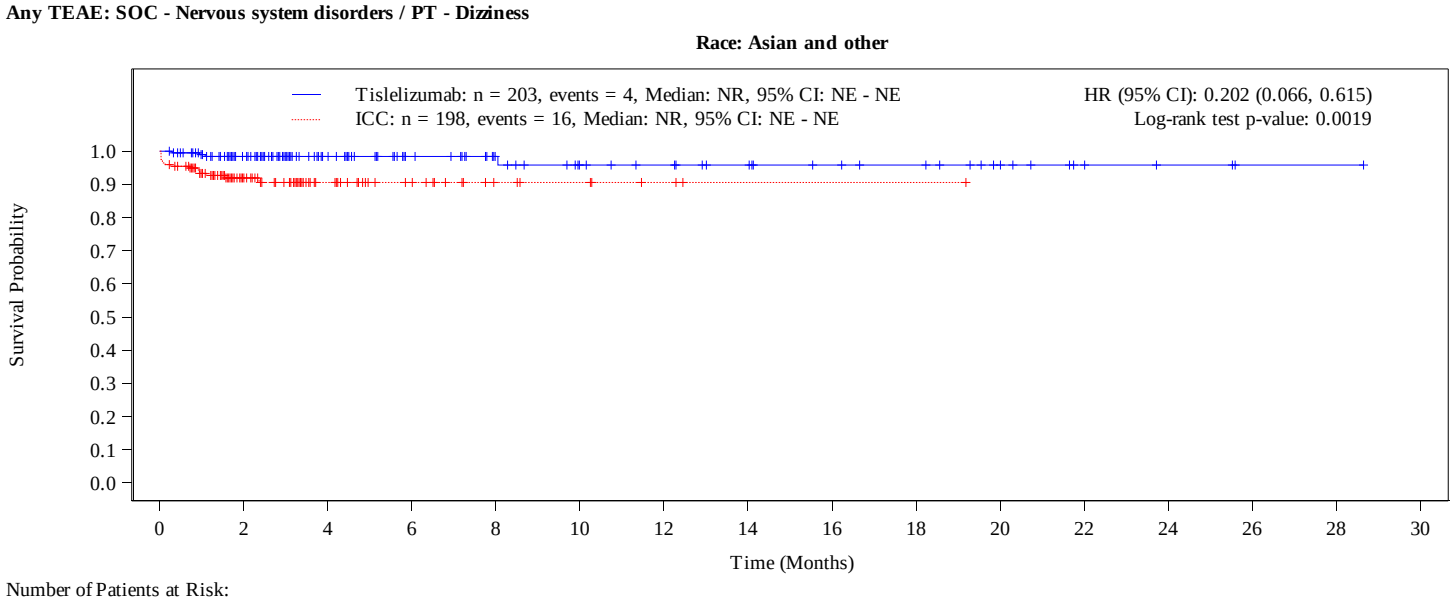
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	203	136	75	50	38	29	26	22	17	15	10	5	3	1	1	0
ICC	198	80	31	17	8	6	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
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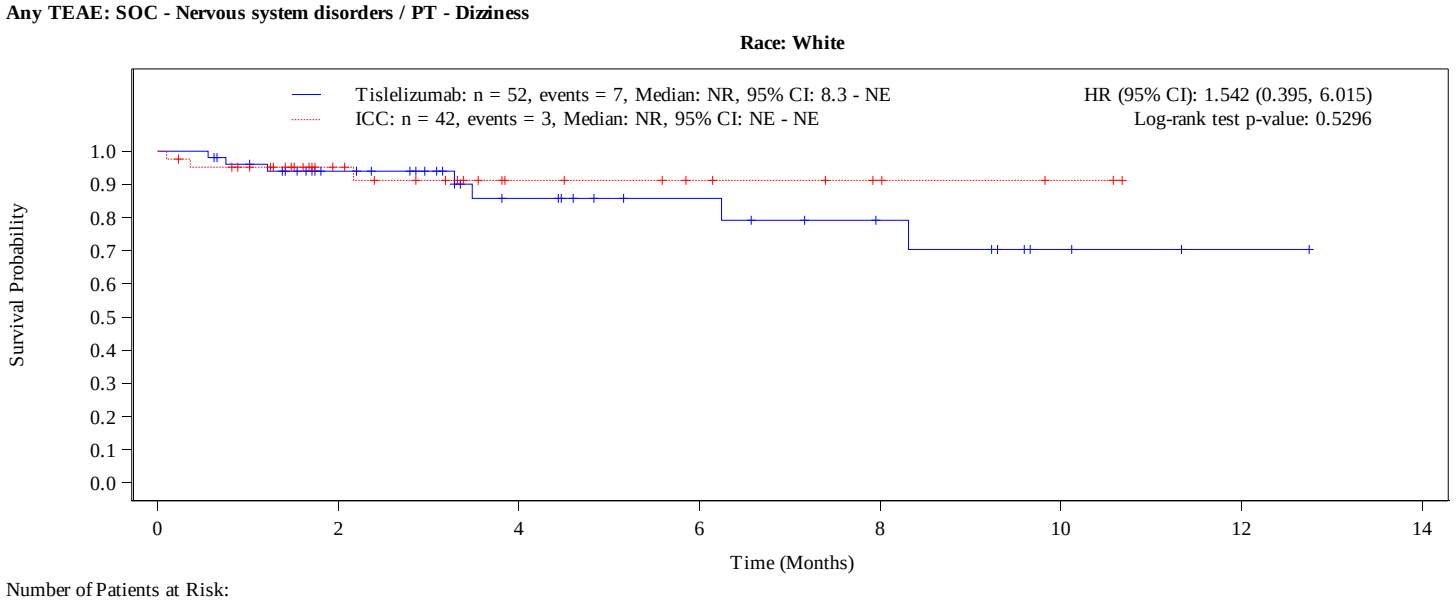
Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
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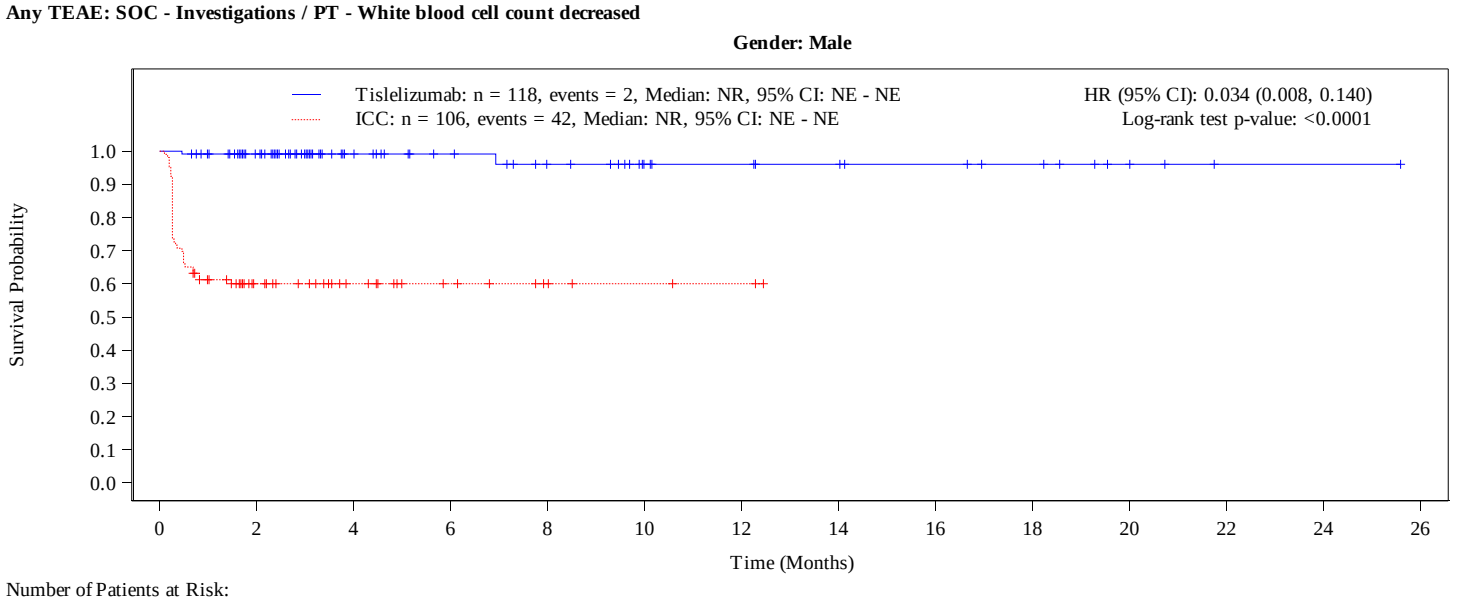
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-s-km-socpt-sub-safety-fa.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	118	83	43	33	25	16	14	12	10	8	4	1	1	0
ICC	106	34	16	9	5	3	2	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
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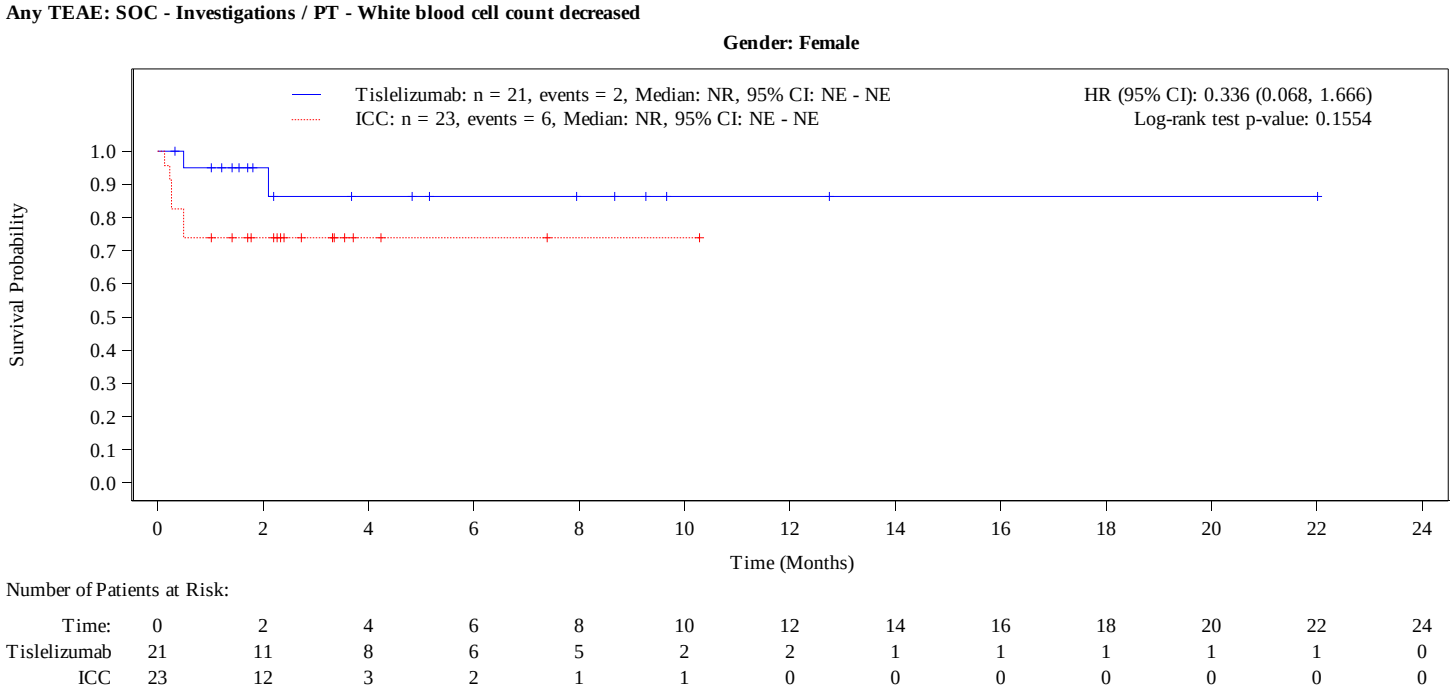
Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
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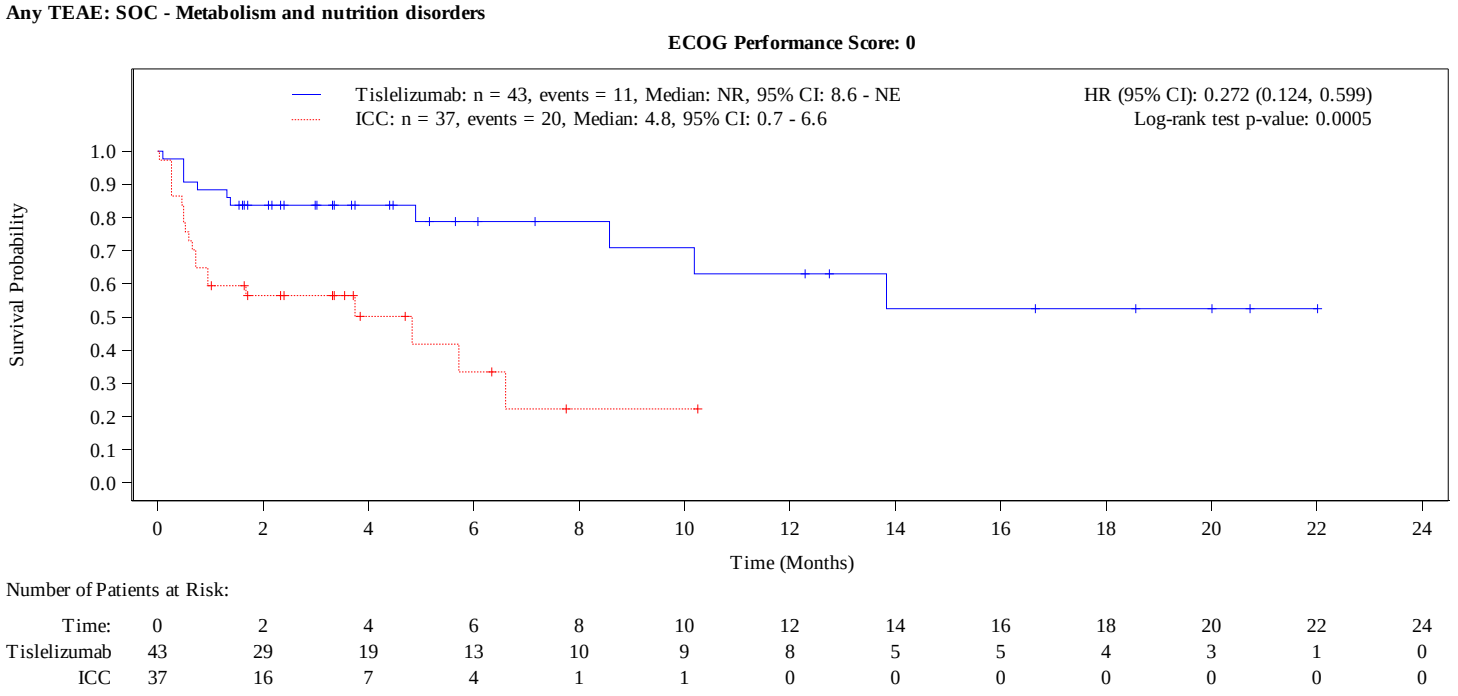
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
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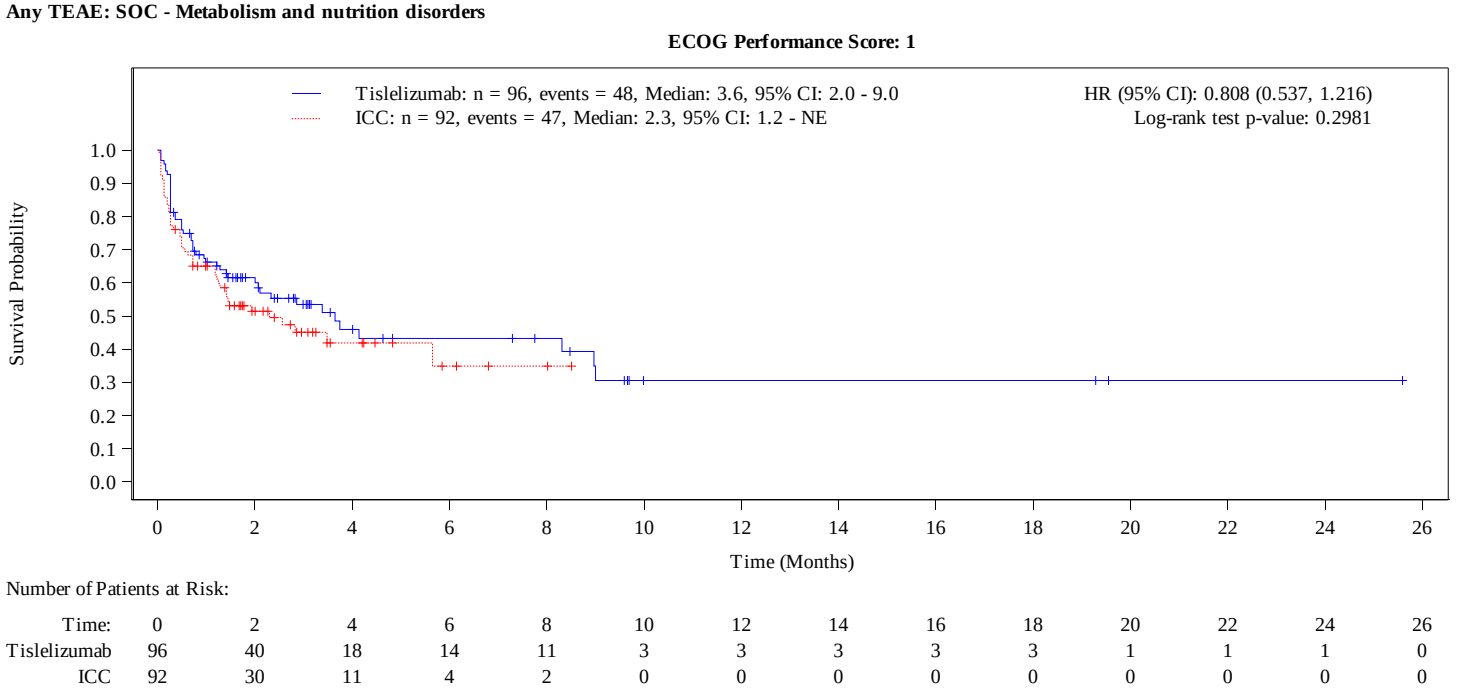
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-b-s-km-socpt-sub-safetys-fa.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
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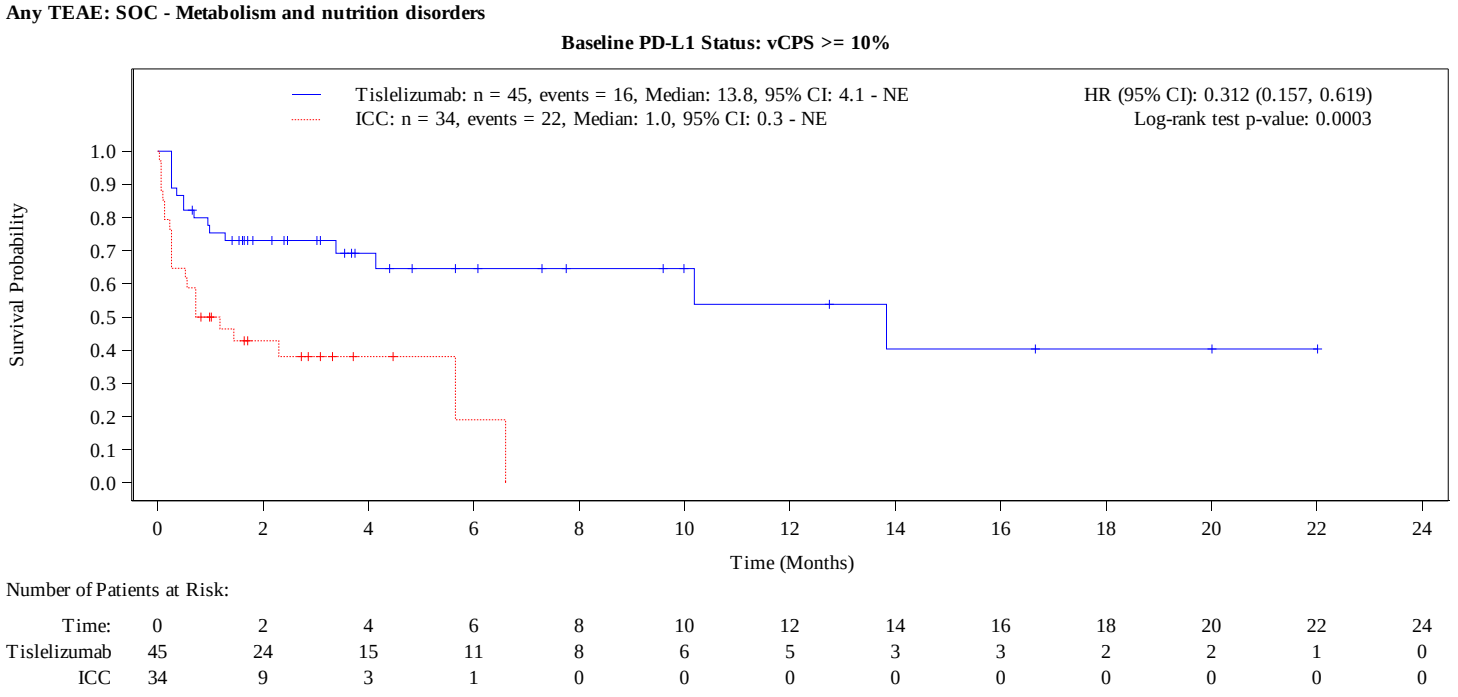
Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



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Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
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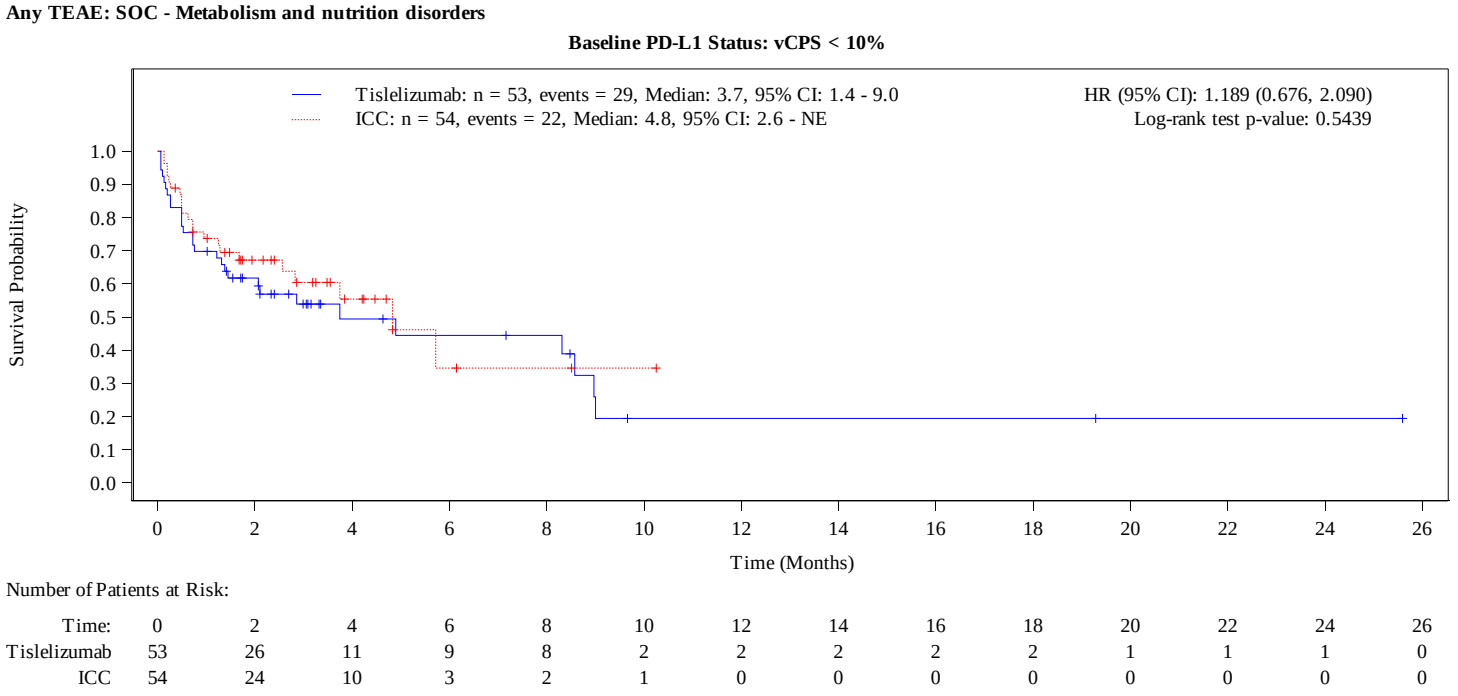
Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
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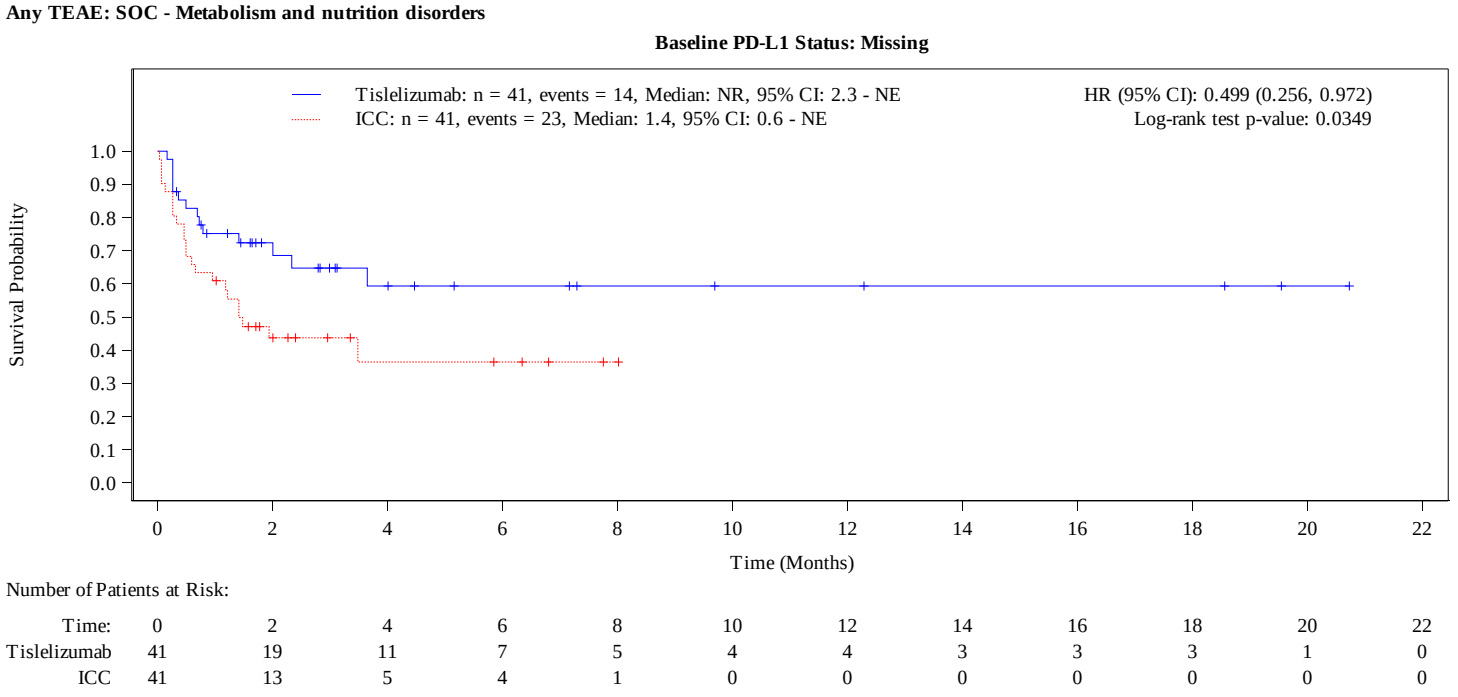
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



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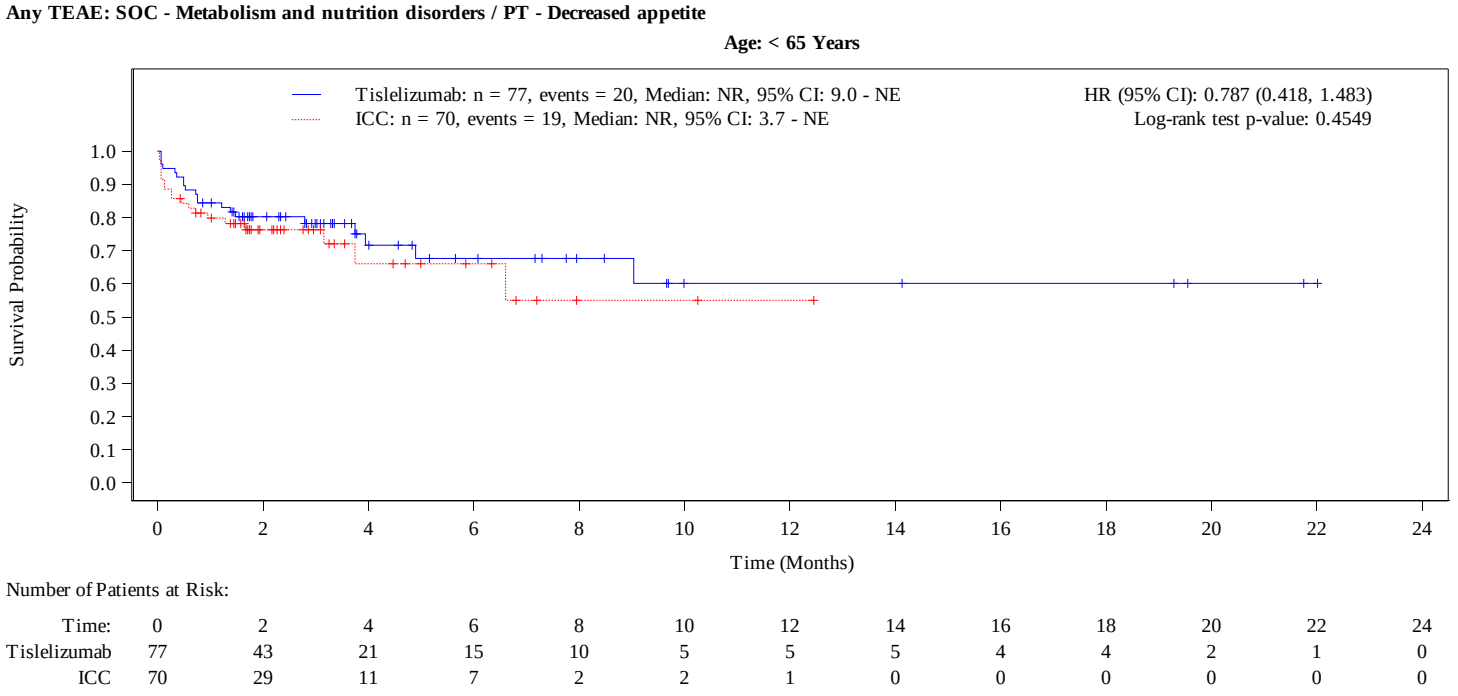
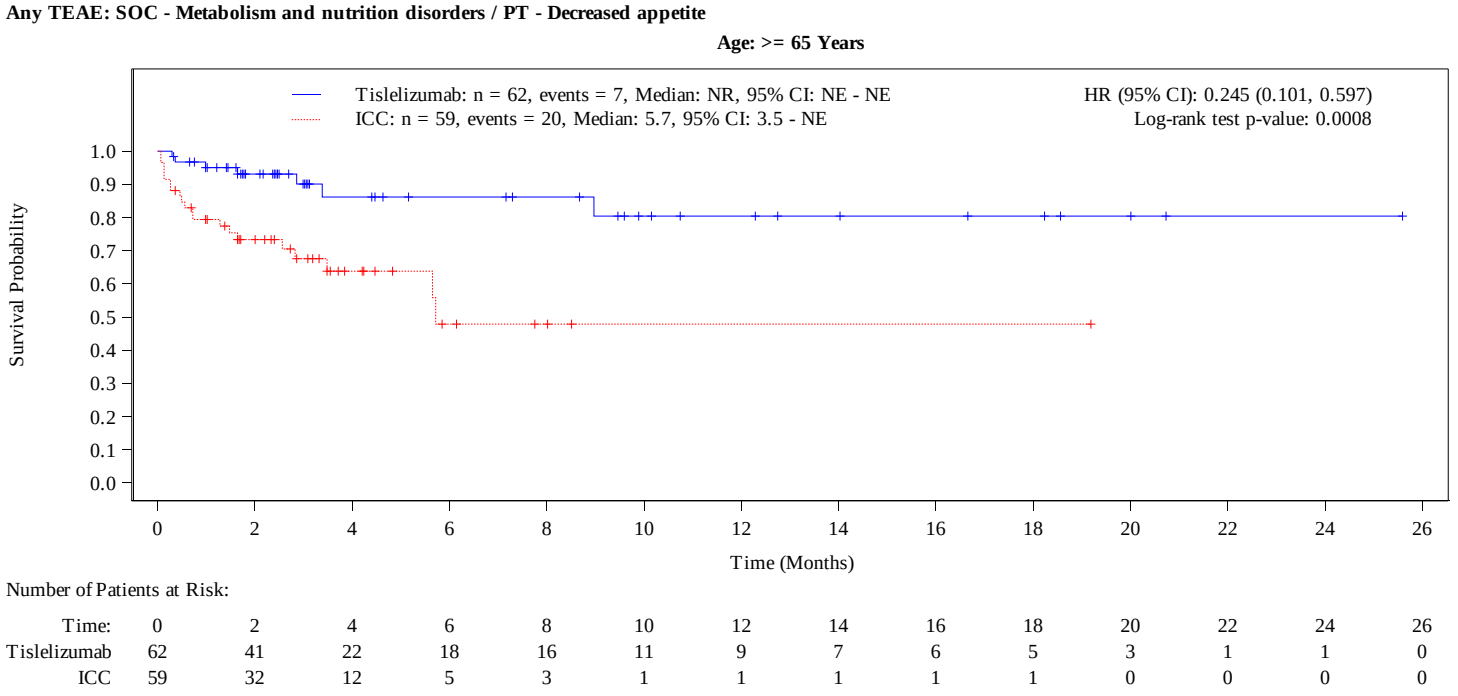
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



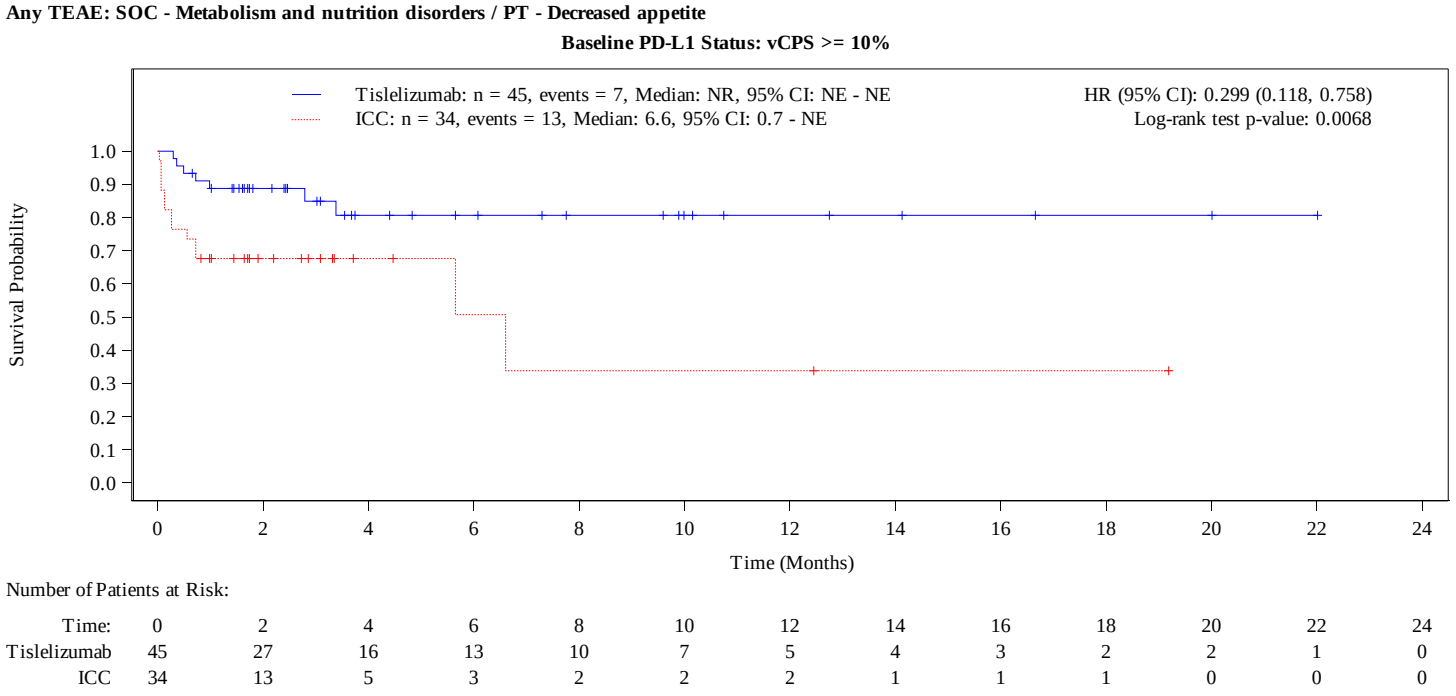
Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-b-s-km-socpt-sub-safetys-fa.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-b-s-km-socpt-sub-safetys-fa.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
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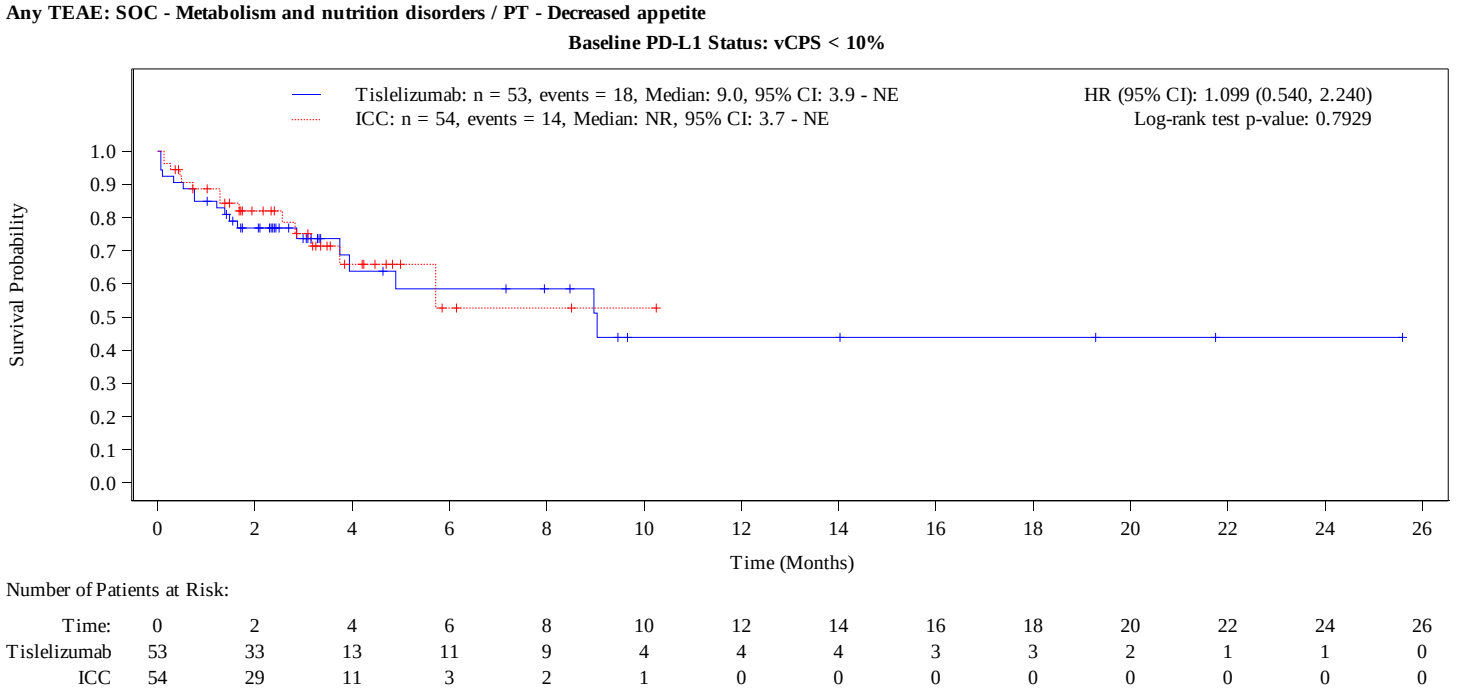
Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
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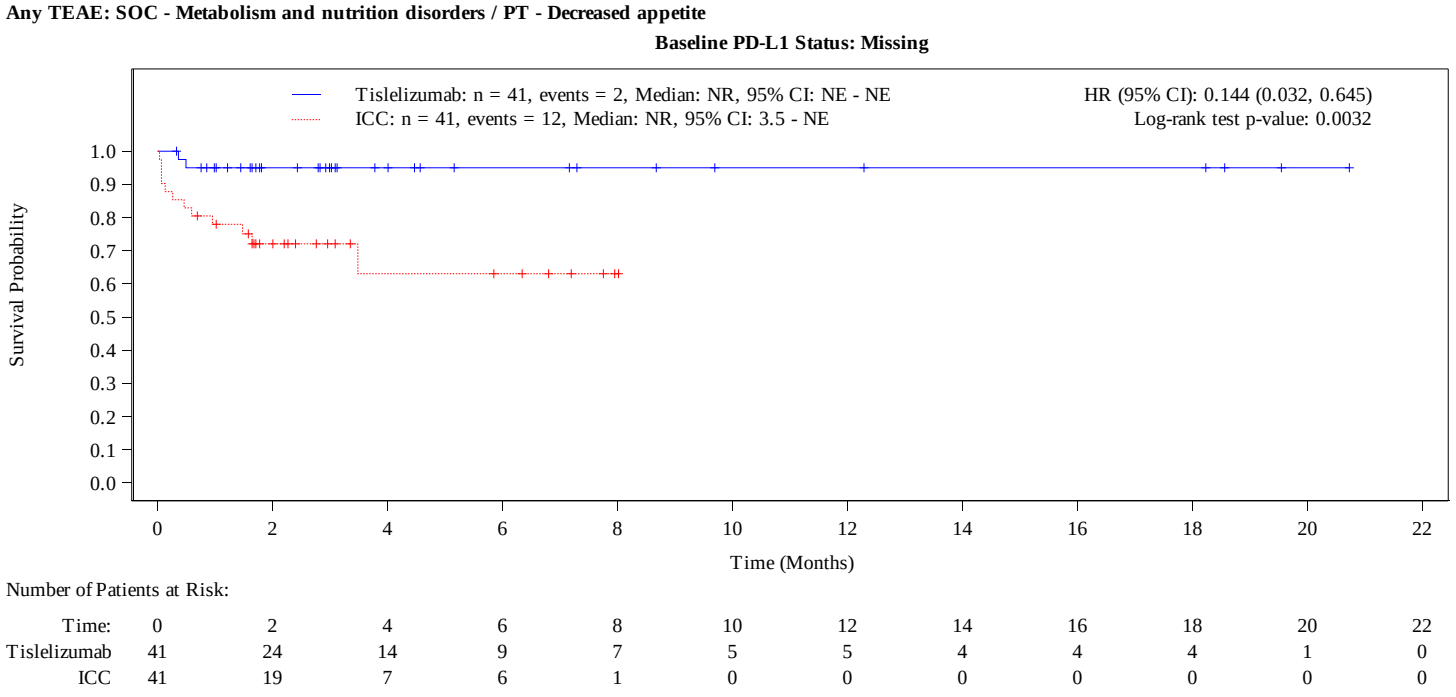
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	41	24	14	9	7	5	5	4	4	4	1	0
ICC	41	19	7	6	1	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
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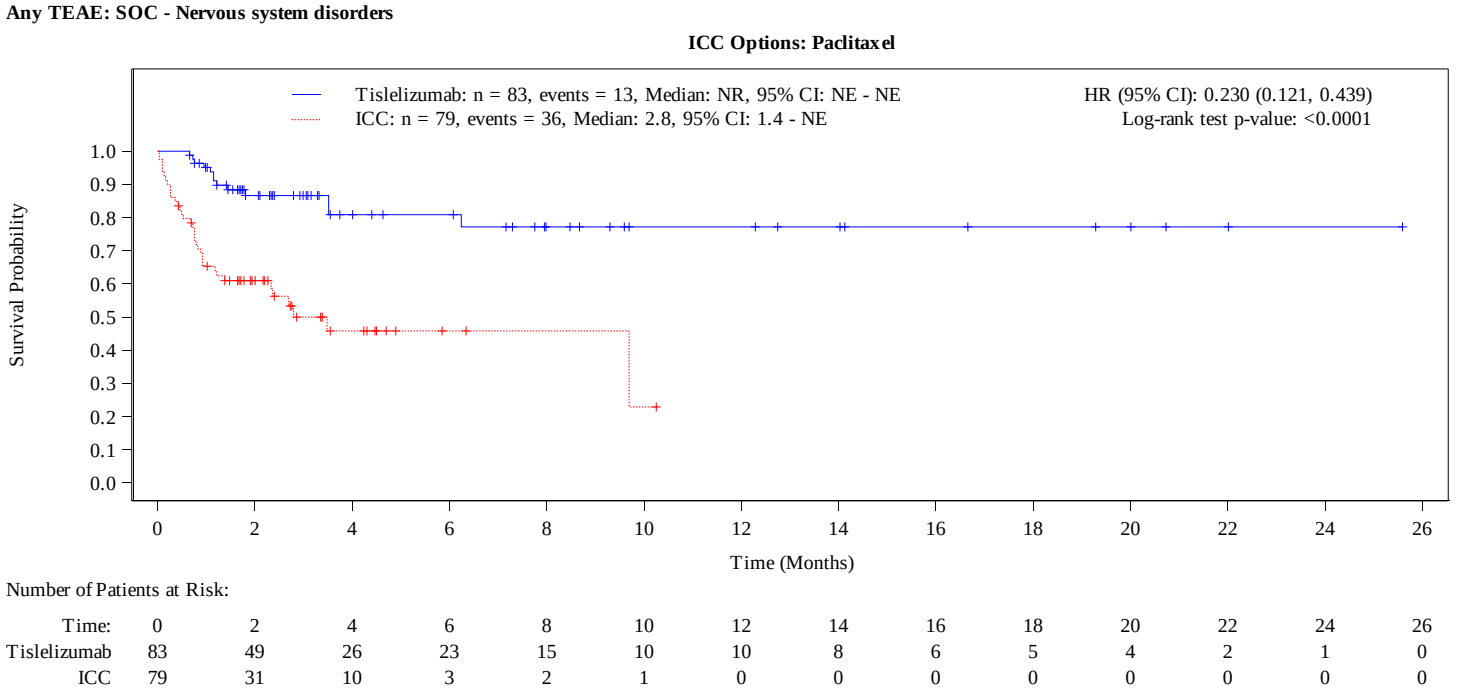
Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
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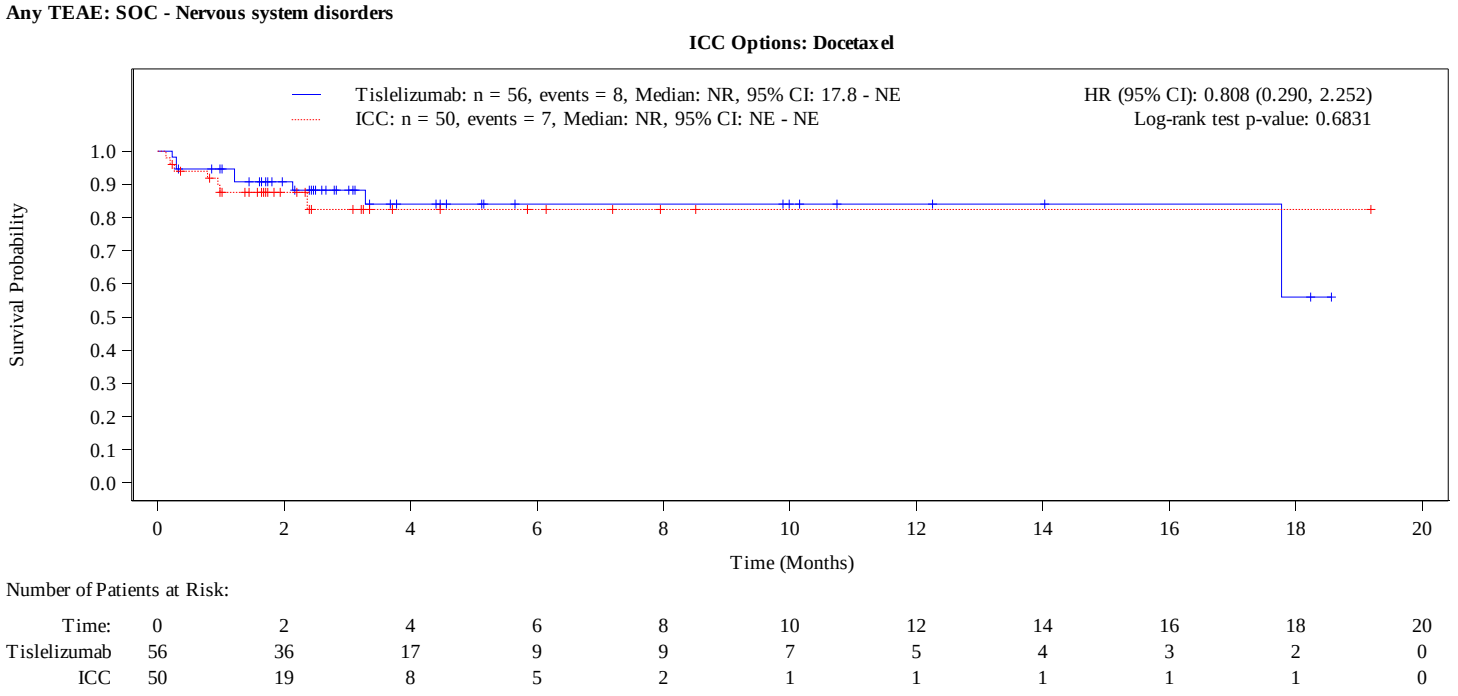
Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
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Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

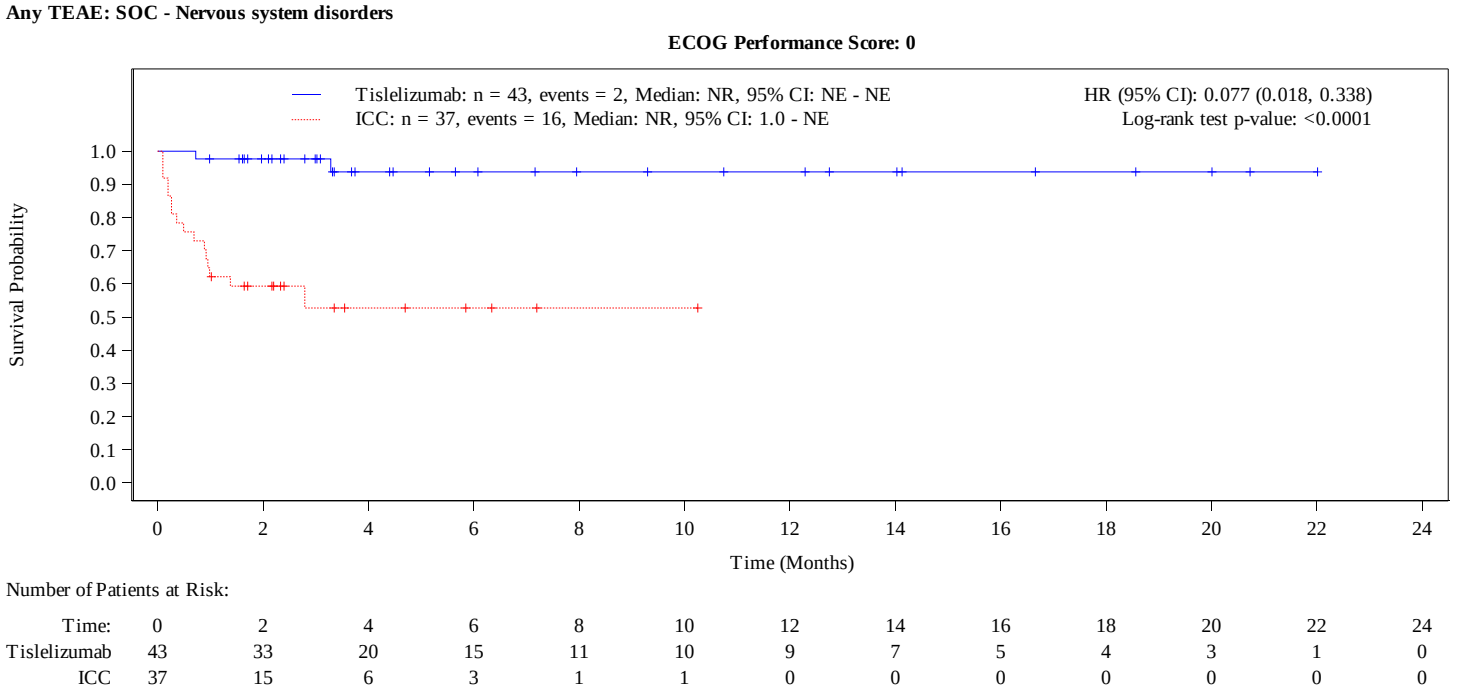

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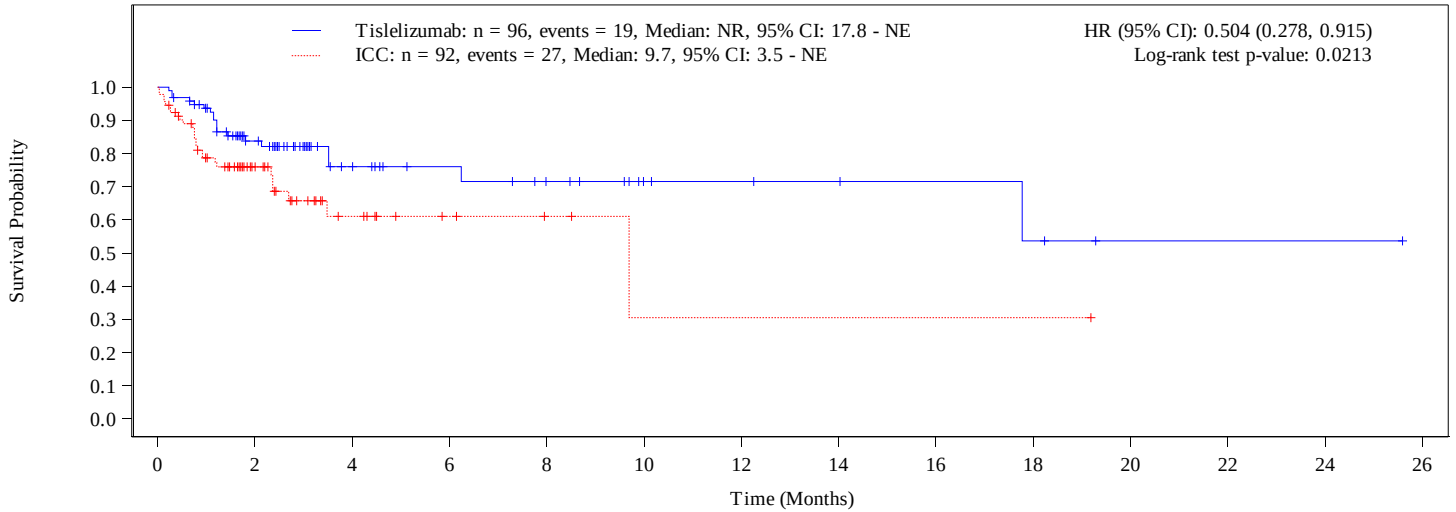
Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Nervous system disorders

ECOG Performance Score: 1

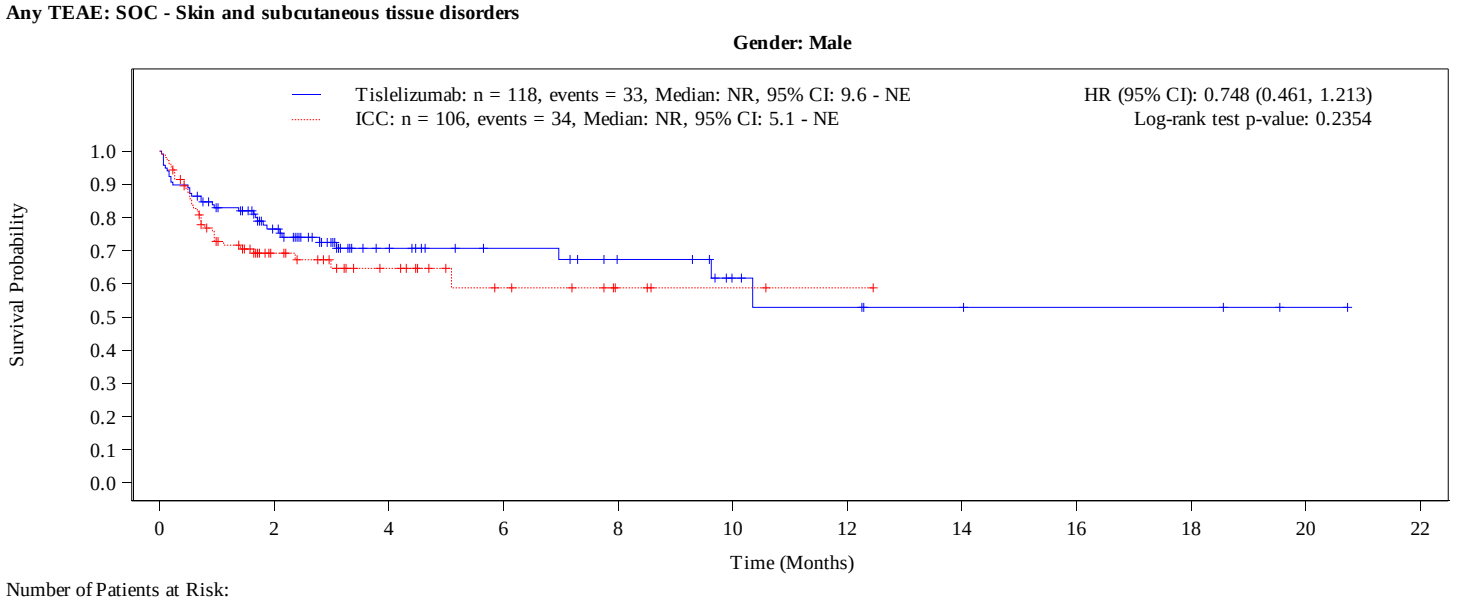


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	96	52	23	17	13	7	6	5	4	3	1	1	1	0
ICC	92	35	12	5	3	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-b-s-km-socpt-sub-safetys-fa.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

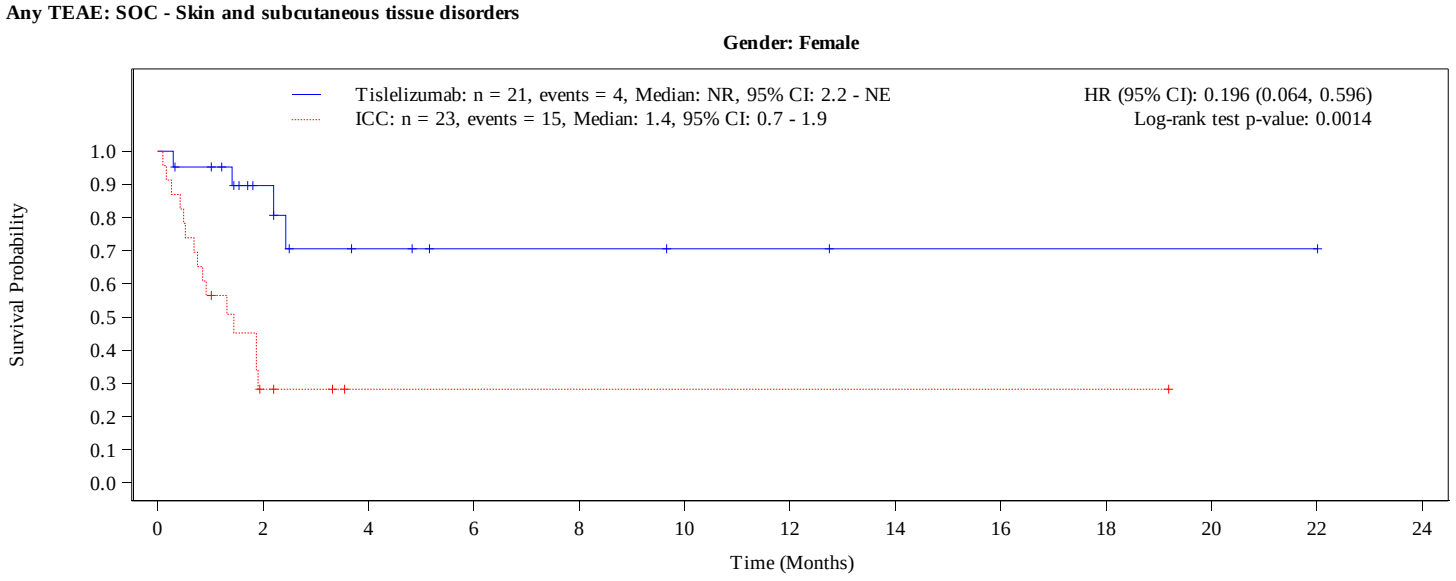


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	118	63	28	21	14	8	6	4	3	3	1	0
ICC	106	39	17	9	4	2	1	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-b-s-km-socpt-sub-safetys-fa.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

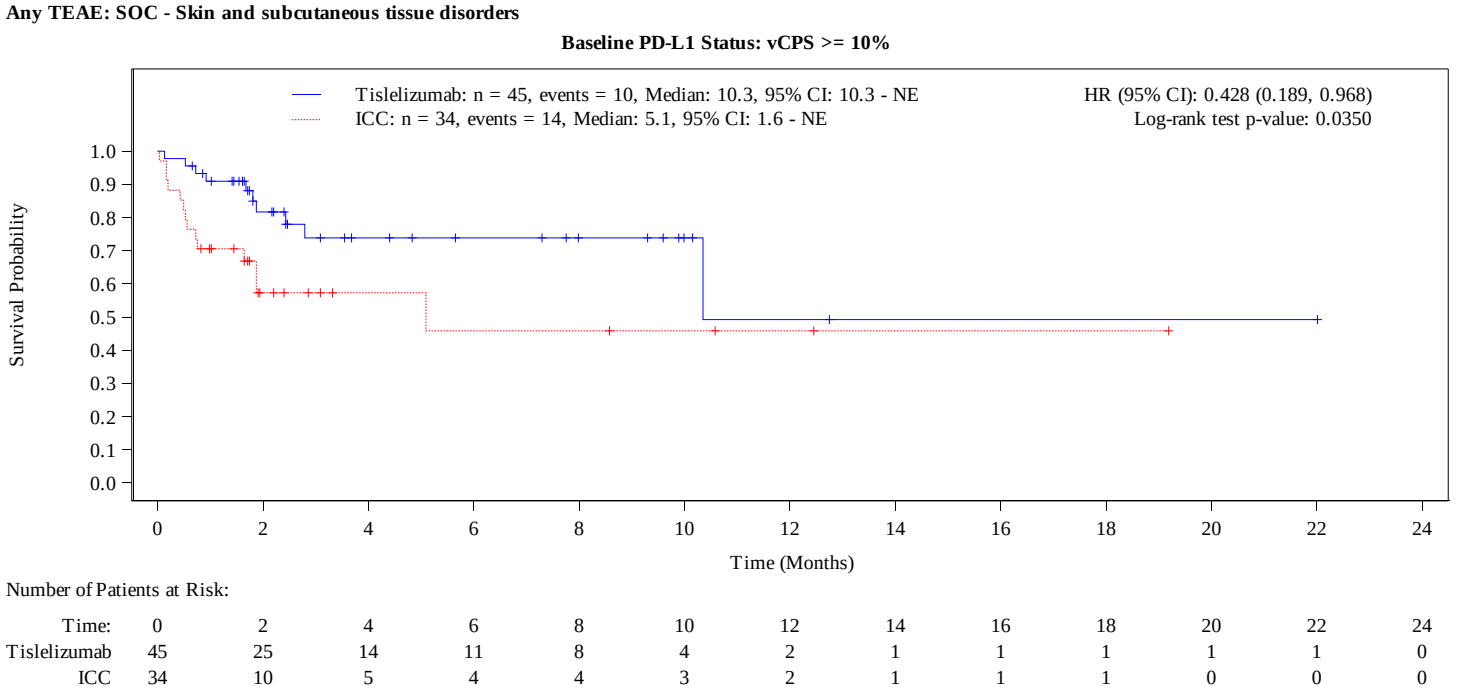


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24
Tislelizumab	21	10	5	3	3	2	2	1	1	1	1	1	0
ICC	23	4	1	1	1	1	1	1	1	1	0	0	0

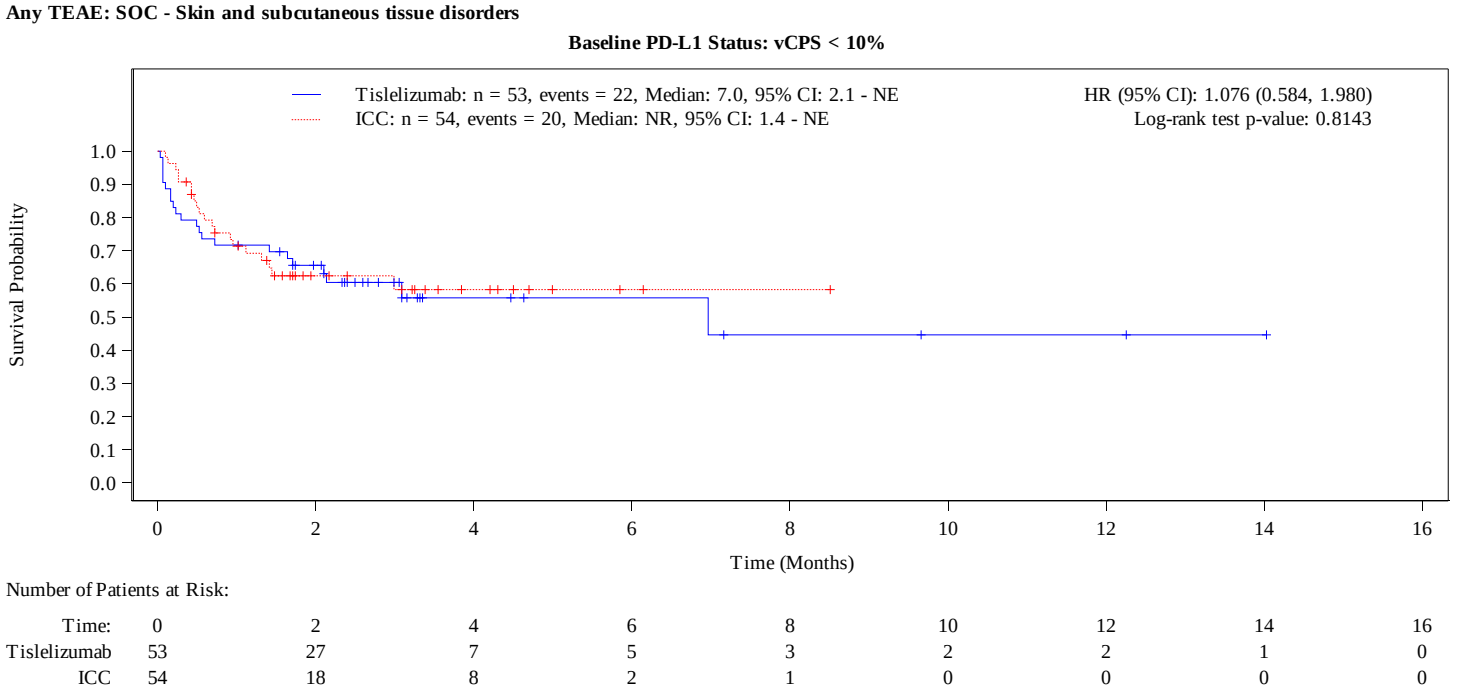
Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-b-s-km-socpt-sub-safetys-fa.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-b-s-km-socpt-sub-safetys-fa.rtf

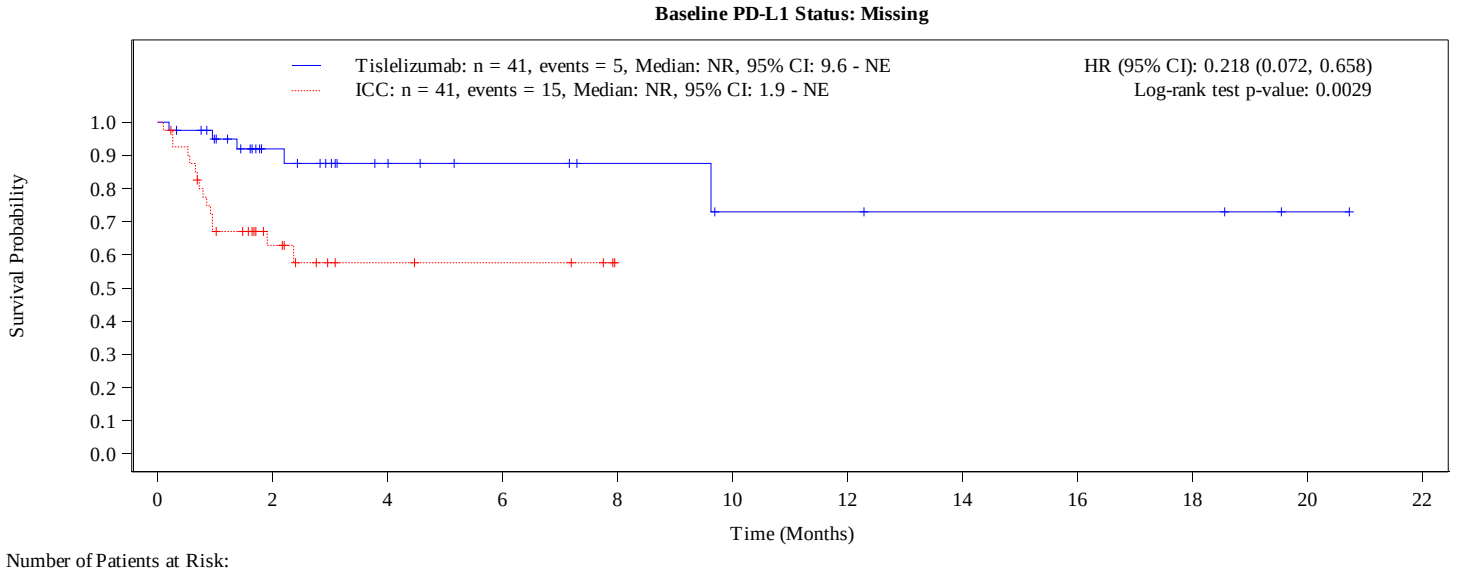
Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-b-s-km-socpt-sub-safetys-fa.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Skin and subcutaneous tissue disorders

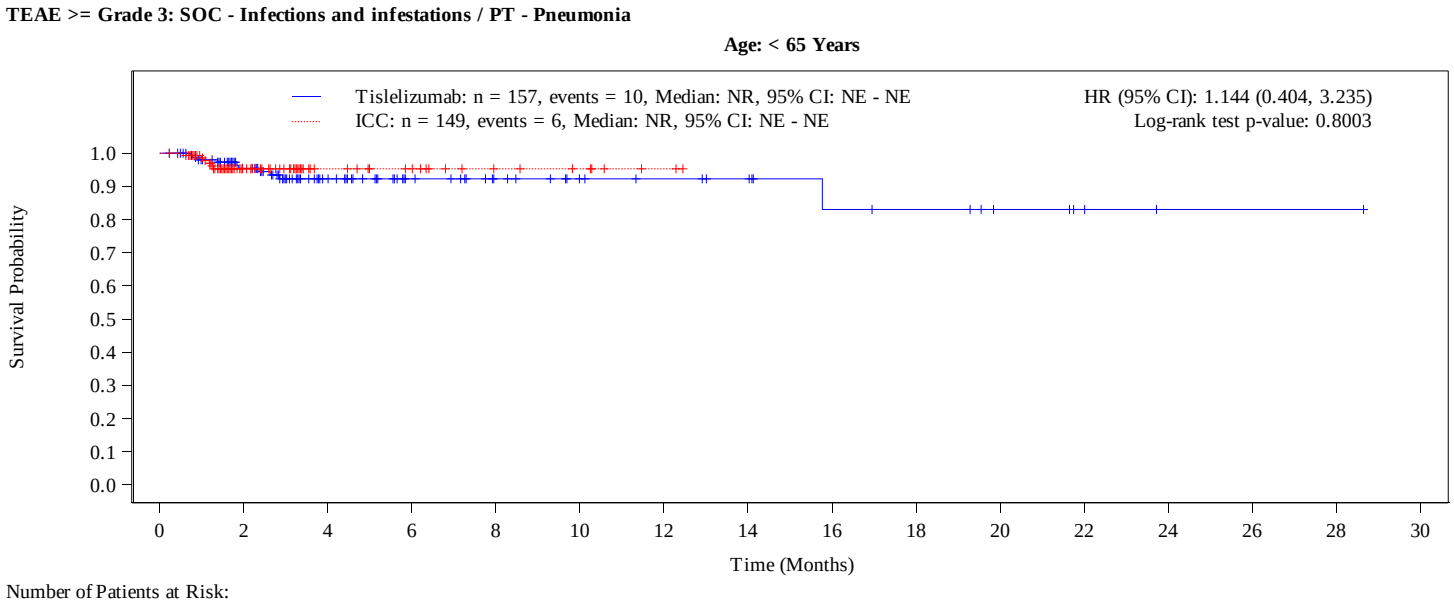


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	41	21	12	8	6	4	4	3	3	3	1	0
ICC	41	15	5	4	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-02-b-s-km-socpt-sub-safetys-fa.rtf

Figure 14.3.1.3.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

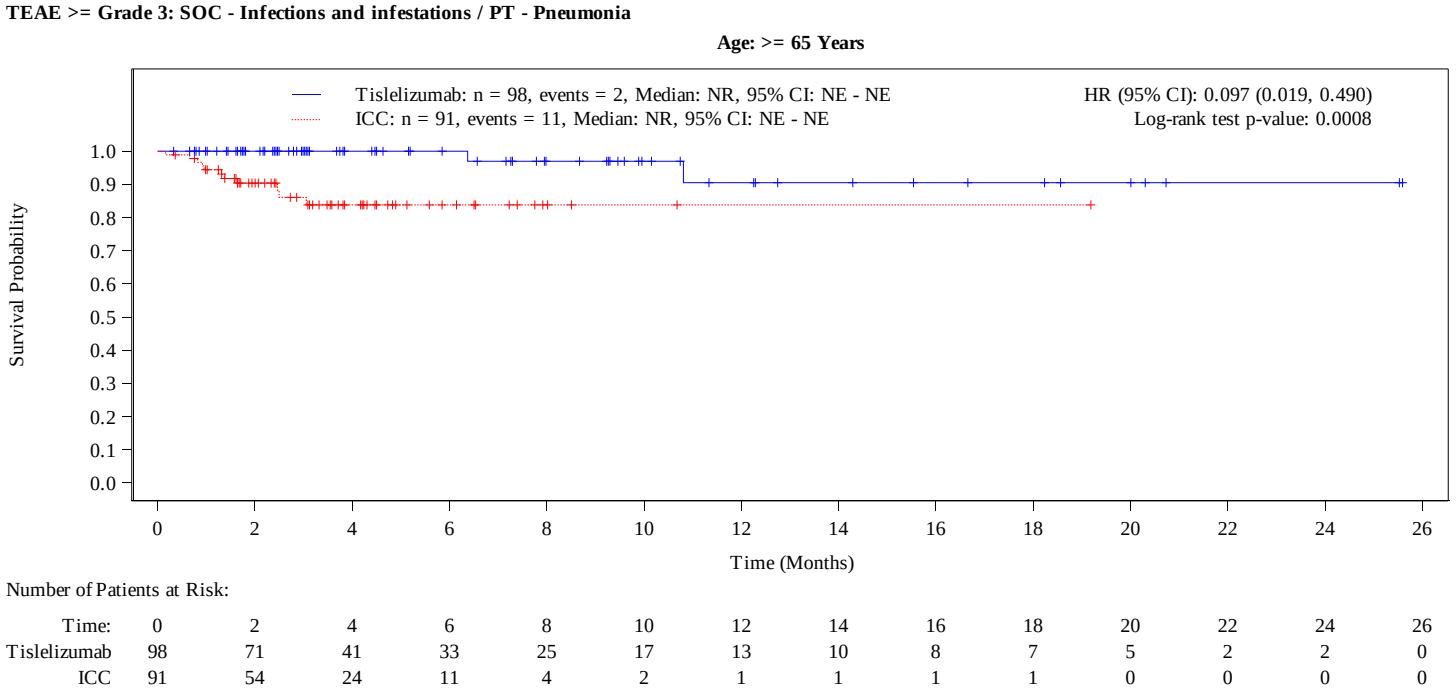


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	157	102	56	32	24	17	15	13	9	8	5	3	1	1	1	0
ICC	149	58	21	15	8	6	2	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-03-s-km-socpt-sub-g3-safety-fa.rtf

Figure 14.3.1.3.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

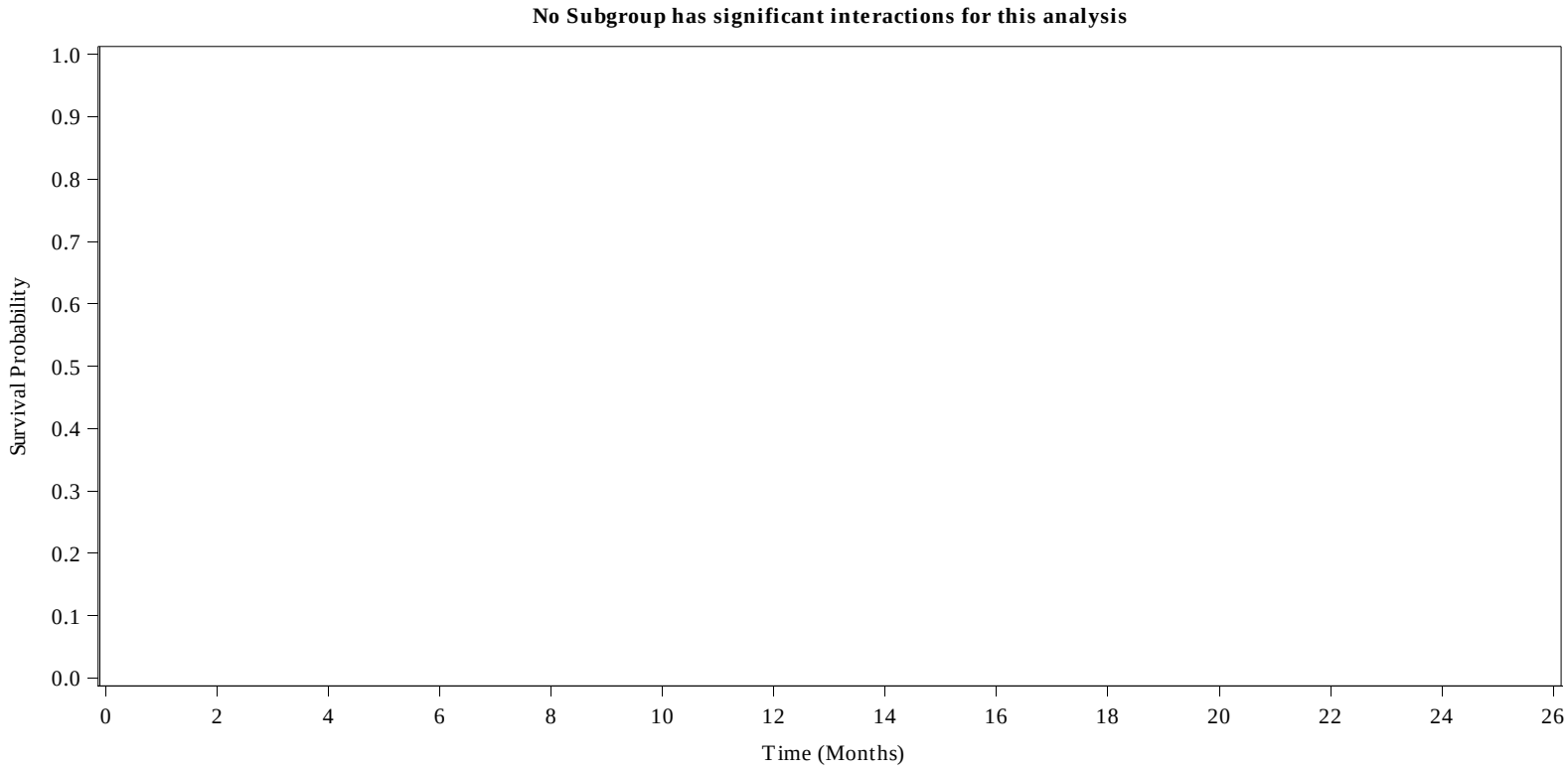


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	98	71	41	33	25	17	13	10	8	7	5	2	2	0
ICC	91	54	24	11	4	2	1	1	1	1	0	0	0	0

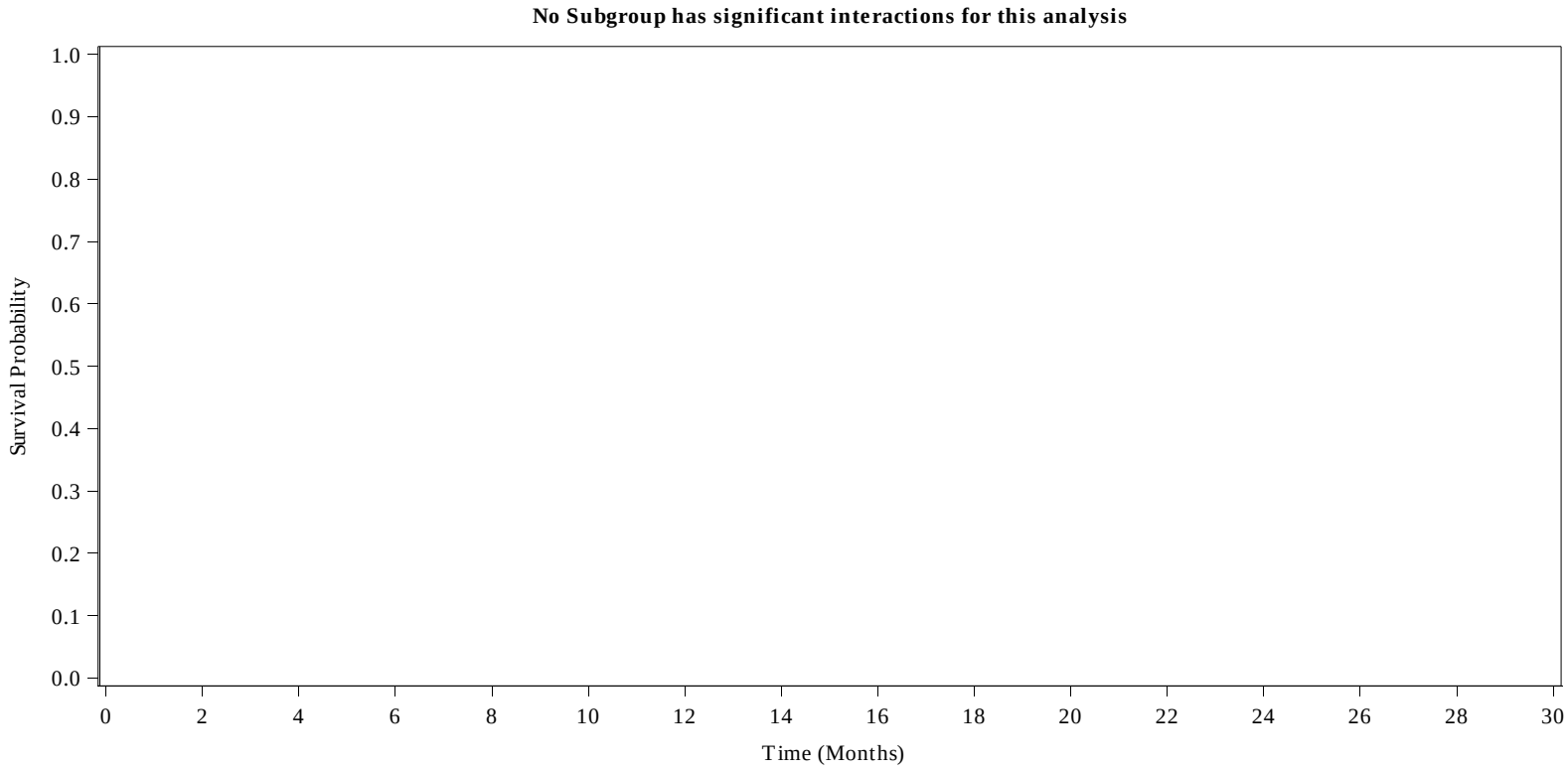
Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-03-s-km-socpt-sub-g3-safety-fa.rtf

Figure 14.3.1.3.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-03-b-s-km-socpt-sub-g3-safetys-fa.rtf

Figure 14.3.1.4.s:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
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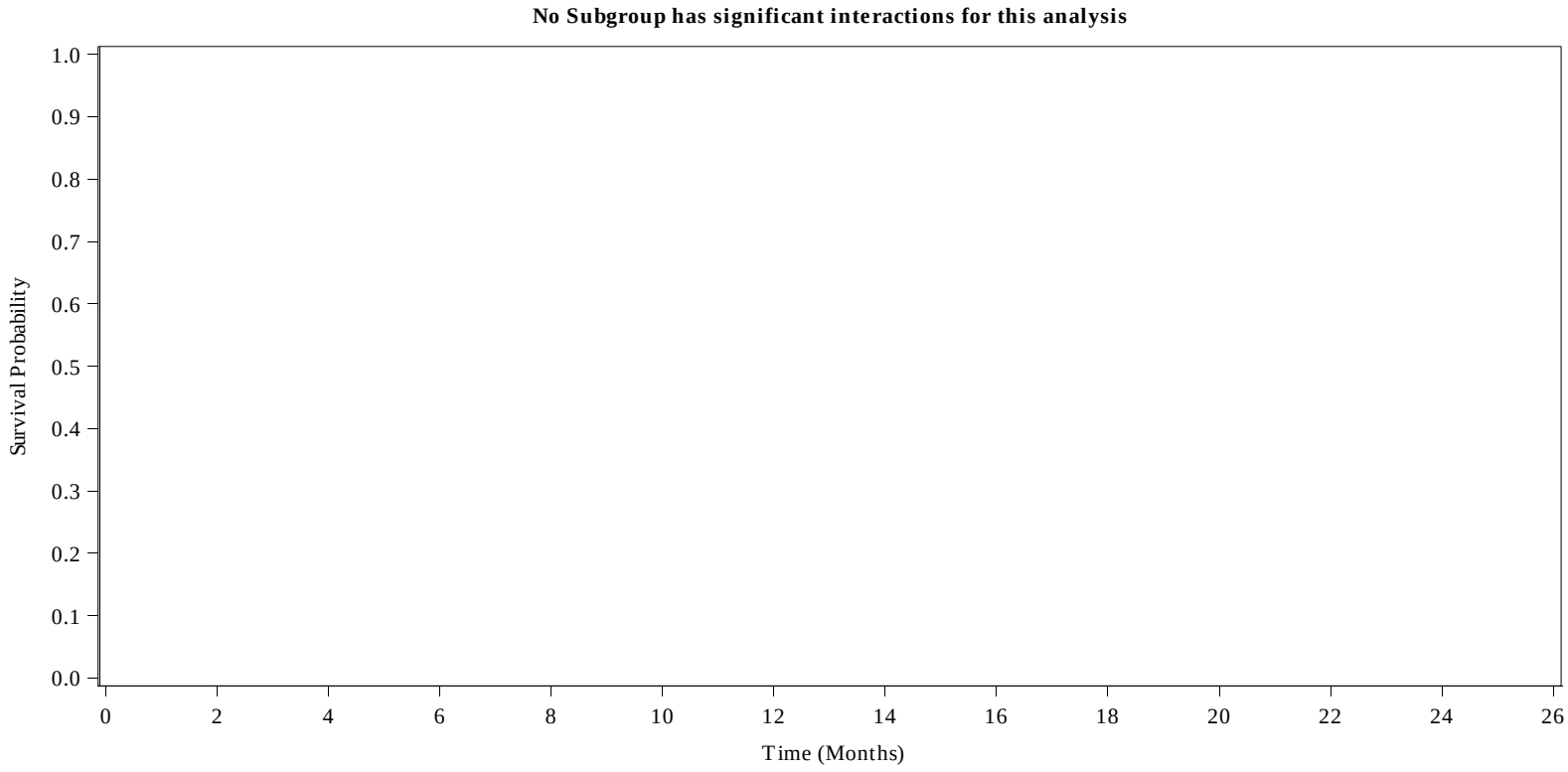
Figure 14.3.1.4.b.s:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 20AUG2024 18:19 f-14-03-01-04-b-s-km-socpt-sub-sae-safetys-fa.rtf

Table 14.2.8.3.b:
Summary of Post-Treatment Systemic Therapies and Immunotherapies
ITT Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 138) n (%)
Systemic Therapy	65 (46.8)	74 (53.6)
Taxanes	44 (31.7)	15 (10.9)
Paclitaxel	32 (23.0)	8 (5.8)
Docetaxel	15 (10.8)	5 (3.6)
Paclitaxel Liposome	1 (0.7)	0 (0.0)
Paclitaxel Albumin	0 (0.0)	3 (2.2)
Pyrimidine Analogues	26 (18.7)	22 (15.9)
Fluorouracil	16 (11.5)	9 (6.5)
Gimeracil;oteracil Potassium;tegafur	6 (4.3)	7 (5.1)
Capecitabine	3 (2.2)	1 (0.7)
Gemcitabine Hydrochloride	3 (2.2)	1 (0.7)
Gemcitabine	2 (1.4)	5 (3.6)
Tegafur	2 (1.4)	2 (1.4)
Tegafur;uracil	1 (0.7)	0 (0.0)

Source: Listing 16.2.4.10,16.2.4.11. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
* Monoclonal antibodies included 4 anti-PD-1 antibodies (2 Geptanolimab, 1 Nivolumab, 1 unknow name anti-PD-1 antibody).
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-postsys.sas 24APR2024 01:38 t-14-02-08-03-b-postsys-itts-fa.rtf

Table 14.2.8.3.b:
Summary of Post-Treatment Systemic Therapies and Immunotherapies
ITT Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 138) n (%)
Platinum Compounds	22 (15.8)	20 (14.5)
Cisplatin	15 (10.8)	15 (10.9)
Carboplatin	3 (2.2)	1 (0.7)
Nedaplatin	3 (2.2)	1 (0.7)
Oxaliplatin	2 (1.4)	3 (2.2)
Lobaplatin	1 (0.7)	0 (0.0)
Other Antineoplastic Agents	17 (12.2)	15 (10.9)
Irinotecan	12 (8.6)	10 (7.2)
Endostatin	3 (2.2)	2 (1.4)
Irinotecan Hydrochloride	1 (0.7)	3 (2.2)
Lenalidomide	1 (0.7)	0 (0.0)
Other Antineoplastic Agents	0 (0.0)	1 (0.7)

Source: Listing 16.2.4.10,16.2.4.11. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
* Monoclonal antibodies included 4 anti-PD-1 antibodies (2 Geptanolimab, 1 Nivolumab, 1 unknow name anti-PD-1 antibody).
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-postsys.sas 24APR2024 01:38 t-14-02-08-03-b-postsys-itts-fa.rtf

Table 14.2.8.3.b:
Summary of Post-Treatment Systemic Therapies and Immunotherapies
ITT Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 138) n (%)
Protein Kinase Inhibitors	12 (8.6)	12 (8.7)
Apatinib Mesylate	5 (3.6)	3 (2.2)
Anlotinib Dihydrochloride	4 (2.9)	7 (5.1)
Apatinib	2 (1.4)	1 (0.7)
Anlotinib	1 (0.7)	2 (1.4)
Oteracil Potassium	1 (0.7)	0 (0.0)
Palbociclib	1 (0.7)	0 (0.0)
Tak 931	0 (0.0)	1 (0.7)
Detoxifying Agents For Antineoplastic Treatment	6 (4.3)	6 (4.3)
Calcium Folinate	2 (1.4)	1 (0.7)
Calcium Levofolinate	2 (1.4)	2 (1.4)
Folinic Acid	2 (1.4)	2 (1.4)
Levofolinic Acid	0 (0.0)	1 (0.7)

Source: Listing 16.2.4.10,16.2.4.11. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
* Monoclonal antibodies included 4 anti-PD-1 antibodies (2 Geptanolimab, 1 Nivolumab, 1 unknow name anti-PD-1 antibody).
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-postsys.sas 24APR2024 01:38 t-14-02-08-03-b-postsys-itts-fa.rtf

Table 14.2.8.3.b:
Summary of Post-Treatment Systemic Therapies and Immunotherapies
ITT Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 138) n (%)
Folic Acid Analogues	5 (3.6)	3 (2.2)
Methotrexate	3 (2.2)	1 (0.7)
Raltitrexed	2 (1.4)	0 (0.0)
Methotrexate Sodium	0 (0.0)	1 (0.7)
Pemetrexed Disodium	0 (0.0)	1 (0.7)

Source: Listing 16.2.4.10,16.2.4.11. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
* Monoclonal antibodies included 4 anti-PD-1 antibodies (2 Geptanolimab, 1 Nivolumab, 1 unknow name anti-PD-1 antibody).
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-postsys.sas 24APR2024 01:38 t-14-02-08-03-b-postsys-itts-fa.rtf

Table 14.2.8.3.b:
Summary of Post-Treatment Systemic Therapies and Immunotherapies
ITT Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 138) n (%)
Monoclonal Antibodies	5 (3.6)	34 (24.6)
Nivolumab	4 (2.9)	15 (10.9)
Bevacizumab	1 (0.7)	0 (0.0)
Camrelizumab	1 (0.7)	3 (2.2)
Atezolizumab	0 (0.0)	1 (0.7)
Bgb A317	0 (0.0)	1 (0.7)
Bi 754091	0 (0.0)	2 (1.4)
Bi 754111	0 (0.0)	2 (1.4)
Cetuximab	0 (0.0)	1 (0.7)
Kn 035	0 (0.0)	1 (0.7)
Monoclonal Antibodies *	0 (0.0)	4 (2.9)
Nimotuzumab	0 (0.0)	1 (0.7)
Pembrolizumab	0 (0.0)	2 (1.4)
Ro 6874281	0 (0.0)	1 (0.7)
Sct I10a	0 (0.0)	1 (0.7)
Sintilimab	0 (0.0)	3 (2.2)
Toripalimab	0 (0.0)	1 (0.7)

Source: Listing 16.2.4.10,16.2.4.11. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
* Monoclonal antibodies included 4 anti-PD-1 antibodies (2 Geptanolimab, 1 Nivolumab, 1 unknow name anti-PD-1 antibody).
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-postsys.sas 24APR2024 01:38 t-14-02-08-03-b-postsys-itts-fa.rtf

Table 14.2.8.3.b:
Summary of Post-Treatment Systemic Therapies and Immunotherapies
ITT Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 138) n (%)
Vinca Alkaloids And Analogues	5 (3.6)	4 (2.9)
Vinorelbine	2 (1.4)	3 (2.2)
Vinorelbine Tartrate	2 (1.4)	1 (0.7)
Vincristine Sulfate	1 (0.7)	0 (0.0)
Combinations Of Antineoplastic Agents	3 (2.2)	0 (0.0)
Gimeracil;oteracil	3 (2.2)	0 (0.0)
Anthracyclines And Related Substances	2 (1.4)	2 (1.4)
Doxorubicin	1 (0.7)	0 (0.0)
Epirubicin Hydrochloride	1 (0.7)	0 (0.0)
Epirubicin	0 (0.0)	2 (1.4)
Antineoplastic Agents	2 (1.4)	0 (0.0)
Antineoplastic Agents	2 (1.4)	0 (0.0)
Herbal Immunomodulators	2 (1.4)	0 (0.0)
Astragalus Mongholicus Root;oxymatrine;panax Ginseng Dry Extract	2 (1.4)	0 (0.0)

Source: Listing 16.2.4.10,16.2.4.11. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
* Monoclonal antibodies included 4 anti-PD-1 antibodies (2 Geptanolimab, 1 Nivolumab, 1 unknow name anti-PD-1 antibody).
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-postsys.sas 24APR2024 01:38 t-14-02-08-03-b-postsys-itts-fa.rtf

Table 14.2.8.3.b:
Summary of Post-Treatment Systemic Therapies and Immunotherapies
ITT Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 138) n (%)
Plant Alkaloids And Other Natural Products	2 (1.4)	0 (0.0)
Brucea Javanica Oil	2 (1.4)	0 (0.0)
Antimetabolites	1 (0.7)	0 (0.0)
Gimeracil	1 (0.7)	0 (0.0)
Immunostimulants	1 (0.7)	0 (0.0)
Immunotherapy	1 (0.7)	0 (0.0)
Other Cytotoxic Antibiotics	1 (0.7)	1 (0.7)
Bleomycin	1 (0.7)	0 (0.0)
Mitomycin	0 (0.0)	1 (0.7)
Other Immunostimulants	1 (0.7)	0 (0.0)
D-Ribose;peptides Nos	1 (0.7)	0 (0.0)
Other Immunostimulants	1 (0.7)	0 (0.0)
Ribonucleic Acid	1 (0.7)	0 (0.0)

Source: Listing 16.2.4.10,16.2.4.11. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
* Monoclonal antibodies included 4 anti-PD-1 antibodies (2 Geptanolimab, 1 Nivolumab, 1 unknow name anti-PD-1 antibody).
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-postsys.sas 24APR2024 01:38 t-14-02-08-03-b-postsys-itts-fa.rtf

Table 14.2.8.3.b:
Summary of Post-Treatment Systemic Therapies and Immunotherapies
ITT Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 138) n (%)
Other Plant Alkaloids And Natural Products	1 (0.7)	0 (0.0)
Cinobufagin	1 (0.7)	0 (0.0)
Podophyllotoxin Derivatives	1 (0.7)	3 (2.2)
Etoposide	1 (0.7)	3 (2.2)
Unspecified Herbal And Traditional Medicine	1 (0.7)	3 (2.2)
Unspecified Herbal And Traditional Medicine	1 (0.7)	3 (2.2)
All Other Therapeutic Products	0 (0.0)	1 (0.7)
All Other Therapeutic Products	0 (0.0)	1 (0.7)
Herbal Anticancer Remedies	0 (0.0)	2 (1.4)
Astragalus Spp. Root;cantharidin;eleutherococcus Senticosus Root With Rhizome;panax Ginseng Root	0 (0.0)	1 (0.7)
Marsdenia Tenacissima Stem	0 (0.0)	1 (0.7)

Source: Listing 16.2.4.10,16.2.4.11. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
* Monoclonal antibodies included 4 anti-PD-1 antibodies (2 Geptanolimab, 1 Nivolumab, 1 unknow name anti-PD-1 antibody).
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Table 14.2.8.3.b:
Summary of Post-Treatment Systemic Therapies and Immunotherapies
ITT Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 138) n (%)
Nitrogen Mustard Analogues	0 (0.0)	2 (1.4)
Cyclophosphamide	0 (0.0)	2 (1.4)
Immunotherapy	6 (4.3)	33 (23.9)
Monoclonal Antibodies	5 (3.6)	33 (23.9)
Nivolumab	4 (2.9)	15 (10.9)
Camrelizumab	1 (0.7)	3 (2.2)
Atezolizumab	0 (0.0)	1 (0.7)
Bgb A317	0 (0.0)	1 (0.7)
Bi 754091	0 (0.0)	2 (1.4)
Bi 754111	0 (0.0)	2 (1.4)
Kn 035	0 (0.0)	1 (0.7)
Monoclonal Antibodies *	0 (0.0)	4 (2.9)
Pembrolizumab	0 (0.0)	2 (1.4)
Sct I10a	0 (0.0)	1 (0.7)
Sintilimab	0 (0.0)	3 (2.2)
Toripalimab	0 (0.0)	1 (0.7)

Source: Listing 16.2.4.10,16.2.4.11. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
* Monoclonal antibodies included 4 anti-PD-1 antibodies (2 Geptanolimab, 1 Nivolumab, 1 unknow name anti-PD-1 antibody).
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-postsys.sas 24APR2024 01:38 t-14-02-08-03-b-postsys-itts-fa.rtf

Table 14.2.8.3.b:
Summary of Post-Treatment Systemic Therapies and Immunotherapies
ITT Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 138) n (%)
Immunostimulants	1 (0.7)	0 (0.0)
Immunotherapy	1 (0.7)	0 (0.0)

Source: Listing 16.2.4.10,16.2.4.11. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
* Monoclonal antibodies included 4 anti-PD-1 antibodies (2 Geptanolimab, 1 Nivolumab, 1 unknow name anti-PD-1 antibody).
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-postsys.sas 24APR2024 01:38 t-14-02-08-03-b-postsys-itts-fa.rtf

Table 14.3.1.3.1:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR
Safety Analysis Set

	Tislelizumab (N = 255)			ICC (N = 240)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
IRR	255	8 (3.1)	NR (NE, NE)	240	11 (4.6)	NR (NE, NE)	0.580 (0.231, 1.459)	0.2379
IRR of Grade 1 and 2	255	8 (3.1)	NR (NE, NE)	240	11 (4.6)	NR (NE, NE)	0.580 (0.231, 1.459)	0.2379
IRR >= Grade 3	255	0 (0.0)	NR (NE, NE)	240	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Serious IRR	255	0 (0.0)	NR (NE, NE)	240	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.
Adverse events were graded for severity using CTCAE v4.03.
Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.
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Table 14.3.1.3.1.b:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 129)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
IRR	139	8 (5.8)	NR (NE, NE)	129	7 (5.4)	NR (NE, NE)	0.977 (0.352, 2.706)	0.9634
IRR of Grade 1 and 2	139	8 (5.8)	NR (NE, NE)	129	7 (5.4)	NR (NE, NE)	0.977 (0.352, 2.706)	0.9634
IRR >= Grade 3	139	0 (0.0)	NR (NE, NE)	129	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Serious IRR	139	0 (0.0)	NR (NE, NE)	129	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.
Adverse events were graded for severity using CTCAE v4.03.
Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.
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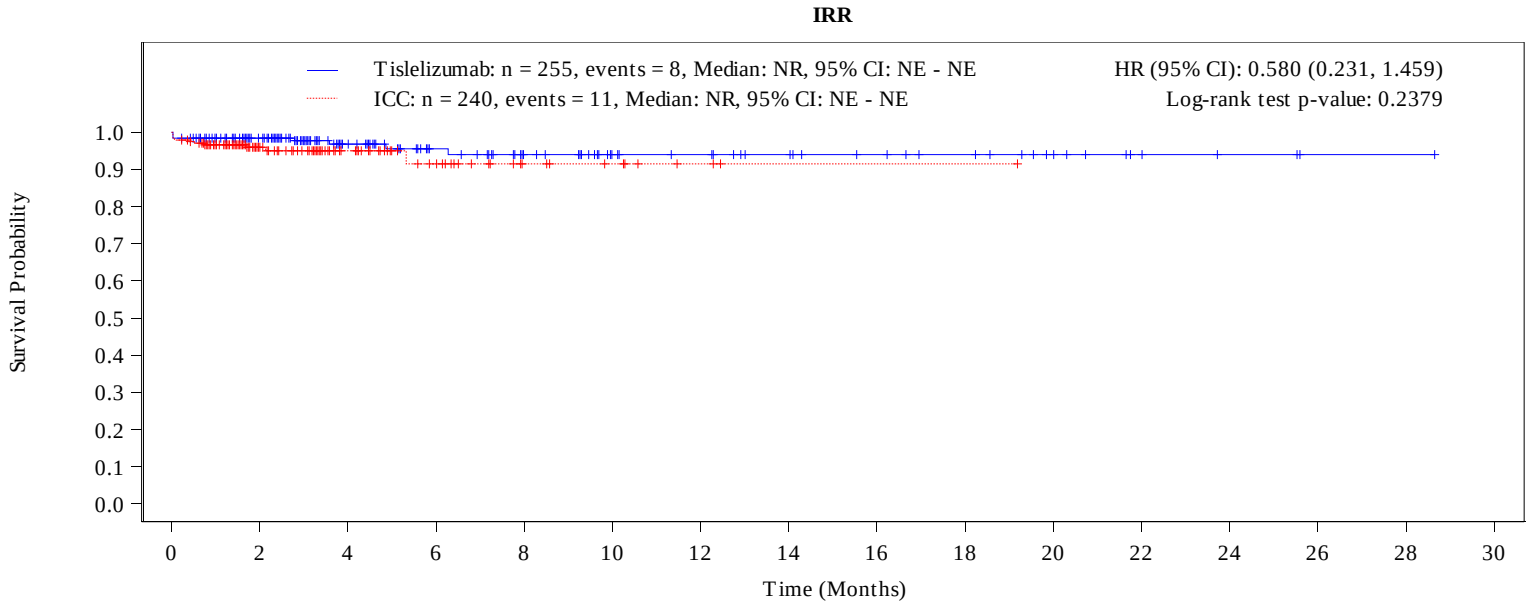
Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest: IRR
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	173	94	61	45	31	27	22	18	15	10	5	3	1	1	0
ICC	240	106	41	22	10	7	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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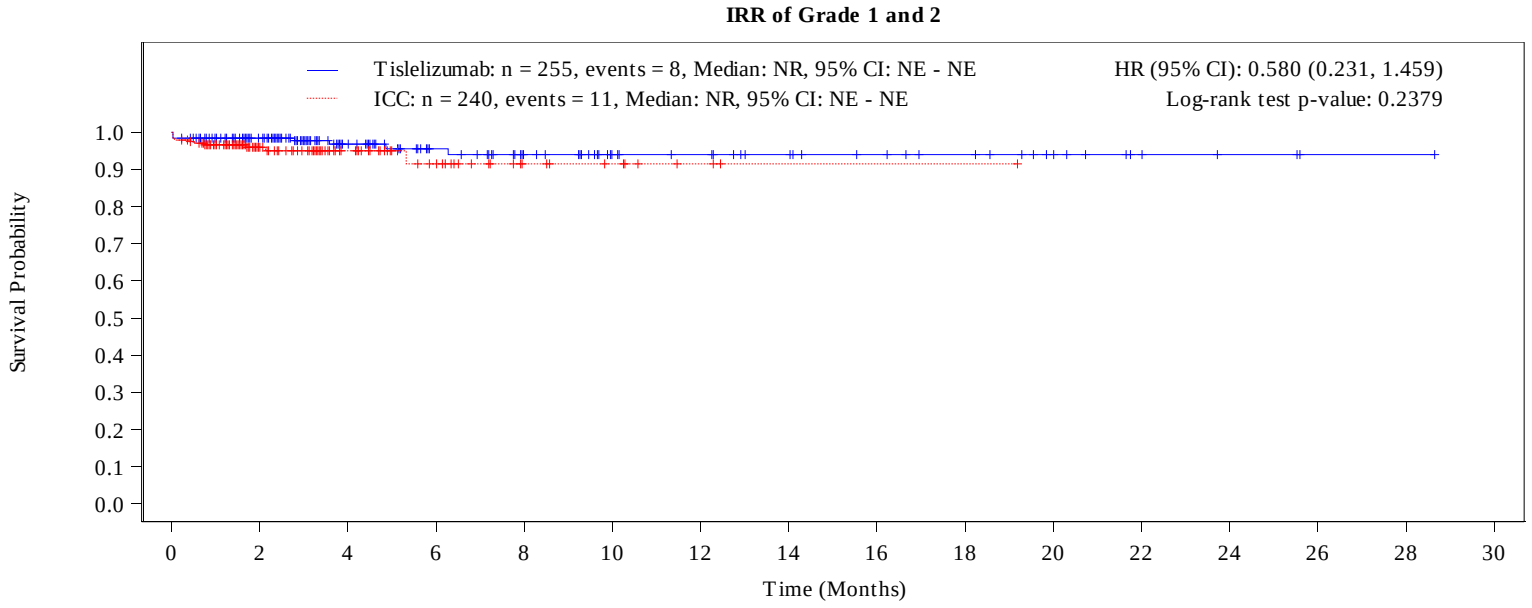
Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest: IRR
Safety Analysis Set

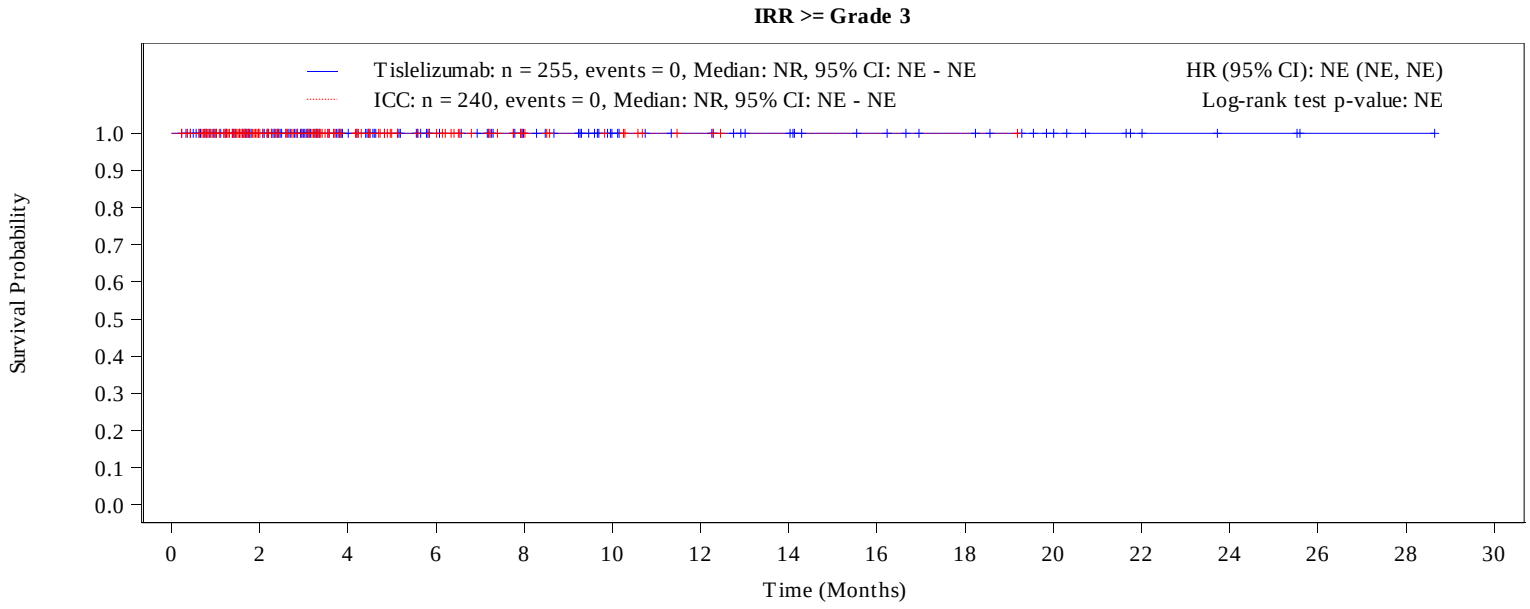


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	173	94	61	45	31	27	22	18	15	10	5	3	1	1	0
ICC	240	106	41	22	10	7	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesi.sas 20AUG2024 23:25 f-14-03-01-05-km-aesi-safety-fa.rtf

Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest: IRR
Safety Analysis Set

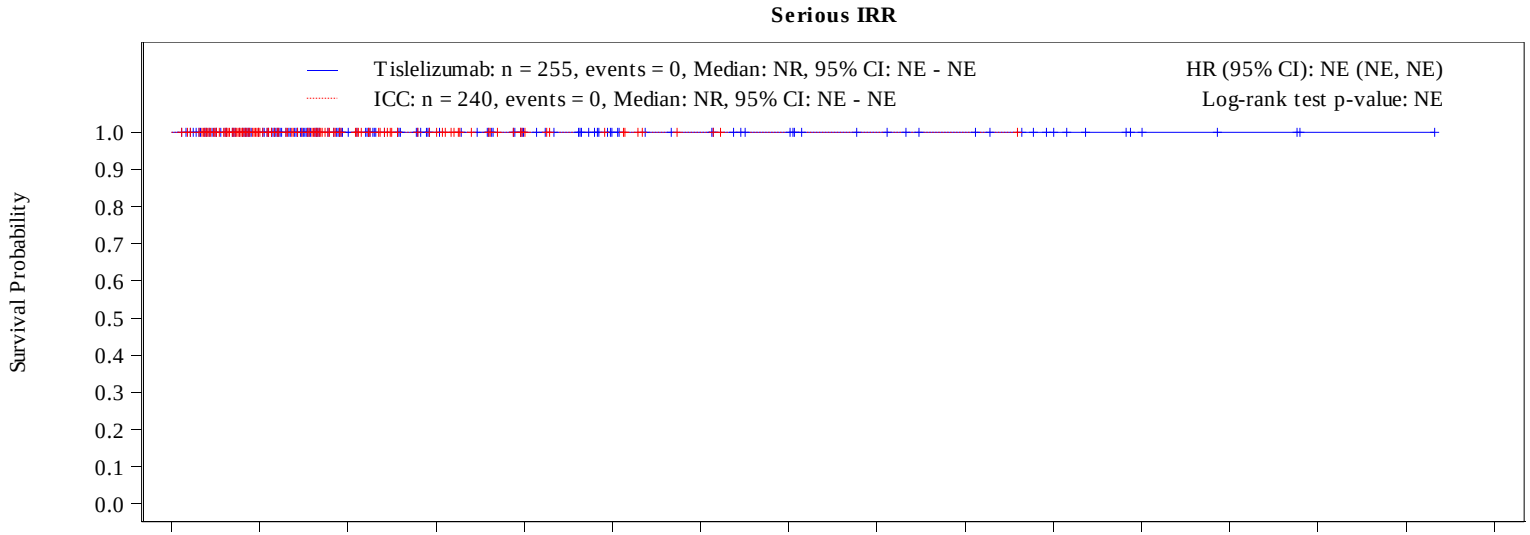


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	175	97	65	49	34	29	24	18	15	10	5	3	1	1	0
ICC	240	113	45	26	12	8	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesi.sas 20AUG2024 23:25 f-14-03-01-05-km-aesi-safety-fa.rtf

Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest: IRR
Safety Analysis Set

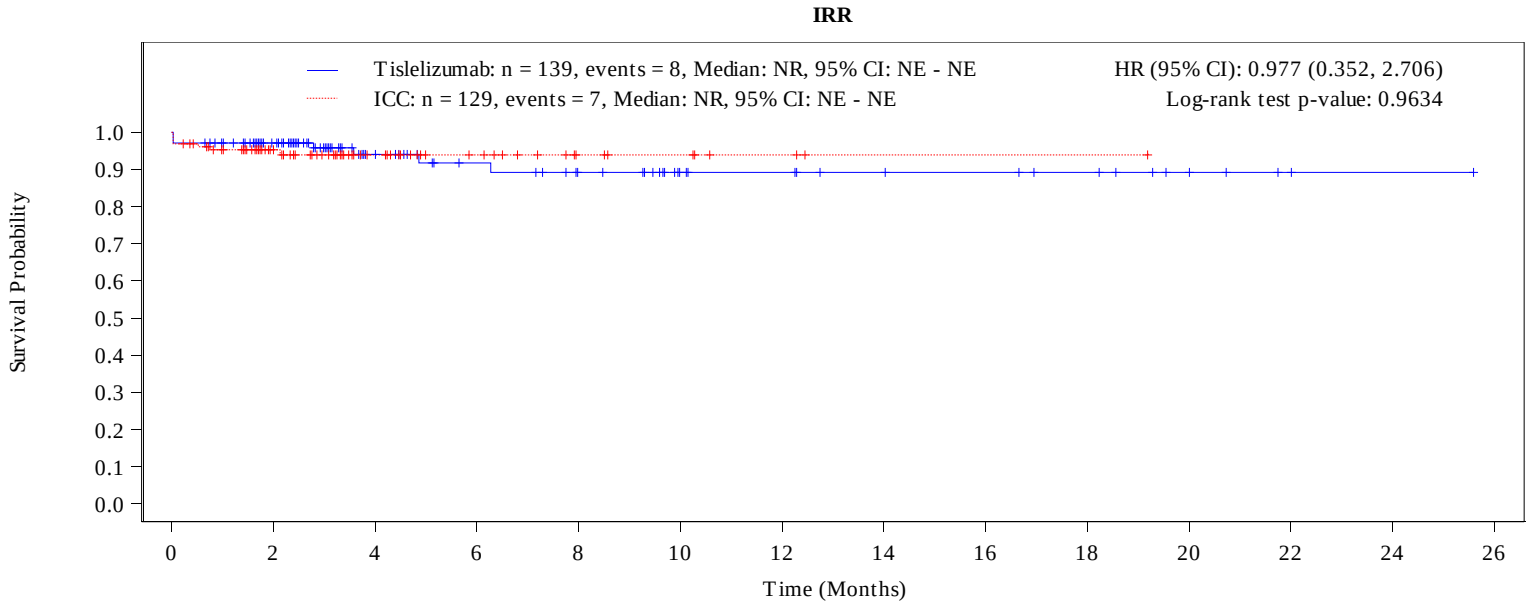


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	175	97	65	49	34	29	24	18	15	10	5	3	1	1	0
ICC	240	113	45	26	12	8	3	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesi.sas 20AUG2024 23:25 f-14-03-01-05-km-aesi-safety-fa.rtf

Figure 14.3.1.5.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest: IRR
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	93	49	36	28	17	15	12	11	9	5	2	1	0
ICC	129	70	29	16	8	6	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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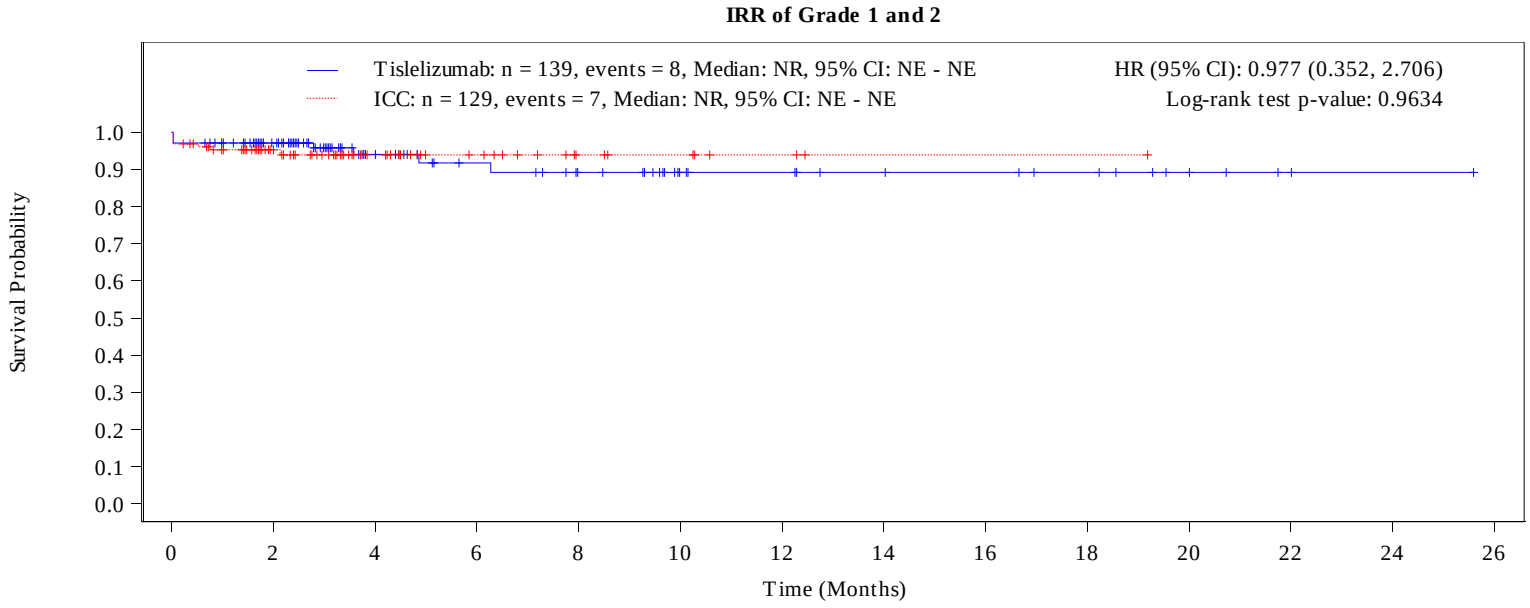
Figure 14.3.1.5.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest: IRR
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	93	49	36	28	17	15	12	11	9	5	2	1	0
ICC	129	70	29	16	8	6	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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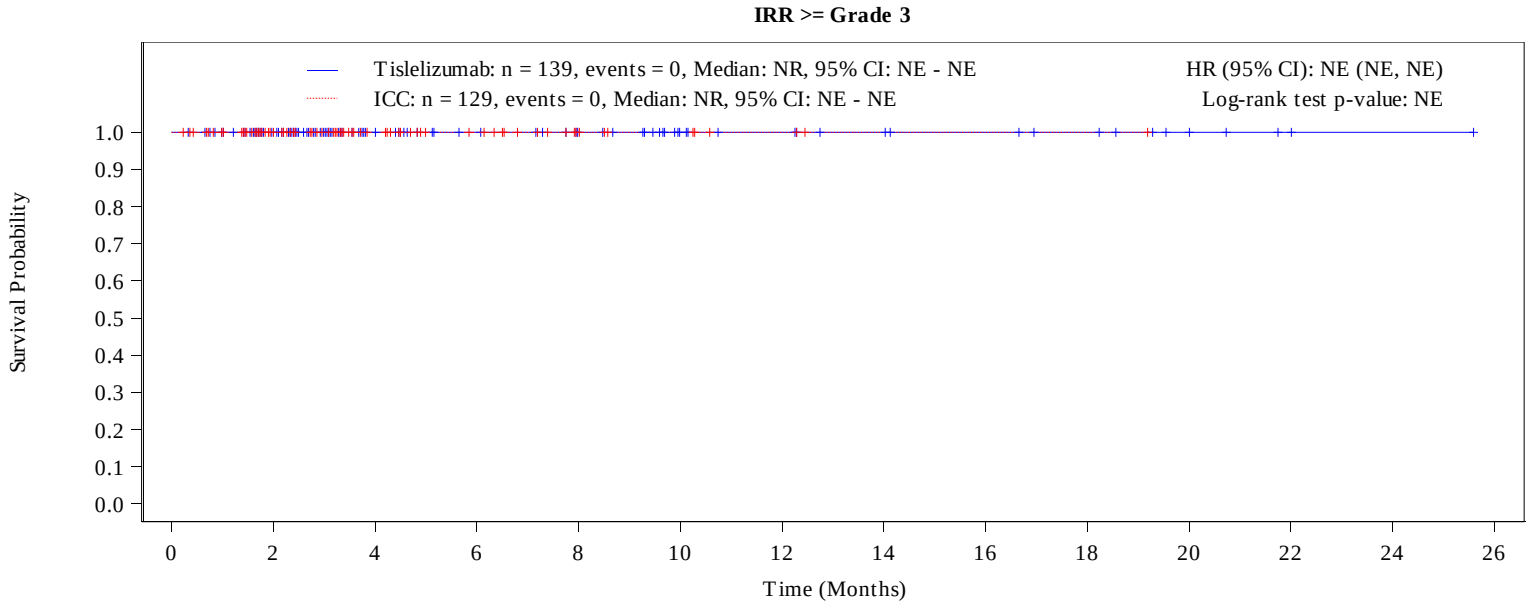
Figure 14.3.1.5.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest: IRR
Safety Analysis Set - Subpopulation without Irinotecan

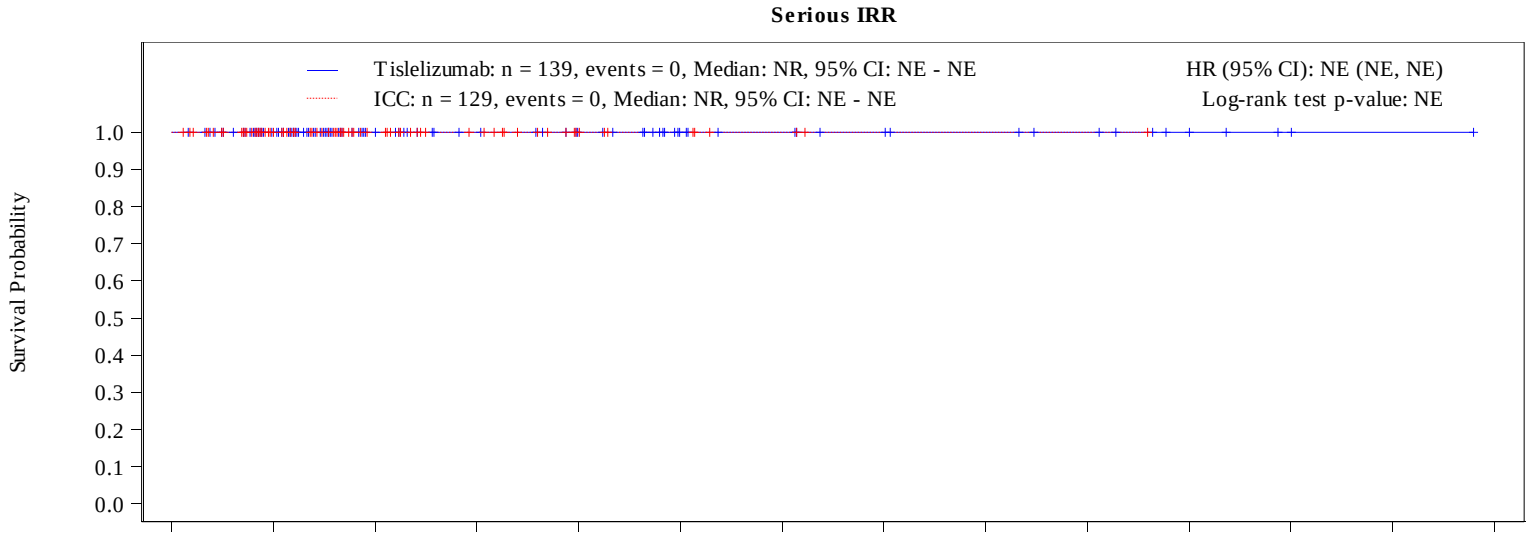


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	95	52	40	32	20	17	14	11	9	5	2	1	0
ICC	129	75	33	19	9	6	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesi.sas 20AUG2024 23:25 f-14-03-01-05-b-km-aesi-safetys-fa.rtf

Figure 14.3.1.5.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest: IRR
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	95	52	40	32	20	17	14	11	9	5	2	1	0
ICC	129	75	33	19	9	6	3	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set

IRR

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	4 (2.5)	NR (NE, NE)	149	5 (3.4)	NR (NE, NE)	0.565 (0.149, 2.147)	0.3963
>= 65 Years	98	4 (4.1)	NR (NE, NE)	91	6 (6.6)	NR (NE, NE)	0.511 (0.142, 1.846)	0.2917
Interaction								0.7883
Gender								
Male	216	6 (2.8)	NR (NE, NE)	204	8 (3.9)	NR (NE, NE)	0.500 (0.170, 1.467)	0.1977
Female	39	2 (5.1)	NR (NE, NE)	36	3 (8.3)	NR (NE, NE)	0.618 (0.103, 3.698)	0.5913
Interaction								0.8896

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set

IRR

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	5 (2.7)	NR (NE, NE)	183	9 (4.9)	NR (NE, NE)	0.371 (0.122, 1.131)	0.0702
Non-Smoker	68	3 (4.4)	NR (NE, NE)	57	2 (3.5)	NR (NE, NE)	1.271 (0.212, 7.608)	0.7912
Interaction								0.4070
ICC Options								
Paclitaxel	83	4 (4.8)	NR (NE, NE)	79	6 (7.6)	NR (NE, NE)	0.566 (0.159, 2.021)	0.3703
Docetaxel	56	4 (7.1)	NR (NE, NE)	50	1 (2.0)	NR (NE, NE)	2.920 (0.323, 26.438)	0.3173
Irinotecan	116	0 (0.0)	NR (NE, NE)	111	4 (3.6)	NR (5.3, NE)	0.000 (0.000, NE)	0.0100
Interaction								0.3827

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set

IRR

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	4 (6.3)	NR (NE, NE)	57	2 (3.5)	NR (NE, NE)	1.145 (0.208, 6.318)	0.8764
1	192	4 (2.1)	NR (NE, NE)	183	9 (4.9)	NR (NE, NE)	0.394 (0.121, 1.283)	0.1070
Interaction								0.1514
Region #1								
Asia	201	8 (4.0)	NR (NE, NE)	191	6 (3.1)	NR (NE, NE)	0.988 (0.337, 2.899)	0.9824
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	5 (10.2)	NR (5.3, NE)	0.000 (0.000, NE)	0.0102
Interaction								0.9907

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set

IRR

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	5 (2.8)	NR (NE, NE)	168	6 (3.6)	NR (NE, NE)	0.654 (0.196, 2.182)	0.4846
Japan	25	3 (12.0)	NR (4.9, NE)	23	0 (0.0)	NR (NE, NE)	55301530.201 (0.000, NE)	0.1794
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	5 (10.2)	NR (5.3, NE)	0.000 (0.000, NE)	0.0102
Interaction								0.9999
Race								
Asian and other	203	8 (3.9)	NR (NE, NE)	198	7 (3.5)	NR (NE, NE)	0.884 (0.315, 2.479)	0.8145
White	52	0 (0.0)	NR (NE, NE)	42	4 (9.5)	NR (5.3, NE)	0.000 (0.000, NE)	0.0132
Interaction								0.9905

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set

IRR

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	3 (3.8)	--	60	2 (3.3)	--	--	--
vCPS < 10%	100	3 (3.0)	--	119	4 (3.4)	--	--	--
Missing	75	2 (2.7)	--	61	5 (8.2)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set

IRR of Grade 1 and 2

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	4 (2.5)	NR (NE, NE)	149	5 (3.4)	NR (NE, NE)	0.565 (0.149, 2.147)	0.3963
>= 65 Years	98	4 (4.1)	NR (NE, NE)	91	6 (6.6)	NR (NE, NE)	0.511 (0.142, 1.846)	0.2917
Interaction								0.7883
Gender								
Male	216	6 (2.8)	NR (NE, NE)	204	8 (3.9)	NR (NE, NE)	0.500 (0.170, 1.467)	0.1977
Female	39	2 (5.1)	NR (NE, NE)	36	3 (8.3)	NR (NE, NE)	0.618 (0.103, 3.698)	0.5913
Interaction								0.8896

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set

IRR of Grade 1 and 2

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	5 (2.7)	NR (NE, NE)	183	9 (4.9)	NR (NE, NE)	0.371 (0.122, 1.131)	0.0702
Non-Smoker	68	3 (4.4)	NR (NE, NE)	57	2 (3.5)	NR (NE, NE)	1.271 (0.212, 7.608)	0.7912
Interaction								0.4070
ICC Options								
Paclitaxel	83	4 (4.8)	NR (NE, NE)	79	6 (7.6)	NR (NE, NE)	0.566 (0.159, 2.021)	0.3703
Docetaxel	56	4 (7.1)	NR (NE, NE)	50	1 (2.0)	NR (NE, NE)	2.920 (0.323, 26.438)	0.3173
Irinotecan	116	0 (0.0)	NR (NE, NE)	111	4 (3.6)	NR (5.3, NE)	0.000 (0.000, NE)	0.0100
Interaction								0.3827

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set

IRR of Grade 1 and 2

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	4 (6.3)	NR (NE, NE)	57	2 (3.5)	NR (NE, NE)	1.145 (0.208, 6.318)	0.8764
1	192	4 (2.1)	NR (NE, NE)	183	9 (4.9)	NR (NE, NE)	0.394 (0.121, 1.283)	0.1070
Interaction								0.1514
Region #1								
Asia	201	8 (4.0)	NR (NE, NE)	191	6 (3.1)	NR (NE, NE)	0.988 (0.337, 2.899)	0.9824
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	5 (10.2)	NR (5.3, NE)	0.000 (0.000, NE)	0.0102
Interaction								0.9907

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set

IRR of Grade 1 and 2

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	5 (2.8)	NR (NE, NE)	168	6 (3.6)	NR (NE, NE)	0.654 (0.196, 2.182)	0.4846
Japan	25	3 (12.0)	NR (4.9, NE)	23	0 (0.0)	NR (NE, NE)	55301530.201 (0.000, NE)	0.1794
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	5 (10.2)	NR (5.3, NE)	0.000 (0.000, NE)	0.0102
Interaction								0.9999
Race								
Asian and other	203	8 (3.9)	NR (NE, NE)	198	7 (3.5)	NR (NE, NE)	0.884 (0.315, 2.479)	0.8145
White	52	0 (0.0)	NR (NE, NE)	42	4 (9.5)	NR (5.3, NE)	0.000 (0.000, NE)	0.0132
Interaction								0.9905

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set

IRR of Grade 1 and 2

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	3 (3.8)	--	60	2 (3.3)	--	--	--
vCPS < 10%	100	3 (3.0)	--	119	4 (3.4)	--	--	--
Missing	75	2 (2.7)	--	61	5 (8.2)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set

IRR >= Grade 3

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	0 (0.0)	--	149	0 (0.0)	--	--	--
>= 65 Years	98	0 (0.0)	--	91	0 (0.0)	--	--	--
Interaction								--
Gender								
Male	216	0 (0.0)	--	204	0 (0.0)	--	--	--
Female	39	0 (0.0)	--	36	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set

IRR >= Grade 3

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	0 (0.0)	--	183	0 (0.0)	--	--	--
Non-Smoker	68	0 (0.0)	--	57	0 (0.0)	--	--	--
Interaction								--
ICC Options								
Paclitaxel	83	0 (0.0)	--	79	0 (0.0)	--	--	--
Docetaxel	56	0 (0.0)	--	50	0 (0.0)	--	--	--
Irinotecan	116	0 (0.0)	--	111	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set

IRR >= Grade 3

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	0 (0.0)	--	57	0 (0.0)	--	--	--
1	192	0 (0.0)	--	183	0 (0.0)	--	--	--
Interaction								--
Region #1								
Asia	201	0 (0.0)	--	191	0 (0.0)	--	--	--
Europe/North America	54	0 (0.0)	--	49	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set

IRR >= Grade 3

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	0 (0.0)	--	168	0 (0.0)	--	--	--
Japan	25	0 (0.0)	--	23	0 (0.0)	--	--	--
Europe/North America	54	0 (0.0)	--	49	0 (0.0)	--	--	--
Interaction								--
Race								
Asian and other	203	0 (0.0)	--	198	0 (0.0)	--	--	--
White	52	0 (0.0)	--	42	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set

IRR >= Grade 3

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	0 (0.0)	--	60	0 (0.0)	--	--	--
vCPS < 10%	100	0 (0.0)	--	119	0 (0.0)	--	--	--
Missing	75	0 (0.0)	--	61	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set

Serious IRR

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	0 (0.0)	--	149	0 (0.0)	--	--	--
>= 65 Years	98	0 (0.0)	--	91	0 (0.0)	--	--	--
Interaction								--
Gender								
Male	216	0 (0.0)	--	204	0 (0.0)	--	--	--
Female	39	0 (0.0)	--	36	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set

Serious IRR

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	0 (0.0)	--	183	0 (0.0)	--	--	--
Non-Smoker	68	0 (0.0)	--	57	0 (0.0)	--	--	--
Interaction								--
ICC Options								
Paclitaxel	83	0 (0.0)	--	79	0 (0.0)	--	--	--
Docetaxel	56	0 (0.0)	--	50	0 (0.0)	--	--	--
Irinotecan	116	0 (0.0)	--	111	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set

Serious IRR

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	0 (0.0)	--	57	0 (0.0)	--	--	--
1	192	0 (0.0)	--	183	0 (0.0)	--	--	--
Interaction								--
Region #1								
Asia	201	0 (0.0)	--	191	0 (0.0)	--	--	--
Europe/North America	54	0 (0.0)	--	49	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set

Serious IRR

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	0 (0.0)	--	168	0 (0.0)	--	--	--
Japan	25	0 (0.0)	--	23	0 (0.0)	--	--	--
Europe/North America	54	0 (0.0)	--	49	0 (0.0)	--	--	--
Interaction								--
Race								
Asian and other	203	0 (0.0)	--	198	0 (0.0)	--	--	--
White	52	0 (0.0)	--	42	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set

Serious IRR

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	0 (0.0)	--	60	0 (0.0)	--	--	--
vCPS < 10%	100	0 (0.0)	--	119	0 (0.0)	--	--	--
Missing	75	0 (0.0)	--	61	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	4 (5.2)	--	70	2 (2.9)	--	--	--
>= 65 Years	62	4 (6.5)	--	59	5 (8.5)	--	--	--
Interaction								--
Gender								
Male	118	6 (5.1)	NR (NE, NE)	106	5 (4.7)	NR (NE, NE)	0.878 (0.266, 2.904)	0.8310
Female	21	2 (9.5)	NR (NE, NE)	23	2 (8.7)	NR (NE, NE)	1.111 (0.156, 7.887)	0.9149
Interaction								0.9889

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	5 (4.8)	NR (NE, NE)	101	6 (5.9)	NR (NE, NE)	0.617 (0.185, 2.053)	0.4247
Non-Smoker	35	3 (8.6)	NR (NE, NE)	28	1 (3.6)	NR (NE, NE)	2.432 (0.253, 23.387)	0.4207
Interaction								0.3361
ICC Options								
Paclitaxel	83	4 (4.8)	NR (NE, NE)	79	6 (7.6)	NR (NE, NE)	0.566 (0.159, 2.021)	0.3703
Docetaxel	56	4 (7.1)	NR (NE, NE)	50	1 (2.0)	NR (NE, NE)	2.920 (0.323, 26.438)	0.3173
Interaction								0.1739

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	4 (9.3)	NR (NE, NE)	37	0 (0.0)	NR (NE, NE)	54390180.130 (0.000, NE)	0.1138
1	96	4 (4.2)	NR (NE, NE)	92	7 (7.6)	NR (NE, NE)	0.527 (0.154, 1.804)	0.2930
Interaction								0.9901
Region #1								
Asia	103	8 (7.8)	NR (NE, NE)	99	4 (4.0)	NR (NE, NE)	1.623 (0.485, 5.434)	0.4237
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	3 (10.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0567
Interaction								0.9901

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	5 (6.4)	--	76	4 (5.3)	--	--	--
Japan	25	3 (12.0)	--	23	0 (0.0)	--	--	--
Europe/North America	36	0 (0.0)	--	30	3 (10.0)	--	--	--
Interaction								--
Race								
Asian and other	105	8 (7.6)	NR (NE, NE)	106	5 (4.7)	NR (NE, NE)	1.383 (0.449, 4.259)	0.5672
White	34	0 (0.0)	NR (NE, NE)	23	2 (8.7)	NR (NE, NE)	0.000 (0.000, NE)	0.0892
Interaction								0.9903

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	3 (6.7)	--	34	2 (5.9)	--	--	--
vCPS < 10%	53	3 (5.7)	--	54	1 (1.9)	--	--	--
Missing	41	2 (4.9)	--	41	4 (9.8)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR of Grade 1 and 2

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	4 (5.2)	--	70	2 (2.9)	--	--	--
>= 65 Years	62	4 (6.5)	--	59	5 (8.5)	--	--	--
Interaction								--
Gender								
Male	118	6 (5.1)	NR (NE, NE)	106	5 (4.7)	NR (NE, NE)	0.878 (0.266, 2.904)	0.8310
Female	21	2 (9.5)	NR (NE, NE)	23	2 (8.7)	NR (NE, NE)	1.111 (0.156, 7.887)	0.9149
Interaction								0.9889

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR of Grade 1 and 2

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	5 (4.8)	NR (NE, NE)	101	6 (5.9)	NR (NE, NE)	0.617 (0.185, 2.053)	0.4247
Non-Smoker	35	3 (8.6)	NR (NE, NE)	28	1 (3.6)	NR (NE, NE)	2.432 (0.253, 23.387)	0.4207
Interaction								0.3361
ICC Options								
Paclitaxel	83	4 (4.8)	NR (NE, NE)	79	6 (7.6)	NR (NE, NE)	0.566 (0.159, 2.021)	0.3703
Docetaxel	56	4 (7.1)	NR (NE, NE)	50	1 (2.0)	NR (NE, NE)	2.920 (0.323, 26.438)	0.3173
Interaction								0.1739

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR of Grade 1 and 2

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	4 (9.3)	NR (NE, NE)	37	0 (0.0)	NR (NE, NE)	54390180.130 (0.000, NE)	0.1138
1	96	4 (4.2)	NR (NE, NE)	92	7 (7.6)	NR (NE, NE)	0.527 (0.154, 1.804)	0.2930
Interaction								0.9901
Region #1								
Asia	103	8 (7.8)	NR (NE, NE)	99	4 (4.0)	NR (NE, NE)	1.623 (0.485, 5.434)	0.4237
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	3 (10.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0567
Interaction								0.9901

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR of Grade 1 and 2

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	5 (6.4)	--	76	4 (5.3)	--	--	--
Japan	25	3 (12.0)	--	23	0 (0.0)	--	--	--
Europe/North America	36	0 (0.0)	--	30	3 (10.0)	--	--	--
Interaction								--
Race								
Asian and other	105	8 (7.6)	NR (NE, NE)	106	5 (4.7)	NR (NE, NE)	1.383 (0.449, 4.259)	0.5672
White	34	0 (0.0)	NR (NE, NE)	23	2 (8.7)	NR (NE, NE)	0.000 (0.000, NE)	0.0892
Interaction								0.9903

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR of Grade 1 and 2

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	3 (6.7)	--	34	2 (5.9)	--	--	--
vCPS < 10%	53	3 (5.7)	--	54	1 (1.9)	--	--	--
Missing	41	2 (4.9)	--	41	4 (9.8)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR >= Grade 3

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	0 (0.0)	--	70	0 (0.0)	--	--	--
>= 65 Years	62	0 (0.0)	--	59	0 (0.0)	--	--	--
Interaction								--
Gender								
Male	118	0 (0.0)	--	106	0 (0.0)	--	--	--
Female	21	0 (0.0)	--	23	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR >= Grade 3

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	0 (0.0)	--	101	0 (0.0)	--	--	--
Non-Smoker	35	0 (0.0)	--	28	0 (0.0)	--	--	--
Interaction								--
ICC Options								
Paclitaxel	83	0 (0.0)	--	79	0 (0.0)	--	--	--
Docetaxel	56	0 (0.0)	--	50	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR >= Grade 3

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	0 (0.0)	--	37	0 (0.0)	--	--	--
1	96	0 (0.0)	--	92	0 (0.0)	--	--	--
Interaction								--
Region #1								
Asia	103	0 (0.0)	--	99	0 (0.0)	--	--	--
Europe/North America	36	0 (0.0)	--	30	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR >= Grade 3

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	0 (0.0)	--	76	0 (0.0)	--	--	--
Japan	25	0 (0.0)	--	23	0 (0.0)	--	--	--
Europe/North America	36	0 (0.0)	--	30	0 (0.0)	--	--	--
Interaction								--
Race								
Asian and other	105	0 (0.0)	--	106	0 (0.0)	--	--	--
White	34	0 (0.0)	--	23	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR >= Grade 3

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	0 (0.0)	--	34	0 (0.0)	--	--	--
vCPS < 10%	53	0 (0.0)	--	54	0 (0.0)	--	--	--
Missing	41	0 (0.0)	--	41	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious IRR

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	0 (0.0)	--	70	0 (0.0)	--	--	--
>= 65 Years	62	0 (0.0)	--	59	0 (0.0)	--	--	--
Interaction								--
Gender								
Male	118	0 (0.0)	--	106	0 (0.0)	--	--	--
Female	21	0 (0.0)	--	23	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious IRR

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	0 (0.0)	--	101	0 (0.0)	--	--	--
Non-Smoker	35	0 (0.0)	--	28	0 (0.0)	--	--	--
Interaction								--
ICC Options								
Paclitaxel	83	0 (0.0)	--	79	0 (0.0)	--	--	--
Docetaxel	56	0 (0.0)	--	50	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious IRR

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	0 (0.0)	--	37	0 (0.0)	--	--	--
1	96	0 (0.0)	--	92	0 (0.0)	--	--	--
Interaction								--
Region #1								
Asia	103	0 (0.0)	--	99	0 (0.0)	--	--	--
Europe/North America	36	0 (0.0)	--	30	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious IRR

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	0 (0.0)	--	76	0 (0.0)	--	--	--
Japan	25	0 (0.0)	--	23	0 (0.0)	--	--	--
Europe/North America	36	0 (0.0)	--	30	0 (0.0)	--	--	--
Interaction								--
Race								
Asian and other	105	0 (0.0)	--	106	0 (0.0)	--	--	--
White	34	0 (0.0)	--	23	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious IRR

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	0 (0.0)	--	34	0 (0.0)	--	--	--
vCPS < 10%	53	0 (0.0)	--	54	0 (0.0)	--	--	--
Missing	41	0 (0.0)	--	41	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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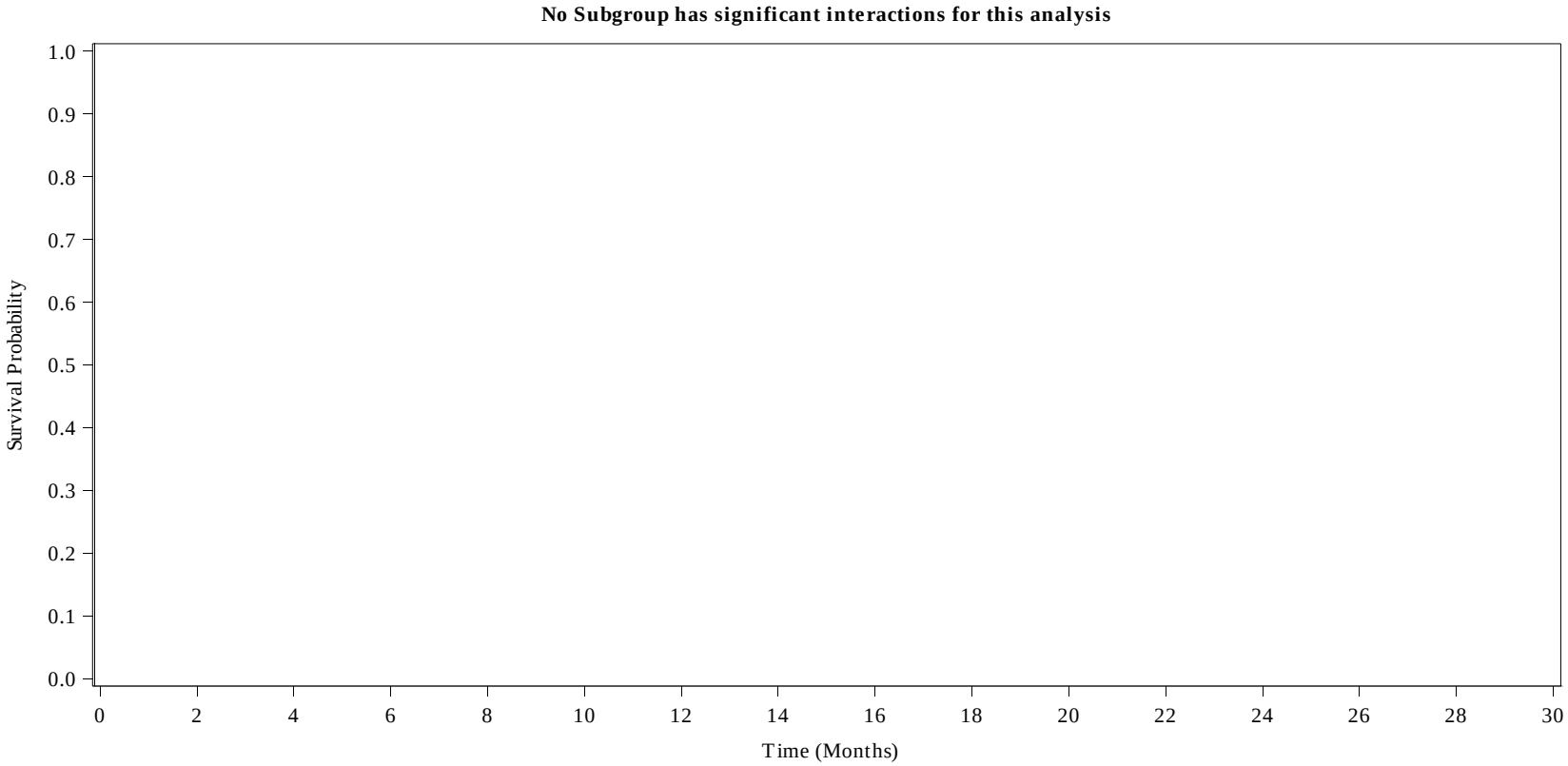
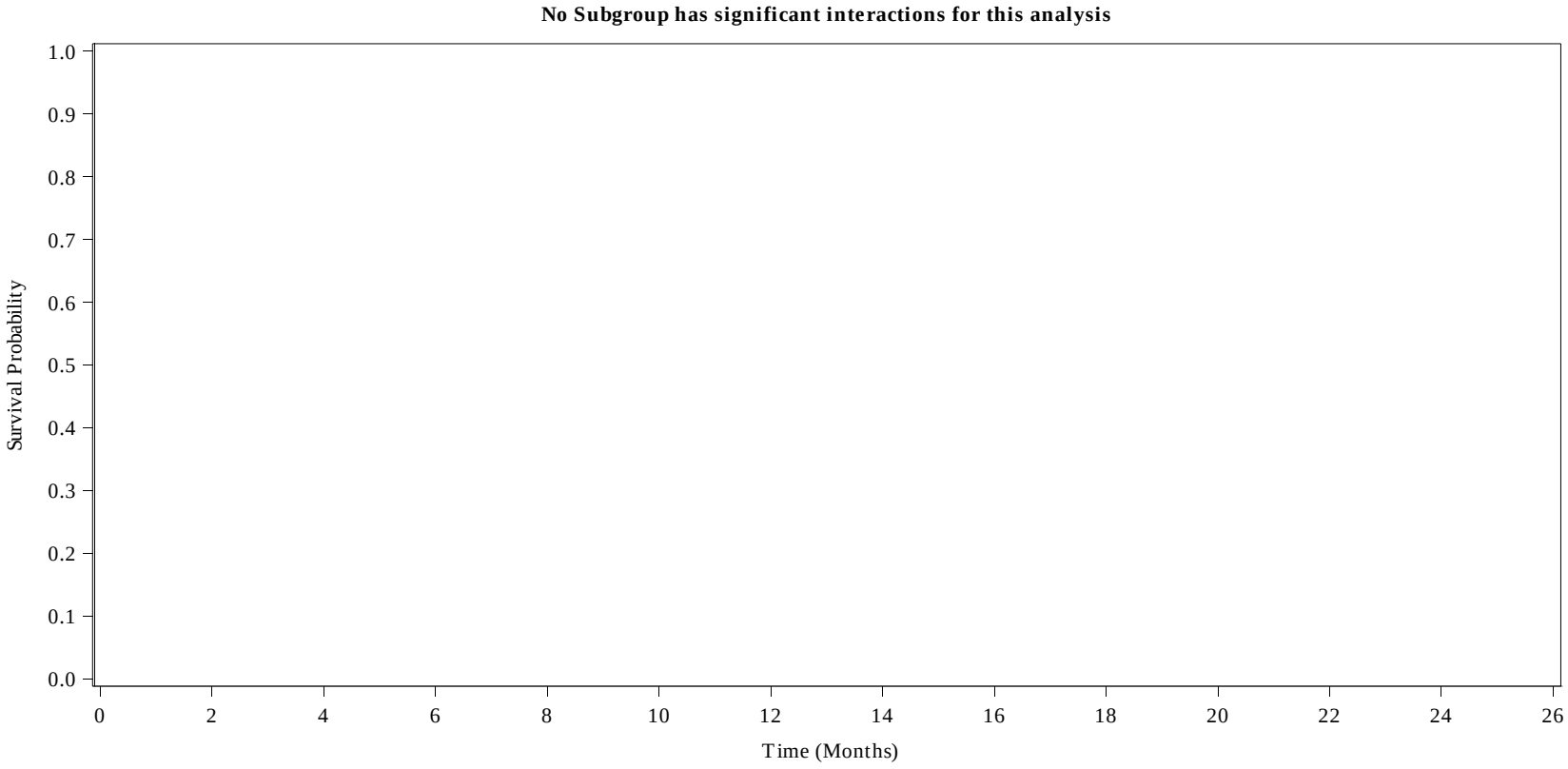
Figure 14.3.1.5.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesi-subgrp.sas 20AUG2024 23:25 f-14-03-01-05-s-km-aesi-subgrp-safety-fa.rtf

Figure 14.3.1.5.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01DEC2020. Data extraction: 15JAN2021.
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Table 14.1.8.2:
Summary of Follow-up Time by Safety-related Endpoint
Safety Analysis Set

Endpoint (Months)	Tislelizumab (N = 255)	ICC (N = 240)	Total (N = 495)
Safety for TEAEs except imAE [a]			
n	255	240	495
Mean (SD)	5.52 (6.268)	2.90 (2.677)	4.25 (5.038)
Median	3.02	1.94	2.43
Q1, Q3	1.71, 6.57	1.38, 3.37	1.61, 4.50
Min, Max	0.2, 31.6	0.2, 24.0	0.2, 31.6
Safety for imAEs [b]			
n	255	240	495
Mean (SD)	7.01 (6.219)	4.45 (2.890)	5.77 (5.056)
Median	5.06	3.81	4.17
Q1, Q3	3.65, 7.95	2.99, 5.29	3.15, 6.44
Min, Max	0.2, 31.6	0.2, 25.2	0.2, 31.6

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; imAE = immune-mediated adverse event.

[a] The time from the first dose date to the earliest date among the date of death, study discontinuation date, cut-off date, last date of study treatment + 30 days, and the date of the initiation of new anticancer therapy.

[b] The time from the first dose date to the earliest date among the date of death, study discontinuation date, cut-off date, last date of study treatment + 90 days.

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Table 14.1.8.2.b:
Summary of Follow-up Time by Safety-related Endpoint
Safety Analysis Set - Subpopulation without Irinotecan

Endpoint (Months)	Tislelizumab (N = 139)	ICC (N = 129)	Total (N = 268)
Safety for TEAEs except imAE [a]			
n	139	129	268
Mean (SD)	5.73 (6.368)	3.41 (3.096)	4.61 (5.187)
Median	3.02	2.40	2.71
Q1, Q3	1.71, 7.75	1.71, 4.21	1.71, 4.94
Min, Max	0.3, 31.6	0.2, 24.0	0.2, 31.6
Safety for imAEs [b]			
n	139	129	268
Mean (SD)	7.22 (6.259)	4.94 (3.294)	6.12 (5.172)
Median	4.99	4.11	4.37
Q1, Q3	3.65, 9.43	3.19, 5.78	3.45, 6.83
Min, Max	0.3, 31.6	0.2, 25.2	0.2, 31.6

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; imAE = immune-mediated adverse event.
[a] The time from the first dose date to the earliest date among the date of death, study discontinuation date, cut-off date, last date of study treatment + 30 days, and the date of the initiation of new anticancer therapy.
[b] The time from the first dose date to the earliest date among the date of death, study discontinuation date, cut-off date, last date of study treatment + 90 days.
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Table 14.3.1.1.1.b:
Study Medication Administration - Tislelizumab
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)
Duration of Exposure (Days)	
n	139
Mean (SD)	168.7 (194.42)
Median	84.0
Q1, Q3	43.0, 229.0
Min, Max	10, 961
Duration of Exposure, n (%)	
<1 month	12 (8.6)
>=1 to <3 month	69 (49.6)
>=3 to <6 month	18 (12.9)
>=6 to <12 month	23 (16.5)
>=12 to <18 month	8 (5.8)
>=18 to <24 month	3 (2.2)
>=24 month	6 (4.3)

Source: ADSL, ADEXSUM. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Percentages were based on N.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/cycle) is defined as total dose (mg) / duration of exposure (day) * cycle length in days.

[c] RDI is defined as the ratio of the actual dose intensity (mg/cycle) and the planned dose intensity (mg/cycle) = dose intensity / (200 mg/cycle). The planned dose intensity is the total planned dose in a cycle. For a patient in the tislelizumab arm, the planned dose intensity is 200 mg once every three weeks.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.1.b:
Study Medication Administration - Tislelizumab
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)
Number of Cycles Received, n (%)	
1	12 (8.6)
2	28 (20.1)
3	22 (15.8)
4	19 (13.7)
5	4 (2.9)
6	11 (7.9)
7	2 (1.4)
8	1 (0.7)
9	1 (0.7)
10	4 (2.9)
>10	35 (25.2)

Source: ADSL, ADEXSUM. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Percentages were based on N.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/cycle) is defined as total dose (mg) / duration of exposure (day) * cycle length in days.

[c] RDI is defined as the ratio of the actual dose intensity (mg/cycle) and the planned dose intensity (mg/cycle) = dose intensity / (200 mg/cycle). The planned dose intensity is the total planned dose in a cycle. For a patient in the tislelizumab arm, the planned dose intensity is 200 mg once every three weeks.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.1.b:
Study Medication Administration - Tislelizumab
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)
Number of Cycles Received, n (%)	
1-3	62 (44.6)
4-6	34 (24.5)
7-9	4 (2.9)
10-12	10 (7.2)
13-18	13 (9.4)
>18	16 (11.5)
Number of Treatment Cycles	
n	139
Mean (SD)	7.8 (9.02)
Median	4.0
Q1, Q3	2.0, 11.0
Min, Max	1, 46

Source: ADSL, ADEXSUM. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Percentages were based on N.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/cycle) is defined as total dose (mg) / duration of exposure (day) * cycle length in days.

[c] RDI is defined as the ratio of the actual dose intensity (mg/cycle) and the planned dose intensity (mg/cycle) = dose intensity / (200 mg/cycle). The planned dose intensity is the total planned dose in a cycle. For a patient in the tislelizumab arm, the planned dose intensity is 200 mg once every three weeks.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.1.b:
Study Medication Administration - Tislelizumab
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)
Cumulative Total Dose (mg) per Patient [a]	
n	139
Mean (SD)	1568.35 (1804.705)
Median	800.00
Q1, Q3	400.00, 2200.00
Min, Max	200.0, 9200.0
Actual Dose Intensity (mg/cycle) per Patient [b]	
n	139
Mean (SD)	198.12 (21.808)
Median	200.00
Q1, Q3	195.35, 200.00
Min, Max	133.3, 420.0

Source: ADSL, ADEXSUM. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Percentages were based on N.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/cycle) is defined as total dose (mg) / duration of exposure (day) * cycle length in days.

[c] RDI is defined as the ratio of the actual dose intensity (mg/cycle) and the planned dose intensity (mg/cycle) = dose intensity / (200 mg/cycle). The planned dose intensity is the total planned dose in a cycle. For a patient in the tislelizumab arm, the planned dose intensity is 200 mg once every three weeks.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.1.b:
Study Medication Administration - Tislelizumab
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)
Relative Dose Intensity (%) per Patient [c]	
n	139
Mean (SD)	99.06 (10.904)
Median	100.00
Q1, Q3	97.67, 100.00
Min, Max	66.7, 210.0
Patients with Any Dose Modification, n (%) [d]	42 (30.2)
Dose Delay	42 (30.2)
Adverse Event	23 (16.5)
Other	24 (17.3)
COVID-19	6 (4.3)

Source: ADSL, ADEXSUM. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Percentages were based on N.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

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[c] RDI is defined as the ratio of the actual dose intensity (mg/cycle) and the planned dose intensity (mg/cycle) = dose intensity / (200 mg/cycle). The planned dose intensity is the total planned dose in a cycle. For a patient in the tislelizumab arm, the planned dose intensity is 200 mg once every three weeks.

[d] A patient was counted only once within each category but may be counted in multiple categories.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-ex-tis.sas 25APR2024 01:35 t-14-03-01-01-01-b-ex-tis-safetys-sa.rtf

Table 14.3.1.1.1.b:
Study Medication Administration - Tislelizumab
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)
Infusion Interrupted	0 (0.0)
Adverse Event	0 (0.0)
Other	0 (0.0)
COVID-19	0 (0.0)

Source: ADSL, ADEXSUM. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Percentages were based on N.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/cycle) is defined as total dose (mg) / duration of exposure (day) * cycle length in days.

[c] RDI is defined as the ratio of the actual dose intensity (mg/cycle) and the planned dose intensity (mg/cycle) = dose intensity / (200 mg/cycle). The planned dose intensity is the total planned dose in a cycle. For a patient in the tislelizumab arm, the planned dose intensity is 200 mg once every three weeks.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.2.b:
Study Medication Administration - Investigator Chosen Chemotherapy (ICC)
Safety Analysis Set - Subpopulation without Irinotecan

	Paclitaxel			Docetaxel			
	Paclitaxel Grp1 (N = 62)	Paclitaxel Grp2 (N = 17)	Overall (N = 79)	Docetaxel Grp1 (N = 44)	Docetaxel Grp2 (N = 6)	Overall (N = 50)	Overall (N = 129)
Duration of Exposure (Days)							
n	62	17	79	44	6	50	129
Mean (SD)	94.9 (80.28)	89.9 (89.70)	93.8 (81.83)	91.0 (117.58)	69.8 (26.81)	88.5 (110.70)	91.8 (93.69)
Median	63.0	49.0	59.0	45.0	66.5	47.5	50.0
Q1, Q3	42.0, 126.0	37.0, 91.0	42.0, 126.0	41.5, 95.0	49.0, 87.0	42.0, 92.0	42.0, 108.0
Min, Max	7, 357	21, 357	7, 357	7, 731	42, 108	7, 731	7, 731

Source: ADSL, ADEXSUM. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Percentages were based on N. Paclitaxel Grp1: 135-175mg/m^2 IV on Day 1, given every 21 days. Paclitaxel may also be given in doses of 80-100mg/m^2 IV on a weekly schedule; Paclitaxel Grp2--Paclitaxel (Japan): 100 mg/m^2 IV on Day 1, 8, 15, 22, 29, and 36, followed by one week of rest. Docetaxel Grp1: 75 mg/m^2 IV on Day 1, given every 21 days; Docetaxel Grp2--70 mg/m^2 IV on Day 1, given every 21 days for Japan patients.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/ m^2/cycle) = (total dose received / BSA) / Duration of Treatment in cycle * cycle length in days. Baseline weights are used to derive BSA, unless the change of the BSA at the visit are at least 10% or greater than the baseline (increased or decreased).

[c] Relative dose intensity (RDI) is defined as the ratio of the actual dose intensity (mg/ m^2/cycle) and the planned dose intensity (mg/ m^2/cycle). The planned dose intensity is the total planned dose in a cycle.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.2.b:
Study Medication Administration - Investigator Chosen Chemotherapy (ICC)
Safety Analysis Set - Subpopulation without Irinotecan

	Paclitaxel			Docetaxel			
	Paclitaxel Grp1 (N = 62)	Paclitaxel Grp2 (N = 17)	Overall (N = 79)	Docetaxel Grp1 (N = 44)	Docetaxel Grp2 (N = 6)	Overall (N = 50)	Overall (N = 129)
Duration of Exposure, n (%)							
<1 month	9 (14.5)	1 (5.9)	10 (12.7)	9 (20.5)	0 (0.0)	9 (18.0)	19 (14.7)
>=1 to <3 month	30 (48.4)	12 (70.6)	42 (53.2)	23 (52.3)	5 (83.3)	28 (56.0)	70 (54.3)
>=3 to <6 month	14 (22.6)	2 (11.8)	16 (20.3)	6 (13.6)	1 (16.7)	7 (14.0)	23 (17.8)
>=6 to <12 month	9 (14.5)	2 (11.8)	11 (13.9)	5 (11.4)	0 (0.0)	5 (10.0)	16 (12.4)
>=12 to <18 month	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
>=18 to <24 month	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
>=24 month	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (2.0)	1 (0.8)

Source: ADSL, ADEXSUM. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Percentages were based on N. Paclitaxel Grp1: 135-175mg/m^2 IV on Day 1, given every 21 days. Paclitaxel may also be given in doses of 80-100mg/m^2 IV on a weekly schedule; Paclitaxel Grp2--Paclitaxel (Japan): 100 mg/m^2 IV on Day 1, 8, 15, 22, 29, and 36, followed by one week of rest. Docetaxel Grp1: 75 mg/m^2 IV on Day 1, given every 21 days; Docetaxel Grp2--70 mg/m^2 IV on Day 1, given every 21 days for Japan patients.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/ m^2/cycle) = (total dose received / BSA) / Duration of Treatment in cycle * cycle length in days. Baseline weights are used to derive BSA, unless the change of the BSA at the visit are at least 10% or greater than the baseline (increased or decreased).

[c] Relative dose intensity (RDI) is defined as the ratio of the actual dose intensity (mg/ m^2/cycle) and the planned dose intensity (mg/ m^2/cycle). The planned dose intensity is the total planned dose in a cycle.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.2.b:
Study Medication Administration - Investigator Chosen Chemotherapy (ICC)
Safety Analysis Set - Subpopulation without Irinotecan

	Paclitaxel			Docetaxel			
	Paclitaxel Grp1 (N = 62)	Paclitaxel Grp2 (N = 17)	Overall (N = 79)	Docetaxel Grp1 (N = 44)	Docetaxel Grp2 (N = 6)	Overall (N = 50)	Overall (N = 129)
Number of Cycles Received							
n	62	17	79	44	6	50	129
Mean (SD)	4.0 (3.20)	2.1 (1.82)	3.6 (3.06)	4.3 (5.43)	3.2 (1.33)	4.2 (5.12)	3.8 (3.97)
Median	3.0	1.0	2.0	2.0	3.0	2.0	2.0
Q1, Q3	2.0, 5.0	1.0, 2.0	1.0, 4.0	2.0, 4.5	2.0, 4.0	2.0, 4.0	2.0, 4.0
Min, Max	1, 14	1, 7	1, 14	1, 34	2, 5	1, 34	1, 34

Source: ADSL, ADEXSUM. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Percentages were based on N. Paclitaxel Grp1: 135-175mg/m^2 IV on Day 1, given every 21 days. Paclitaxel may also be given in doses of 80-100mg/m^2 IV on a weekly schedule; Paclitaxel Grp2--Paclitaxel (Japan): 100 mg/m^2 IV on Day 1, 8, 15, 22, 29, and 36, followed by one week of rest. Docetaxel Grp1: 75 mg/m^2 IV on Day 1, given every 21 days; Docetaxel Grp2--70 mg/m^2 IV on Day 1, given every 21 days for Japan patients.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/ m^2/cycle) = (total dose received / BSA) / Duration of Treatment in cycle * cycle length in days. Baseline weights are used to derive BSA, unless the change of the BSA at the visit are at least 10% or greater than the baseline (increased or decreased).

[c] Relative dose intensity (RDI) is defined as the ratio of the actual dose intensity (mg/ m^2/cycle) and the planned dose intensity (mg/ m^2/cycle). The planned dose intensity is the total planned dose in a cycle.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.2.b:
Study Medication Administration - Investigator Chosen Chemotherapy (ICC)
Safety Analysis Set - Subpopulation without Irinotecan

	Paclitaxel			Docetaxel			
	Paclitaxel Grp1 (N = 62)	Paclitaxel Grp2 (N = 17)	Overall (N = 79)	Docetaxel Grp1 (N = 44)	Docetaxel Grp2 (N = 6)	Overall (N = 50)	Overall (N = 129)
Number of Cycles Received, n (%)							
1	9 (14.5)	11 (64.7)	20 (25.3)	7 (15.9)	0 (0.0)	7 (14.0)	27 (20.9)
2	19 (30.6)	2 (11.8)	21 (26.6)	18 (40.9)	3 (50.0)	21 (42.0)	42 (32.6)
3	6 (9.7)	0 (0.0)	6 (7.6)	3 (6.8)	0 (0.0)	3 (6.0)	9 (7.0)
4	11 (17.7)	2 (11.8)	13 (16.5)	5 (11.4)	2 (33.3)	7 (14.0)	20 (15.5)
5	2 (3.2)	1 (5.9)	3 (3.8)	2 (4.5)	1 (16.7)	3 (6.0)	6 (4.7)
6	5 (8.1)	0 (0.0)	5 (6.3)	1 (2.3)	0 (0.0)	1 (2.0)	6 (4.7)
7	2 (3.2)	1 (5.9)	3 (3.8)	0 (0.0)	0 (0.0)	0 (0.0)	3 (2.3)

Source: ADSL, ADEXSUM. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Percentages were based on N. Paclitaxel Grp1: 135-175mg/m^2 IV on Day 1, given every 21 days. Paclitaxel may also be given in doses of 80-100mg/m^2 IV on a weekly schedule; Paclitaxel Grp2--Paclitaxel (Japan): 100 mg/m^2 IV on Day 1, 8, 15, 22, 29, and 36, followed by one week of rest. Docetaxel Grp1: 75 mg/m^2 IV on Day 1, given every 21 days; Docetaxel Grp2--70 mg/m^2 IV on Day 1, given every 21 days for Japan patients.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/ m^2/cycle) = (total dose received / BSA) / Duration of Treatment in cycle * cycle length in days. Baseline weights are used to derive BSA, unless the change of the BSA at the visit are at least 10% or greater than the baseline (increased or decreased).

[c] Relative dose intensity (RDI) is defined as the ratio of the actual dose intensity (mg/ m^2/cycle) and the planned dose intensity (mg/ m^2/cycle). The planned dose intensity is the total planned dose in a cycle.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.2.b:
Study Medication Administration - Investigator Chosen Chemotherapy (ICC)
Safety Analysis Set - Subpopulation without Irinotecan

	Paclitaxel			Docetaxel			
	Paclitaxel Grp1 (N = 62)	Paclitaxel Grp2 (N = 17)	Overall (N = 79)	Docetaxel Grp1 (N = 44)	Docetaxel Grp2 (N = 6)	Overall (N = 50)	Overall (N = 129)
8	2 (3.2)	0 (0.0)	2 (2.5)	2 (4.5)	0 (0.0)	2 (4.0)	4 (3.1)
9	1 (1.6)	0 (0.0)	1 (1.3)	1 (2.3)	0 (0.0)	1 (2.0)	2 (1.6)
10	1 (1.6)	0 (0.0)	1 (1.3)	2 (4.5)	0 (0.0)	2 (4.0)	3 (2.3)
>10	4 (6.5)	0 (0.0)	4 (5.1)	3 (6.8)	0 (0.0)	3 (6.0)	7 (5.4)

Source: ADSL, ADEXSUM. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Percentages were based on N. Paclitaxel Grp1: 135-175mg/m^2 IV on Day 1, given every 21 days. Paclitaxel may also be given in doses of 80-100mg/m^2 IV on a weekly schedule; Paclitaxel Grp2--Paclitaxel (Japan): 100 mg/m^2 IV on Day 1, 8, 15, 22, 29, and 36, followed by one week of rest. Docetaxel Grp1: 75 mg/m^2 IV on Day 1, given every 21 days; Docetaxel Grp2--70 mg/m^2 IV on Day 1, given every 21 days for Japan patients.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/ m^2/cycle) = (total dose received / BSA) / Duration of Treatment in cycle * cycle length in days. Baseline weights are used to derive BSA, unless the change of the BSA at the visit are at least 10% or greater than the baseline (increased or decreased).

[c] Relative dose intensity (RDI) is defined as the ratio of the actual dose intensity (mg/ m^2/cycle) and the planned dose intensity (mg/ m^2/cycle). The planned dose intensity is the total planned dose in a cycle.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.2.b:
Study Medication Administration - Investigator Chosen Chemotherapy (ICC)
Safety Analysis Set - Subpopulation without Irinotecan

	Paclitaxel			Docetaxel			
	Paclitaxel Grp1 (N = 62)	Paclitaxel Grp2 (N = 17)	Overall (N = 79)	Docetaxel Grp1 (N = 44)	Docetaxel Grp2 (N = 6)	Overall (N = 50)	Overall (N = 129)
Number of Cycles Received, n (%)							
1-3	34 (54.8)	13 (76.5)	47 (59.5)	28 (63.6)	3 (50.0)	31 (62.0)	78 (60.5)
4-6	18 (29.0)	3 (17.6)	21 (26.6)	8 (18.2)	3 (50.0)	11 (22.0)	32 (24.8)
7-9	5 (8.1)	1 (5.9)	6 (7.6)	3 (6.8)	0 (0.0)	3 (6.0)	9 (7.0)
10-12	3 (4.8)	0 (0.0)	3 (3.8)	4 (9.1)	0 (0.0)	4 (8.0)	7 (5.4)
13-18	2 (3.2)	0 (0.0)	2 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)
>18	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (2.0)	1 (0.8)

Source: ADSL, ADEXSUM. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Percentages were based on N. Paclitaxel Grp1: 135-175mg/m^2 IV on Day 1, given every 21 days. Paclitaxel may also be given in doses of 80-100mg/m^2 IV on a weekly schedule; Paclitaxel Grp2--Paclitaxel (Japan): 100 mg/m^2 IV on Day 1, 8, 15, 22, 29, and 36, followed by one week of rest. Docetaxel Grp1: 75 mg/m^2 IV on Day 1, given every 21 days; Docetaxel Grp2--70 mg/m^2 IV on Day 1, given every 21 days for Japan patients.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/ m^2/cycle) = (total dose received / BSA) / Duration of Treatment in cycle * cycle length in days. Baseline weights are used to derive BSA, unless the change of the BSA at the visit are at least 10% or greater than the baseline (increased or decreased).

[c] Relative dose intensity (RDI) is defined as the ratio of the actual dose intensity (mg/ m^2/cycle) and the planned dose intensity (mg/ m^2/cycle). The planned dose intensity is the total planned dose in a cycle.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.2.b:
Study Medication Administration - Investigator Chosen Chemotherapy (ICC)
Safety Analysis Set - Subpopulation without Irinotecan

	Paclitaxel			Docetaxel			
	Paclitaxel Grp1 (N = 62)	Paclitaxel Grp2 (N = 17)	Overall (N = 79)	Docetaxel Grp1 (N = 44)	Docetaxel Grp2 (N = 6)	Overall (N = 50)	Overall (N = 129)
Cumulative Total Dose (mg/m^2) per Patient [a]							
n	62	17	79	44	6	50	
Mean (SD)	705.89 (537.063)	713.20 (668.246)	707.46 (563.189)	304.40 (341.437)	208.37 (85.386)	292.87 (322.555)	
Median	564.40	415.83	540.54	150.96	198.53	150.96	
Q1, Q3	347.00, 865.74	314.83, 731.13	322.55, 865.74	143.55, 333.20	133.93, 258.37	141.99, 299.22	
Min, Max	79.7, 2175.3	210.4, 2675.2	79.7, 2675.2	72.7, 2020.5	128.3, 332.5	72.7, 2020.5	

Source: ADSL, ADEXSUM. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Percentages were based on N. Paclitaxel Grp1: 135-175mg/m^2 IV on Day 1, given every 21 days. Paclitaxel may also be given in doses of 80-100mg/m^2 IV on a weekly schedule; Paclitaxel Grp2--Paclitaxel (Japan): 100 mg/m^2 IV on Day 1, 8, 15, 22, 29, and 36, followed by one week of rest. Docetaxel Grp1: 75 mg/m^2 IV on Day 1, given every 21 days; Docetaxel Grp2--70 mg/m^2 IV on Day 1, given every 21 days for Japan patients.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/ m^2/cycle) = (total dose received / BSA) / Duration of Treatment in cycle * cycle length in days. Baseline weights are used to derive BSA, unless the change of the BSA at the visit are at least 10% or greater than the baseline (increased or decreased).

[c] Relative dose intensity (RDI) is defined as the ratio of the actual dose intensity (mg/ m^2/cycle) and the planned dose intensity (mg/ m^2/cycle). The planned dose intensity is the total planned dose in a cycle.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.2.b:
Study Medication Administration - Investigator Chosen Chemotherapy (ICC)
Safety Analysis Set - Subpopulation without Irinotecan

	Paclitaxel			Docetaxel			
	Paclitaxel Grp1 (N = 62)	Paclitaxel Grp2 (N = 17)	Overall (N = 79)	Docetaxel Grp1 (N = 44)	Docetaxel Grp2 (N = 6)	Overall (N = 50)	Overall (N = 129)
Actual Dose Intensity (mg/m^2/cycle) per Patient [b]							
n	62	17		44	6		
Mean (SD)	170.55 (42.141)	417.24 (79.515)		78.08 (25.893)	62.37 (5.732)		
Median	166.95	421.48		73.69	63.08		
Q1, Q3	137.53, 194.95	367.18, 447.24		70.26, 75.40	57.40, 64.66		
Min, Max	91.8, 289.8	264.2, 572.1		50.0, 219.3	55.0, 71.0		

Source: ADSL, ADEXSUM. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Percentages were based on N. Paclitaxel Grp1: 135-175mg/m^2 IV on Day 1, given every 21 days. Paclitaxel may also be given in doses of 80-100mg/m^2 IV on a weekly schedule; Paclitaxel Grp2--Paclitaxel (Japan): 100 mg/m^2 IV on Day 1, 8, 15, 22, 29, and 36, followed by one week of rest. Docetaxel Grp1: 75 mg/m^2 IV on Day 1, given every 21 days; Docetaxel Grp2--70 mg/m^2 IV on Day 1, given every 21 days for Japan patients.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/ m^2/cycle) = (total dose received / BSA) / Duration of Treatment in cycle * cycle length in days. Baseline weights are used to derive BSA, unless the change of the BSA at the visit are at least 10% or greater than the baseline (increased or decreased).

[c] Relative dose intensity (RDI) is defined as the ratio of the actual dose intensity (mg/ m^2/cycle) and the planned dose intensity (mg/ m^2/cycle). The planned dose intensity is the total planned dose in a cycle.

[d] A patient was counted only once within each category but may be counted in multiple categories.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-ex-icc.sas 25APR2024 01:35 t-14-03-01-01-02-b-ex-icc-safetys-sa.rtf

Table 14.3.1.1.2.b:
Study Medication Administration - Investigator Chosen Chemotherapy (ICC)
Safety Analysis Set - Subpopulation without Irinotecan

	Paclitaxel			Docetaxel			
	Paclitaxel Grp1 (N = 62)	Paclitaxel Grp2 (N = 17)	Overall (N = 79)	Docetaxel Grp1 (N = 44)	Docetaxel Grp2 (N = 6)	Overall (N = 50)	Overall (N = 129)
Relative Dose Intensity (%) per Patient [c]							
n	62	17	79	44	6	50	129
Mean (SD)	84.96 (17.668)	69.54 (13.252)	81.64 (17.911)	104.11 (34.524)	89.10 (8.189)	102.31 (32.819)	89.65 (26.645)
Median	87.31	70.25	82.83	98.25	90.12	97.65	92.54
Q1, Q3	71.71, 100.00	61.20, 74.54	67.51, 100.00	93.68, 100.53	82.00, 92.37	92.27, 100.51	75.56, 100.00
Min, Max	37.6, 126.0	44.0, 95.4	37.6, 126.0	66.7, 292.4	78.6, 101.4	66.7, 292.4	37.6, 292.4

Source: ADSL, ADEXSUM. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Percentages were based on N. Paclitaxel Grp1: 135-175mg/m^2 IV on Day 1, given every 21 days. Paclitaxel may also be given in doses of 80-100mg/m^2 IV on a weekly schedule; Paclitaxel Grp2--Paclitaxel (Japan): 100 mg/m^2 IV on Day 1, 8, 15, 22, 29, and 36, followed by one week of rest. Docetaxel Grp1: 75 mg/m^2 IV on Day 1, given every 21 days; Docetaxel Grp2--70 mg/m^2 IV on Day 1, given every 21 days for Japan patients.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/ m^2/cycle) = (total dose received / BSA) / Duration of Treatment in cycle * cycle length in days. Baseline weights are used to derive BSA, unless the change of the BSA at the visit are at least 10% or greater than the baseline (increased or decreased).

[c] Relative dose intensity (RDI) is defined as the ratio of the actual dose intensity (mg/ m^2/cycle) and the planned dose intensity (mg/ m^2/cycle). The planned dose intensity is the total planned dose in a cycle.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.2.b:
Study Medication Administration - Investigator Chosen Chemotherapy (ICC)
Safety Analysis Set - Subpopulation without Irinotecan

	Paclitaxel			Docetaxel			
	Paclitaxel Grp1 (N = 62)	Paclitaxel Grp2 (N = 17)	Overall (N = 79)	Docetaxel Grp1 (N = 44)	Docetaxel Grp2 (N = 6)	Overall (N = 50)	Overall (N = 129)
Patients with Any Dose Modification, n (%) [d]	38 (61.3)	15 (88.2)	53 (67.1)	17 (38.6)	4 (66.7)	21 (42.0)	74 (57.4)
Dose Reduction	19 (30.6)	10 (58.8)	29 (36.7)	8 (18.2)	4 (66.7)	12 (24.0)	41 (31.8)
Adverse Event	18 (29.0)	5 (29.4)	23 (29.1)	8 (18.2)	4 (66.7)	12 (24.0)	35 (27.1)

Source: ADSL, ADEXSUM. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Percentages were based on N. Paclitaxel Grp1: 135-175mg/m^2 IV on Day 1, given every 21 days. Paclitaxel may also be given in doses of 80-100mg/m^2 IV on a weekly schedule; Paclitaxel Grp2--Paclitaxel (Japan): 100 mg/m^2 IV on Day 1, 8, 15, 22, 29, and 36, followed by one week of rest. Docetaxel Grp1: 75 mg/m^2 IV on Day 1, given every 21 days; Docetaxel Grp2--70 mg/m^2 IV on Day 1, given every 21 days for Japan patients.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/ m^2/cycle) = (total dose received / BSA) / Duration of Treatment in cycle * cycle length in days. Baseline weights are used to derive BSA, unless the change of the BSA at the visit are at least 10% or greater than the baseline (increased or decreased).

[c] Relative dose intensity (RDI) is defined as the ratio of the actual dose intensity (mg/ m^2/cycle) and the planned dose intensity (mg/ m^2/cycle). The planned dose intensity is the total planned dose in a cycle.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.2.b:
Study Medication Administration - Investigator Chosen Chemotherapy (ICC)
Safety Analysis Set - Subpopulation without Irinotecan

	Paclitaxel			Docetaxel			
	Paclitaxel Grp1 (N = 62)	Paclitaxel Grp2 (N = 17)	Overall (N = 79)	Docetaxel Grp1 (N = 44)	Docetaxel Grp2 (N = 6)	Overall (N = 50)	Overall (N = 129)
Dose Delay	26 (41.9)	15 (88.2)	41 (51.9)	15 (34.1)	2 (33.3)	17 (34.0)	58 (45.0)
Adverse Event	21 (33.9)	14 (82.4)	35 (44.3)	8 (18.2)	2 (33.3)	10 (20.0)	45 (34.9)
Other	10 (16.1)	3 (17.6)	13 (16.5)	4 (9.1)	0 (0.0)	4 (8.0)	17 (13.2)
COVID-19	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (2.0)	1 (0.8)

Source: ADSL, ADEXSUM. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Percentages were based on N. Paclitaxel Grp1: 135-175mg/m^2 IV on Day 1, given every 21 days. Paclitaxel may also be given in doses of 80-100mg/m^2 IV on a weekly schedule; Paclitaxel Grp2--Paclitaxel (Japan): 100 mg/m^2 IV on Day 1, 8, 15, 22, 29, and 36, followed by one week of rest. Docetaxel Grp1: 75 mg/m^2 IV on Day 1, given every 21 days; Docetaxel Grp2--70 mg/m^2 IV on Day 1, given every 21 days for Japan patients.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/ m^2/cycle) = (total dose received / BSA) / Duration of Treatment in cycle * cycle length in days. Baseline weights are used to derive BSA, unless the change of the BSA at the visit are at least 10% or greater than the baseline (increased or decreased).

[c] Relative dose intensity (RDI) is defined as the ratio of the actual dose intensity (mg/ m^2/cycle) and the planned dose intensity (mg/ m^2/cycle). The planned dose intensity is the total planned dose in a cycle.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.2.b:
Study Medication Administration - Investigator Chosen Chemotherapy (ICC)
Safety Analysis Set - Subpopulation without Irinotecan

	Paclitaxel			Docetaxel			
	Paclitaxel Grp1 (N = 62)	Paclitaxel Grp2 (N = 17)	Overall (N = 79)	Docetaxel Grp1 (N = 44)	Docetaxel Grp2 (N = 6)	Overall (N = 50)	Overall (N = 129)
Infusion Interrupted	7 (11.3)	0 (0.0)	7 (8.9)	1 (2.3)	0 (0.0)	1 (2.0)	8 (6.2)
Adverse Event	4 (6.5)	0 (0.0)	4 (5.1)	1 (2.3)	0 (0.0)	1 (2.0)	5 (3.9)
Other	3 (4.8)	0 (0.0)	3 (3.8)	0 (0.0)	0 (0.0)	0 (0.0)	3 (2.3)
COVID-19	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Source: ADSL, ADEXSUM. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Percentages were based on N. Paclitaxel Grp1: 135-175mg/m^2 IV on Day 1, given every 21 days. Paclitaxel may also be given in doses of 80-100mg/m^2 IV on a weekly schedule; Paclitaxel Grp2--Paclitaxel (Japan): 100 mg/m^2 IV on Day 1, 8, 15, 22, 29, and 36, followed by one week of rest. Docetaxel Grp1: 75 mg/m^2 IV on Day 1, given every 21 days; Docetaxel Grp2--70 mg/m^2 IV on Day 1, given every 21 days for Japan patients.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/ m^2/cycle) = (total dose received / BSA) / Duration of Treatment in cycle * cycle length in days. Baseline weights are used to derive BSA, unless the change of the BSA at the visit are at least 10% or greater than the baseline (increased or decreased).

[c] Relative dose intensity (RDI) is defined as the ratio of the actual dose intensity (mg/ m^2/cycle) and the planned dose intensity (mg/ m^2/cycle). The planned dose intensity is the total planned dose in a cycle.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.2.1.1:
Time to Treatment-Emergent Adverse Events
Safety Analysis Set

	Tislelizumab (N = 255)			ICC (N = 240)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Any TEAE	255	244 (95.7)	0.3 (0.3, 0.5)	240	236 (98.3)	0.1 (0.1, 0.1)	0.441 (0.362, 0.536)	<0.0001
TEAE >= Grade 3	255	118 (46.3)	6.2 (3.6, 10.1)	240	163 (67.9)	0.9 (0.5, 1.0)	0.360 (0.280, 0.463)	<0.0001
Serious TEAE	255	105 (41.2)	9.0 (6.3, 14.0)	240	106 (44.2)	4.2 (2.8, 8.6)	0.614 (0.463, 0.816)	0.0006
TEAE Leading to Treatment Discontinuation	255	49 (19.2)	NR (14.0, NE)	240	64 (26.7)	7.9 (6.1, NE)	0.432 (0.290, 0.642)	<0.0001

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.1.1.b:
Time to Treatment-Emergent Adverse Events
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 129)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Any TEAE	139	135 (97.1)	0.3 (0.3, 0.5)	129	126 (97.7)	0.1 (0.1, 0.2)	0.513 (0.395, 0.667)	<0.0001
TEAE >= Grade 3	139	65 (46.8)	6.9 (3.1, 10.8)	129	88 (68.2)	0.9 (0.5, 1.2)	0.379 (0.269, 0.532)	<0.0001
Serious TEAE	139	60 (43.2)	9.7 (4.4, 14.0)	129	55 (42.6)	6.1 (3.0, 8.6)	0.692 (0.470, 1.017)	0.0585
TEAE Leading to Treatment Discontinuation	139	25 (18.0)	NR (14.0, NE)	129	28 (21.7)	NR (6.5, NE)	0.544 (0.306, 0.966)	0.0351

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.
Adverse events were graded for severity using CTCAE v4.03.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.
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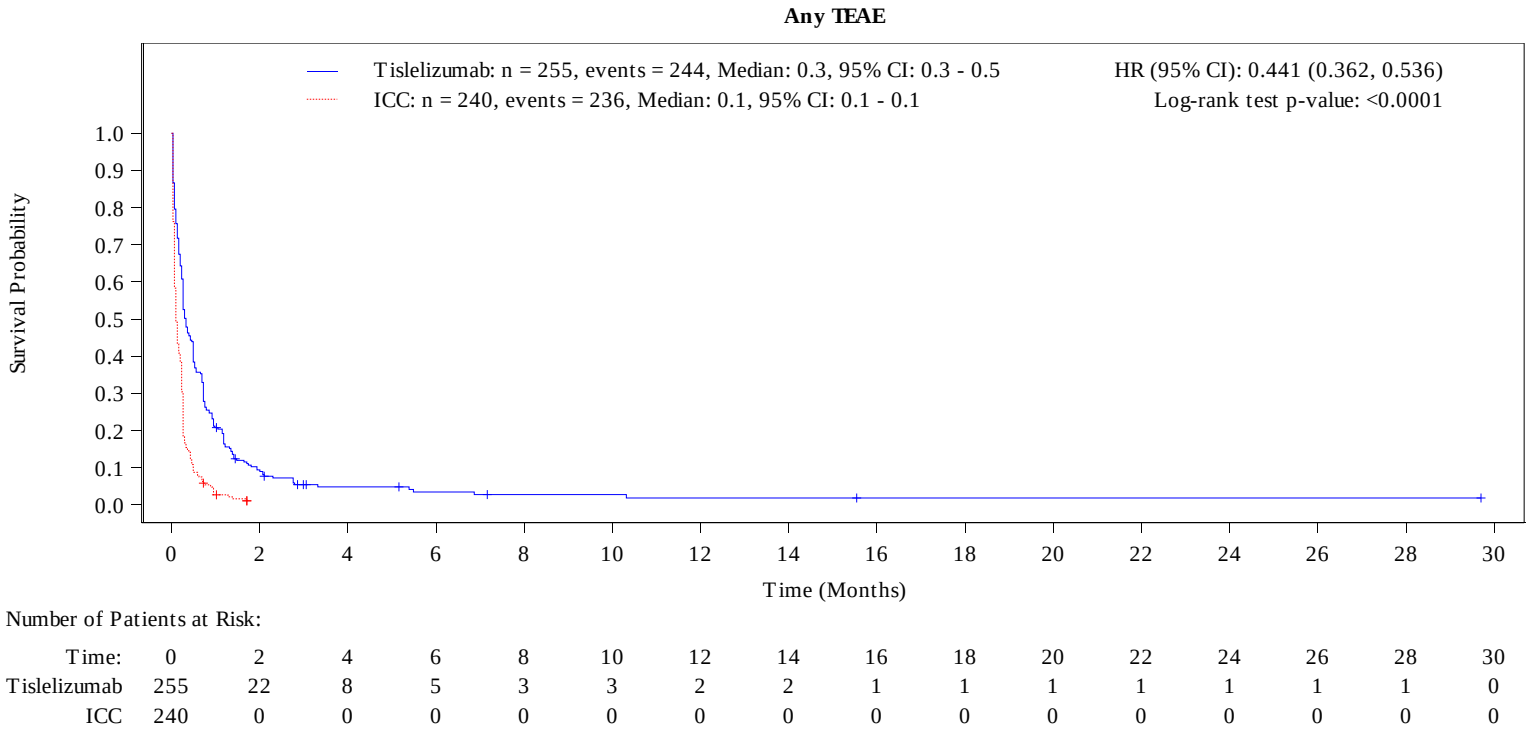
Figure 14.3.1.1:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	255	22	8	5	3	3	2	2	1	1	1	1	1	1	1	0
ICC	240	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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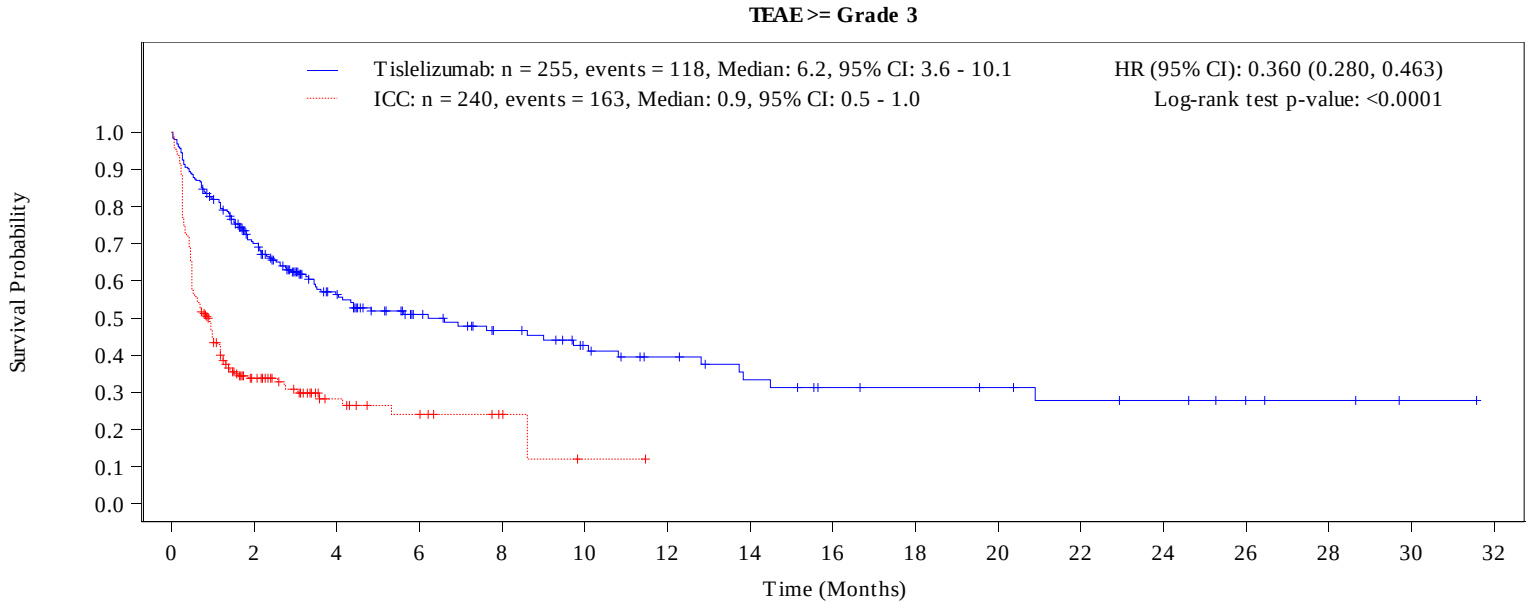
Figure 14.3.1.1:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	143	79	50	38	28	21	16	12	11	10	8	7	4	3	1	0
ICC	240	49	16	10	5	1	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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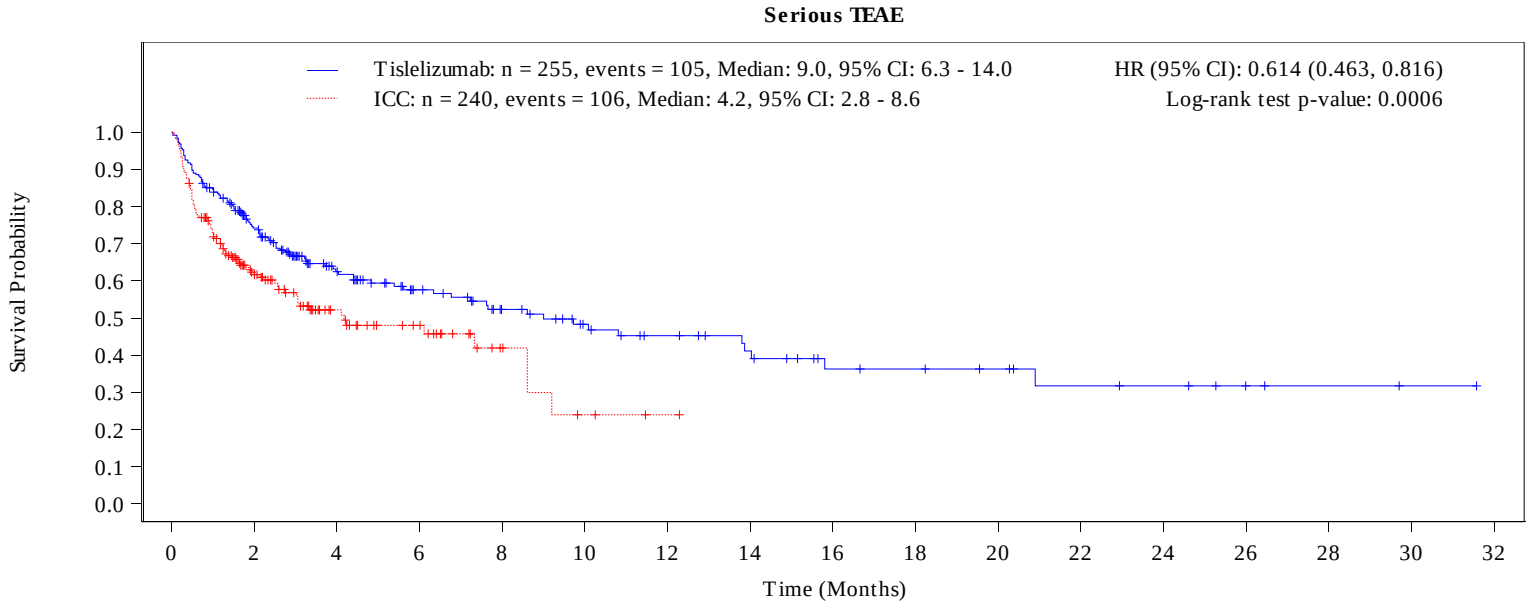
Figure 14.3.1.1:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	154	85	59	43	32	25	20	13	12	10	7	6	3	2	1	0
ICC	240	92	38	22	8	3	1	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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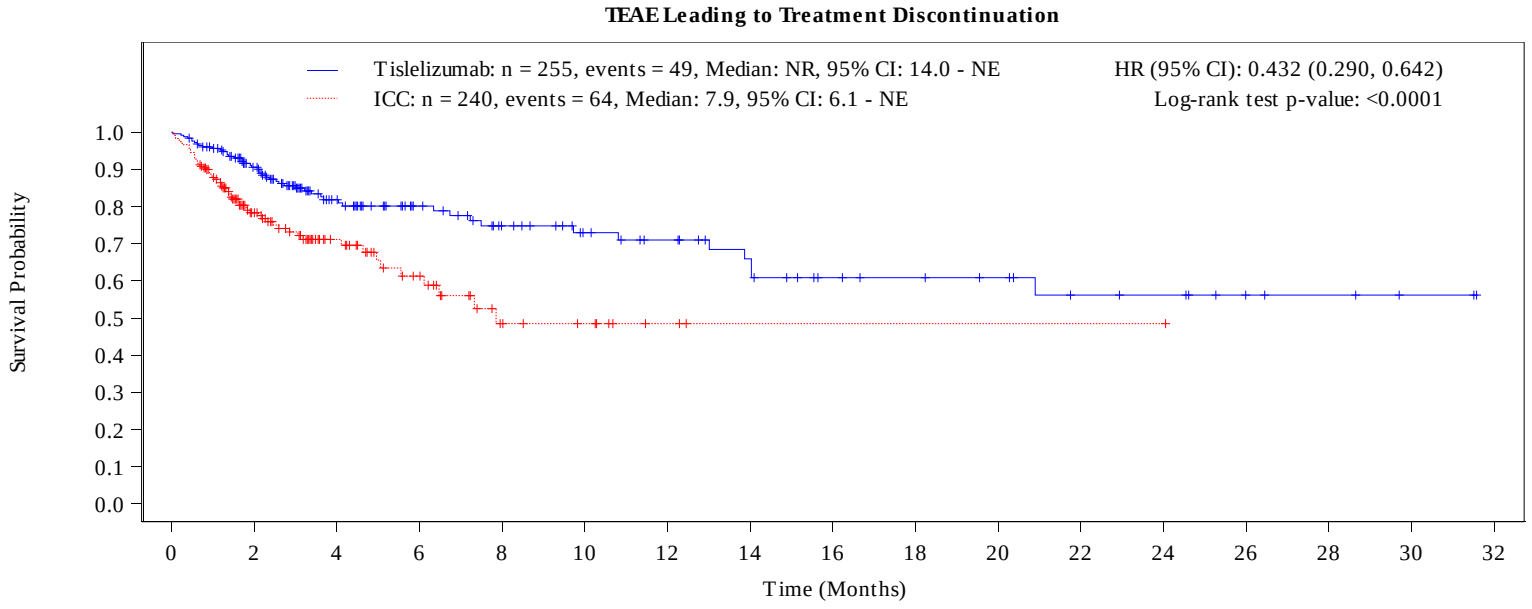
Figure 14.3.1.1:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	172	97	64	49	38	32	26	19	17	15	11	10	5	4	2	0
ICC	240	106	45	26	11	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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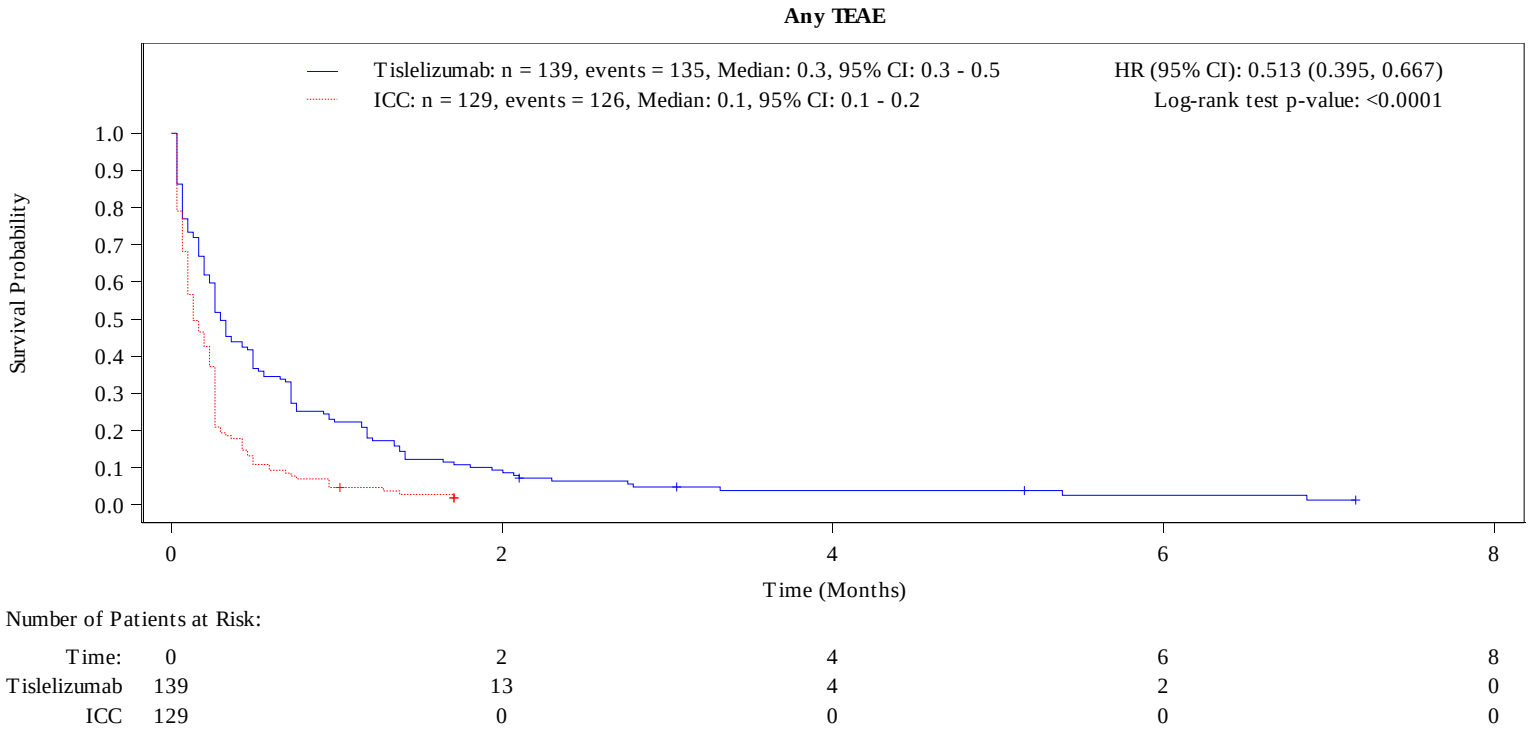
Figure 14.3.1.1.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events
Safety Analysis Set - Subpopulation without Irinotecan



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Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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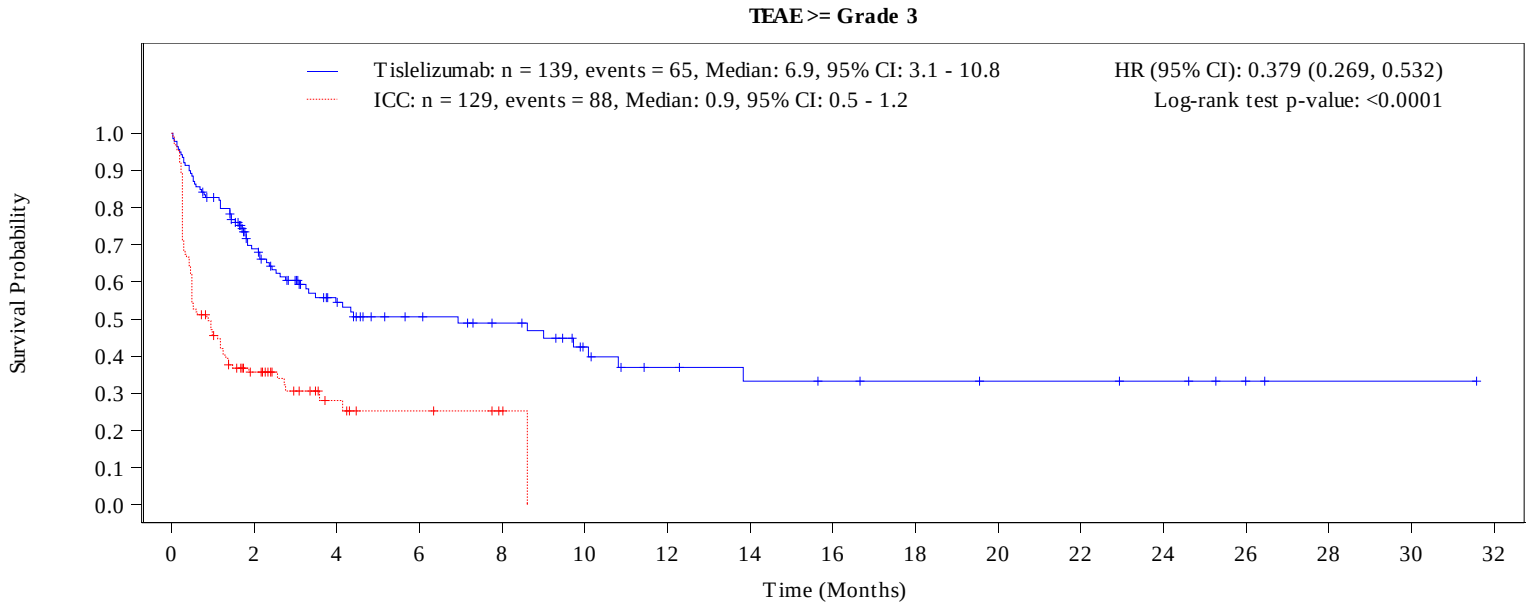
Figure 14.3.1.1.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	75	43	31	25	16	11	9	8	7	6	6	5	2	1	1	0
ICC	129	33	10	6	3	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteae.sas 21AUG2024 18:55 f-14-03-01-01-b-km-tteae-safetys-sa.rtf

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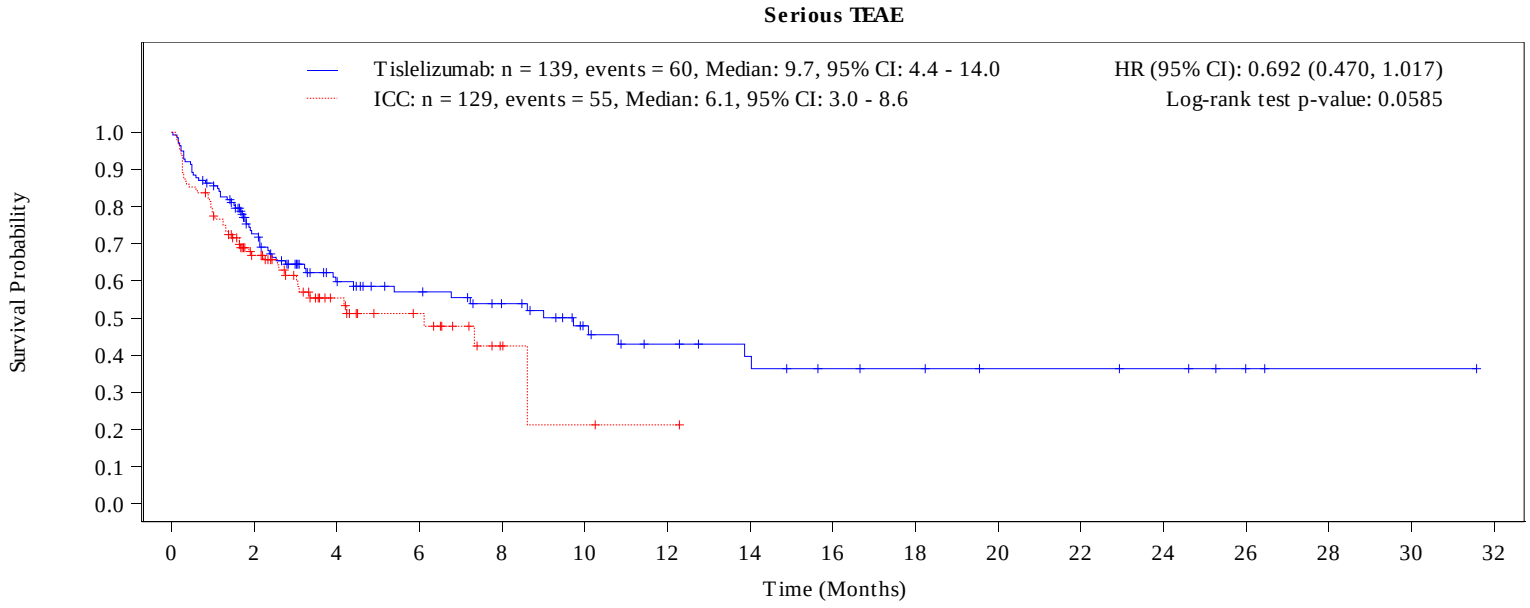
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events
Safety Analysis Set - Subpopulation without Irinotecan

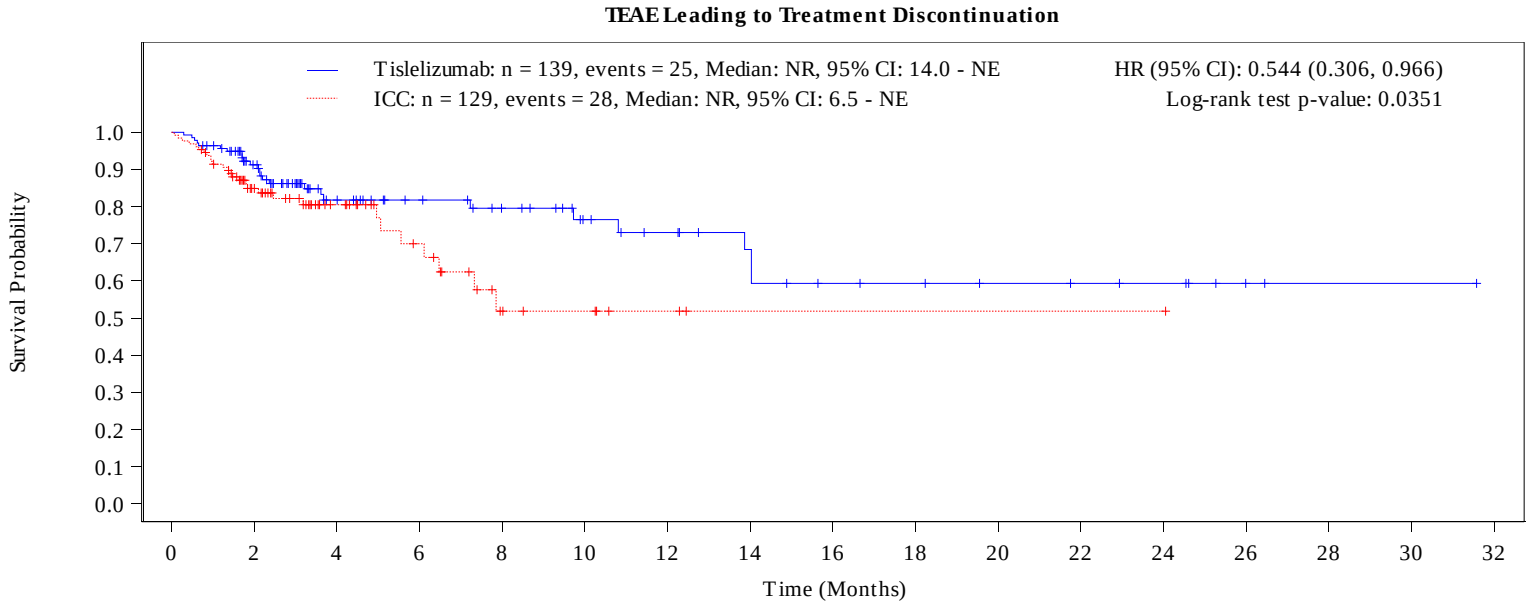


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	82	49	38	30	20	15	12	9	8	6	6	5	2	1	1	0
ICC	129	62	27	15	5	2	1	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteae.sas 21AUG2024 18:55 f-14-03-01-01-b-km-tteae-safetys-sa.rtf

Figure 14.3.1.1.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	93	52	40	32	23	19	15	11	10	8	7	6	2	1	1	0
ICC	129	71	33	19	8	6	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteae.sas 21AUG2024 18:55 f-14-03-01-01-b-km-tteae-safetys-sa.rtf

Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Any TEAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	154 (98.1)	0.3 (0.3, 0.4)	149	146 (98.0)	0.1 (0.1, 0.1)	0.476 (0.374, 0.605)	<0.0001
>= 65 Years	98	90 (91.8)	0.4 (0.3, 0.5)	91	90 (98.9)	0.1 (0.1, 0.2)	0.427 (0.311, 0.585)	<0.0001
Interaction								0.5244
Gender								
Male	216	206 (95.4)	0.3 (0.3, 0.5)	204	201 (98.5)	0.1 (0.1, 0.2)	0.444 (0.360, 0.547)	<0.0001
Female	39	38 (97.4)	0.2 (0.2, 0.4)	36	35 (97.2)	0.1 (0.1, 0.2)	0.525 (0.323, 0.852)	0.0046
Interaction								0.5658

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-tteae-subgrp.sas 21AUG2024 19:19 t-14-03-01-02-01-01-s-tteae-subgrp-safety-sa.rtf

Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Any TEAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	178 (95.2)	0.3 (0.3, 0.5)	183	179 (97.8)	0.1 (0.1, 0.1)	0.480 (0.385, 0.599)	<0.0001
Non-Smoker	68	66 (97.1)	0.4 (0.2, 0.6)	57	57 (100.0)	0.1 (0.1, 0.2)	0.346 (0.229, 0.523)	<0.0001
Interaction								0.8992
ICC Options								
Paclitaxel	83	80 (96.4)	0.3 (0.2, 0.5)	79	78 (98.7)	0.2 (0.1, 0.3)	0.560 (0.403, 0.778)	0.0002
Docetaxel	56	55 (98.2)	0.3 (0.2, 0.5)	50	48 (96.0)	0.1 (0.1, 0.2)	0.483 (0.319, 0.733)	0.0002
Irinotecan	116	109 (94.0)	0.4 (0.3, 0.5)	111	110 (99.1)	0.1 (0.1, 0.1)	0.365 (0.272, 0.490)	<0.0001
Interaction								0.1070

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-tteae-subgrp.sas 21AUG2024 19:19 t-14-03-01-02-01-01-s-tteae-subgrp-safety-sa.rtf

Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Any TEAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	60 (95.2)	0.5 (0.3, 0.7)	57	55 (96.5)	0.2 (0.1, 0.3)	0.549 (0.374, 0.806)	0.0010
1	192	184 (95.8)	0.3 (0.3, 0.4)	183	181 (98.9)	0.1 (0.1, 0.1)	0.422 (0.337, 0.528)	<0.0001
Interaction								0.1940
Region #1								
Asia	201	192 (95.5)	0.4 (0.3, 0.5)	191	189 (99.0)	0.1 (0.1, 0.1)	0.375 (0.301, 0.466)	<0.0001
Europe/North America	54	52 (96.3)	0.1 (0.1, 0.2)	49	47 (95.9)	0.2 (0.1, 0.3)	0.889 (0.593, 1.333)	0.5348
Interaction								0.0018

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Any TEAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	168 (95.5)	0.3 (0.3, 0.5)	168	167 (99.4)	0.1 (0.1, 0.1)	0.355 (0.280, 0.450)	<0.0001
Japan	25	24 (96.0)	0.6 (0.4, 1.1)	23	22 (95.7)	0.2 (0.1, 0.3)	0.452 (0.246, 0.832)	0.0074
Europe/North America	54	52 (96.3)	0.1 (0.1, 0.2)	49	47 (95.9)	0.2 (0.1, 0.3)	0.889 (0.593, 1.333)	0.5348
Interaction								0.0032
Race								
Asian and other	203	194 (95.6)	0.4 (0.3, 0.5)	198	195 (98.5)	0.1 (0.1, 0.1)	0.400 (0.323, 0.496)	<0.0001
White	52	50 (96.2)	0.1 (0.1, 0.2)	42	41 (97.6)	0.1 (0.1, 0.3)	0.774 (0.505, 1.186)	0.1931
Interaction								0.0413

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-tteae-subgrp.sas 21AUG2024 19:19 t-14-03-01-02-01-01-s-tteae-subgrp-safety-sa.rtf

Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Any TEAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	76 (95.0)	0.3 (0.3, 0.5)	60	58 (96.7)	0.1 (0.1, 0.2)	0.459 (0.319, 0.661)	<0.0001
vCPS < 10%	100	95 (95.0)	0.2 (0.2, 0.3)	119	117 (98.3)	0.1 (0.1, 0.2)	0.573 (0.431, 0.760)	<0.0001
Missing	75	73 (97.3)	0.5 (0.3, 0.7)	61	61 (100.0)	0.1 (0.1, 0.2)	0.335 (0.229, 0.489)	<0.0001
Interaction								0.2741

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	74 (47.1)	5.6 (3.3, 12.8)	149	97 (65.1)	1.0 (0.6, 1.2)	0.392 (0.285, 0.538)	<0.0001
>= 65 Years	98	44 (44.9)	6.6 (3.5, 13.7)	91	66 (72.5)	0.7 (0.5, 1.2)	0.330 (0.220, 0.494)	<0.0001
Interaction								0.3987
Gender								
Male	216	101 (46.8)	6.6 (4.0, 10.8)	204	138 (67.6)	0.9 (0.5, 1.0)	0.366 (0.279, 0.480)	<0.0001
Female	39	17 (43.6)	3.5 (2.0, NE)	36	25 (69.4)	0.9 (0.5, 1.4)	0.365 (0.194, 0.690)	0.0012
Interaction								0.9965

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-tteae-subgrp.sas 21AUG2024 19:19 t-14-03-01-02-01-01-s-tteae-subgrp-safety-sa.rtf

Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	87 (46.5)	6.6 (3.6, 10.8)	183	124 (67.8)	0.9 (0.5, 1.2)	0.359 (0.269, 0.478)	<0.0001
Non-Smoker	68	31 (45.6)	6.2 (2.5, 20.9)	57	39 (68.4)	1.0 (0.5, 1.3)	0.386 (0.234, 0.636)	<0.0001
Interaction								0.7930
ICC Options								
Paclitaxel	83	37 (44.6)	10.8 (2.5, NE)	79	53 (67.1)	1.2 (0.5, 1.9)	0.418 (0.271, 0.646)	<0.0001
Docetaxel	56	28 (50.0)	6.9 (2.4, 9.7)	50	35 (70.0)	0.3 (0.3, 1.0)	0.313 (0.181, 0.541)	<0.0001
Irinotecan	116	53 (45.7)	6.2 (3.5, 13.7)	111	75 (67.6)	0.9 (0.6, 1.0)	0.345 (0.237, 0.502)	<0.0001
Interaction								0.7936

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-tteae-subgrp.sas 21AUG2024 19:19 t-14-03-01-02-01-01-s-tteae-subgrp-safety-sa.rtf

Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	21 (33.3)	13.8 (6.9, NE)	57	33 (57.9)	1.2 (0.5, NE)	0.299 (0.166, 0.539)	<0.0001
1	192	97 (50.5)	3.6 (2.8, 7.6)	183	130 (71.0)	0.7 (0.5, 1.0)	0.377 (0.286, 0.496)	<0.0001
Interaction								0.5081
Region #1								
Asia	201	88 (43.8)	7.6 (4.3, 12.8)	191	128 (67.0)	0.7 (0.5, 1.0)	0.318 (0.238, 0.426)	<0.0001
Europe/North America	54	30 (55.6)	2.5 (1.7, NE)	49	35 (71.4)	1.2 (0.5, 2.6)	0.567 (0.346, 0.929)	0.0216
Interaction								0.0567

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-tteae-subgrp.sas 21AUG2024 19:19 t-14-03-01-02-01-01-s-tteae-subgrp-safety-sa.rtf

Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	77 (43.8)	6.9 (4.0, 10.8)	168	112 (66.7)	0.8 (0.5, 1.0)	0.322 (0.236, 0.438)	<0.0001
Japan	25	11 (44.0)	10.1 (1.9, NE)	23	16 (69.6)	0.5 (0.3, 1.3)	0.298 (0.129, 0.688)	0.0023
Europe/North America	54	30 (55.6)	2.5 (1.7, NE)	49	35 (71.4)	1.2 (0.5, 2.6)	0.567 (0.346, 0.929)	0.0216
Interaction								0.1385
Race								
Asian and other	203	89 (43.8)	7.6 (4.3, 10.8)	198	132 (66.7)	0.7 (0.5, 1.0)	0.326 (0.245, 0.435)	<0.0001
White	52	29 (55.8)	2.5 (1.7, NE)	42	31 (73.8)	1.2 (0.5, 2.6)	0.538 (0.322, 0.897)	0.0152
Interaction								0.1079

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-tteae-subgrp.sas 21AUG2024 19:19 t-14-03-01-02-01-01-s-tteae-subgrp-safety-sa.rtf

Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	36 (45.0)	6.6 (3.4, 14.5)	60	44 (73.3)	1.0 (0.5, 1.3)	0.259 (0.161, 0.417)	<0.0001
vCPS < 10%	100	52 (52.0)	4.0 (2.2, 10.8)	119	84 (70.6)	0.7 (0.5, 1.0)	0.416 (0.291, 0.595)	<0.0001
Missing	75	30 (40.0)	13.7 (3.5, NE)	61	35 (57.4)	1.2 (0.5, 5.3)	0.426 (0.255, 0.711)	0.0006
Interaction								0.4530

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Serious TEAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	72 (45.9)	7.2 (3.7, 13.9)	149	63 (42.3)	4.2 (2.2, NE)	0.743 (0.525, 1.051)	0.0914
>= 65 Years	98	33 (33.7)	13.8 (8.6, NE)	91	43 (47.3)	4.1 (2.5, NE)	0.474 (0.293, 0.766)	0.0018
Interaction								0.1062
Gender								
Male	216	92 (42.6)	8.6 (5.4, 13.9)	204	92 (45.1)	4.1 (2.6, 8.6)	0.637 (0.473, 0.859)	0.0028
Female	39	13 (33.3)	NR (4.4, NE)	36	14 (38.9)	8.6 (1.9, NE)	0.652 (0.301, 1.412)	0.2732
Interaction								0.8146

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Serious TEAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	80 (42.8)	8.6 (4.4, 13.9)	183	81 (44.3)	4.2 (2.8, 8.6)	0.655 (0.476, 0.902)	0.0088
Non-Smoker	68	25 (36.8)	20.9 (6.3, NE)	57	25 (43.9)	7.3 (1.8, NE)	0.594 (0.336, 1.052)	0.0698
Interaction								0.5520
ICC Options								
Paclitaxel	83	29 (34.9)	NR (7.2, NE)	79	30 (38.0)	8.6 (3.4, NE)	0.770 (0.455, 1.301)	0.3261
Docetaxel	56	31 (55.4)	4.4 (2.1, 9.0)	50	25 (50.0)	3.1 (1.3, 7.3)	0.640 (0.367, 1.116)	0.1100
Irinotecan	116	45 (38.8)	7.7 (4.8, 20.9)	111	51 (45.9)	3.1 (1.6, NE)	0.533 (0.351, 0.810)	0.0027
Interaction								0.5495

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Serious TEAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	22 (34.9)	13.9 (7.2, NE)	57	18 (31.6)	8.6 (4.2, NE)	0.676 (0.351, 1.302)	0.2382
1	192	83 (43.2)	7.6 (4.4, 13.8)	183	88 (48.1)	3.0 (1.9, 6.1)	0.622 (0.456, 0.847)	0.0023
Interaction								0.4614
Region #1								
Asia	201	84 (41.8)	9.0 (5.6, 13.9)	191	82 (42.9)	4.2 (2.2, NE)	0.628 (0.458, 0.861)	0.0035
Europe/North America	54	21 (38.9)	NR (2.6, NE)	49	24 (49.0)	6.1 (2.5, 9.2)	0.679 (0.376, 1.227)	0.1957
Interaction								0.8395

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Serious TEAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	75 (42.6)	7.7 (4.0, 13.8)	168	72 (42.9)	4.2 (2.2, NE)	0.644 (0.460, 0.900)	0.0093
Japan	25	9 (36.0)	13.9 (6.8, NE)	23	10 (43.5)	NR (1.1, NE)	0.511 (0.197, 1.327)	0.1596
Europe/North America	54	21 (38.9)	NR (2.6, NE)	49	24 (49.0)	6.1 (2.5, 9.2)	0.679 (0.376, 1.227)	0.1957
Interaction								0.8582
Race								
Asian and other	203	85 (41.9)	9.0 (5.6, 13.9)	198	84 (42.4)	4.2 (2.6, NE)	0.650 (0.475, 0.889)	0.0064
White	52	20 (38.5)	NR (4.4, NE)	42	22 (52.4)	6.1 (2.5, 8.6)	0.616 (0.335, 1.136)	0.1156
Interaction								0.8526

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Serious TEAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	29 (36.3)	13.9 (6.3, NE)	60	27 (45.0)	3.1 (1.9, NE)	0.432 (0.246, 0.757)	0.0026
vCPS < 10%	100	47 (47.0)	6.8 (3.7, 10.8)	119	53 (44.5)	4.2 (2.5, NE)	0.824 (0.552, 1.228)	0.3389
Missing	75	29 (38.7)	13.8 (3.3, NE)	61	26 (42.6)	7.3 (1.6, NE)	0.628 (0.363, 1.085)	0.0910
Interaction								0.2438

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

TEAE Leading to Treatment Discontinuation

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	31 (19.7)	20.9 (13.0, NE)	149	34 (22.8)	7.9 (5.0, NE)	0.505 (0.303, 0.844)	0.0079
>= 65 Years	98	18 (18.4)	NR (14.0, NE)	91	30 (33.0)	7.3 (5.1, NE)	0.395 (0.216, 0.724)	0.0019
Interaction								0.2831
Gender								
Male	216	42 (19.4)	NR (14.0, NE)	204	55 (27.0)	7.9 (5.6, NE)	0.442 (0.289, 0.676)	0.0001
Female	39	7 (17.9)	NR (7.2, NE)	36	9 (25.0)	NR (2.6, NE)	0.563 (0.207, 1.534)	0.2548
Interaction								0.8075

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

TEAE Leading to Treatment Discontinuation

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	35 (18.7)	NR (14.0, NE)	183	48 (26.2)	NR (6.1, NE)	0.458 (0.290, 0.722)	0.0006
Non-Smoker	68	14 (20.6)	20.9 (7.5, NE)	57	16 (28.1)	7.3 (4.6, NE)	0.492 (0.236, 1.027)	0.0542
Interaction								0.8262
ICC Options								
Paclitaxel	83	11 (13.3)	NR (14.0, NE)	79	19 (24.1)	NR (5.1, NE)	0.365 (0.163, 0.815)	0.0105
Docetaxel	56	14 (25.0)	14.0 (9.7, NE)	50	9 (18.0)	7.3 (5.6, NE)	0.936 (0.397, 2.207)	0.8791
Irinotecan	116	24 (20.7)	20.9 (13.0, NE)	111	36 (32.4)	4.6 (2.9, NE)	0.359 (0.208, 0.619)	0.0001
Interaction								0.0808

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

TEAE Leading to Treatment Discontinuation

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	9 (14.3)	NR (13.9, NE)	57	14 (24.6)	NR (5.0, NE)	0.284 (0.112, 0.720)	0.0049
1	192	40 (20.8)	NR (14.0, NE)	183	50 (27.3)	7.9 (6.1, NE)	0.516 (0.336, 0.792)	0.0021
Interaction								0.6114
Region #1								
Asia	201	41 (20.4)	NR (13.9, NE)	191	49 (25.7)	NR (6.5, NE)	0.492 (0.319, 0.760)	0.0011
Europe/North America	54	8 (14.8)	NR (NE, NE)	49	15 (30.6)	7.3 (5.0, NE)	0.401 (0.169, 0.949)	0.0313
Interaction								0.5887

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

TEAE Leading to Treatment Discontinuation

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	39 (22.2)	NR (14.0, NE)	168	45 (26.8)	NR (6.5, NE)	0.530 (0.340, 0.826)	0.0044
Japan	25	2 (8.0)	NR (10.8, NE)	23	4 (17.4)	NR (5.1, NE)	0.114 (0.011, 1.160)	0.0366
Europe/North America	54	8 (14.8)	NR (NE, NE)	49	15 (30.6)	7.3 (5.0, NE)	0.401 (0.169, 0.949)	0.0313
Interaction								0.6890
Race								
Asian and other	203	42 (20.7)	NR (13.9, NE)	198	50 (25.3)	NR (6.5, NE)	0.513 (0.334, 0.787)	0.0019
White	52	7 (13.5)	NR (NE, NE)	42	14 (33.3)	6.1 (5.0, NE)	0.333 (0.134, 0.829)	0.0129
Interaction								0.3338

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Safety Analysis Set

TEAE Leading to Treatment Discontinuation

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	15 (18.8)	NR (10.8, NE)	60	19 (31.7)	7.9 (4.6, NE)	0.343 (0.170, 0.692)	0.0018
vCPS < 10%	100	20 (20.0)	14.0 (13.0, NE)	119	28 (23.5)	NR (5.6, NE)	0.559 (0.305, 1.025)	0.0565
Missing	75	14 (18.7)	NR (20.9, NE)	61	17 (27.9)	7.3 (5.1, NE)	0.495 (0.238, 1.027)	0.0540
Interaction								0.4542

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	77 (100.0)	0.3 (0.2, 0.4)	70	68 (97.1)	0.1 (0.1, 0.2)	0.569 (0.404, 0.802)	0.0005
>= 65 Years	62	58 (93.5)	0.4 (0.2, 0.6)	59	58 (98.3)	0.2 (0.1, 0.2)	0.487 (0.330, 0.718)	<0.0001
Interaction								0.4541
Gender								
Male	118	115 (97.5)	0.3 (0.3, 0.5)	106	104 (98.1)	0.1 (0.1, 0.2)	0.530 (0.400, 0.702)	<0.0001
Female	21	20 (95.2)	0.3 (0.2, 0.5)	23	22 (95.7)	0.1 (0.1, 0.2)	0.539 (0.285, 1.018)	0.0423
Interaction								0.9361

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	102 (98.1)	0.3 (0.2, 0.4)	101	98 (97.0)	0.1 (0.1, 0.2)	0.562 (0.420, 0.753)	<0.0001
Non-Smoker	35	33 (94.3)	0.4 (0.2, 0.7)	28	28 (100.0)	0.2 (0.1, 0.3)	0.370 (0.206, 0.667)	0.0003
Interaction								0.7055
ICC Options								
Paclitaxel	83	80 (96.4)	0.3 (0.2, 0.5)	79	78 (98.7)	0.2 (0.1, 0.3)	0.560 (0.403, 0.778)	0.0002
Docetaxel	56	55 (98.2)	0.3 (0.2, 0.5)	50	48 (96.0)	0.1 (0.1, 0.2)	0.483 (0.319, 0.733)	0.0002
Interaction								0.4758

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	40 (93.0)	0.4 (0.3, 0.7)	37	35 (94.6)	0.3 (0.1, 0.3)	0.567 (0.352, 0.915)	0.0119
1	96	95 (99.0)	0.3 (0.2, 0.4)	92	91 (98.9)	0.1 (0.1, 0.2)	0.501 (0.367, 0.683)	<0.0001
Interaction								0.8389
Region #1								
Asia	103	101 (98.1)	0.4 (0.3, 0.5)	99	98 (99.0)	0.1 (0.1, 0.2)	0.435 (0.323, 0.586)	<0.0001
Europe/North America	36	34 (94.4)	0.2 (0.1, 0.2)	30	28 (93.3)	0.2 (0.1, 0.3)	0.943 (0.564, 1.577)	0.8102
Interaction								0.0751

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	77 (98.7)	0.3 (0.3, 0.5)	76	76 (100.0)	0.1 (0.1, 0.2)	0.418 (0.296, 0.591)	<0.0001
Japan	25	24 (96.0)	0.6 (0.4, 1.1)	23	22 (95.7)	0.2 (0.1, 0.3)	0.452 (0.246, 0.832)	0.0074
Europe/North America	36	34 (94.4)	0.2 (0.1, 0.2)	30	28 (93.3)	0.2 (0.1, 0.3)	0.943 (0.564, 1.577)	0.8102
Interaction								0.1632
Race								
Asian and other	105	103 (98.1)	0.4 (0.3, 0.5)	106	104 (98.1)	0.1 (0.1, 0.2)	0.477 (0.357, 0.637)	<0.0001
White	34	32 (94.1)	0.2 (0.1, 0.3)	23	22 (95.7)	0.2 (0.0, 0.3)	0.783 (0.448, 1.369)	0.3484
Interaction								0.5525

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	45 (100.0)	0.3 (0.2, 0.5)	34	33 (97.1)	0.1 (0.1, 0.2)	0.541 (0.337, 0.867)	0.0062
vCPS < 10%	53	50 (94.3)	0.2 (0.1, 0.3)	54	52 (96.3)	0.2 (0.1, 0.3)	0.746 (0.501, 1.112)	0.1240
Missing	41	40 (97.6)	0.5 (0.3, 1.2)	41	41 (100.0)	0.1 (0.1, 0.3)	0.338 (0.208, 0.549)	<0.0001
Interaction								0.1685

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	37 (48.1)	6.9 (2.4, 13.8)	70	49 (70.0)	0.9 (0.5, 1.2)	0.352 (0.224, 0.553)	<0.0001
>= 65 Years	62	28 (45.2)	8.6 (3.1, NE)	59	39 (66.1)	0.9 (0.4, 2.7)	0.406 (0.244, 0.674)	0.0003
Interaction								0.9810
Gender								
Male	118	55 (46.6)	8.6 (3.3, 10.8)	106	74 (69.8)	0.6 (0.5, 1.2)	0.344 (0.238, 0.498)	<0.0001
Female	21	10 (47.6)	3.1 (1.5, NE)	23	14 (60.9)	1.4 (0.5, NE)	0.599 (0.264, 1.356)	0.2110
Interaction								0.2673

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	52 (50.0)	4.4 (2.8, 10.8)	101	71 (70.3)	0.9 (0.5, 1.2)	0.378 (0.260, 0.551)	<0.0001
Non-Smoker	35	13 (37.1)	9.0 (2.1, NE)	28	17 (60.7)	1.0 (0.5, 3.6)	0.393 (0.184, 0.839)	0.0116
Interaction								0.9878
ICC Options								
Paclitaxel	83	37 (44.6)	10.8 (2.5, NE)	79	53 (67.1)	1.2 (0.5, 1.9)	0.418 (0.271, 0.646)	<0.0001
Docetaxel	56	28 (50.0)	6.9 (2.4, 9.7)	50	35 (70.0)	0.3 (0.3, 1.0)	0.313 (0.181, 0.541)	<0.0001
Interaction								0.4637

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	15 (34.9)	13.8 (6.9, NE)	37	23 (62.2)	1.1 (0.5, NE)	0.290 (0.143, 0.588)	0.0002
1	96	50 (52.1)	3.1 (2.1, 9.7)	92	65 (70.7)	0.7 (0.5, 1.2)	0.410 (0.279, 0.601)	<0.0001
Interaction								0.4613
Region #1								
Asia	103	46 (44.7)	8.6 (3.3, 13.8)	99	68 (68.7)	0.5 (0.4, 1.2)	0.312 (0.208, 0.467)	<0.0001
Europe/North America	36	19 (52.8)	2.5 (1.5, NE)	30	20 (66.7)	1.5 (0.5, 3.6)	0.640 (0.340, 1.204)	0.1607
Interaction								0.0719

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	35 (44.9)	6.9 (2.8, 10.8)	76	52 (68.4)	0.7 (0.3, 1.2)	0.321 (0.203, 0.508)	<0.0001
Japan	25	11 (44.0)	10.1 (1.9, NE)	23	16 (69.6)	0.5 (0.3, 1.3)	0.298 (0.129, 0.688)	0.0023
Europe/North America	36	19 (52.8)	2.5 (1.5, NE)	30	20 (66.7)	1.5 (0.5, 3.6)	0.640 (0.340, 1.204)	0.1607
Interaction								0.1801
Race								
Asian and other	105	47 (44.8)	8.6 (3.3, 10.8)	106	72 (67.9)	0.6 (0.5, 1.2)	0.327 (0.220, 0.486)	<0.0001
White	34	18 (52.9)	3.1 (1.5, NE)	23	16 (69.6)	1.9 (0.5, 3.6)	0.613 (0.311, 1.207)	0.1512
Interaction								0.1384

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	21 (46.7)	9.7 (3.1, NE)	34	25 (73.5)	1.0 (0.5, 2.8)	0.340 (0.183, 0.630)	0.0003
vCPS < 10%	53	29 (54.7)	4.1 (2.1, 10.8)	54	39 (72.2)	0.5 (0.4, 1.0)	0.340 (0.202, 0.571)	<0.0001
Missing	41	15 (36.6)	8.6 (2.5, NE)	41	24 (58.5)	1.2 (0.3, NE)	0.430 (0.221, 0.836)	0.0090
Interaction								0.9761

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious TEAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	37 (48.1)	7.2 (2.8, 14.0)	70	31 (44.3)	4.2 (1.9, 8.6)	0.775 (0.475, 1.265)	0.3052
>= 65 Years	62	23 (37.1)	10.8 (6.8, NE)	59	24 (40.7)	6.1 (2.8, NE)	0.679 (0.372, 1.239)	0.2028
Interaction								0.6310
Gender								
Male	118	52 (44.1)	9.0 (4.0, 14.0)	106	47 (44.3)	4.2 (2.8, NE)	0.705 (0.469, 1.060)	0.0905
Female	21	8 (38.1)	NR (1.7, NE)	23	8 (34.8)	8.6 (1.9, NE)	0.988 (0.361, 2.705)	0.9819
Interaction								0.7221

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious TEAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	48 (46.2)	8.6 (3.9, 14.0)	101	45 (44.6)	4.2 (2.8, 8.6)	0.737 (0.484, 1.122)	0.1520
Non-Smoker	35	12 (34.3)	NR (2.5, NE)	28	10 (35.7)	7.3 (1.9, NE)	0.787 (0.333, 1.863)	0.5846
Interaction								0.9997
ICC Options								
Paclitaxel	83	29 (34.9)	NR (7.2, NE)	79	30 (38.0)	8.6 (3.4, NE)	0.770 (0.455, 1.301)	0.3261
Docetaxel	56	31 (55.4)	4.4 (2.1, 9.0)	50	25 (50.0)	3.1 (1.3, 7.3)	0.640 (0.367, 1.116)	0.1100
Interaction								0.9513

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious TEAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	14 (32.6)	13.9 (7.2, NE)	37	11 (29.7)	8.6 (4.2, NE)	0.685 (0.296, 1.585)	0.3726
1	96	46 (47.9)	4.4 (2.3, 10.8)	92	44 (47.8)	3.1 (2.2, NE)	0.750 (0.491, 1.147)	0.1822
Interaction								0.7477
Region #1								
Asia	103	45 (43.7)	9.0 (3.9, 14.0)	99	43 (43.4)	4.2 (2.6, NE)	0.675 (0.437, 1.041)	0.0726
Europe/North America	36	15 (41.7)	7.2 (2.4, NE)	30	12 (40.0)	7.3 (2.8, NE)	1.011 (0.469, 2.181)	0.9768
Interaction								0.3848

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious TEAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	36 (46.2)	8.6 (2.8, 14.0)	76	33 (43.4)	4.2 (2.2, NE)	0.727 (0.446, 1.186)	0.1977
Japan	25	9 (36.0)	13.9 (6.8, NE)	23	10 (43.5)	NR (1.1, NE)	0.511 (0.197, 1.327)	0.1596
Europe/North America	36	15 (41.7)	7.2 (2.4, NE)	30	12 (40.0)	7.3 (2.8, NE)	1.011 (0.469, 2.181)	0.9768
Interaction								0.5553
Race								
Asian and other	105	46 (43.8)	9.0 (3.9, 14.0)	106	45 (42.5)	4.2 (2.6, NE)	0.714 (0.466, 1.094)	0.1192
White	34	14 (41.2)	NR (2.4, NE)	23	10 (43.5)	7.3 (2.8, NE)	0.928 (0.409, 2.105)	0.8569
Interaction								0.6087

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious TEAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	17 (37.8)	13.9 (3.3, NE)	34	16 (47.1)	4.2 (1.9, NE)	0.481 (0.231, 1.001)	0.0449
vCPS < 10%	53	26 (49.1)	7.2 (2.4, 14.0)	54	23 (42.6)	6.1 (2.6, NE)	0.856 (0.480, 1.526)	0.5975
Missing	41	17 (41.5)	8.6 (2.3, NE)	41	16 (39.0)	7.3 (1.7, NE)	0.879 (0.439, 1.760)	0.7155
Interaction								0.5230

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE Leading to Treatment Discontinuation

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	14 (18.2)	NR (9.7, NE)	70	13 (18.6)	NR (5.6, NE)	0.638 (0.290, 1.405)	0.2604
>= 65 Years	62	11 (17.7)	NR (14.0, NE)	59	15 (25.4)	NR (5.1, NE)	0.516 (0.229, 1.160)	0.1036
Interaction								0.4444
Gender								
Male	118	20 (16.9)	NR (13.9, NE)	106	24 (22.6)	7.9 (6.1, NE)	0.467 (0.248, 0.882)	0.0163
Female	21	5 (23.8)	NR (2.1, NE)	23	4 (17.4)	NR (NE, NE)	1.463 (0.387, 5.528)	0.5725
Interaction								0.3177

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE Leading to Treatment Discontinuation

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	20 (19.2)	NR (13.9, NE)	101	22 (21.8)	NR (6.1, NE)	0.553 (0.290, 1.058)	0.0695
Non-Smoker	35	5 (14.3)	NR (3.7, NE)	28	6 (21.4)	7.3 (5.0, NE)	0.608 (0.185, 2.003)	0.4089
Interaction								0.8663
ICC Options								
Paclitaxel	83	11 (13.3)	NR (14.0, NE)	79	19 (24.1)	NR (5.1, NE)	0.365 (0.163, 0.815)	0.0105
Docetaxel	56	14 (25.0)	14.0 (9.7, NE)	50	9 (18.0)	7.3 (5.6, NE)	0.936 (0.397, 2.207)	0.8791
Interaction								0.0862

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE Leading to Treatment Discontinuation

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	6 (14.0)	NR (13.9, NE)	37	7 (18.9)	NR (5.6, NE)	0.307 (0.084, 1.114)	0.0594
1	96	19 (19.8)	NR (14.0, NE)	92	21 (22.8)	7.9 (6.1, NE)	0.669 (0.355, 1.258)	0.2091
Interaction								0.7722
Region #1								
Asia	103	18 (17.5)	NR (13.9, NE)	99	19 (19.2)	NR (6.5, NE)	0.592 (0.301, 1.163)	0.1238
Europe/North America	36	7 (19.4)	NR (7.2, NE)	30	9 (30.0)	7.3 (5.0, NE)	0.592 (0.219, 1.601)	0.2961
Interaction								0.8865

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE Leading to Treatment Discontinuation

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	16 (20.5)	NR (14.0, NE)	76	15 (19.7)	NR (6.5, NE)	0.765 (0.371, 1.577)	0.4660
Japan	25	2 (8.0)	NR (10.8, NE)	23	4 (17.4)	NR (5.1, NE)	0.114 (0.011, 1.160)	0.0366
Europe/North America	36	7 (19.4)	NR (7.2, NE)	30	9 (30.0)	7.3 (5.0, NE)	0.592 (0.219, 1.601)	0.2961
Interaction								0.5732
Race								
Asian and other	105	19 (18.1)	NR (13.9, NE)	106	20 (18.9)	NR (7.9, NE)	0.635 (0.329, 1.225)	0.1714
White	34	6 (17.6)	NR (7.2, NE)	23	8 (34.8)	6.1 (5.0, NE)	0.472 (0.163, 1.368)	0.1572
Interaction								0.5490

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE Leading to Treatment Discontinuation

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	9 (20.0)	NR (10.8, NE)	34	9 (26.5)	NR (7.9, NE)	0.553 (0.216, 1.417)	0.2107
vCPS < 10%	53	9 (17.0)	NR (14.0, NE)	54	8 (14.8)	NR (5.0, NE)	0.659 (0.235, 1.849)	0.4253
Missing	41	7 (17.1)	NR (NE, NE)	41	11 (26.8)	7.3 (5.1, NE)	0.550 (0.212, 1.427)	0.2126
Interaction								0.7673

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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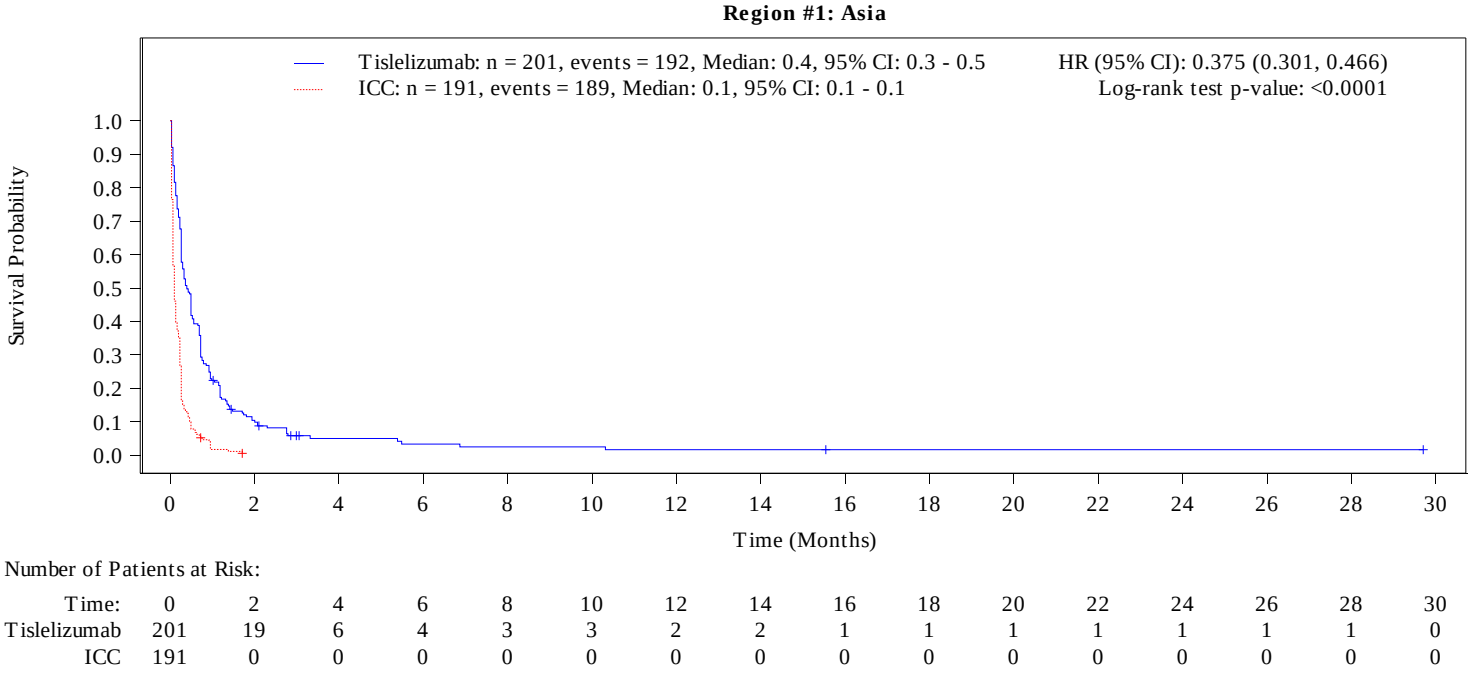
Figure 14.3.1.1.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Any TEAE



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	201	19	6	4	3	3	2	2	1	1	1	1	1	1	1	0
ICC	191	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
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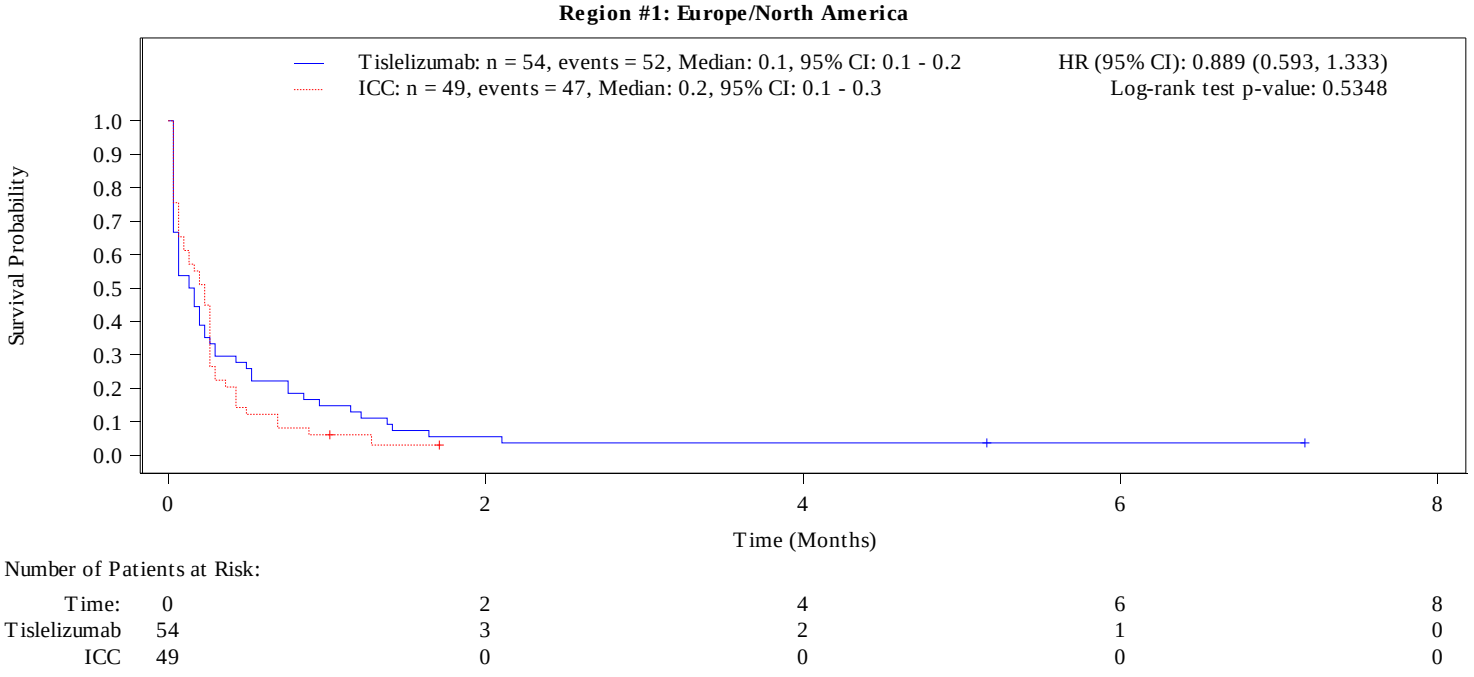
Figure 14.3.1.1.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Any TEAE



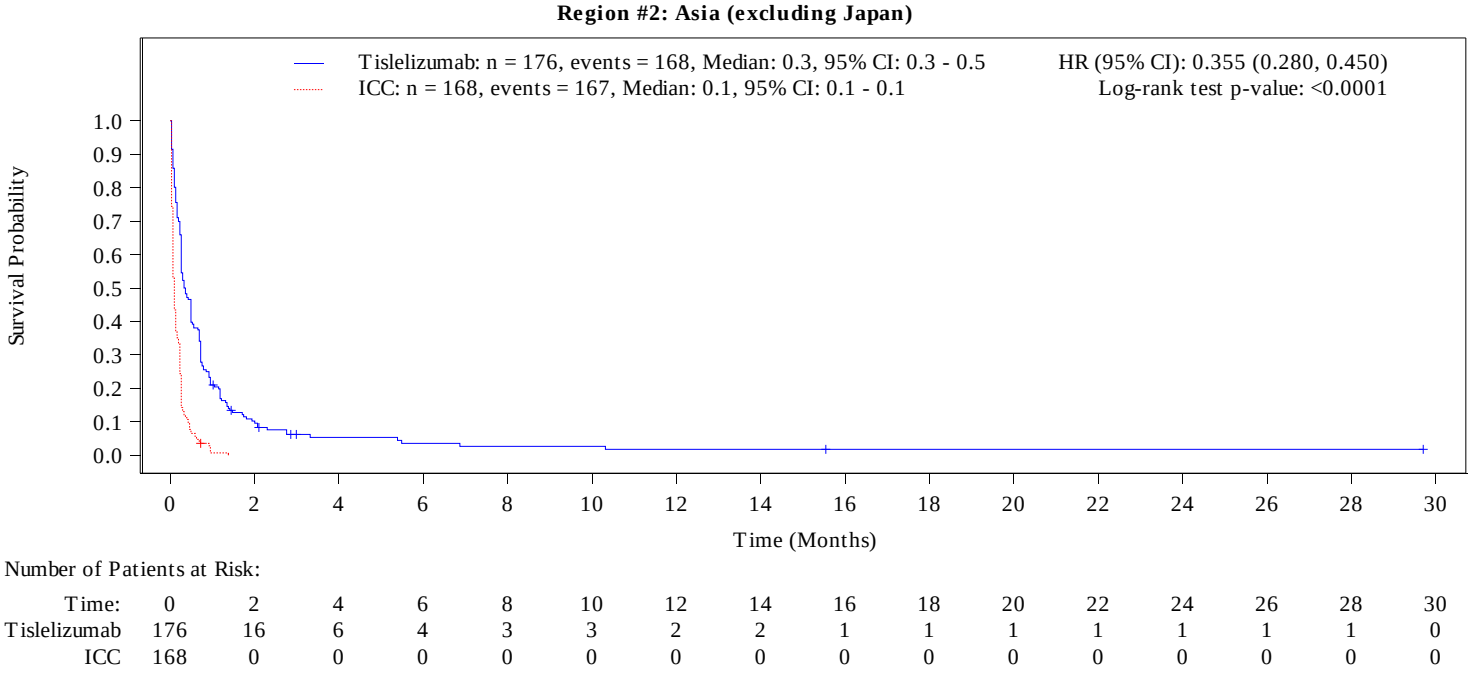
Number of Patients at Risk:

Time:	0	2	4	6	8
Tislelizumab	54	3	2	1	0
ICC	49	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteae-subgrp.sas 21AUG2024 18:49 f-14-03-01-01-s-km-tteae-subgrp-safety-sa.rtf

Figure 14.3.1.1.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Any TEAE



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	176	16	6	4	3	3	2	2	1	1	1	1	1	1	1	0
ICC	168	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
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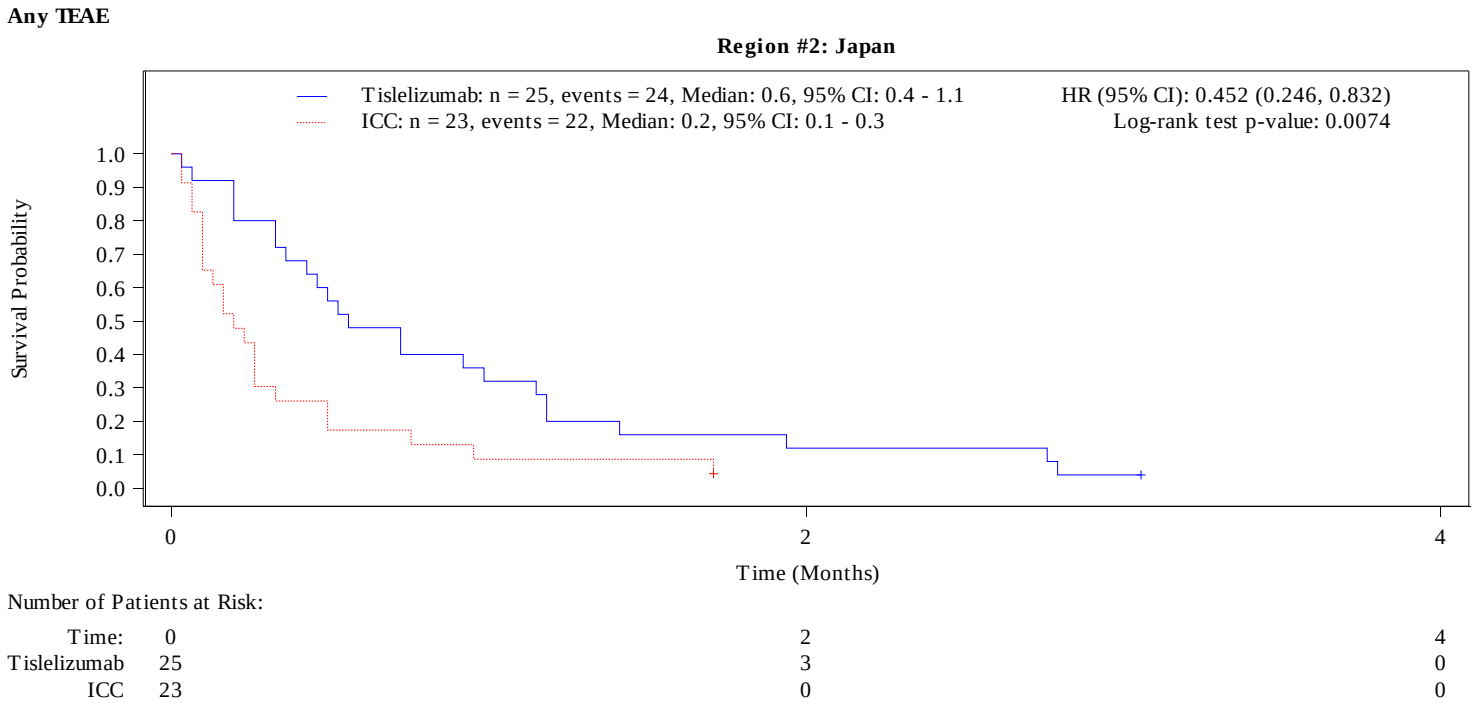
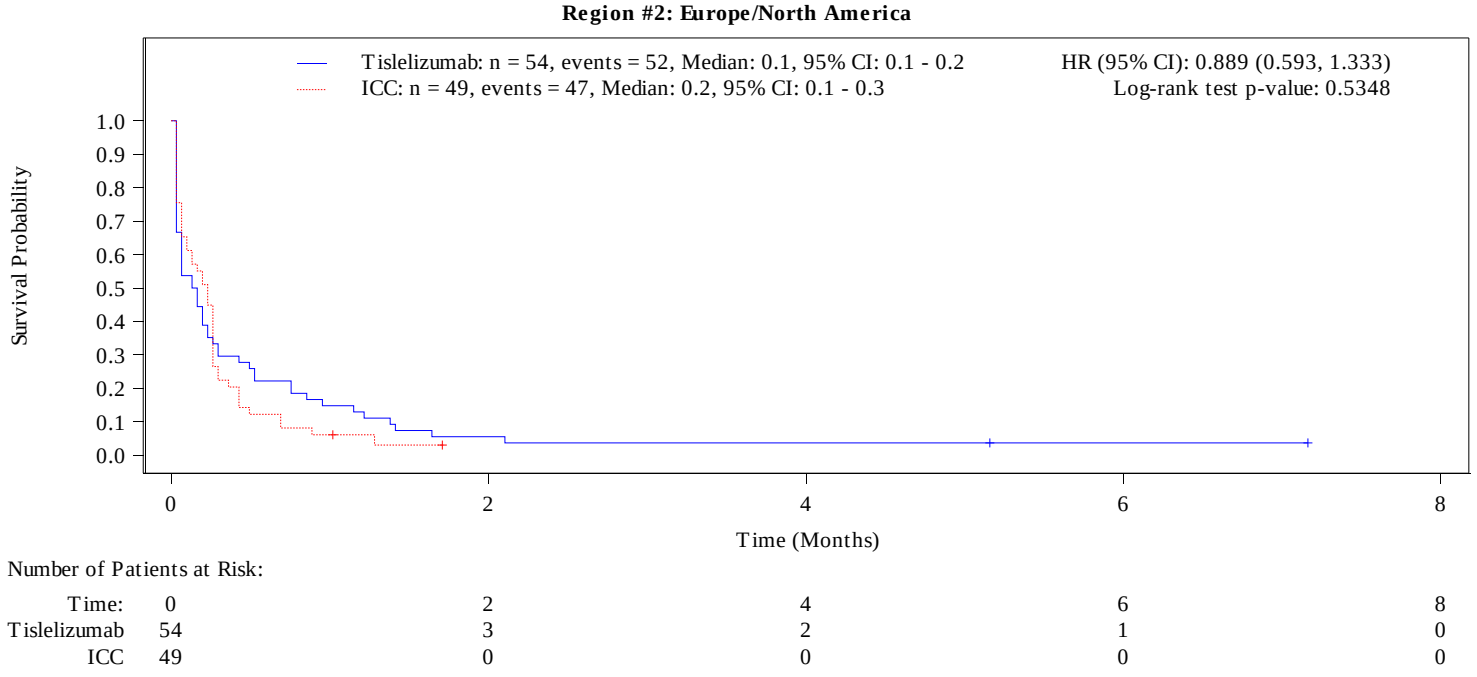
Figure 14.3.1.1.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set



Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteae-subgrp.sas 21AUG2024 18:49 f-14-03-01-01-s-km-tteae-subgrp-safety-sa.rtf

Figure 14.3.1.1.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Any TEAE

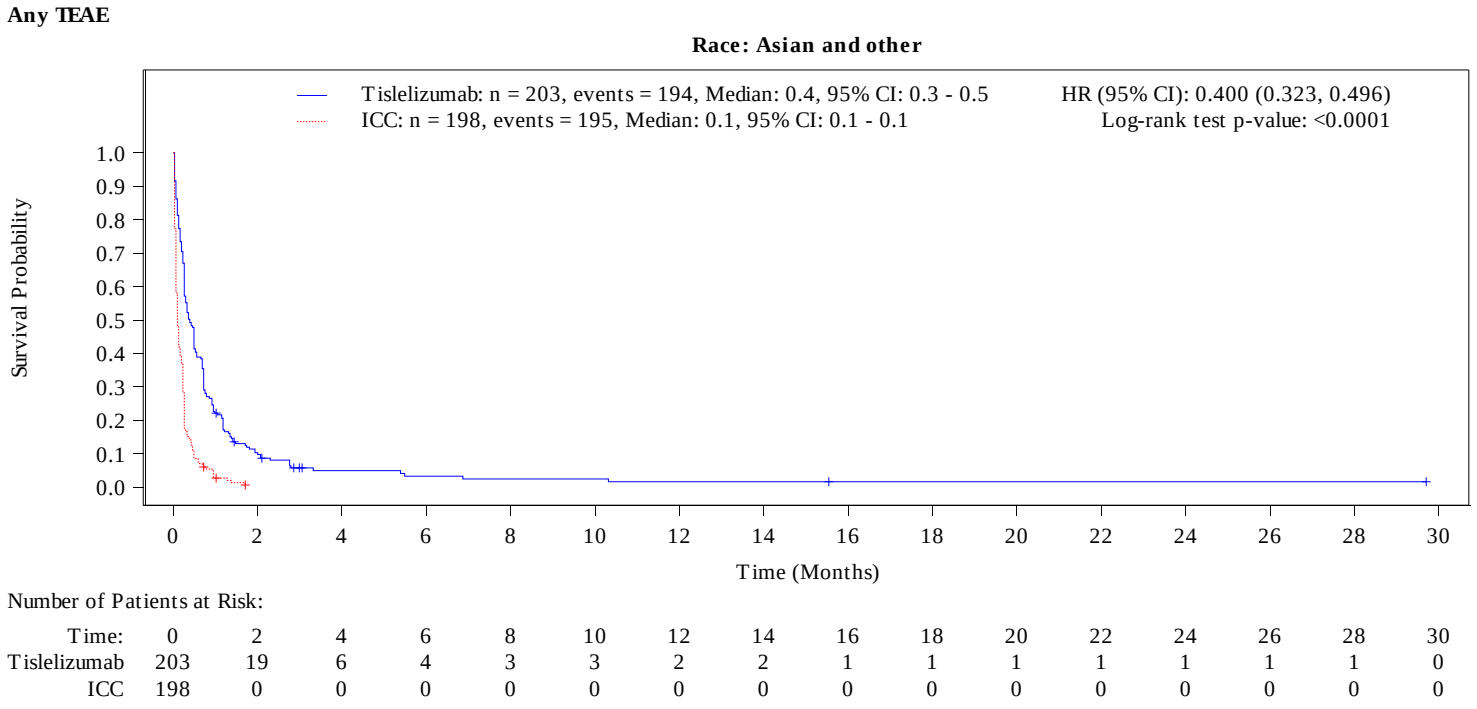


Number of Patients at Risk:

Time:	0	2	4	6	8
Tislelizumab	54	3	2	1	0
ICC	49	0	0	0	0

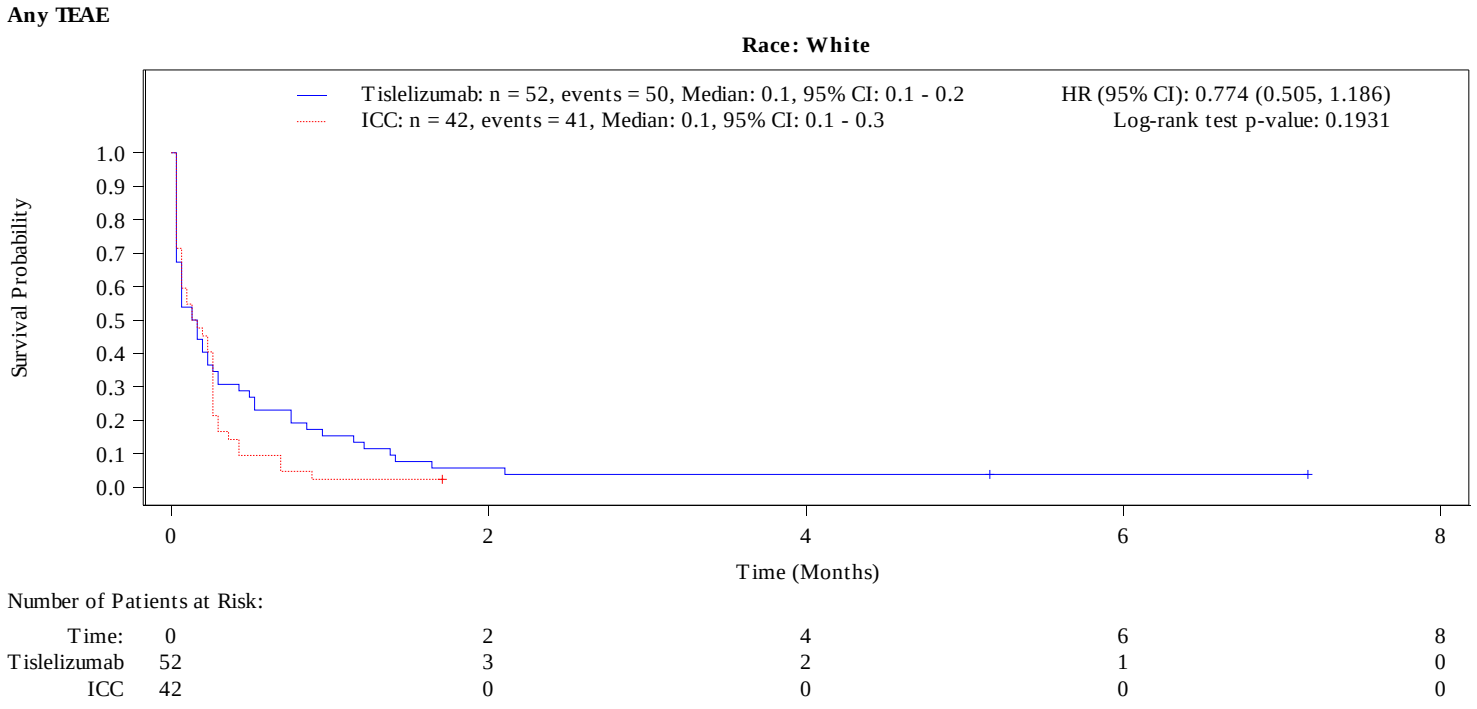
Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteae-subgrp.sas 21AUG2024 18:49 f-14-03-01-01-s-km-tteae-subgrp-safety-sa.rtf

Figure 14.3.1.1.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set



Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteae-subgrp.sas 21AUG2024 18:49 f-14-03-01-01-s-km-tteae-subgrp-safety-sa.rtf

Figure 14.3.1.1.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set



Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
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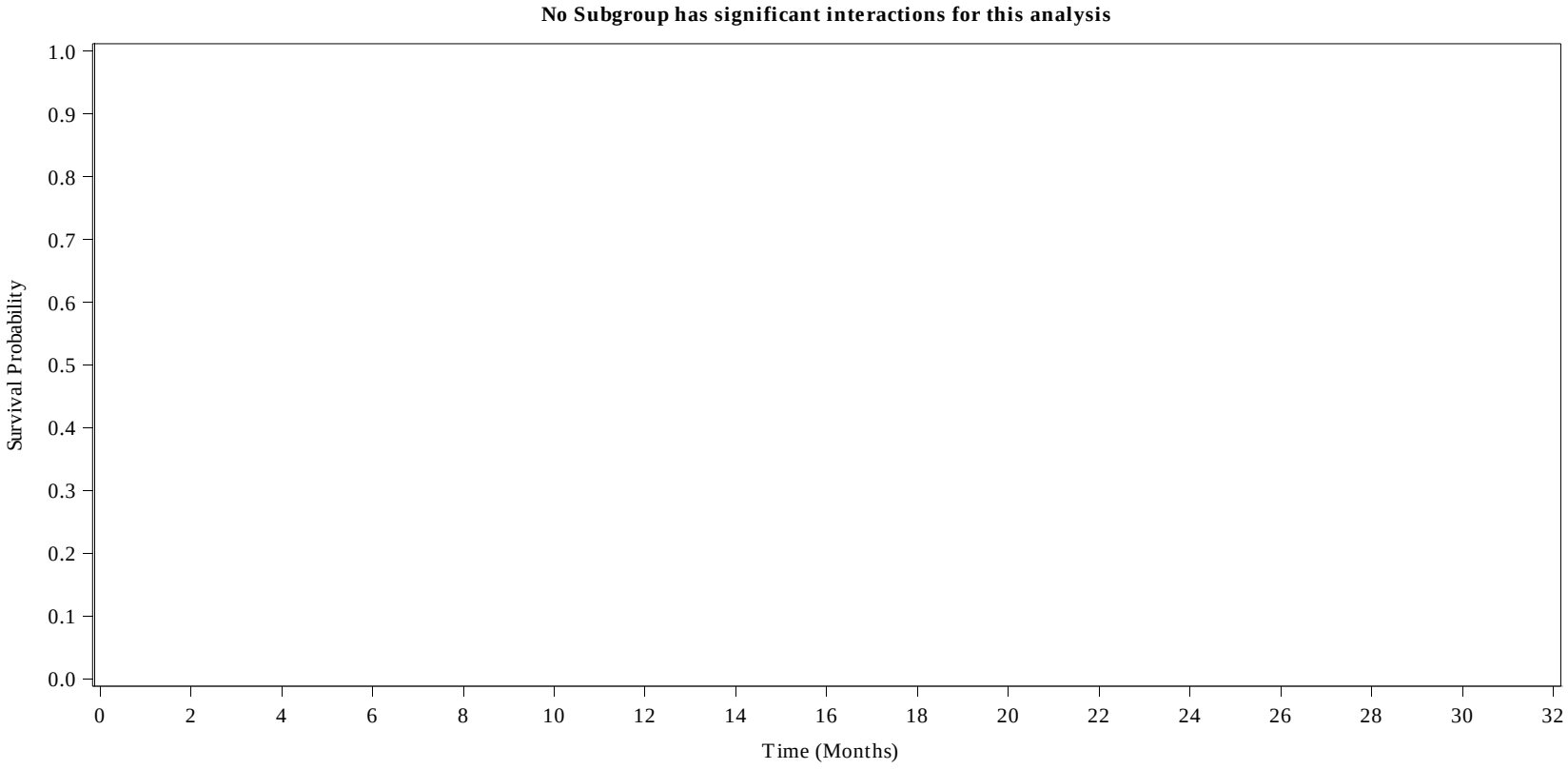
Figure 14.3.1.1.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteae-subgrp.sas 21AUG2024 18:49 f-14-03-01-01-b-s-km-tteae-subgrp-safetys-sa.rtf

Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

System Organ Class Preferred Term	Tislelizumab (N = 255) Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	ICC (N = 240) Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Blood and lymphatic system disorders	255	94 (36.9)	12.4 (8.9, 23.6)	240	139 (57.9)	1.1 (0.9, 2.0)	0.384 (0.291, 0.507)	<0.0001
Anaemia	255	80 (31.4)	19.4 (11.0, NE)	240	107 (44.6)	4.1 (2.0, NE)	0.457 (0.336, 0.621)	<0.0001
Febrile neutropenia	255	0 (0.0)	NR (NE, NE)	240	12 (5.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0002
Leukopenia	255	8 (3.1)	NR (NE, NE)	240	30 (12.5)	NR (NE, NE)	0.168 (0.072, 0.390)	<0.0001
Neutropenia	255	2 (0.8)	NR (NE, NE)	240	31 (12.9)	NR (NE, NE)	0.055 (0.013, 0.231)	<0.0001
Thrombocytopenia	255	5 (2.0)	NR (NE, NE)	240	10 (4.2)	NR (NE, NE)	0.338 (0.105, 1.083)	0.0555
Cardiac disorders	255	28 (11.0)	NR (NE, NE)	240	22 (9.2)	NR (NE, NE)	0.859 (0.479, 1.539)	0.6086

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

System Organ Class Preferred Term	Tislelizumab (N = 255) Total No. of Patients	Tislelizumab (N = 255) Patients with events n (%)	Tislelizumab (N = 255) Median time to event (95% CI) [a]	ICC (N = 240) Total No. of Patients	ICC (N = 240) Patients with events n (%)	ICC (N = 240) Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Endocrine disorders	255	40 (15.7)	NR (16.1, NE)	240	2 (0.8)	NR (NE, NE)	12.287 (2.943, 51.299)	<0.0001
Hypothyroidism	255	30 (11.8)	NR (16.5, NE)	240	1 (0.4)	NR (NE, NE)	17.068 (2.305, 126.377)	0.0002
Eye disorders	255	18 (7.1)	NR (NE, NE)	240	8 (3.3)	NR (NE, NE)	1.516 (0.642, 3.580)	0.3393

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

System Organ Class Preferred Term	Tislelizumab (N = 255) Total No. of Patients	Tislelizumab (N = 255) Patients with events n (%)	Tislelizumab (N = 255) Median time to event (95% CI) [a]	ICC (N = 240) Total No. of Patients	ICC (N = 240) Patients with events n (%)	ICC (N = 240) Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Gastrointestinal disorders	255	149 (58.4)	2.9 (1.8, 4.1)	240	171 (71.3)	0.4 (0.3, 0.7)	0.447 (0.354, 0.564)	<0.0001
Abdominal pain	255	18 (7.1)	NR (NE, NE)	240	22 (9.2)	NR (10.8, NE)	0.555 (0.288, 1.071)	0.0753
Abdominal pain upper	255	9 (3.5)	NR (NE, NE)	240	16 (6.7)	NR (NE, NE)	0.421 (0.183, 0.968)	0.0360
Constipation	255	39 (15.3)	NR (NE, NE)	240	45 (18.8)	NR (NE, NE)	0.651 (0.418, 1.014)	0.0555
Diarrhoea	255	32 (12.5)	NR (NE, NE)	240	77 (32.1)	NR (NE, NE)	0.281 (0.184, 0.431)	<0.0001
Dysphagia	255	28 (11.0)	NR (NE, NE)	240	20 (8.3)	NR (NE, NE)	0.953 (0.526, 1.725)	0.8739
Gastrooesophageal reflux disease	255	14 (5.5)	NR (NE, NE)	240	12 (5.0)	NR (NE, NE)	0.760 (0.339, 1.705)	0.5041
Nausea	255	36 (14.1)	NR (NE, NE)	240	72 (30.0)	NR (5.1, NE)	0.345 (0.229, 0.521)	<0.0001
Stomatitis	255	9 (3.5)	NR (NE, NE)	240	14 (5.8)	NR (NE, NE)	0.505 (0.217, 1.177)	0.1051
Vomiting	255	27 (10.6)	NR (NE, NE)	240	48 (20.0)	NR (NE, NE)	0.392 (0.241, 0.638)	<0.0001

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

System Organ Class Preferred Term	Tislelizumab (N = 255) Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	ICC (N = 240) Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
General disorders and administration site conditions	255	117 (45.9)	7.0 (3.5, 9.9)	240	147 (61.3)	1.0 (0.8, 1.7)	0.484 (0.374, 0.626)	<0.0001
Asthenia	255	27 (10.6)	NR (NE, NE)	240	35 (14.6)	NR (9.0, NE)	0.553 (0.329, 0.930)	0.0234
Fatigue	255	33 (12.9)	NR (NE, NE)	240	42 (17.5)	NR (NE, NE)	0.631 (0.396, 1.005)	0.0502
Malaise	255	16 (6.3)	NR (NE, NE)	240	36 (15.0)	NR (NE, NE)	0.308 (0.166, 0.569)	<0.0001
Oedema peripheral	255	10 (3.9)	NR (NE, NE)	240	11 (4.6)	NR (10.2, NE)	0.632 (0.257, 1.555)	0.3138
Pyrexia	255	41 (16.1)	NR (NE, NE)	240	34 (14.2)	NR (NE, NE)	0.830 (0.518, 1.330)	0.4372
Hepatobiliary disorders	255	12 (4.7)	NR (NE, NE)	240	7 (2.9)	NR (NE, NE)	1.183 (0.451, 3.101)	0.7318

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

	Tislelizumab (N = 255)			ICC (N = 240)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Infections and infestations	255	75 (29.4)	13.7 (9.5, NE)	240	74 (30.8)	8.0 (4.9, NE)	0.694 (0.497, 0.970)	0.0313
Pneumonia	255	36 (14.1)	NR (15.8, NE)	240	27 (11.3)	NR (NE, NE)	0.837 (0.497, 1.409)	0.5013
Upper respiratory tract infection	255	8 (3.1)	NR (NE, NE)	240	11 (4.6)	NR (NE, NE)	0.542 (0.210, 1.401)	0.1993
Injury, poisoning and procedural complications	255	16 (6.3)	NR (NE, NE)	240	7 (2.9)	NR (NE, NE)	1.205 (0.462, 3.146)	0.7023

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

	Tislelizumab (N = 255)			ICC (N = 240)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Investigations	255	128 (50.2)	3.4 (2.1, 7.0)	240	166 (69.2)	0.5 (0.5, 0.7)	0.412 (0.324, 0.525)	<0.0001
Alanine aminotransferase increased	255	33 (12.9)	NR (NE, NE)	240	18 (7.5)	NR (NE, NE)	1.332 (0.741, 2.393)	0.3359
Aspartate aminotransferase increased	255	37 (14.5)	NR (NE, NE)	240	11 (4.6)	NR (NE, NE)	2.359 (1.189, 4.679)	0.0114
Blood alkaline phosphatase increased	255	17 (6.7)	NR (NE, NE)	240	5 (2.1)	NR (NE, NE)	2.779 (1.019, 7.577)	0.0369
Blood creatine phosphokinase MB increased	255	11 (4.3)	NR (NE, NE)	240	1 (0.4)	NR (NE, NE)	7.277 (0.922, 57.448)	0.0286
Blood creatine phosphokinase increased	255	10 (3.9)	NR (NE, NE)	240	0 (0.0)	NR (NE, NE)	26494210.890 (0.000, NE)	0.0056
Gamma-glutamyltransferase increased	255	14 (5.5)	NR (NE, NE)	240	8 (3.3)	NR (NE, NE)	1.442 (0.601, 3.462)	0.4095
Lymphocyte count decreased	255	12 (4.7)	NR (NE, NE)	240	22 (9.2)	NR (NE, NE)	0.391 (0.188, 0.814)	0.0092
Neutrophil count decreased	255	6 (2.4)	NR (NE, NE)	240	94 (39.2)	NR (2.8, NE)	0.047 (0.021, 0.107)	<0.0001
Platelet count decreased	255	14 (5.5)	NR (NE, NE)	240	15 (6.3)	NR (NE, NE)	0.634 (0.292, 1.376)	0.2447
Weight decreased	255	59 (23.1)	NR (NE, NE)	240	45 (18.8)	NR (NE, NE)	0.948 (0.637, 1.410)	0.7905
White blood cell count decreased	255	9 (3.5)	NR (NE, NE)	240	98 (40.8)	NR (NE, NE)	0.064 (0.032, 0.126)	<0.0001
White blood cell count increased	255	11 (4.3)	NR (NE, NE)	240	6 (2.5)	NR (NE, NE)	1.383 (0.505, 3.789)	0.5266

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

	Tislelizumab (N = 255)			ICC (N = 240)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Metabolism and nutrition disorders	255	116 (45.5)	7.7 (3.4, 13.8)	240	141 (58.8)	1.2 (0.8, 2.2)	0.491 (0.380, 0.635)	<0.0001
Decreased appetite	255	40 (15.7)	NR (NE, NE)	240	84 (35.0)	6.6 (3.7, NE)	0.316 (0.214, 0.467)	<0.0001
Hyperglycaemia	255	16 (6.3)	NR (NE, NE)	240	7 (2.9)	NR (NE, NE)	1.758 (0.714, 4.332)	0.2124
Hyperuricaemia	255	6 (2.4)	NR (NE, NE)	240	11 (4.6)	NR (NE, NE)	0.407 (0.148, 1.121)	0.0726
Hypoalbuminaemia	255	34 (13.3)	NR (NE, NE)	240	30 (12.5)	NR (NE, NE)	0.883 (0.536, 1.456)	0.6253
Hypocalcaemia	255	8 (3.1)	NR (NE, NE)	240	11 (4.6)	NR (NE, NE)	0.500 (0.192, 1.303)	0.1485
Hypochloraemia	255	6 (2.4)	NR (NE, NE)	240	10 (4.2)	NR (NE, NE)	0.379 (0.128, 1.129)	0.0702
Hypokalaemia	255	20 (7.8)	NR (NE, NE)	240	22 (9.2)	NR (NE, NE)	0.622 (0.332, 1.168)	0.1362
Hyponatraemia	255	32 (12.5)	NR (NE, NE)	240	33 (13.8)	NR (NE, NE)	0.593 (0.353, 0.995)	0.0437
Hypoproteinaemia	255	13 (5.1)	NR (NE, NE)	240	8 (3.3)	NR (NE, NE)	0.995 (0.396, 2.498)	0.9911

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

	Tislelizumab (N = 255)			ICC (N = 240)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Musculoskeletal and connective tissue disorders	255	69 (27.1)	18.0 (10.7, NE)	240	61 (25.4)	7.3 (6.2, NE)	0.770 (0.539, 1.098)	0.1466
Arthralgia	255	10 (3.9)	NR (NE, NE)	240	13 (5.4)	NR (NE, NE)	0.618 (0.267, 1.433)	0.2578
Back pain	255	26 (10.2)	NR (NE, NE)	240	18 (7.5)	NR (NE, NE)	0.999 (0.536, 1.860)	0.9964
Musculoskeletal pain	255	13 (5.1)	NR (NE, NE)	240	7 (2.9)	NR (NE, NE)	1.355 (0.531, 3.453)	0.5234
Myalgia	255	7 (2.7)	NR (NE, NE)	240	14 (5.8)	NR (NE, NE)	0.373 (0.142, 0.977)	0.0362
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	255	23 (9.0)	NR (NE, NE)	240	8 (3.3)	NR (NE, NE)	2.363 (1.048, 5.330)	0.0327
Cancer pain	255	10 (3.9)	NR (NE, NE)	240	4 (1.7)	NR (NE, NE)	2.014 (0.627, 6.472)	0.2307

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

	Tislelizumab (N = 255)			ICC (N = 240)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Nervous system disorders	255	33 (12.9)	NR (20.6, NE)	240	63 (26.3)	9.7 (7.4, NE)	0.320 (0.205, 0.500)	<0.0001
Dizziness	255	11 (4.3)	NR (NE, NE)	240	19 (7.9)	NR (NE, NE)	0.426 (0.200, 0.908)	0.0231
Peripheral sensory neuropathy	255	2 (0.8)	NR (NE, NE)	240	23 (9.6)	NR (9.7, NE)	0.059 (0.013, 0.258)	<0.0001
Psychiatric disorders	255	26 (10.2)	NR (NE, NE)	240	26 (10.8)	NR (NE, NE)	0.736 (0.421, 1.286)	0.2791
Insomnia	255	20 (7.8)	NR (NE, NE)	240	17 (7.1)	NR (NE, NE)	0.916 (0.473, 1.772)	0.7940
Renal and urinary disorders	255	12 (4.7)	NR (NE, NE)	240	9 (3.8)	NR (NE, NE)	0.683 (0.266, 1.752)	0.4250

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

System Organ Class Preferred Term	Tislelizumab (N = 255) Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	ICC (N = 240) Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Respiratory, thoracic and mediastinal disorders	255	104 (40.8)	11.3 (4.4, 15.8)	240	81 (33.8)	5.7 (4.0, NE)	1.031 (0.766, 1.388)	0.8376
Cough	255	43 (16.9)	NR (NE, NE)	240	28 (11.7)	NR (NE, NE)	1.276 (0.786, 2.072)	0.3224
Dyspnoea	255	24 (9.4)	NR (NE, NE)	240	19 (7.9)	19.8 (NE, NE)	0.932 (0.501, 1.733)	0.8237
Haemoptysis	255	11 (4.3)	NR (NE, NE)	240	7 (2.9)	NR (NE, NE)	1.180 (0.449, 3.102)	0.7373
Pneumonitis	255	12 (4.7)	NR (NE, NE)	240	4 (1.7)	NR (NE, NE)	1.535 (0.464, 5.082)	0.4793
Productive cough	255	18 (7.1)	NR (NE, NE)	240	18 (7.5)	NR (NE, NE)	0.715 (0.363, 1.406)	0.3283

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

System Organ Class Preferred Term	Tislelizumab (N = 255) Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	ICC (N = 240) Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Skin and subcutaneous tissue disorders	255	60 (23.5)	30.5 (NE, NE)	240	67 (27.9)	NR (5.3, NE)	0.670 (0.469, 0.957)	0.0263
Alopecia	255	0 (0.0)	NR (NE, NE)	240	42 (17.5)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Pruritus	255	24 (9.4)	30.5 (NE, NE)	240	11 (4.6)	NR (NE, NE)	1.430 (0.681, 3.001)	0.3422
Rash	255	21 (8.2)	NR (NE, NE)	240	10 (4.2)	NR (NE, NE)	1.796 (0.842, 3.830)	0.1234
Vascular disorders	255	26 (10.2)	NR (NE, NE)	240	17 (7.1)	NR (NE, NE)	1.179 (0.631, 2.205)	0.6042
Hypertension	255	12 (4.7)	NR (NE, NE)	240	6 (2.5)	NR (NE, NE)	1.539 (0.568, 4.171)	0.3918

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1.b:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 129)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Blood and lymphatic system disorders	139	45 (32.4)	NR (21.4, NE)	129	72 (55.8)	1.5 (1.0, 4.7)	0.381 (0.257, 0.565)	<0.0001
Anaemia	139	38 (27.3)	NR (21.4, NE)	129	52 (40.3)	5.6 (2.8, NE)	0.471 (0.303, 0.732)	0.0006
Leukopenia	139	4 (2.9)	NR (NE, NE)	129	12 (9.3)	NR (NE, NE)	0.250 (0.080, 0.780)	0.0098
Neutropenia	139	2 (1.4)	NR (NE, NE)	129	21 (16.3)	NR (NE, NE)	0.079 (0.018, 0.336)	<0.0001
Cardiac disorders	139	18 (12.9)	NR (NE, NE)	129	13 (10.1)	NR (NE, NE)	1.070 (0.517, 2.214)	0.8551
Endocrine disorders	139	25 (18.0)	18.6 (11.6, NE)	129	1 (0.8)	NR (NE, NE)	17.532 (2.354, 130.565)	0.0001
Hypothyroidism	139	18 (12.9)	NR (16.5, NE)	129	0 (0.0)	NR (NE, NE)	63814305.397 (0.000, NE)	0.0006
Eye disorders	139	10 (7.2)	NR (17.1, NE)	129	6 (4.7)	NR (NE, NE)	1.247 (0.442, 3.517)	0.6763

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1.b:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 129)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Gastrointestinal disorders	139	88 (63.3)	2.2 (1.4, 3.3)	129	79 (61.2)	1.1 (0.7, 2.1)	0.721 (0.528, 0.986)	0.0377
Abdominal pain upper	139	4 (2.9)	NR (NE, NE)	129	10 (7.8)	NR (NE, NE)	0.325 (0.101, 1.041)	0.0461
Constipation	139	24 (17.3)	NR (NE, NE)	129	20 (15.5)	NR (NE, NE)	0.925 (0.502, 1.704)	0.8034
Diarrhoea	139	19 (13.7)	NR (NE, NE)	129	23 (17.8)	NR (NE, NE)	0.665 (0.361, 1.225)	0.1870
Dysphagia	139	17 (12.2)	NR (NE, NE)	129	13 (10.1)	NR (NE, NE)	1.021 (0.489, 2.129)	0.9568
Nausea	139	22 (15.8)	NR (NE, NE)	129	19 (14.7)	NR (NE, NE)	0.980 (0.529, 1.818)	0.9500
Stomatitis	139	6 (4.3)	NR (NE, NE)	129	11 (8.5)	NR (NE, NE)	0.406 (0.149, 1.111)	0.0682
Vomiting	139	12 (8.6)	NR (NE, NE)	129	11 (8.5)	NR (NE, NE)	0.930 (0.409, 2.116)	0.8628

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1.b:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 129)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
General disorders and administration site conditions	139	73 (52.5)	6.9 (2.7, 8.5)	129	77 (59.7)	1.3 (0.9, 2.5)	0.570 (0.406, 0.801)	0.0009
Asthenia	139	18 (12.9)	NR (17.5, NE)	129	17 (13.2)	NR (9.0, NE)	0.804 (0.410, 1.578)	0.5253
Fatigue	139	22 (15.8)	NR (NE, NE)	129	25 (19.4)	NR (NE, NE)	0.697 (0.388, 1.254)	0.2248
Malaise	139	11 (7.9)	NR (NE, NE)	129	12 (9.3)	NR (NE, NE)	0.604 (0.255, 1.430)	0.2456
Pyrexia	139	23 (16.5)	NR (NE, NE)	129	20 (15.5)	NR (7.7, NE)	0.778 (0.418, 1.448)	0.4263
Infections and infestations	139	43 (30.9)	11.5 (5.6, NE)	129	46 (35.7)	8.0 (3.1, NE)	0.626 (0.406, 0.966)	0.0327
Pneumonia	139	20 (14.4)	NR (NE, NE)	129	15 (11.6)	NR (NE, NE)	0.904 (0.454, 1.800)	0.7736
Injury, poisoning and procedural complications	139	13 (9.4)	NR (15.9, NE)	129	5 (3.9)	NR (NE, NE)	1.449 (0.482, 4.358)	0.5069

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.
Adverse events were classified based on MedDRA v23.0.
System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.
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Table 14.3.1.2.2.2.1.b:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

System Organ Class Preferred Term	Tislelizumab (N = 139) Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	ICC (N = 129) Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Investigations	139	58 (41.7)	7.7 (3.1, NE)	129	84 (65.1)	0.5 (0.5, 1.2)	0.348 (0.244, 0.496)	<0.0001
Alanine aminotransferase increased	139	11 (7.9)	NR (NE, NE)	129	4 (3.1)	NR (NE, NE)	2.305 (0.731, 7.268)	0.1420
Aspartate aminotransferase increased	139	13 (9.4)	NR (NE, NE)	129	3 (2.3)	NR (NE, NE)	3.604 (1.023, 12.696)	0.0326
Lymphocyte count decreased	139	3 (2.2)	NR (NE, NE)	129	10 (7.8)	NR (NE, NE)	0.255 (0.070, 0.931)	0.0251
Neutrophil count decreased	139	1 (0.7)	NR (NE, NE)	129	55 (42.6)	NR (1.4, NE)	0.013 (0.002, 0.094)	<0.0001
Weight decreased	139	30 (21.6)	NR (NE, NE)	129	16 (12.4)	NR (NE, NE)	1.539 (0.833, 2.844)	0.1638
White blood cell count decreased	139	4 (2.9)	NR (NE, NE)	129	48 (37.2)	NR (NE, NE)	0.059 (0.021, 0.163)	<0.0001

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1.b:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 129)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Metabolism and nutrition disorders	139	59 (42.4)	8.6 (3.7, NE)	129	67 (51.9)	2.8 (1.3, 5.7)	0.595 (0.413, 0.856)	0.0041
Decreased appetite	139	27 (19.4)	NR (NE, NE)	129	39 (30.2)	NR (5.7, NE)	0.508 (0.308, 0.840)	0.0068
Hypoalbuminaemia	139	18 (12.9)	NR (NE, NE)	129	13 (10.1)	NR (NE, NE)	1.002 (0.483, 2.078)	0.9953
Hypokalaemia	139	8 (5.8)	NR (NE, NE)	129	10 (7.8)	NR (NE, NE)	0.622 (0.244, 1.582)	0.3139
Hyponatraemia	139	12 (8.6)	NR (NE, NE)	129	8 (6.2)	NR (NE, NE)	0.952 (0.374, 2.424)	0.9176

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1.b:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 129)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Musculoskeletal and connective tissue disorders	139	39 (28.1)	18.0 (7.6, NE)	129	40 (31.0)	7.3 (6.2, NE)	0.671 (0.427, 1.054)	0.0802
Arthralgia	139	5 (3.6)	NR (NE, NE)	129	12 (9.3)	NR (NE, NE)	0.374 (0.132, 1.062)	0.0542
Back pain	139	12 (8.6)	NR (NE, NE)	129	10 (7.8)	NR (8.6, NE)	0.800 (0.334, 1.917)	0.6154
Myalgia	139	4 (2.9)	NR (NE, NE)	129	14 (10.9)	NR (NE, NE)	0.244 (0.080, 0.748)	0.0074
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	139	14 (10.1)	NR (NE, NE)	129	4 (3.1)	NR (NE, NE)	3.279 (1.077, 9.981)	0.0266
Nervous system disorders	139	22 (15.8)	NR (17.8, NE)	129	43 (33.3)	9.7 (3.5, NE)	0.328 (0.193, 0.557)	<0.0001
Peripheral sensory neuropathy	139	1 (0.7)	NR (NE, NE)	129	22 (17.1)	NR (9.7, NE)	0.029 (0.004, 0.225)	<0.0001

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1.b:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 129)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Psychiatric disorders	139	18 (12.9)	NR (NE, NE)	129	15 (11.6)	NR (NE, NE)	0.948 (0.472, 1.903)	0.8806
Insomnia	139	14 (10.1)	NR (NE, NE)	129	9 (7.0)	NR (NE, NE)	1.243 (0.530, 2.917)	0.6161
Respiratory, thoracic and mediastinal disorders	139	58 (41.7)	8.6 (3.3, NE)	129	46 (35.7)	5.7 (3.3, NE)	1.015 (0.683, 1.508)	0.9404
Cough	139	22 (15.8)	NR (NE, NE)	129	14 (10.9)	NR (NE, NE)	1.237 (0.622, 2.460)	0.5427
Dyspnoea	139	12 (8.6)	NR (NE, NE)	129	14 (10.9)	19.8 (NE, NE)	0.660 (0.297, 1.464)	0.3030
Productive cough	139	8 (5.8)	NR (NE, NE)	129	10 (7.8)	NR (NE, NE)	0.671 (0.263, 1.713)	0.4011

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1.b:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 129)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Skin and subcutaneous tissue disorders	139	37 (26.6)	NR (9.6, NE)	129	49 (38.0)	NR (2.4, NE)	0.581 (0.376, 0.896)	0.0125
Alopecia	139	0 (0.0)	NR (NE, NE)	129	34 (26.4)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Pruritus	139	16 (11.5)	NR (11.8, NE)	129	5 (3.9)	NR (NE, NE)	2.227 (0.797, 6.220)	0.1174
Rash	139	14 (10.1)	NR (NE, NE)	129	7 (5.4)	NR (NE, NE)	1.748 (0.704, 4.341)	0.2216
Vascular disorders	139	20 (14.4)	NR (NE, NE)	129	13 (10.1)	NR (NE, NE)	1.202 (0.591, 2.444)	0.6093
Hypertension	139	10 (7.2)	NR (NE, NE)	129	6 (4.7)	NR (NE, NE)	1.232 (0.437, 3.472)	0.6912

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

System Organ Class Preferred Term	Tislelizumab (N = 255) Total No. of Patients	Tislelizumab (N = 255) Patients with events n (%)	Tislelizumab (N = 255) Median time to event (95% CI) [a]	ICC (N = 240) Total No. of Patients	ICC (N = 240) Patients with events n (%)	ICC (N = 240) Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Blood and lymphatic system disorders	255	18 (7.1)	NR (NE, NE)	240	56 (23.3)	NR (9.2, NE)	0.219 (0.127, 0.380)	<0.0001
Anaemia	255	15 (5.9)	NR (NE, NE)	240	26 (10.8)	NR (NE, NE)	0.415 (0.215, 0.800)	0.0067
Febrile neutropenia	255	0 (0.0)	NR (NE, NE)	240	11 (4.6)	NR (NE, NE)	0.000 (0.000, NE)	0.0003
Leukopenia	255	0 (0.0)	NR (NE, NE)	240	17 (7.1)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Neutropenia	255	1 (0.4)	NR (NE, NE)	240	16 (6.7)	NR (NE, NE)	0.049 (0.006, 0.378)	<0.0001
Gastrointestinal disorders	255	38 (14.9)	NR (NE, NE)	240	45 (18.8)	NR (8.9, NE)	0.583 (0.374, 0.909)	0.0158
Diarrhoea	255	3 (1.2)	NR (NE, NE)	240	15 (6.3)	NR (NE, NE)	0.166 (0.048, 0.575)	0.0013
Dysphagia	255	16 (6.3)	NR (NE, NE)	240	7 (2.9)	NR (8.9, NE)	1.686 (0.683, 4.165)	0.2525

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

	Tislelizumab (N = 255)			ICC (N = 240)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
General disorders and administration site conditions	255	15 (5.9)	NR (NE, NE)	240	25 (10.4)	NR (NE, NE)	0.390 (0.197, 0.772)	0.0052
Infections and infestations	255	20 (7.8)	NR (NE, NE)	240	31 (12.9)	NR (9.2, NE)	0.434 (0.240, 0.786)	0.0047
Pneumonia	255	12 (4.7)	NR (NE, NE)	240	17 (7.1)	NR (NE, NE)	0.457 (0.209, 0.998)	0.0444
Investigations	255	25 (9.8)	NR (NE, NE)	240	90 (37.5)	NR (4.1, NE)	0.171 (0.107, 0.272)	<0.0001
Lymphocyte count decreased	255	6 (2.4)	NR (NE, NE)	240	18 (7.5)	NR (NE, NE)	0.260 (0.102, 0.664)	0.0025
Neutrophil count decreased	255	0 (0.0)	NR (NE, NE)	240	63 (26.3)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
White blood cell count decreased	255	1 (0.4)	NR (NE, NE)	240	48 (20.0)	NR (NE, NE)	0.017 (0.002, 0.120)	<0.0001

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

	Tislelizumab (N = 255)			ICC (N = 240)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Metabolism and nutrition disorders	255	26 (10.2)	NR (NE, NE)	240	31 (12.9)	NR (9.6, NE)	0.518 (0.296, 0.908)	0.0193
Decreased appetite	255	2 (0.8)	NR (NE, NE)	240	10 (4.2)	NR (NE, NE)	0.080 (0.010, 0.635)	0.0024
Hyponatraemia	255	14 (5.5)	NR (NE, NE)	240	10 (4.2)	NR (NE, NE)	0.881 (0.374, 2.075)	0.7722
Respiratory, thoracic and mediastinal disorders	255	25 (9.8)	NR (NE, NE)	240	18 (7.5)	NR (8.6, NE)	0.930 (0.496, 1.743)	0.8216

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.3.1.b:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

System Organ Class Preferred Term	Tislelizumab (N = 139) Total No. of Patients	Tislelizumab (N = 139) Patients with events n (%)	Tislelizumab (N = 139) Median time to event (95% CI) [a]	ICC (N = 129) Total No. of Patients	ICC (N = 129) Patients with events n (%)	ICC (N = 129) Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Blood and lymphatic system disorders	139	13 (9.4)	NR (NE, NE)	129	31 (24.0)	NR (NE, NE)	0.300 (0.156, 0.579)	0.0001
Anaemia	139	10 (7.2)	NR (NE, NE)	129	10 (7.8)	NR (NE, NE)	0.806 (0.334, 1.947)	0.6317
Febrile neutropenia	139	0 (0.0)	NR (NE, NE)	129	8 (6.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0014
Leukopenia	139	0 (0.0)	NR (NE, NE)	129	8 (6.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0019
Neutropenia	139	1 (0.7)	NR (NE, NE)	129	12 (9.3)	NR (NE, NE)	0.063 (0.008, 0.491)	0.0005
Gastrointestinal disorders	139	18 (12.9)	NR (NE, NE)	129	14 (10.9)	NR (8.9, NE)	0.993 (0.490, 2.013)	0.9847
Dysphagia	139	10 (7.2)	NR (NE, NE)	129	4 (3.1)	NR (8.9, NE)	2.016 (0.628, 6.472)	0.2298
General disorders and administration site conditions	139	11 (7.9)	NR (NE, NE)	129	11 (8.5)	NR (NE, NE)	0.675 (0.279, 1.637)	0.3819

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.3.1.b:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 129)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Infections and infestations	139	12 (8.6)	NR (NE, NE)	129	17 (13.2)	NR (NE, NE)	0.536 (0.253, 1.138)	0.0993
Pneumonia	139	7 (5.0)	NR (NE, NE)	129	11 (8.5)	NR (NE, NE)	0.467 (0.177, 1.233)	0.1162
Investigations	139	12 (8.6)	NR (NE, NE)	129	51 (39.5)	NR (2.4, NE)	0.143 (0.074, 0.276)	<0.0001
Lymphocyte count decreased	139	2 (1.4)	NR (NE, NE)	129	9 (7.0)	NR (NE, NE)	0.186 (0.040, 0.863)	0.0156
Neutrophil count decreased	139	0 (0.0)	NR (NE, NE)	129	38 (29.5)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
White blood cell count decreased	139	0 (0.0)	NR (NE, NE)	129	28 (21.7)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Metabolism and nutrition disorders	139	18 (12.9)	NR (NE, NE)	129	13 (10.1)	NR (9.6, NE)	0.896 (0.424, 1.892)	0.7726
Hyponatraemia	139	7 (5.0)	NR (NE, NE)	129	4 (3.1)	NR (NE, NE)	1.158 (0.332, 4.045)	0.8177

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.3.1.b:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 129)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Respiratory, thoracic and mediastinal disorders	139	17 (12.2)	NR (NE, NE)	129	13 (10.1)	NR (8.6, NE)	1.037 (0.496, 2.165)	0.9238
Vascular disorders	139	8 (5.8)	NR (NE, NE)	129	0 (0.0)	NR (NE, NE)	69810561.547 (0.000, NE)	0.0091

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.4.1.1:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

System Organ Class Preferred Term	Tislelizumab (N = 255) Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	ICC (N = 240) Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Blood and lymphatic system disorders	255	1 (0.4)	NR (NE, NE)	240	19 (7.9)	NR (NE, NE)	0.046 (0.006, 0.343)	<0.0001
Gastrointestinal disorders	255	36 (14.1)	NR (NE, NE)	240	30 (12.5)	NR (NE, NE)	0.874 (0.533, 1.433)	0.5930
Dysphagia	255	12 (4.7)	NR (NE, NE)	240	4 (1.7)	NR (NE, NE)	2.491 (0.800, 7.757)	0.1034
General disorders and administration site conditions	255	13 (5.1)	NR (NE, NE)	240	14 (5.8)	NR (NE, NE)	0.731 (0.337, 1.587)	0.4267
Infections and infestations	255	25 (9.8)	NR (NE, NE)	240	31 (12.9)	NR (9.2, NE)	0.511 (0.292, 0.895)	0.0168
Pneumonia	255	18 (7.1)	NR (NE, NE)	240	17 (7.1)	NR (NE, NE)	0.666 (0.332, 1.339)	0.2508
Investigations	255	1 (0.4)	NR (NE, NE)	240	13 (5.4)	NR (NE, NE)	0.069 (0.009, 0.529)	0.0006
Neutrophil count decreased	255	0 (0.0)	NR (NE, NE)	240	10 (4.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0008

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.4.1.1:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

System Organ Class Preferred Term	Tislelizumab (N = 255) Total No. of Patients	Tislelizumab (N = 255) Patients with events n (%)	Tislelizumab (N = 255) Median time to event (95% CI) [a]	ICC (N = 240) Total No. of Patients	ICC (N = 240) Patients with events n (%)	ICC (N = 240) Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Respiratory, thoracic and mediastinal disorders	255	29 (11.4)	NR (NE, NE)	240	19 (7.9)	NR (NE, NE)	1.067 (0.588, 1.937)	0.8306

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.4.1.1.b:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

System Organ Class Preferred Term	Tislelizumab (N = 139) Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	ICC (N = 129) Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Blood and lymphatic system disorders	139	1 (0.7)	NR (NE, NE)	129	10 (7.8)	NR (NE, NE)	0.084 (0.011, 0.658)	0.0024
Gastrointestinal disorders	139	19 (13.7)	NR (NE, NE)	129	9 (7.0)	NR (NE, NE)	1.650 (0.741, 3.672)	0.2151
Dysphagia	139	9 (6.5)	NR (NE, NE)	129	2 (1.6)	NR (NE, NE)	3.836 (0.827, 17.799)	0.0647
General disorders and administration site conditions	139	9 (6.5)	NR (NE, NE)	129	9 (7.0)	NR (NE, NE)	0.768 (0.295, 1.996)	0.5864
Infections and infestations	139	14 (10.1)	NR (NE, NE)	129	18 (14.0)	NR (NE, NE)	0.546 (0.266, 1.120)	0.0937
Pneumonia	139	10 (7.2)	NR (NE, NE)	129	10 (7.8)	NR (NE, NE)	0.714 (0.292, 1.745)	0.4576
Metabolism and nutrition disorders	139	7 (5.0)	NR (NE, NE)	129	3 (2.3)	NR (NE, NE)	1.074 (0.248, 4.659)	0.9235
Respiratory, thoracic and mediastinal disorders	139	19 (13.7)	NR (NE, NE)	129	10 (7.8)	NR (8.6, NE)	1.426 (0.654, 3.109)	0.3702

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.5.1.b:
Treatment-Emergent Adverse Events (TEAEs) Leading to Treatment Discontinuation by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

System Organ Class Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)
Patients With at Least One TEAE Leading to Treatment Discontinuation	25 (18.0)	28 (21.7)
Respiratory, thoracic and mediastinal disorders	8 (5.8)	6 (4.7)
Immune-mediated pneumonitis	2 (1.4)	0 (0.0)
Pneumonitis	2 (1.4)	2 (1.6)
Dyspnoea	1 (0.7)	0 (0.0)
Lung disorder	1 (0.7)	0 (0.0)
Pulmonary arterial hypertension	1 (0.7)	0 (0.0)
Pulmonary haemorrhage	1 (0.7)	0 (0.0)
Acquired tracheo-oesophageal fistula	0 (0.0)	1 (0.8)
Haemoptysis	0 (0.0)	1 (0.8)
Pleural effusion	0 (0.0)	1 (0.8)
Pneumonia aspiration	0 (0.0)	1 (0.8)

Source: ADSL, ADAE. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = Treatment-Emergent Adverse Event.
Percentages were based on N.
Patients with multiple events for a given preferred term and system organ class were counted only once for the preferred term and system organ class, respectively.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 23.0.
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Table 14.3.1.5.1.b:
Treatment-Emergent Adverse Events (TEAEs) Leading to Treatment Discontinuation by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

System Organ Class Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)
Infections and infestations	6 (4.3)	4 (3.1)
Pneumonia	4 (2.9)	2 (1.6)
Bronchitis	1 (0.7)	0 (0.0)
Sepsis	1 (0.7)	0 (0.0)
Endocarditis	0 (0.0)	1 (0.8)
Septic shock	0 (0.0)	1 (0.8)
Gastrointestinal disorders	4 (2.9)	1 (0.8)
Dysphagia	1 (0.7)	0 (0.0)
Gastrointestinal haemorrhage	1 (0.7)	0 (0.0)
Oesophagomediastinal fistula	1 (0.7)	0 (0.0)
Upper gastrointestinal haemorrhage	1 (0.7)	1 (0.8)

Source: ADSL, ADAE. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = Treatment-Emergent Adverse Event.
Percentages were based on N.
Patients with multiple events for a given preferred term and system organ class were counted only once for the preferred term and system organ class, respectively.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 23.0.
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Table 14.3.1.5.1.b:
Treatment-Emergent Adverse Events (TEAEs) Leading to Treatment Discontinuation by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

System Organ Class Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)
General disorders and administration site conditions	4 (2.9)	6 (4.7)
General physical health deterioration	2 (1.4)	0 (0.0)
Death	1 (0.7)	2 (1.6)
Sudden death	1 (0.7)	1 (0.8)
Asthenia	0 (0.0)	2 (1.6)
Fatigue	0 (0.0)	1 (0.8)
Metabolism and nutrition disorders	2 (1.4)	1 (0.8)
Decreased appetite	1 (0.7)	1 (0.8)
Type 1 diabetes mellitus	1 (0.7)	0 (0.0)
Hepatobiliary disorders	1 (0.7)	0 (0.0)
Bile duct obstruction	1 (0.7)	0 (0.0)
Investigations	1 (0.7)	1 (0.8)
Platelet count decreased	1 (0.7)	0 (0.0)
Neutrophil count decreased	0 (0.0)	1 (0.8)

Source: ADSL, ADAE. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = Treatment-Emergent Adverse Event.
Percentages were based on N.
Patients with multiple events for a given preferred term and system organ class were counted only once for the preferred term and system organ class, respectively.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 23.0.
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Table 14.3.1.5.1.b:
Treatment-Emergent Adverse Events (TEAEs) Leading to Treatment Discontinuation by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

System Organ Class Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.7)	1 (0.8)
Tumour fistulisation	1 (0.7)	0 (0.0)
Tumour haemorrhage	0 (0.0)	1 (0.8)
Blood and lymphatic system disorders	0 (0.0)	4 (3.1)
Febrile neutropenia	0 (0.0)	3 (2.3)
Lymphadenopathy	0 (0.0)	1 (0.8)
Cardiac disorders	0 (0.0)	3 (2.3)
Acute left ventricular failure	0 (0.0)	1 (0.8)
Atrial flutter	0 (0.0)	1 (0.8)
Atrioventricular block	0 (0.0)	1 (0.8)
Cardiac arrest	0 (0.0)	1 (0.8)
Musculoskeletal and connective tissue disorders	0 (0.0)	1 (0.8)
Muscle spasms	0 (0.0)	1 (0.8)

Source: ADSL, ADAE. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = Treatment-Emergent Adverse Event.
Percentages were based on N.
Patients with multiple events for a given preferred term and system organ class were counted only once for the preferred term and system organ class, respectively.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 23.0.
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Table 14.3.1.5.1.b:
Treatment-Emergent Adverse Events (TEAEs) Leading to Treatment Discontinuation by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

System Organ Class Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)
Nervous system disorders	0 (0.0)	2 (1.6)
Hypoaesthesia	0 (0.0)	1 (0.8)
Peripheral sensory neuropathy	0 (0.0)	1 (0.8)

Source: ADSL, ADAE. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = Treatment-Emergent Adverse Event.
Percentages were based on N.
Patients with multiple events for a given preferred term and system organ class were counted only once for the preferred term and system organ class, respectively.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 23.0.
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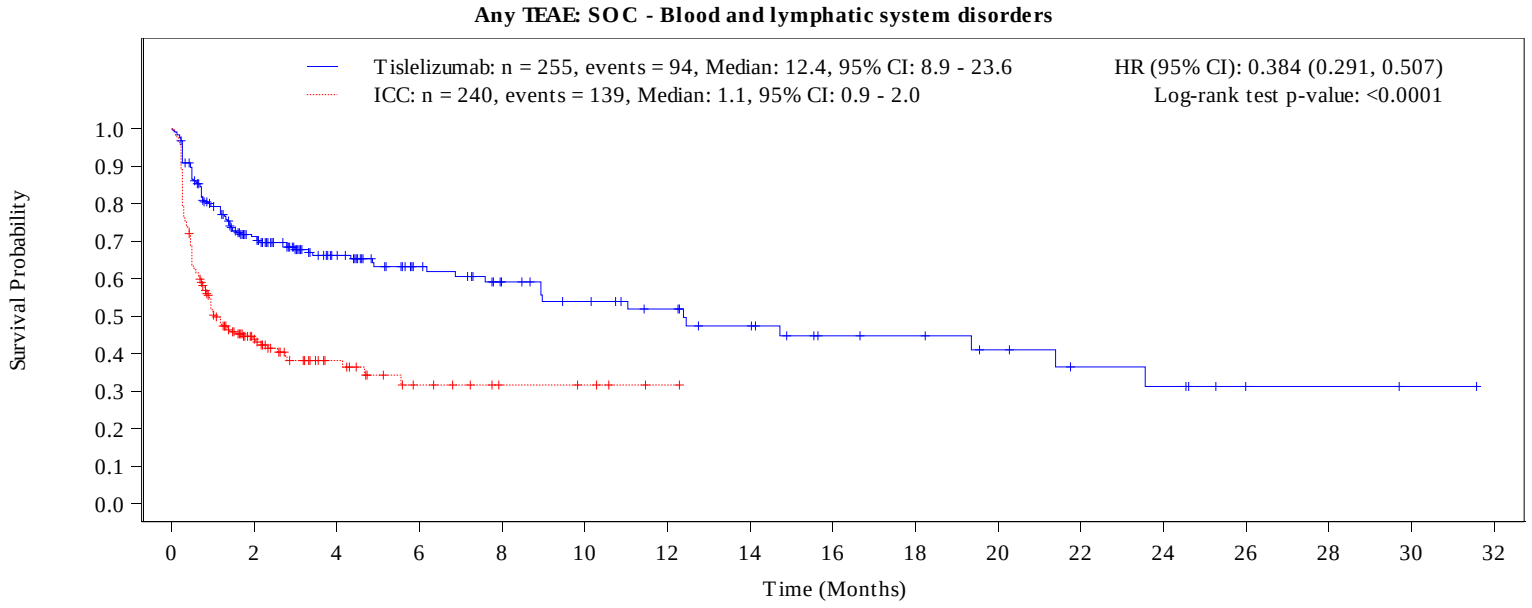
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

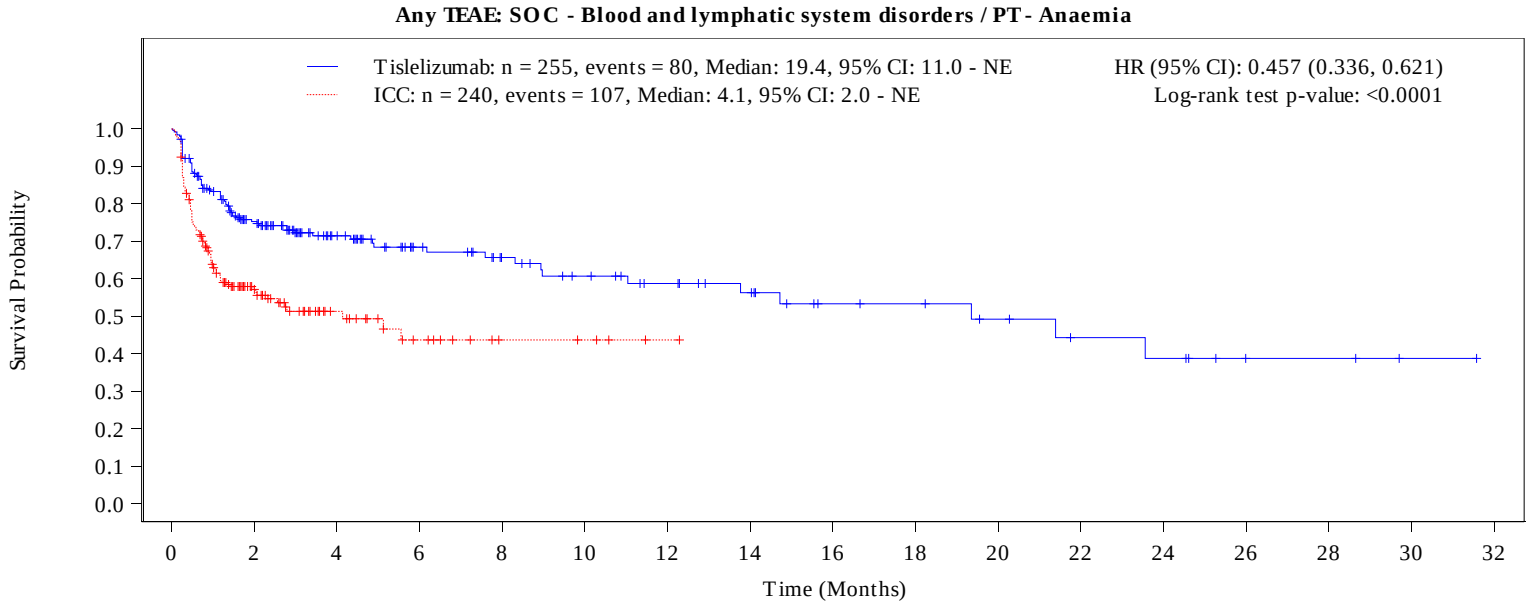


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	134	77	49	36	30	25	20	14	13	10	7	6	2	2	1	0
ICC	240	58	22	10	5	4	1	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-km-aesocpt-safety-sa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	141	81	53	41	34	28	23	15	14	11	8	7	3	3	1	0
ICC	240	74	26	12	5	4	1	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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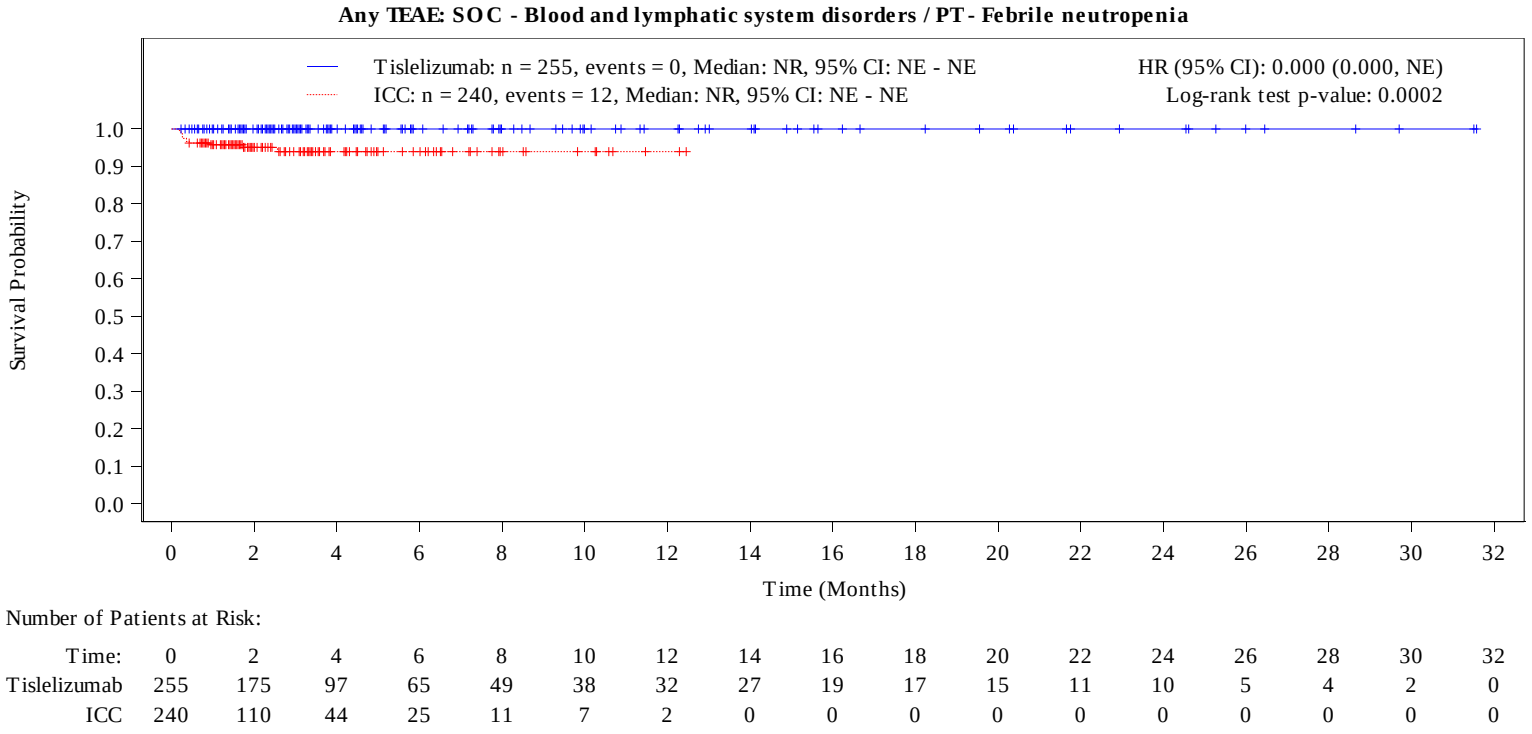
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	175	97	65	49	38	32	27	19	17	15	11	10	5	4	2	0
ICC	240	110	44	25	11	7	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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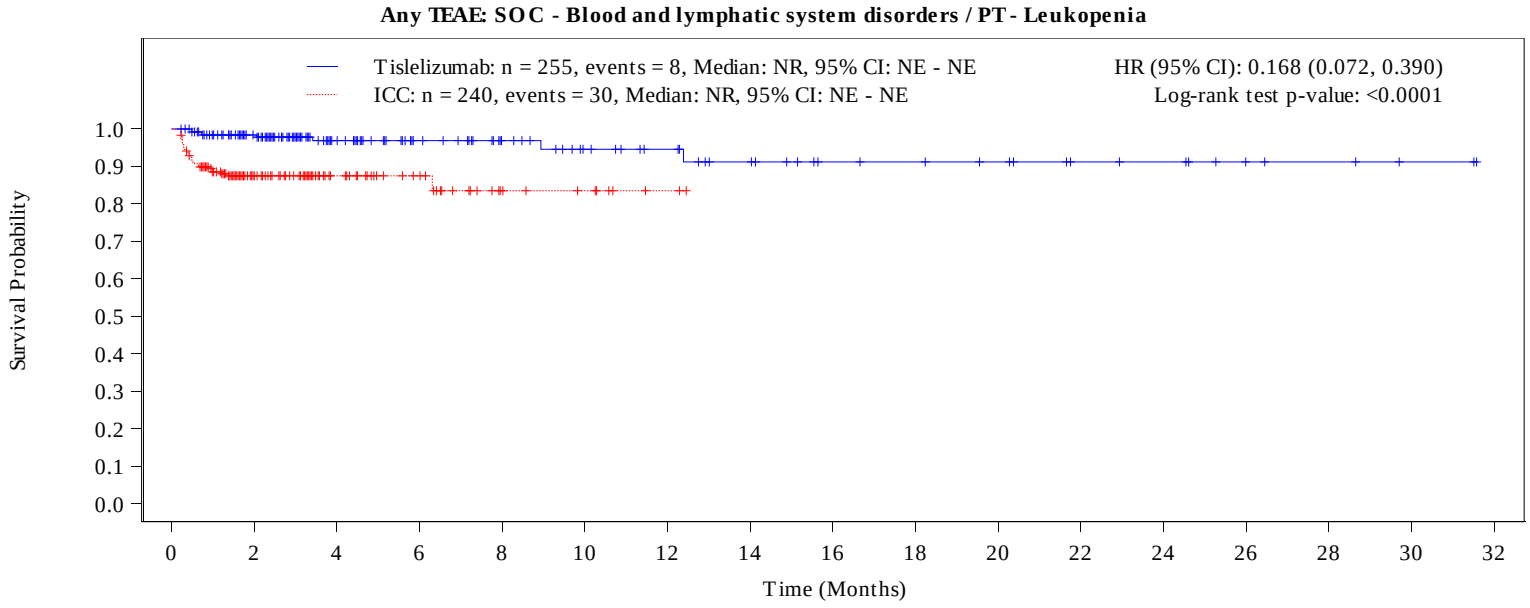
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

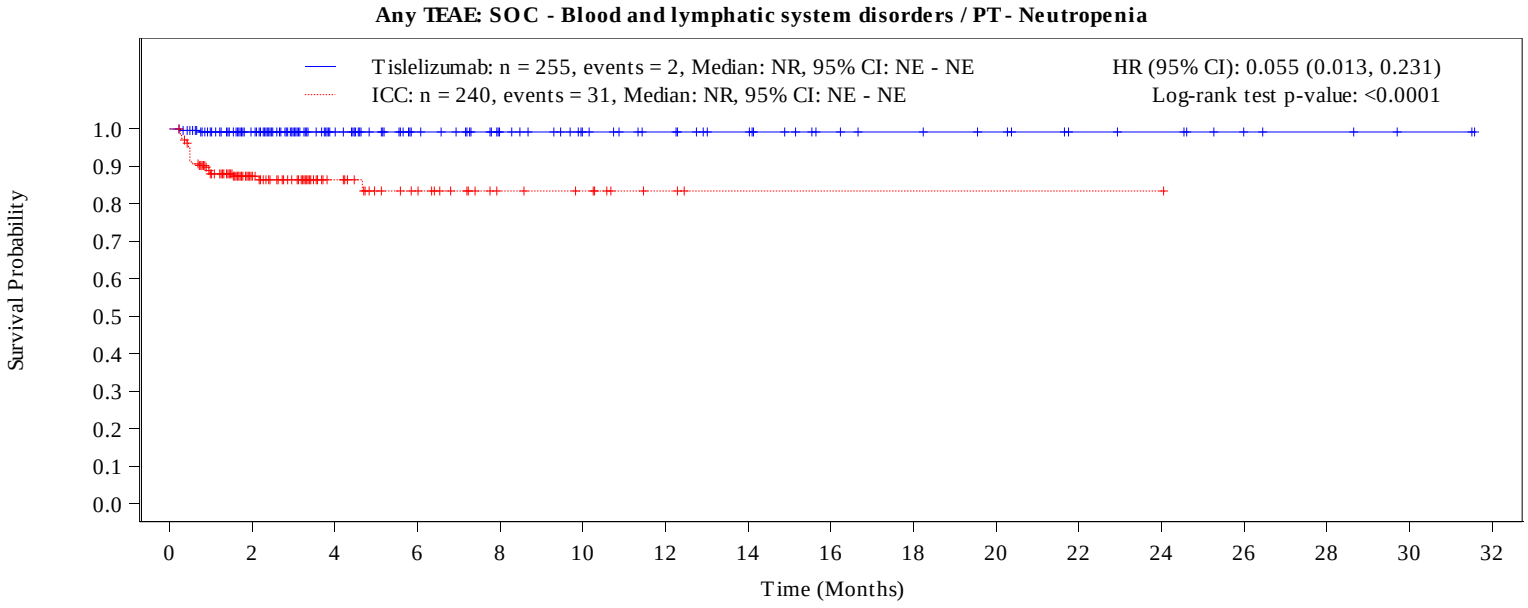


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	171	94	62	46	35	30	24	18	17	15	11	10	5	4	2	0
ICC	240	101	40	24	10	7	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-km-aesocpt-safety-sa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

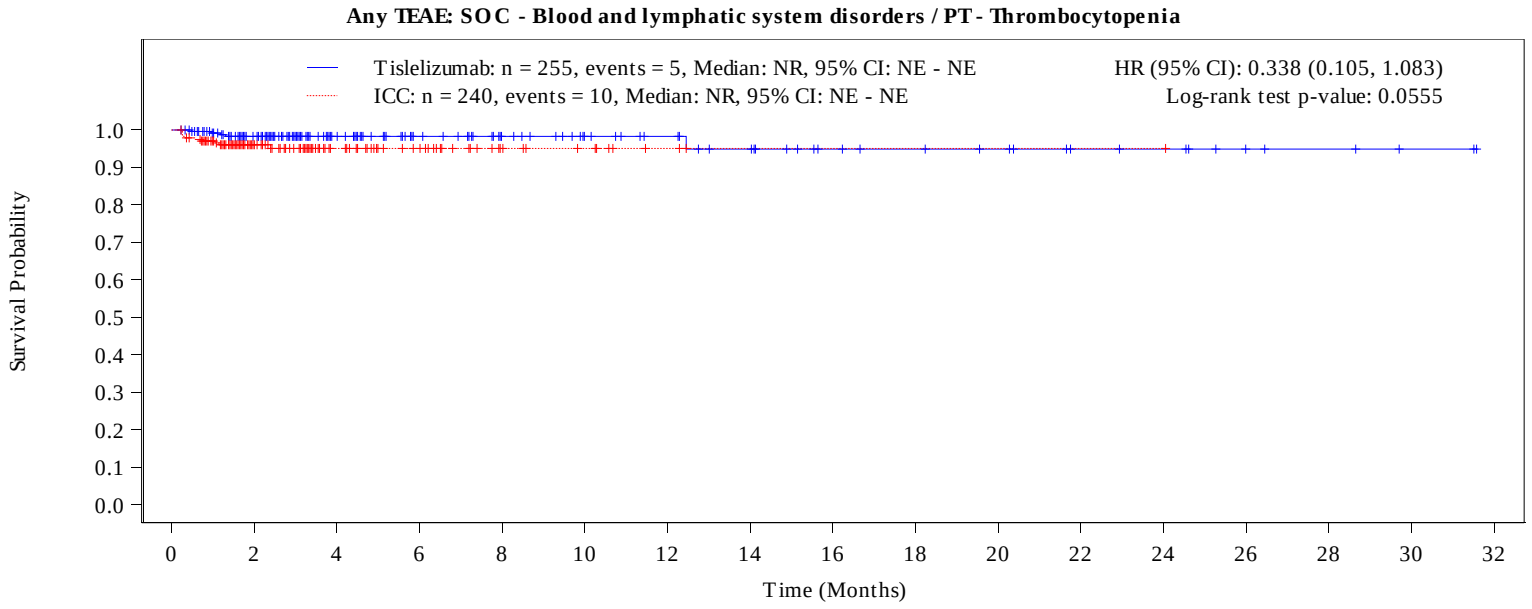


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	174	96	64	48	37	31	26	19	17	15	11	10	5	4	2	0
ICC	240	96	35	20	10	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-km-aesocpt-safety-sa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	172	96	64	48	37	31	26	19	17	15	11	10	5	4	2	0
ICC	240	112	44	26	12	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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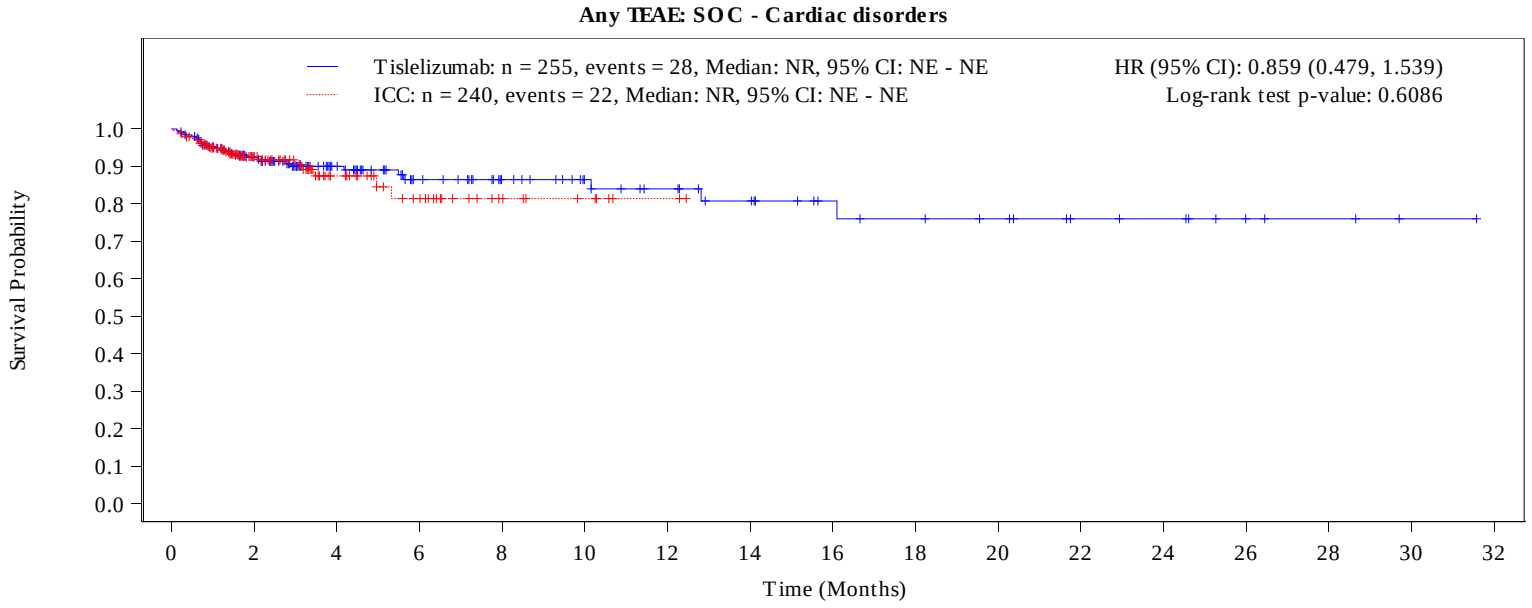
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	167	94	61	46	35	29	24	17	15	13	9	8	4	3	1	0
ICC	240	108	40	22	10	6	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-km-aesocpt-safety-sa.rtf

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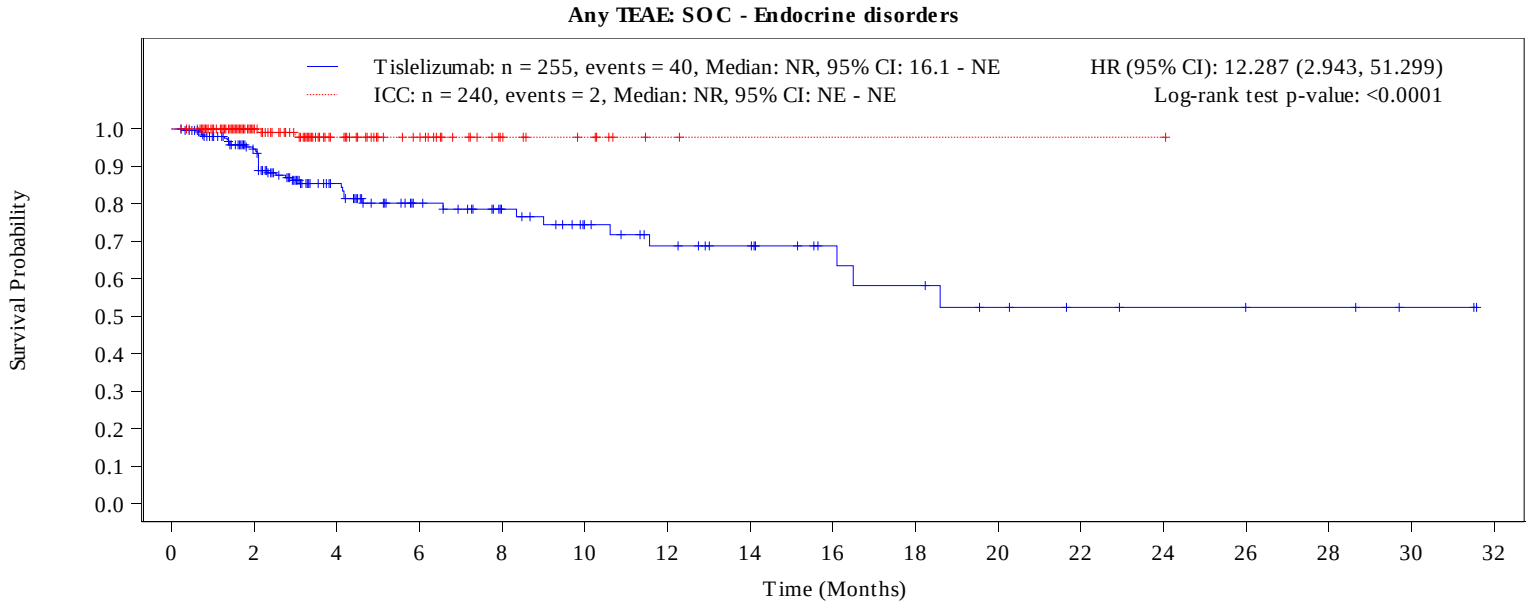
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	166	85	51	39	29	23	19	13	11	8	6	5	4	4	2	0
ICC	240	113	44	25	11	7	2	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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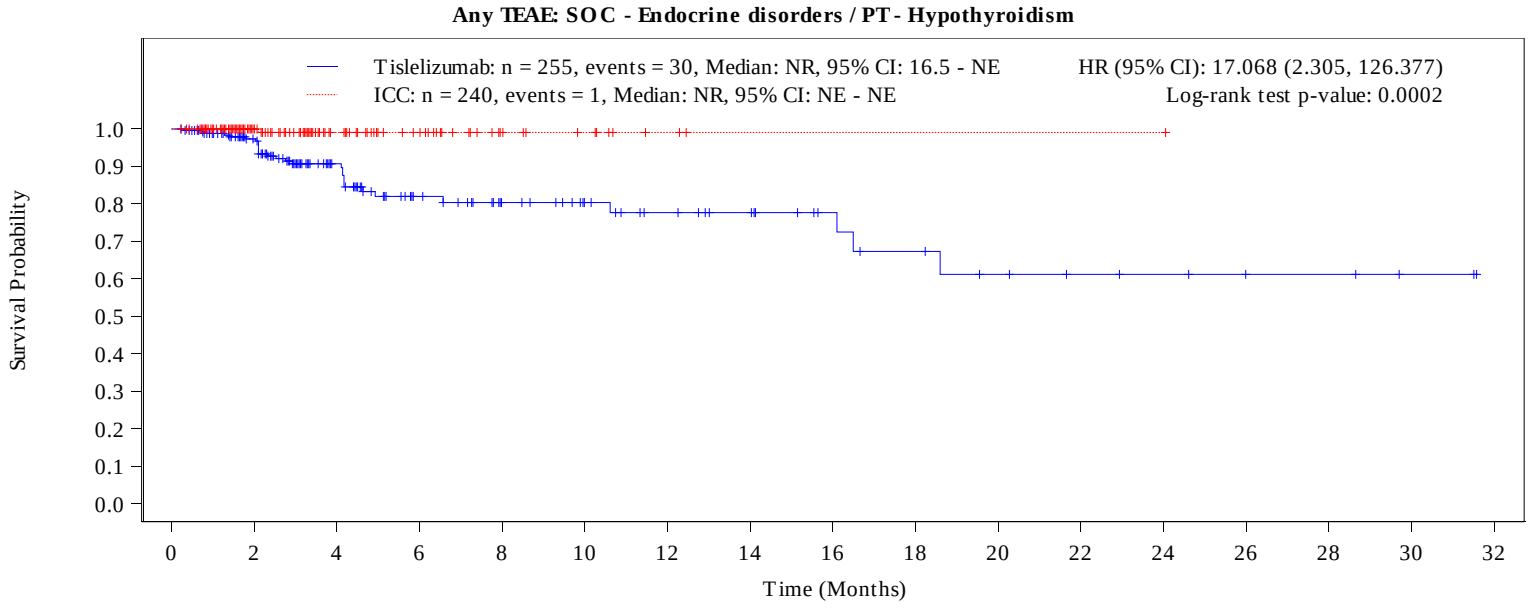
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	171	88	51	39	31	25	21	15	12	9	7	6	4	4	2	0
ICC	240	113	45	26	12	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-km-aesocpt-safety-sa.rtf

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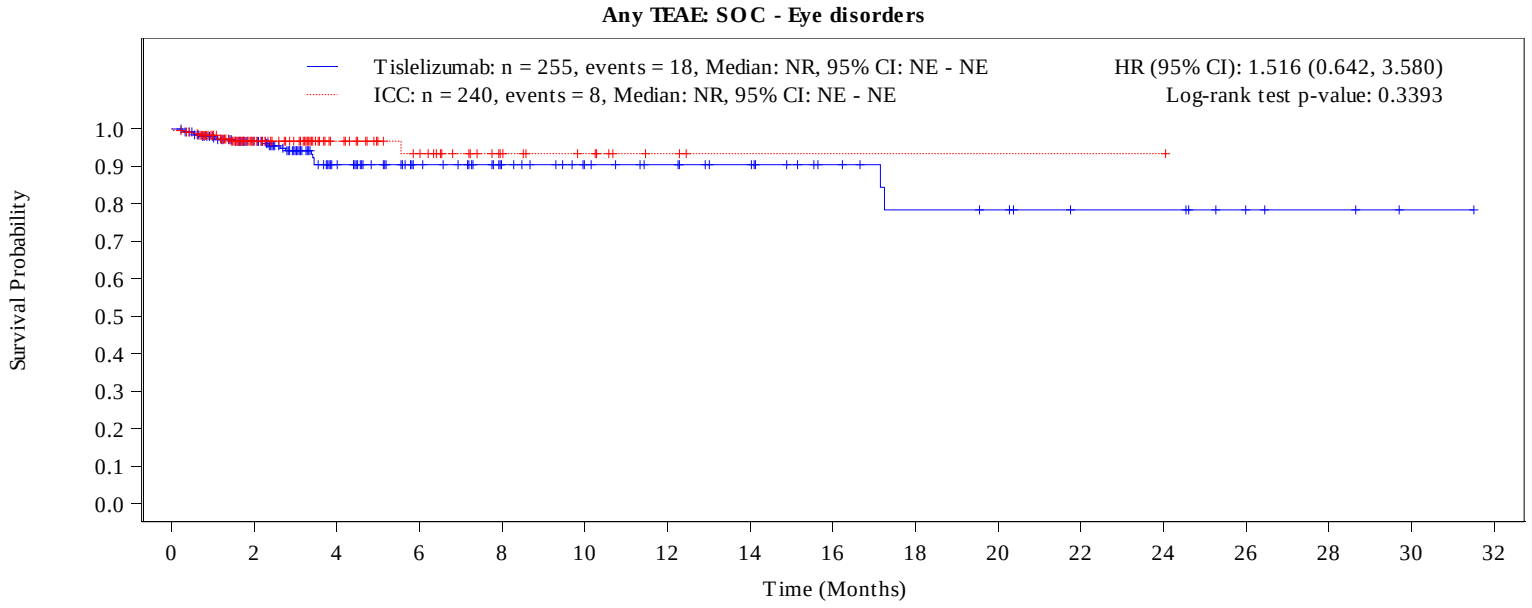
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	172	88	60	44	34	29	25	17	13	12	9	9	4	3	1	0
ICC	240	109	42	25	12	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-km-aesocpt-safety-sa.rtf

Figure 14.3.1.2:
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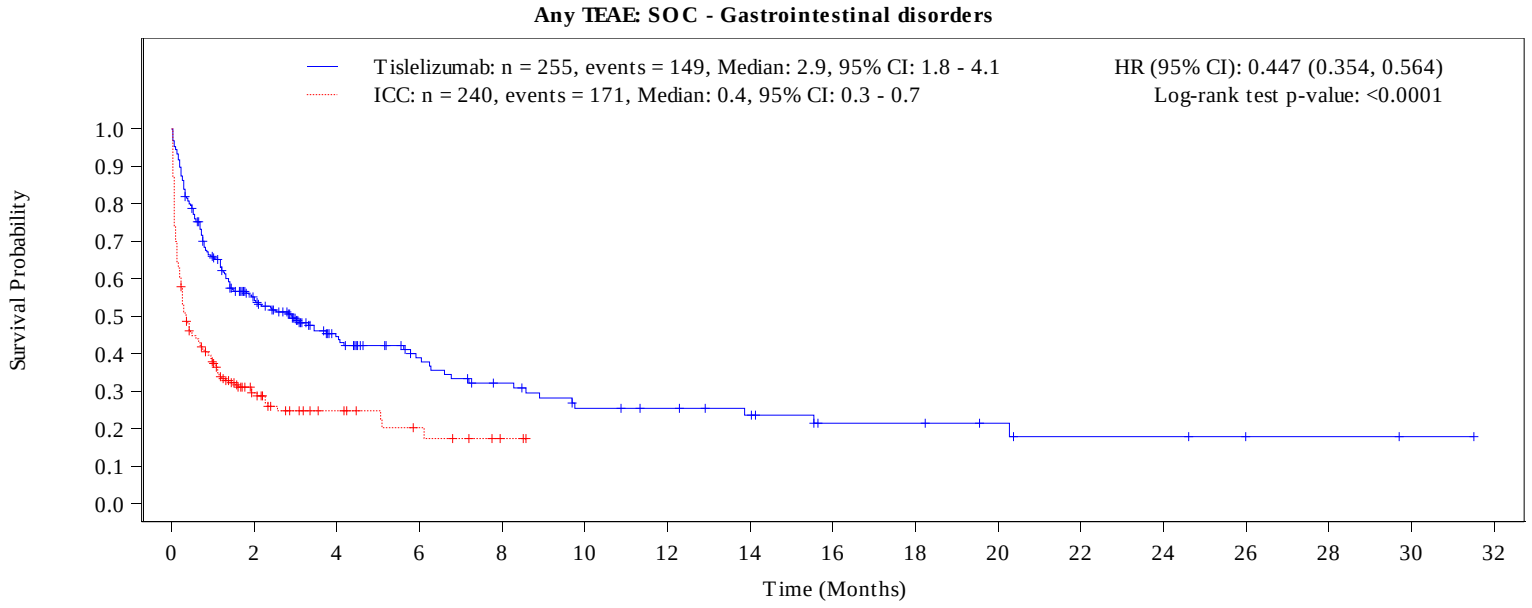
Safety Analysis Set

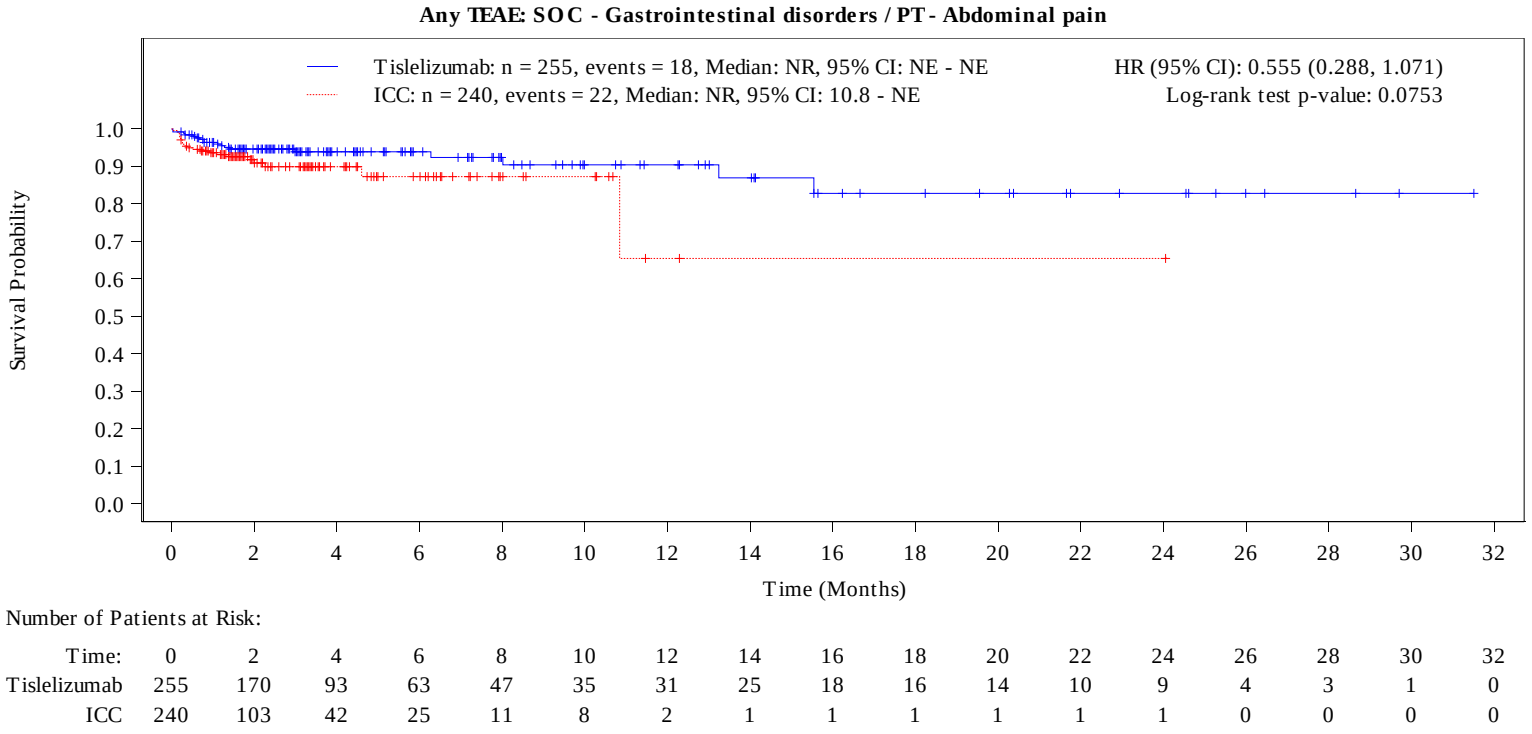


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	112	56	35	25	18	16	13	8	8	6	4	4	2	2	1	0
ICC	240	36	15	7	2	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-km-aesocpt-safety-sa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	170	93	63	47	35	31	25	18	16	14	10	9	4	3	1	0
ICC	240	103	42	25	11	8	2	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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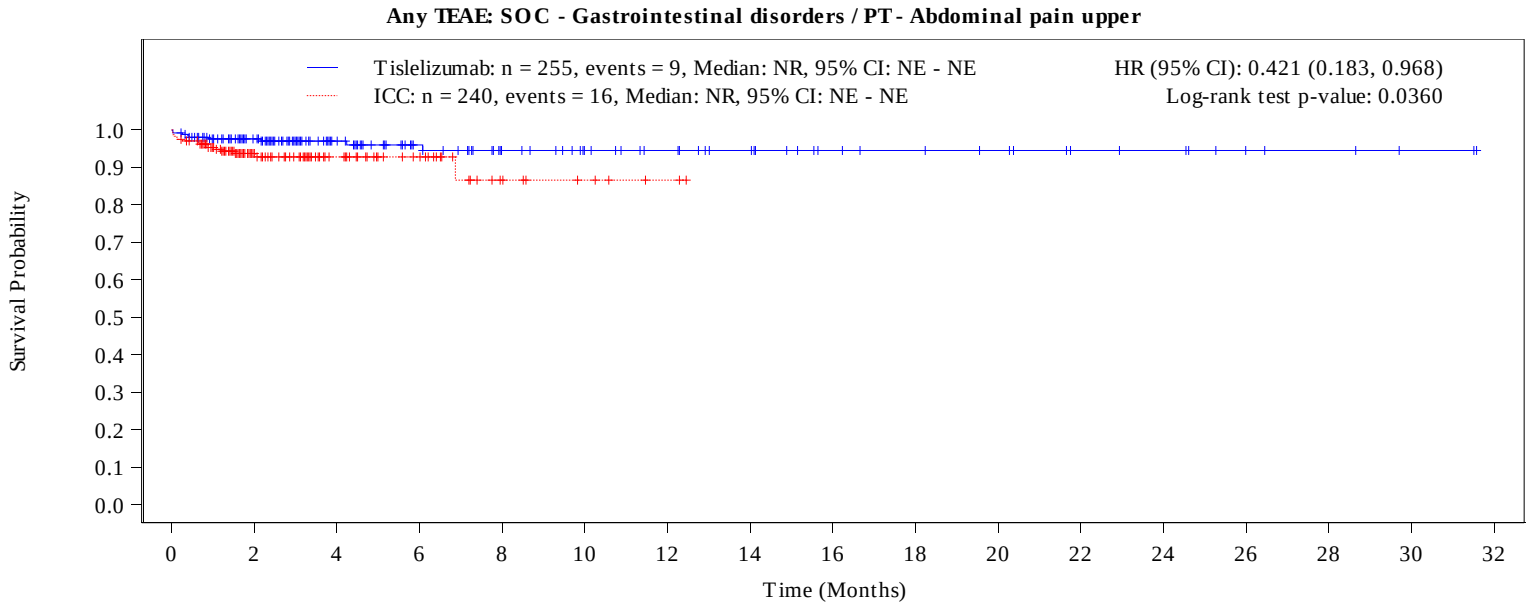
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	170	96	65	48	38	32	27	19	17	15	11	10	5	4	2	0
ICC	240	104	41	23	9	5	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-km-aesocpt-safety-sa.rtf

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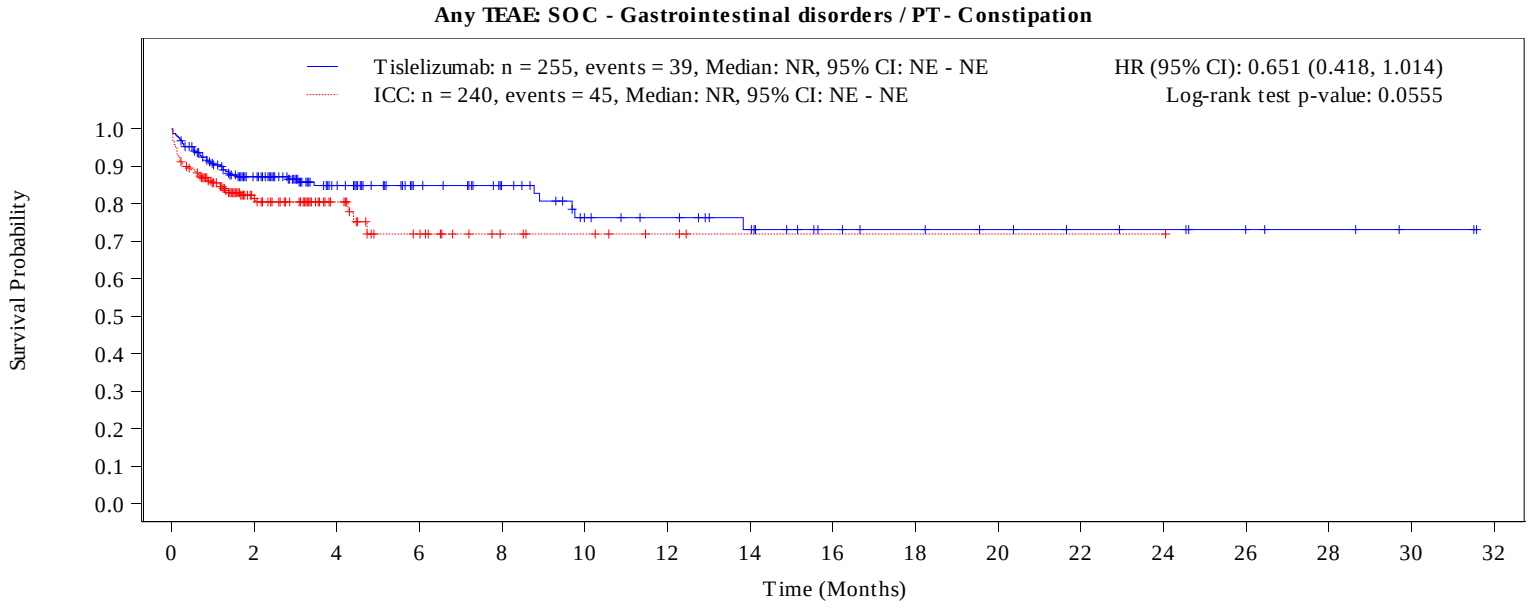
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	157	86	59	45	32	28	23	16	14	12	10	9	5	4	2	0
ICC	240	92	34	17	8	6	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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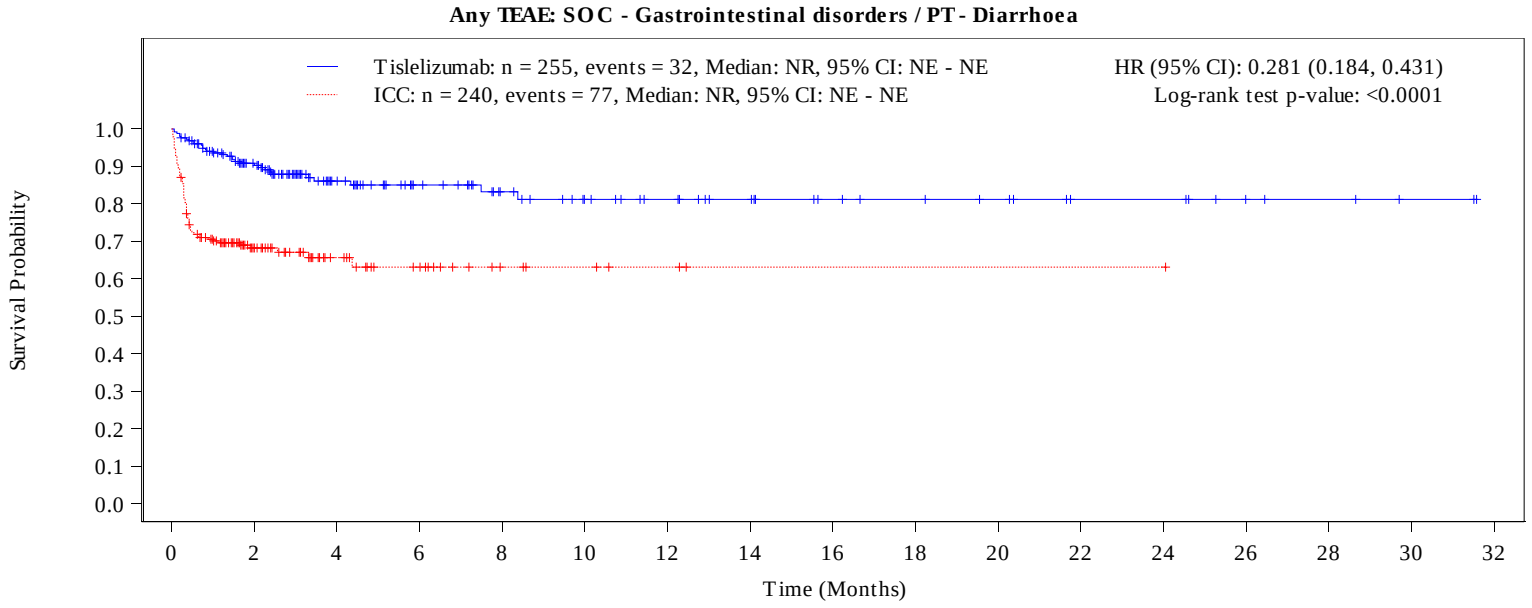
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	159	84	56	42	34	29	24	18	16	14	10	10	5	4	2	0
ICC	240	80	29	16	7	5	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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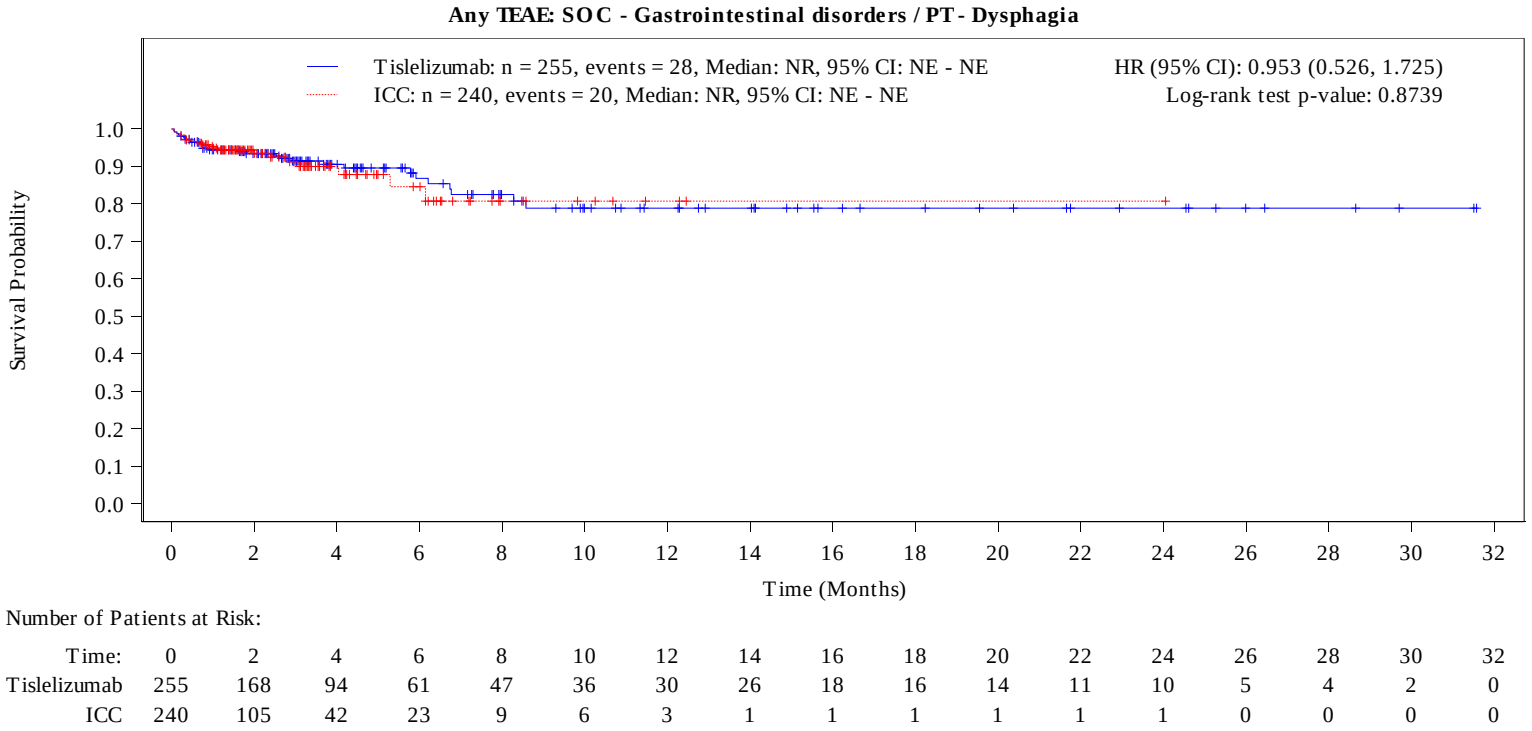
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	168	94	61	47	36	30	26	18	16	14	11	10	5	4	2	0
ICC	240	105	42	23	9	6	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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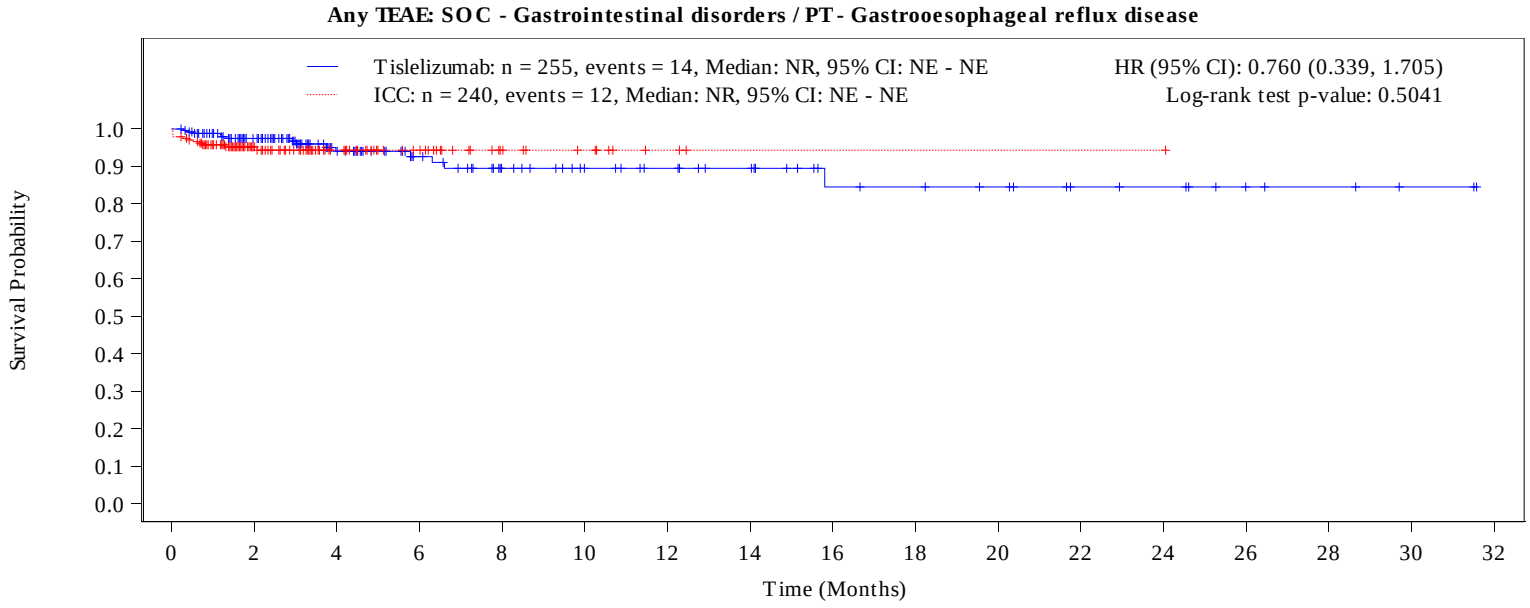

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	170	93	61	45	35	30	26	17	16	14	10	9	5	4	2	0
ICC	240	108	44	25	12	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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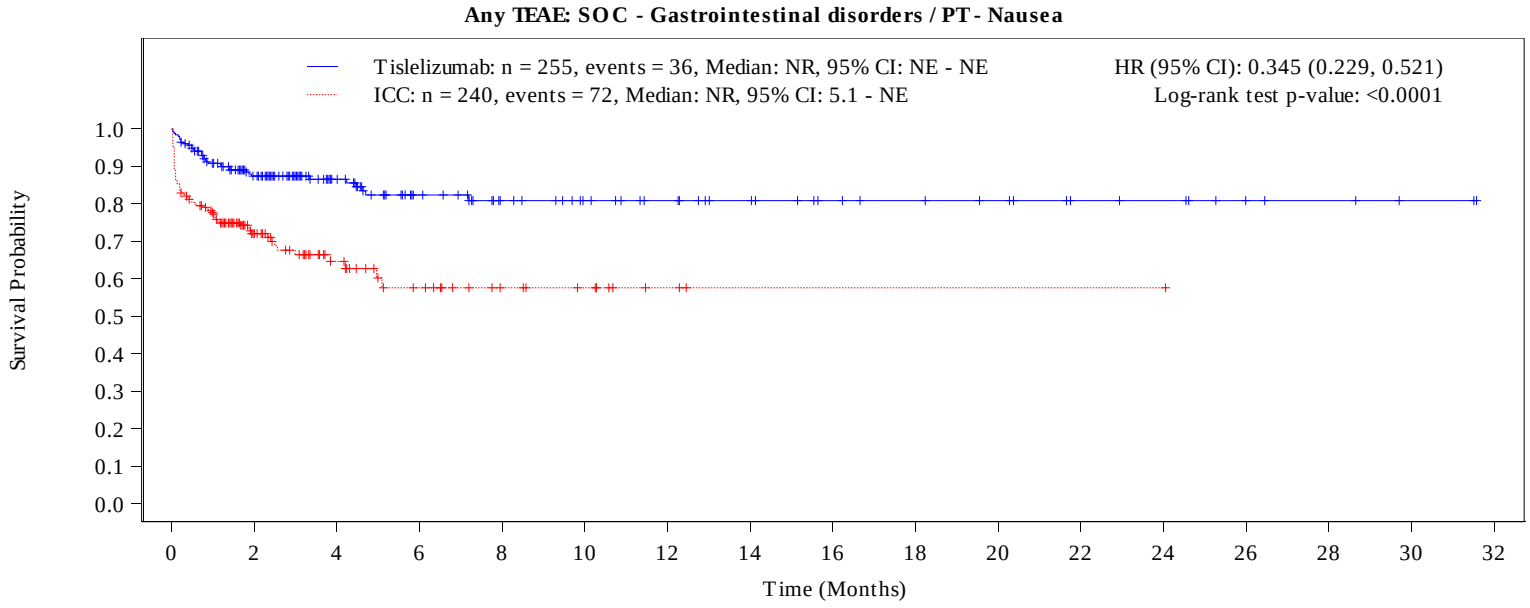

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	159	91	60	45	36	30	25	19	17	15	11	10	5	4	2	0
ICC	240	85	35	19	11	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-km-aesocpt-safety-sa.rtf

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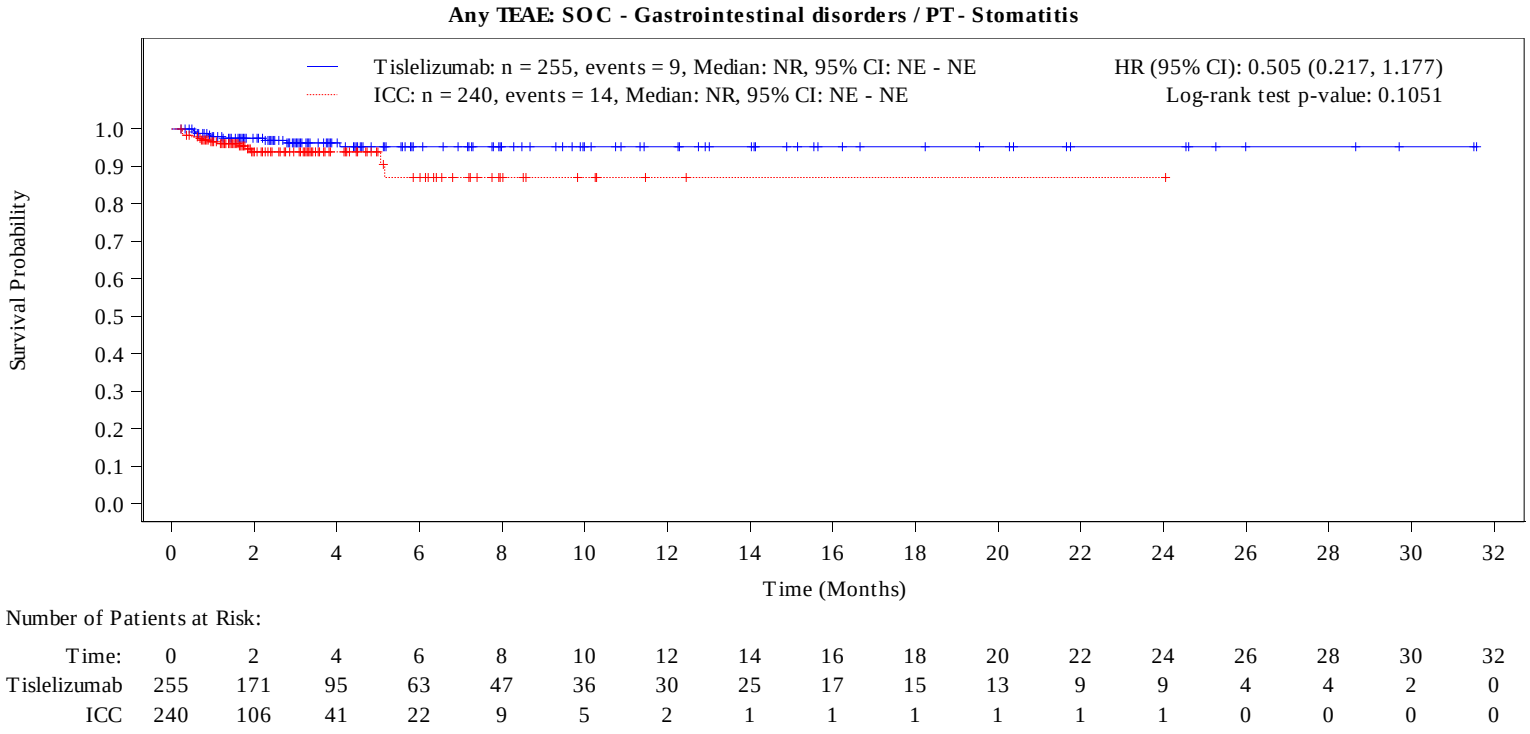

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-km-aesocpt-safety-sa.rtf

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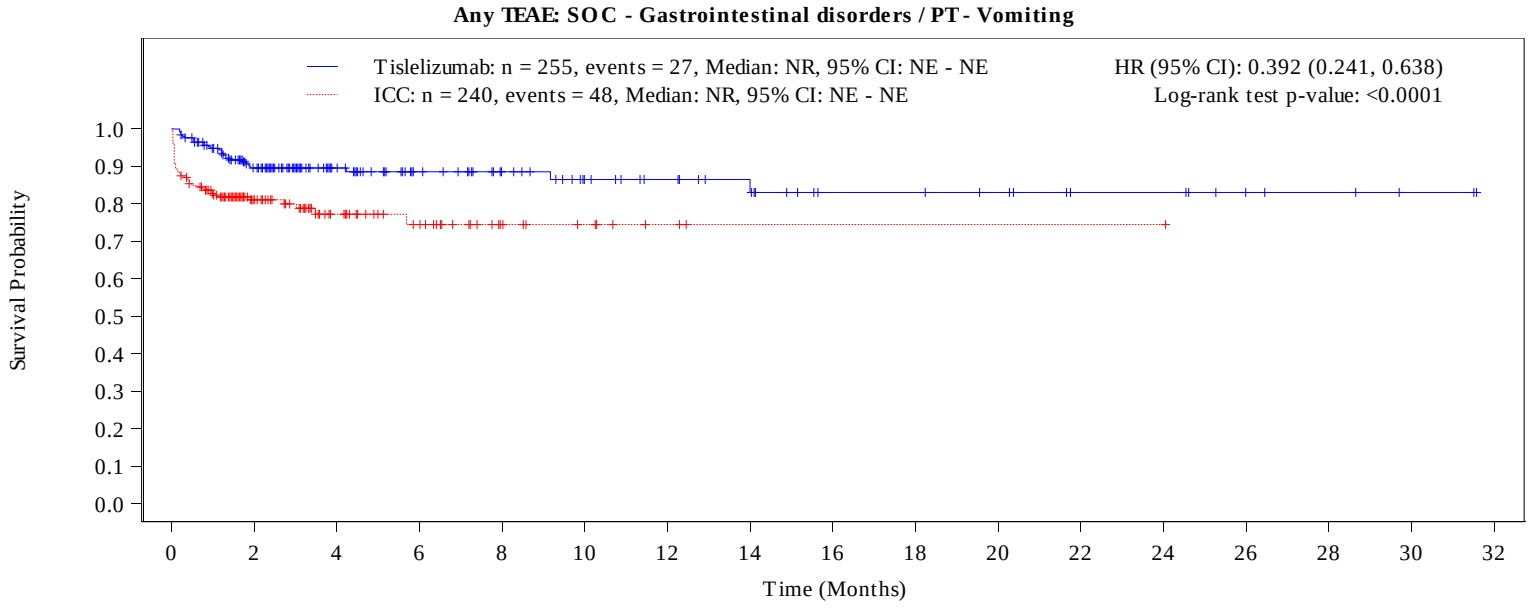

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	162	91	61	47	35	29	24	16	16	14	10	10	5	4	2	0
ICC	240	97	40	24	11	7	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-km-aesocpt-safety-sa.rtf

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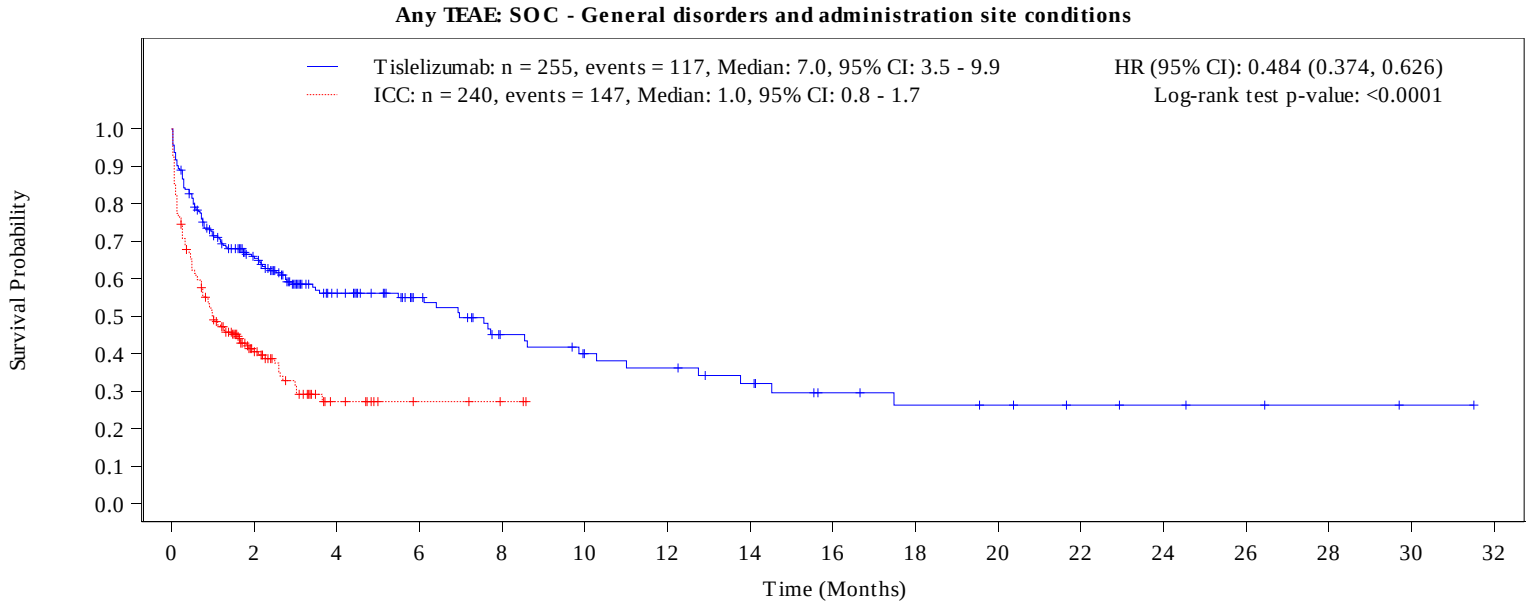

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	123	65	42	27	21	19	15	10	8	7	5	4	3	2	1	0
ICC	240	49	11	4	2	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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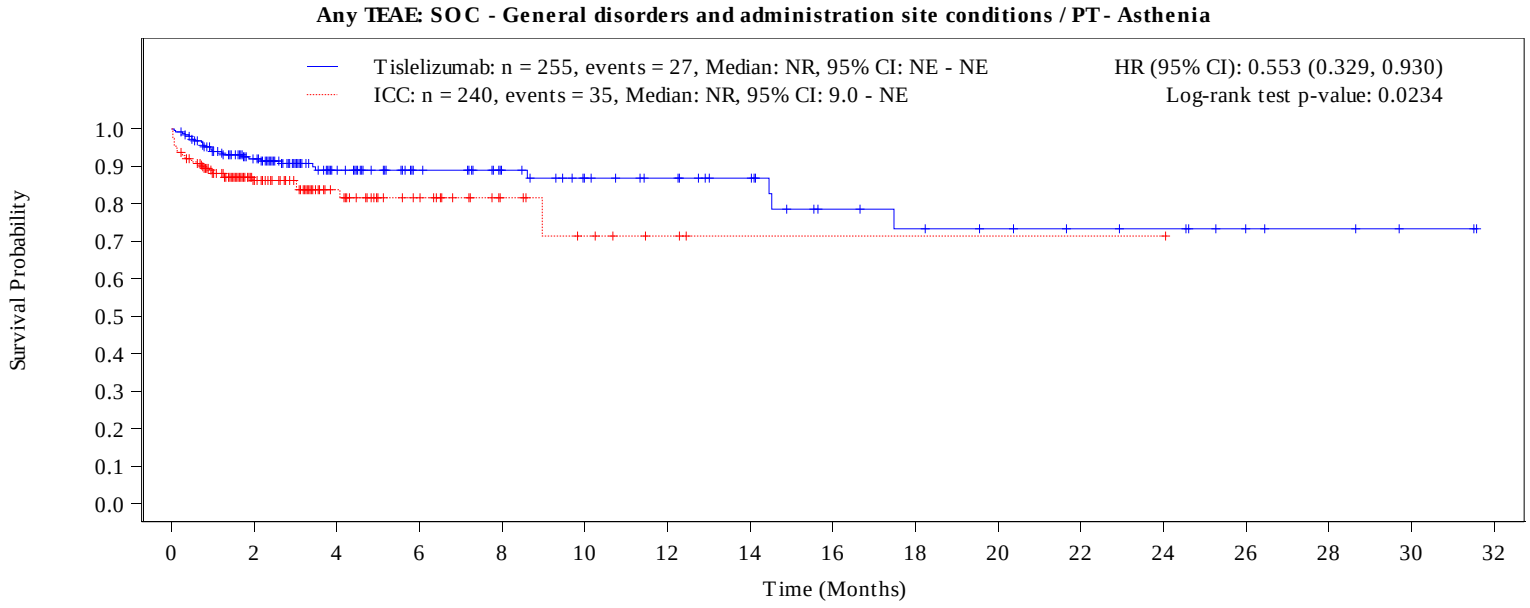
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	163	90	58	44	35	30	25	16	14	12	10	9	5	4	2	0
ICC	240	101	39	21	10	6	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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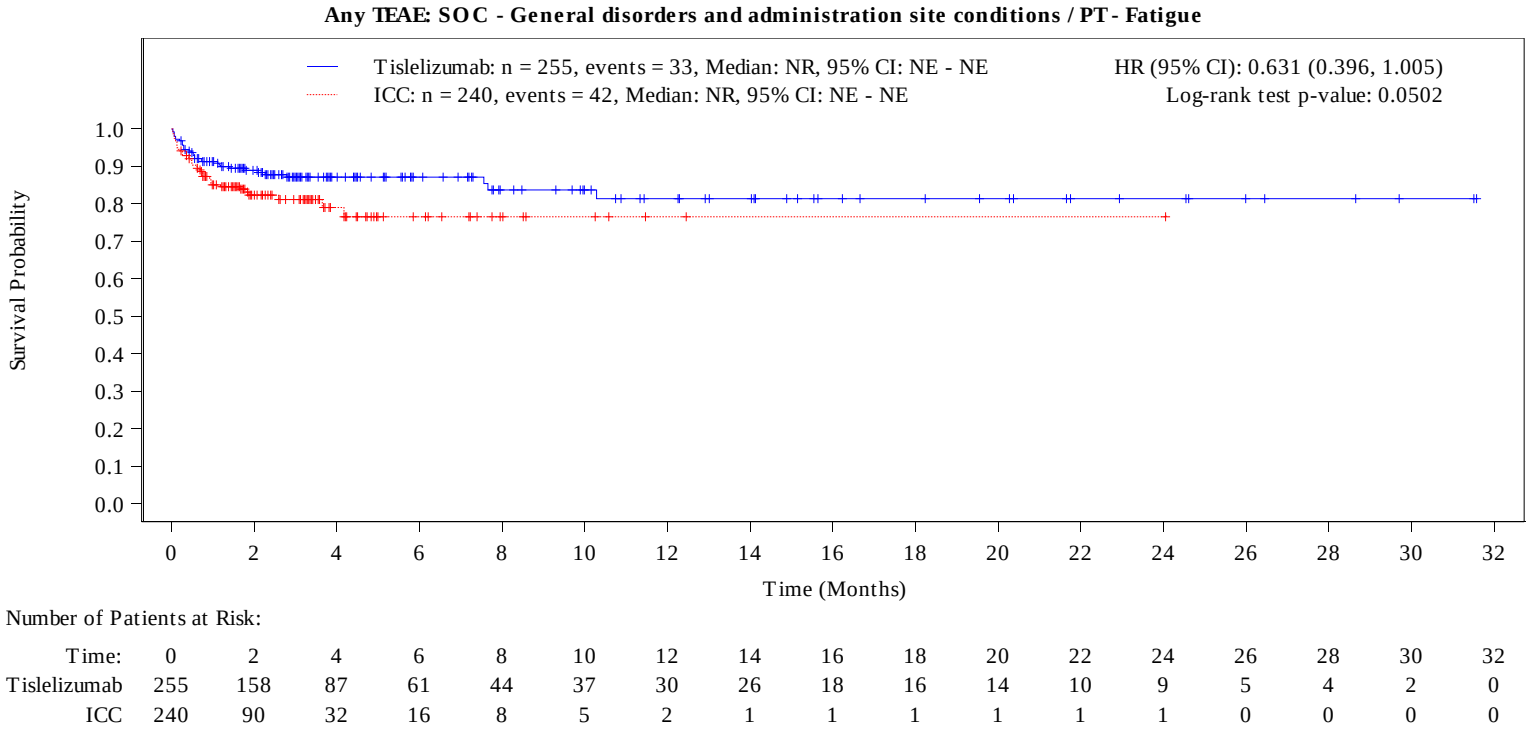
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	158	87	61	44	37	30	26	18	16	14	10	9	5	4	2	0
ICC	240	90	32	16	8	5	2	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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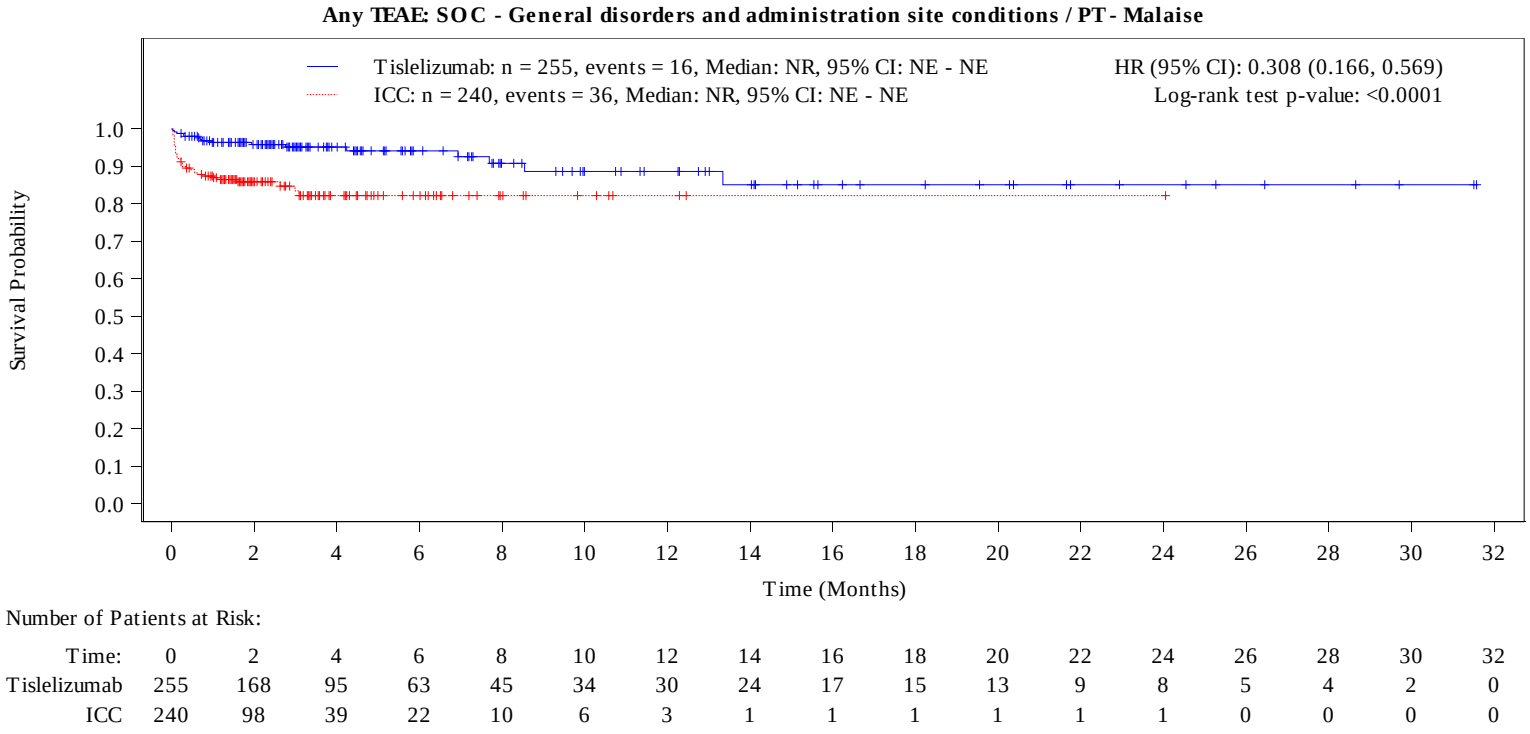
Safety Analysis Set



Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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Figure 14.3.1.2:
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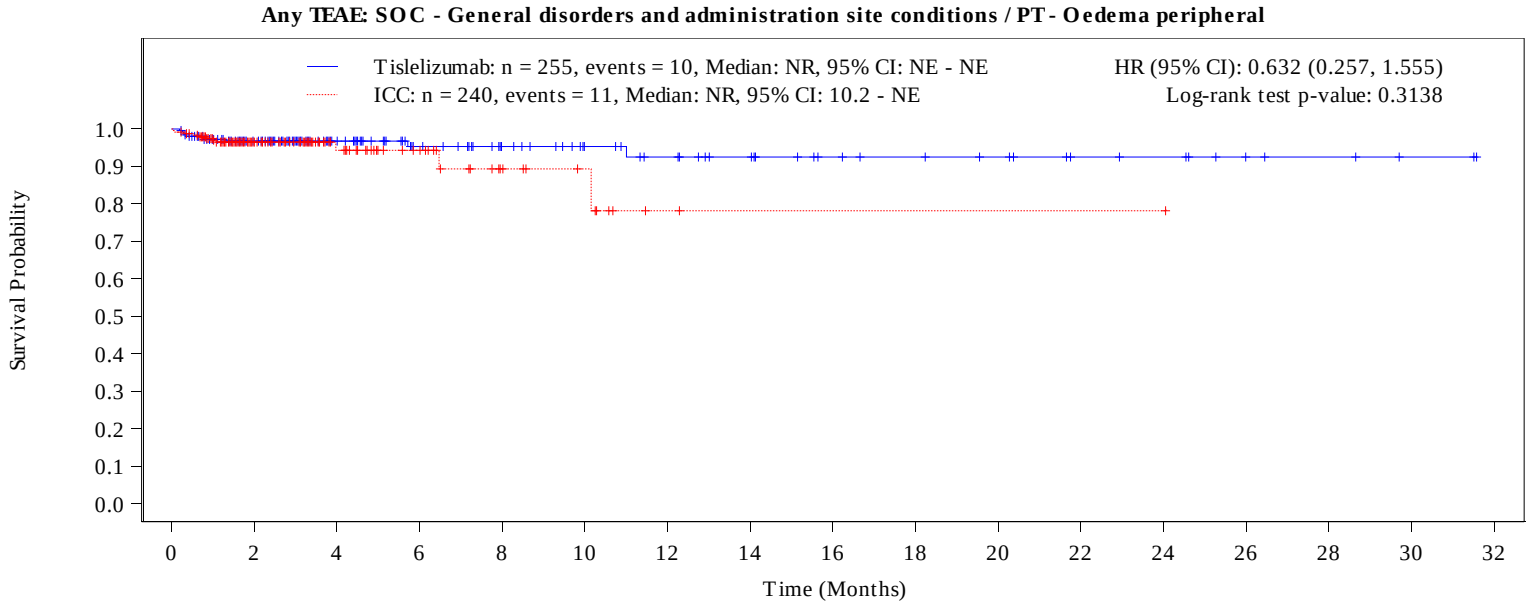
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	170	94	62	47	36	30	25	19	17	15	11	10	5	4	2	0
ICC	240	109	43	24	12	8	2	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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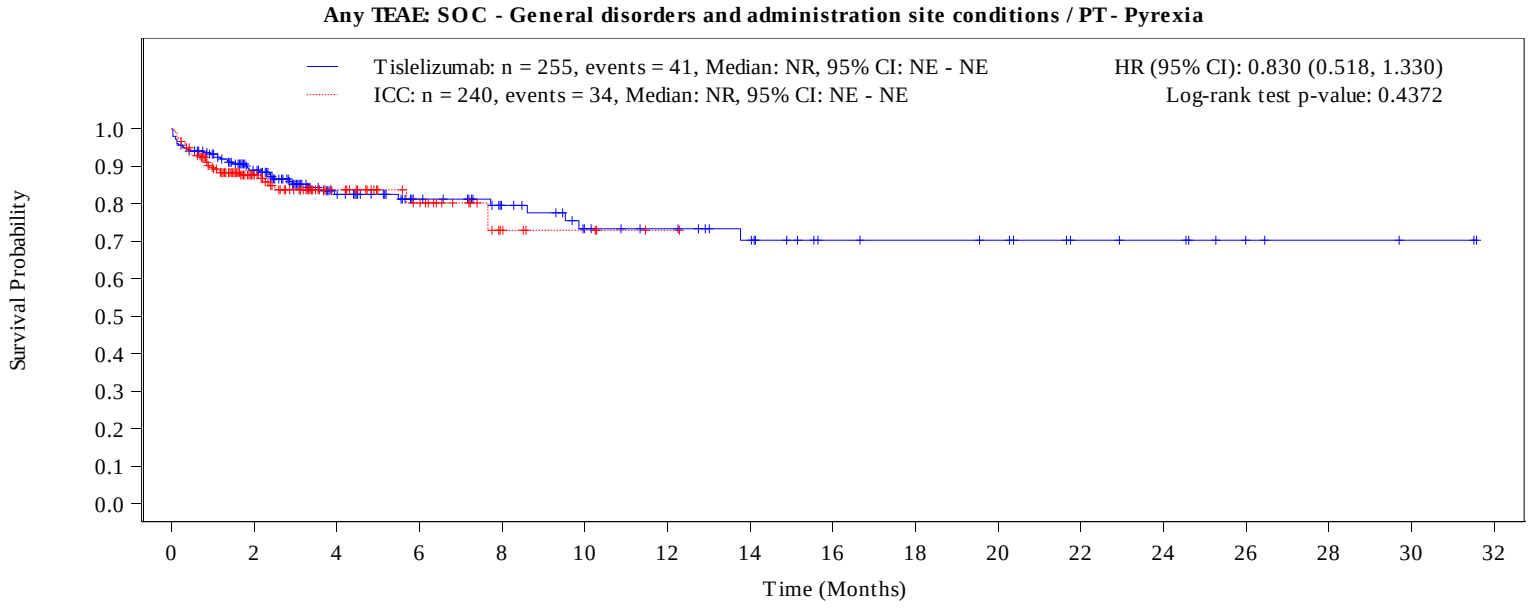
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	159	85	58	43	32	28	23	16	15	14	10	9	4	3	2	0
ICC	240	102	37	21	7	4	1	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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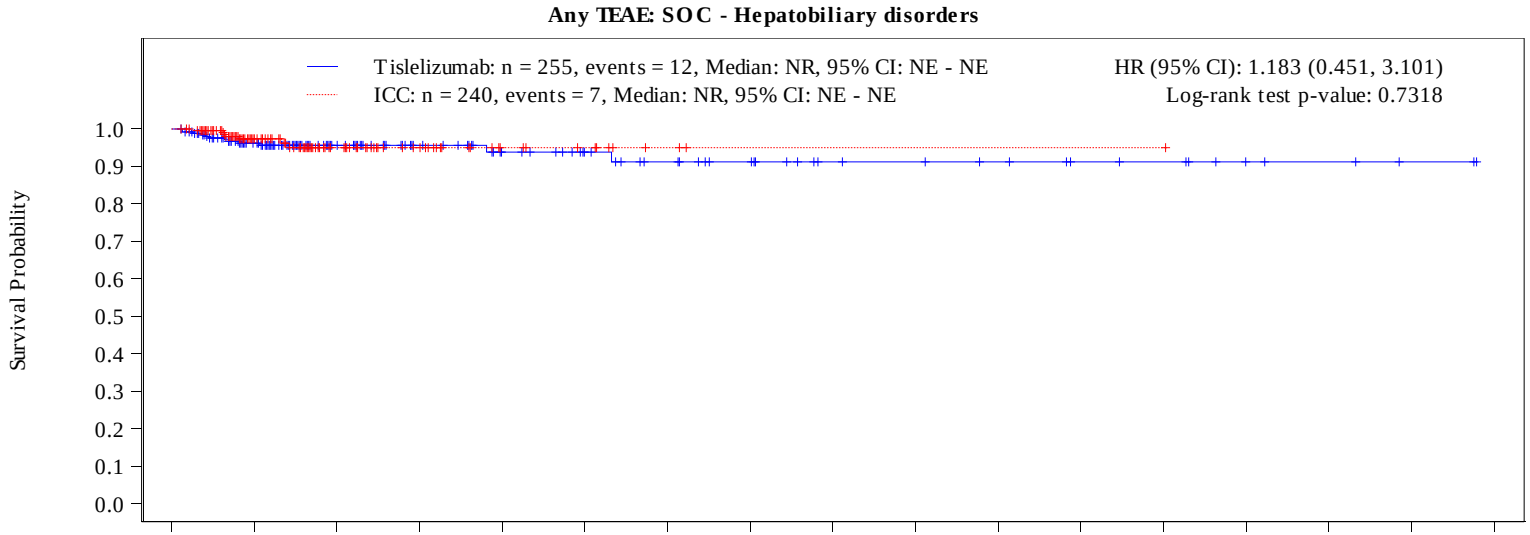
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	170	94	63	47	37	30	25	17	16	14	11	10	5	4	2	0
ICC	240	111	42	23	11	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-km-aesocpt-safety-sa.rtf

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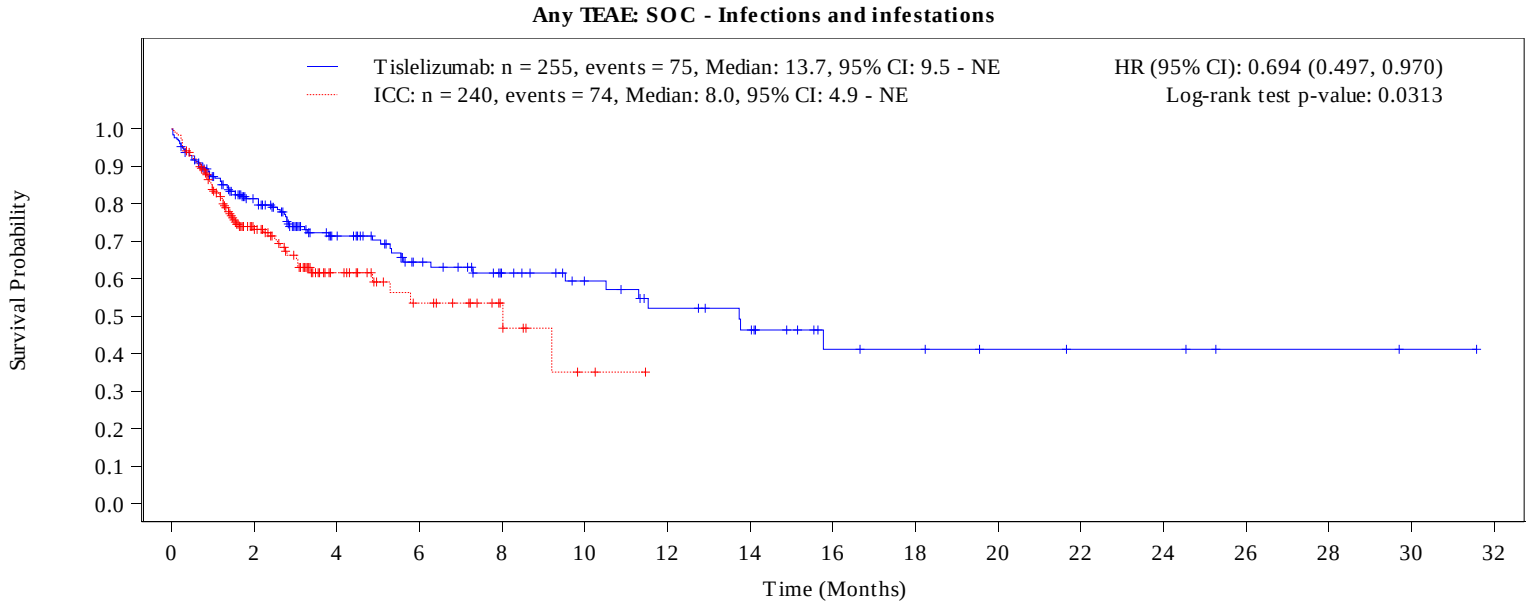
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	145	78	48	35	26	20	16	8	7	5	4	4	2	2	1	0
ICC	240	94	32	17	8	2	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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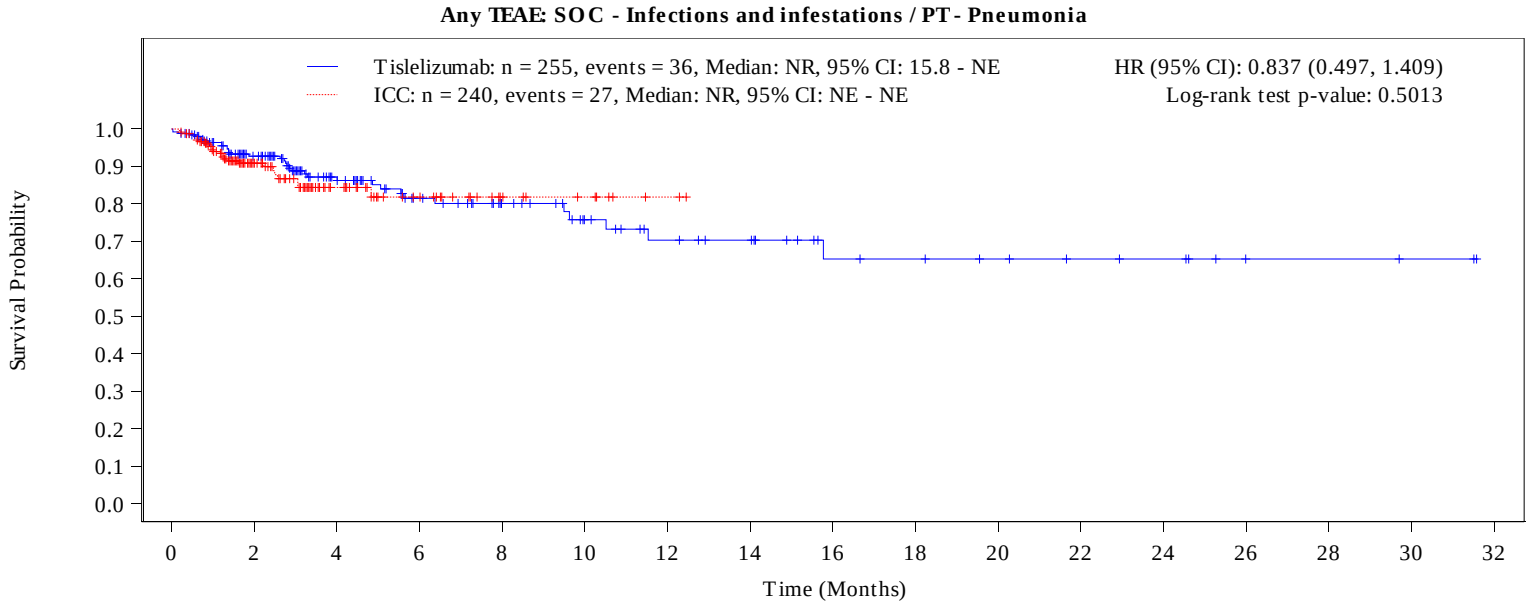
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	166	94	60	44	31	24	21	13	12	10	8	7	3	3	2	0
ICC	240	110	43	23	11	7	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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Figure 14.3.1.2:
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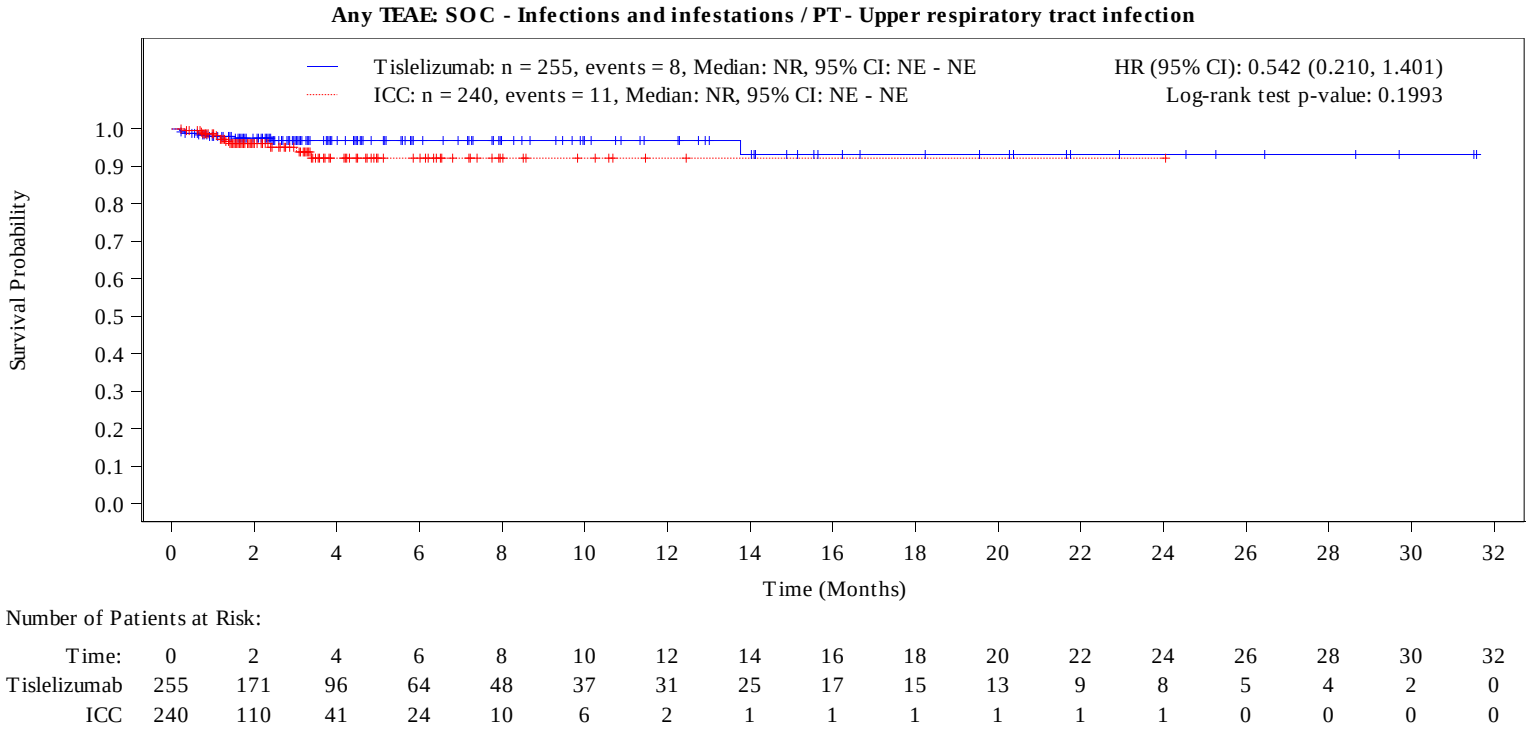
Safety Analysis Set



Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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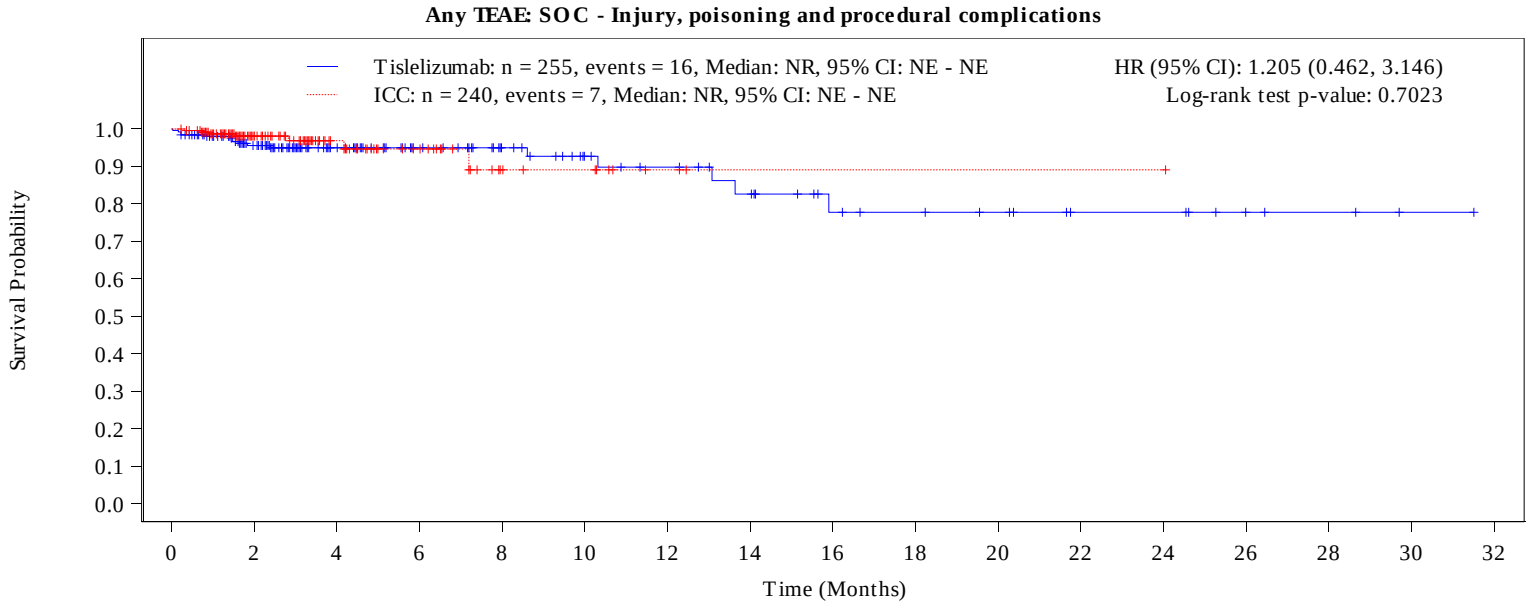
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

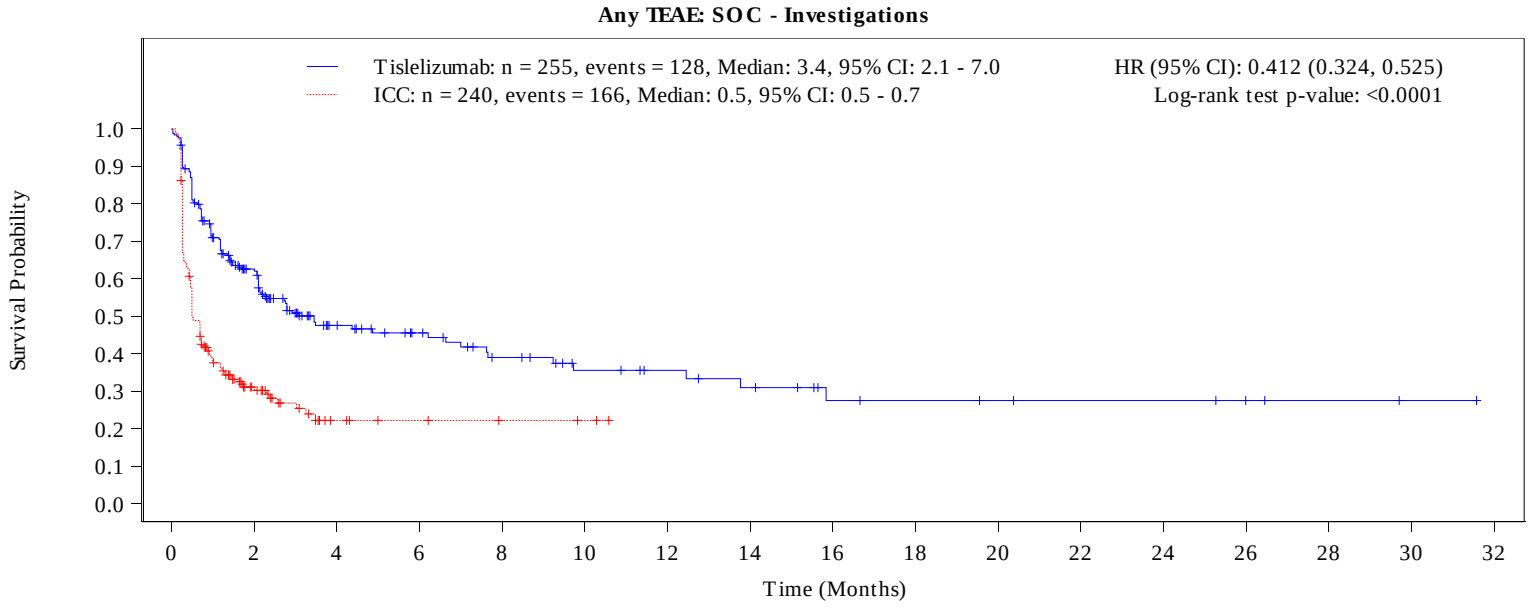


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	167	93	61	45	33	28	23	16	14	12	8	8	4	3	1	0
ICC	240	110	44	24	10	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-km-aesocpt-safety-sa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	113	52	38	27	19	16	13	8	7	6	5	5	3	2	1	0
ICC	240	35	8	5	3	2	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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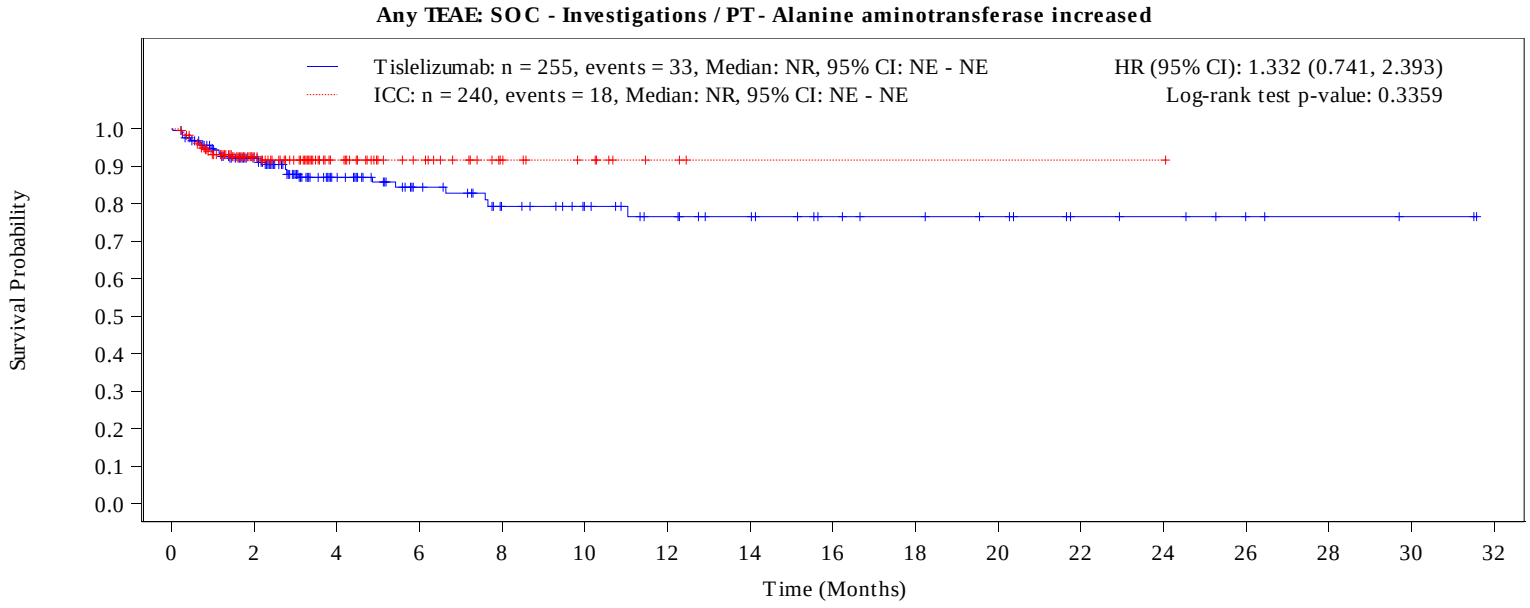

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	165	85	55	40	32	25	21	16	14	12	8	7	4	3	2	0
ICC	240	110	42	23	12	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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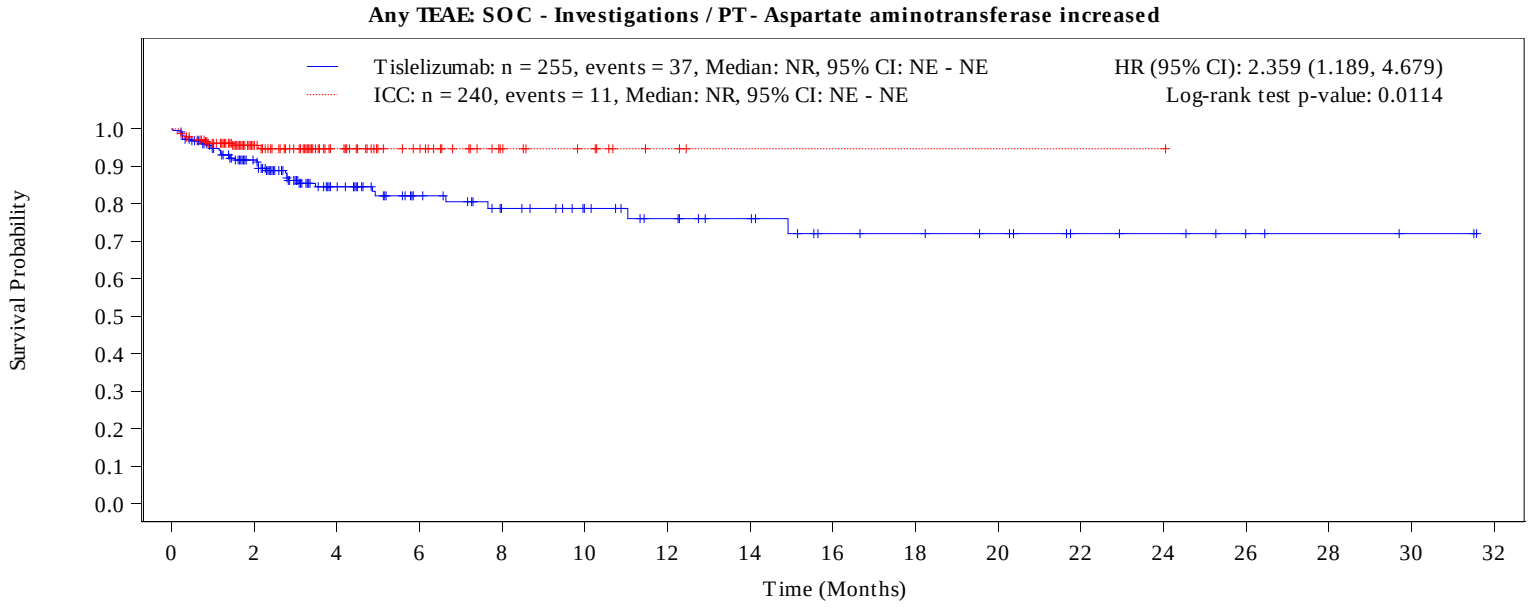
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	165	85	54	41	32	25	21	15	14	12	8	7	4	3	2	0
ICC	240	112	44	25	12	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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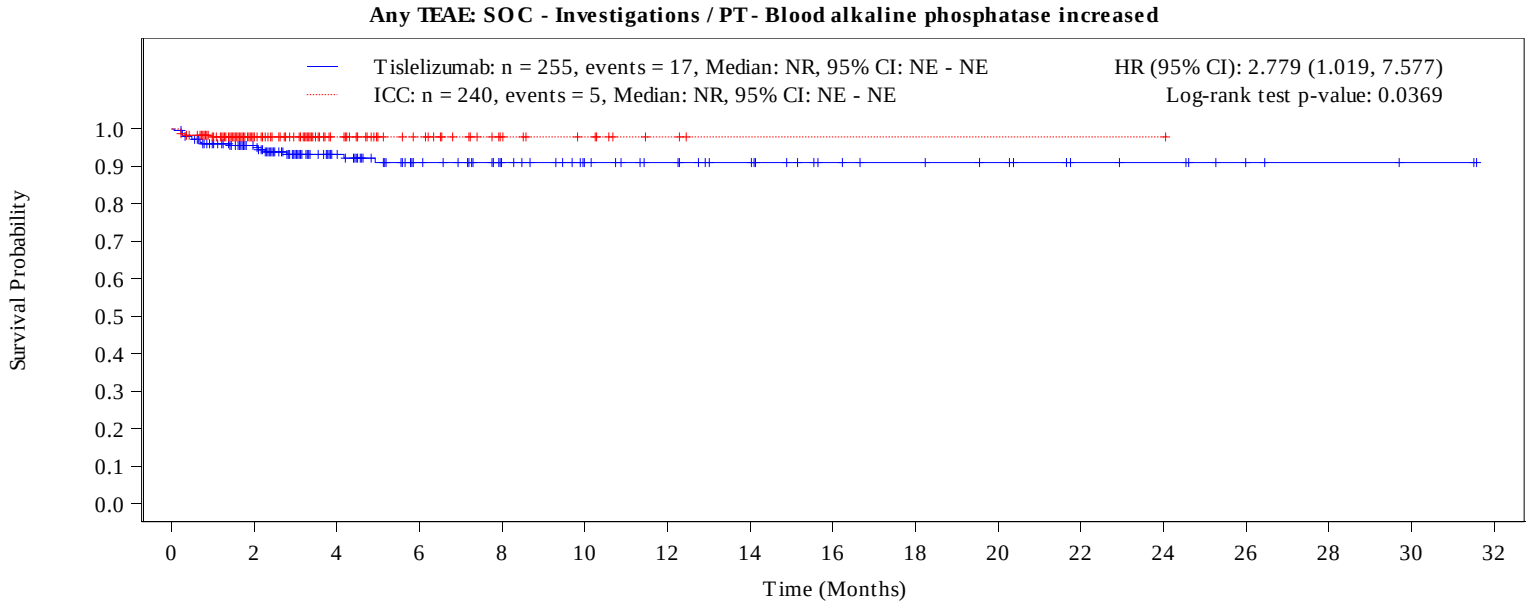

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	169	95	62	47	36	30	25	18	16	14	10	9	4	3	2	0
ICC	240	110	43	24	12	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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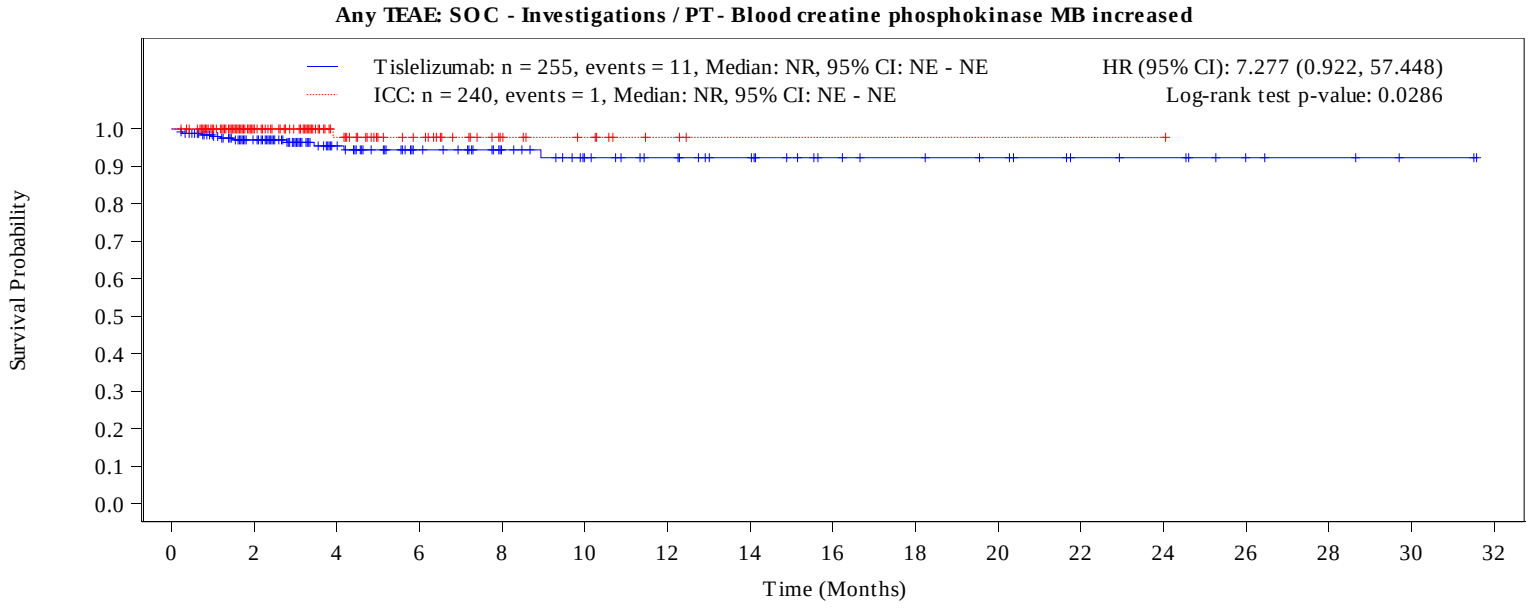

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	170	92	63	48	37	32	27	19	17	15	11	10	5	4	2	0
ICC	240	113	44	25	12	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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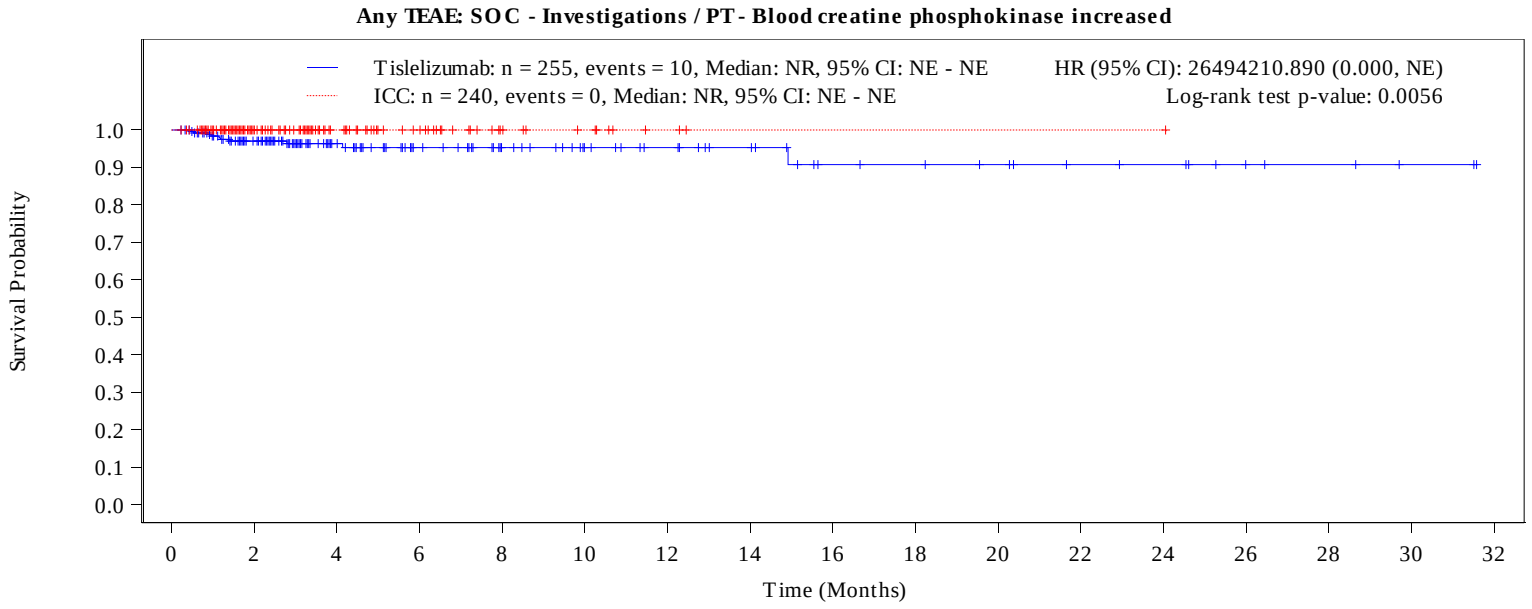

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	170	92	62	47	36	30	25	17	16	14	11	10	5	4	2	0
ICC	240	113	45	26	12	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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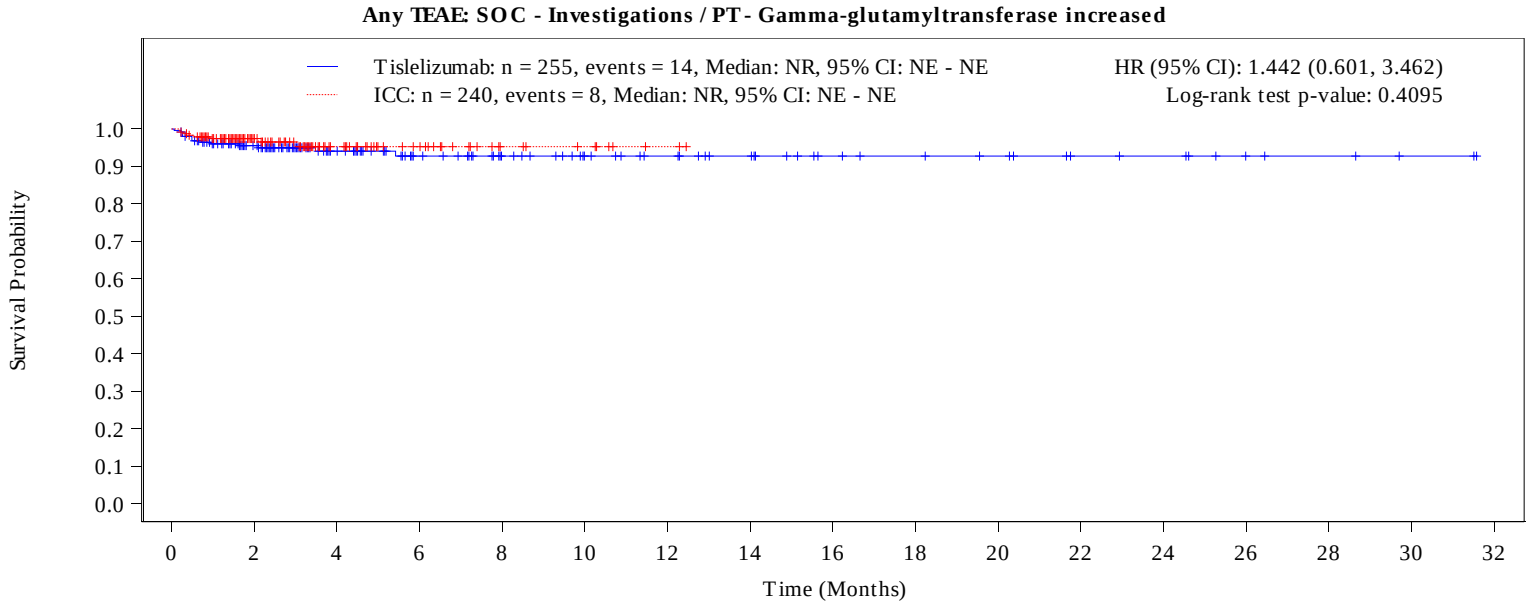
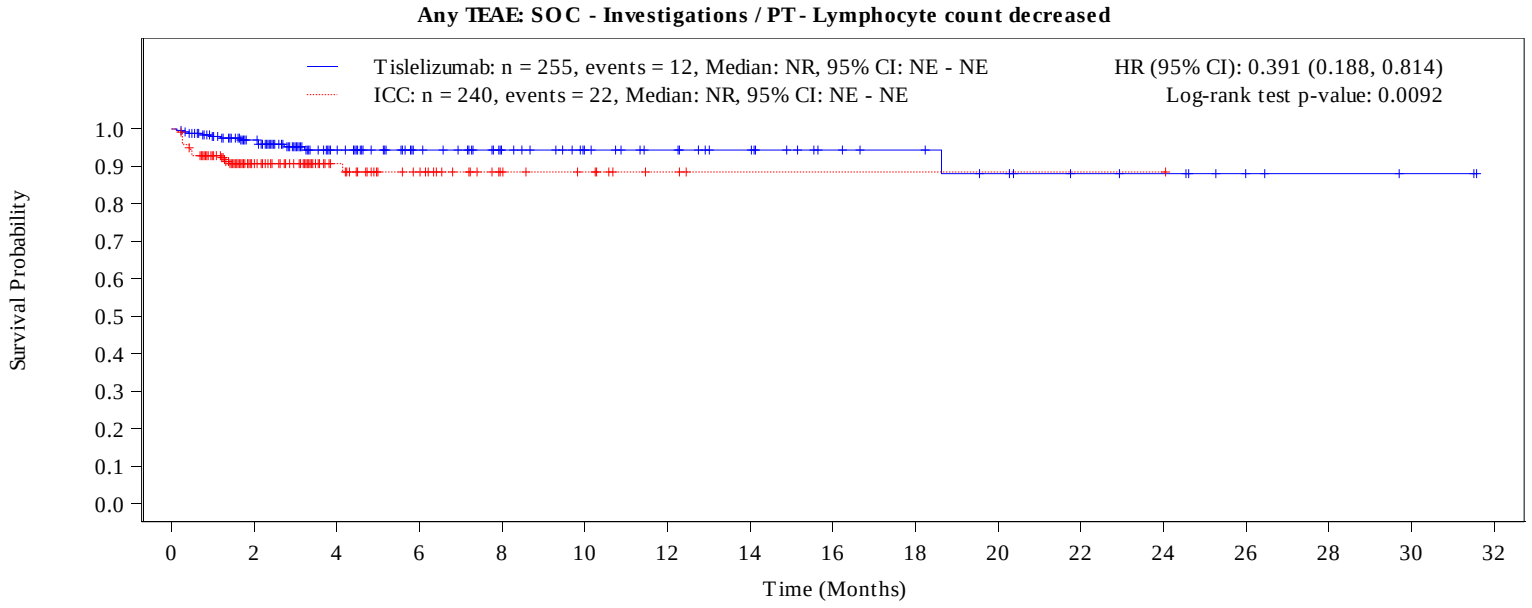


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	168	96	64	49	38	32	27	19	17	15	11	10	5	4	2	0
ICC	240	111	42	23	10	7	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-km-aesocpt-safety-sa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	171	96	64	48	37	31	26	18	16	13	10	9	4	3	2	0
ICC	240	104	41	24	11	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-km-aesocpt-safety-sa.rtf

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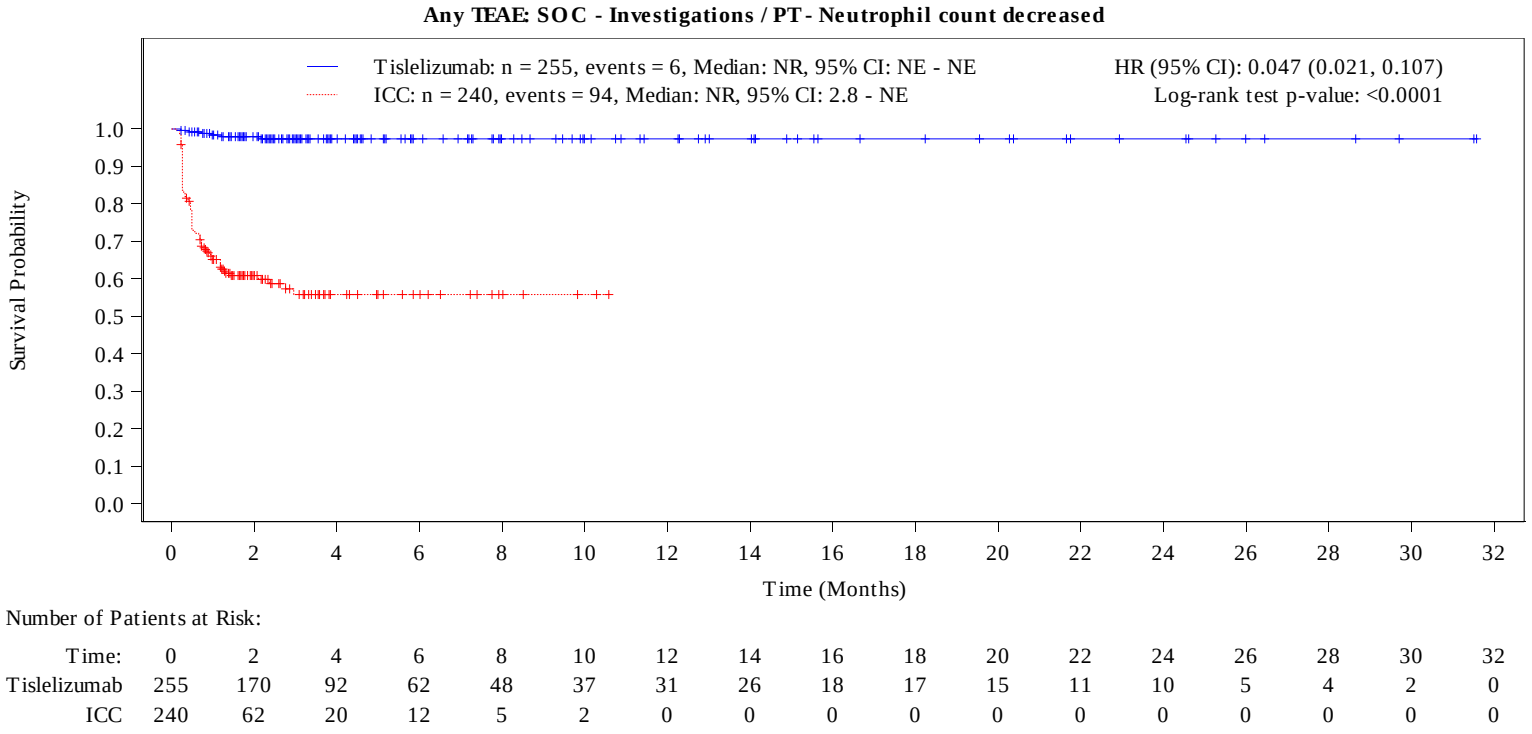
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	170	92	62	48	37	31	26	18	17	15	11	10	5	4	2	0
ICC	240	62	20	12	5	2	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-km-aesocpt-safety-sa.rtf

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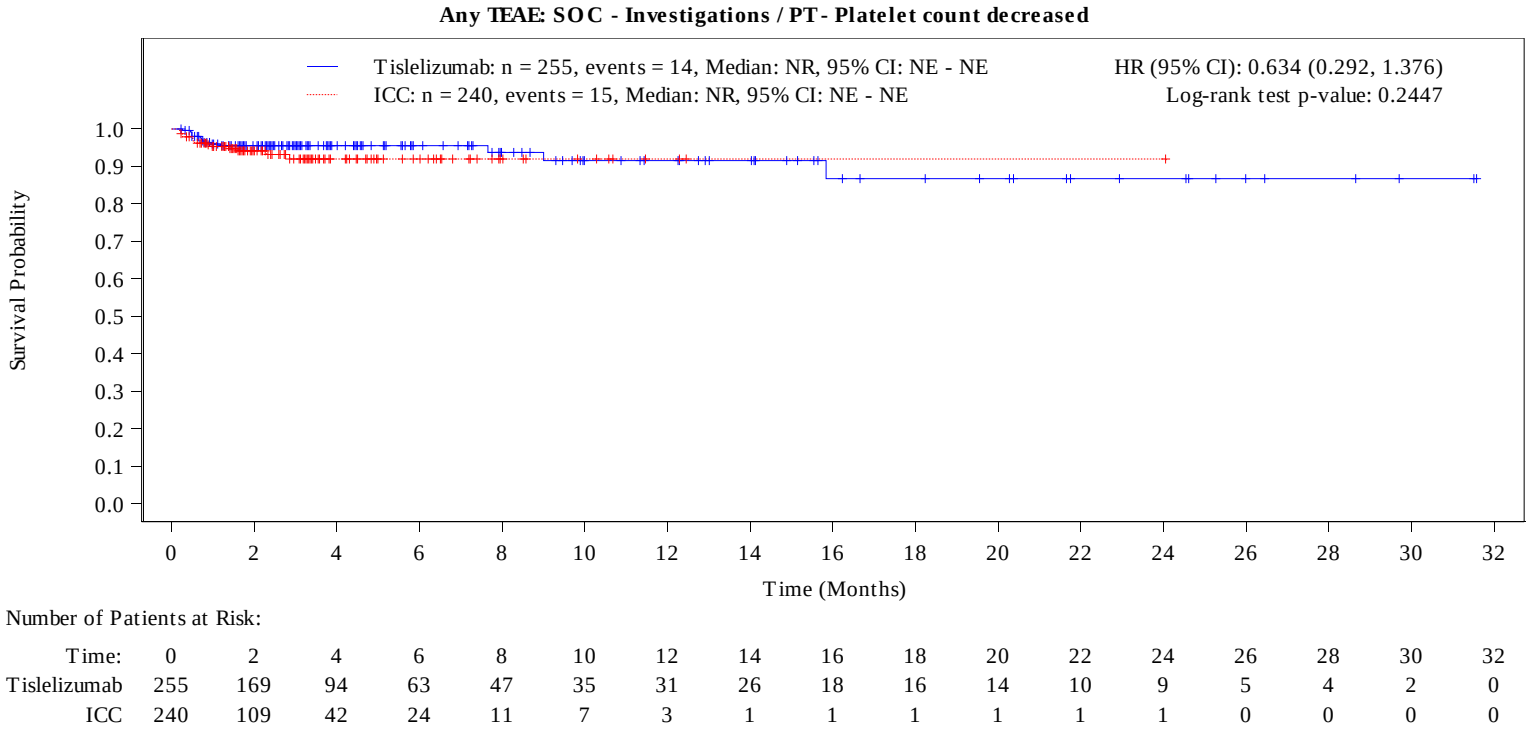
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

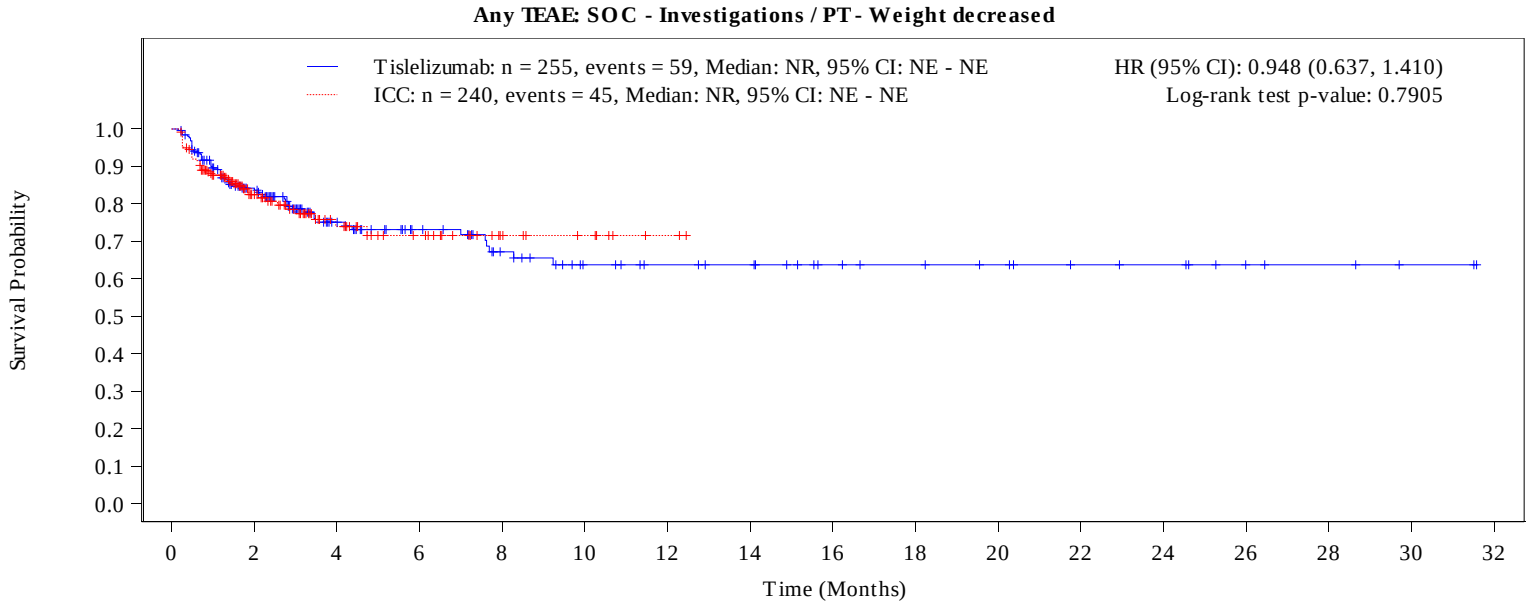


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	169	94	63	47	35	31	26	18	16	14	10	9	5	4	2	0
ICC	240	109	42	24	11	7	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-km-aesocpt-safety-sa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	151	78	56	41	29	25	23	17	15	13	10	9	5	4	2	0
ICC	240	101	39	23	11	7	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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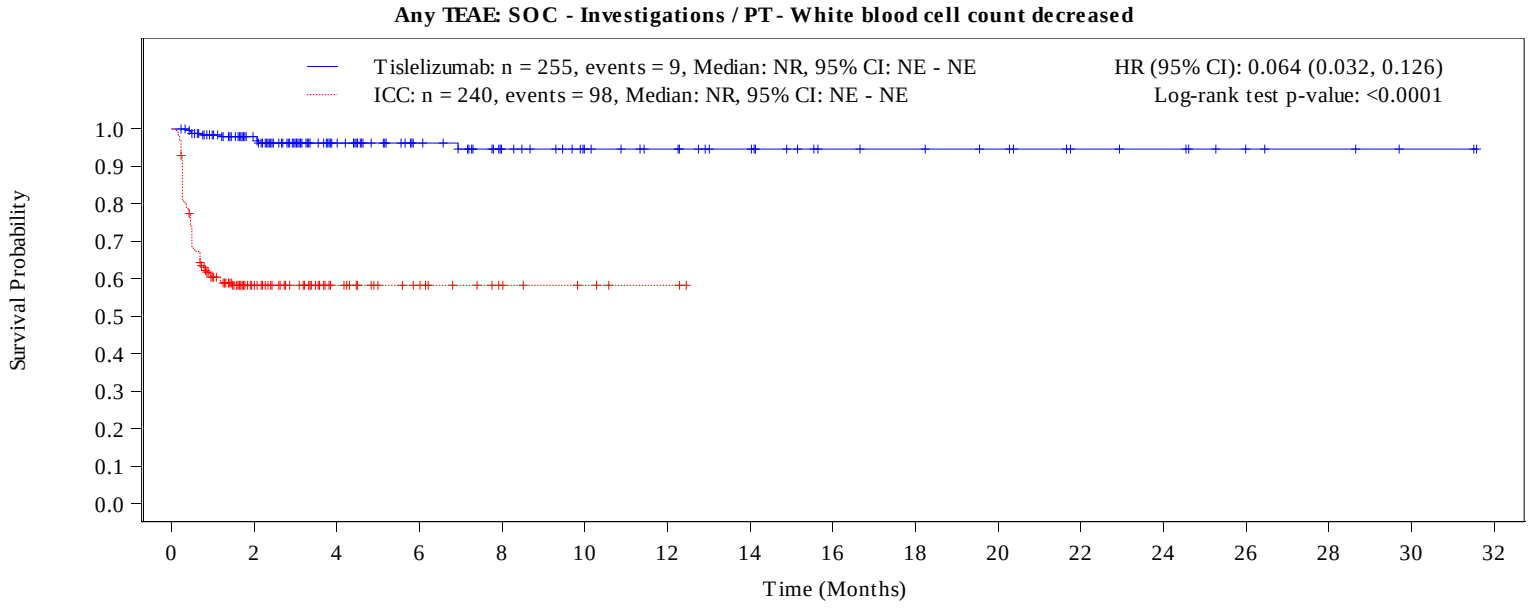
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	171	92	62	46	35	30	25	18	17	15	11	10	5	4	2	0
ICC	240	64	24	14	7	4	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-km-aesocpt-safety-sa.rtf

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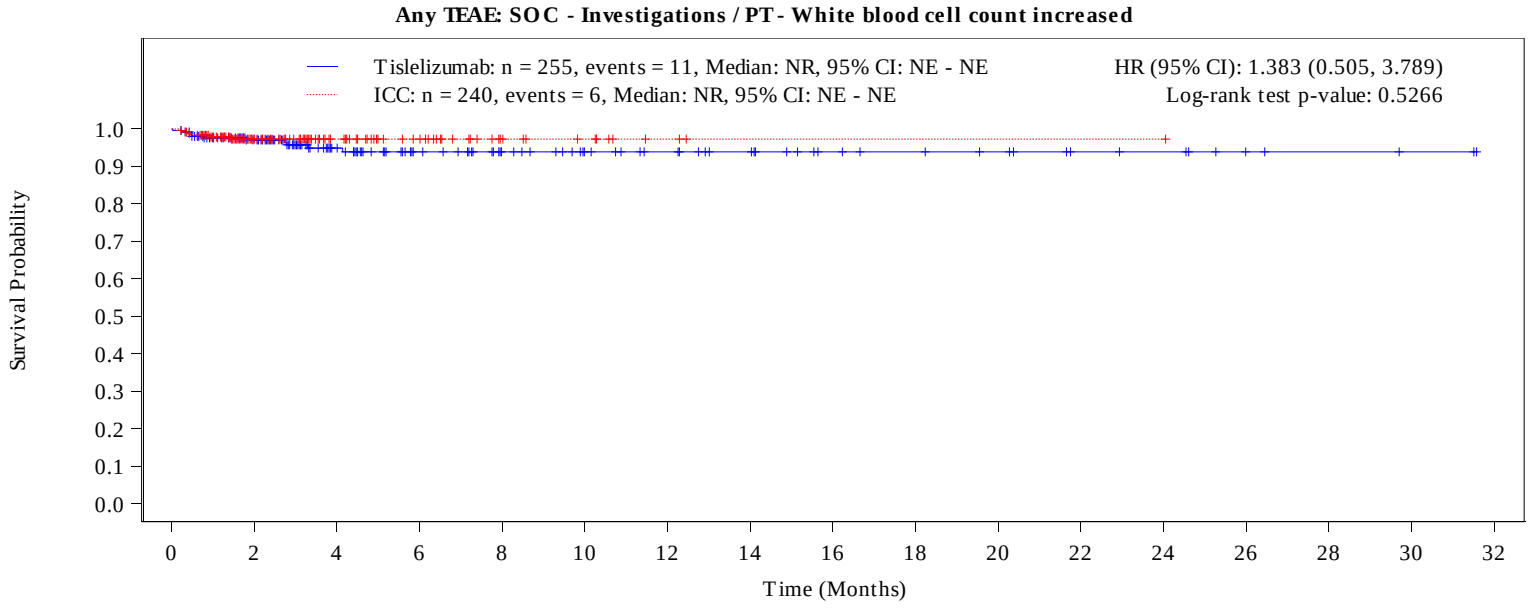
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	174	96	64	48	37	31	26	18	16	14	10	9	4	3	2	0
ICC	240	111	45	26	12	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-km-aesocpt-safety-sa.rtf

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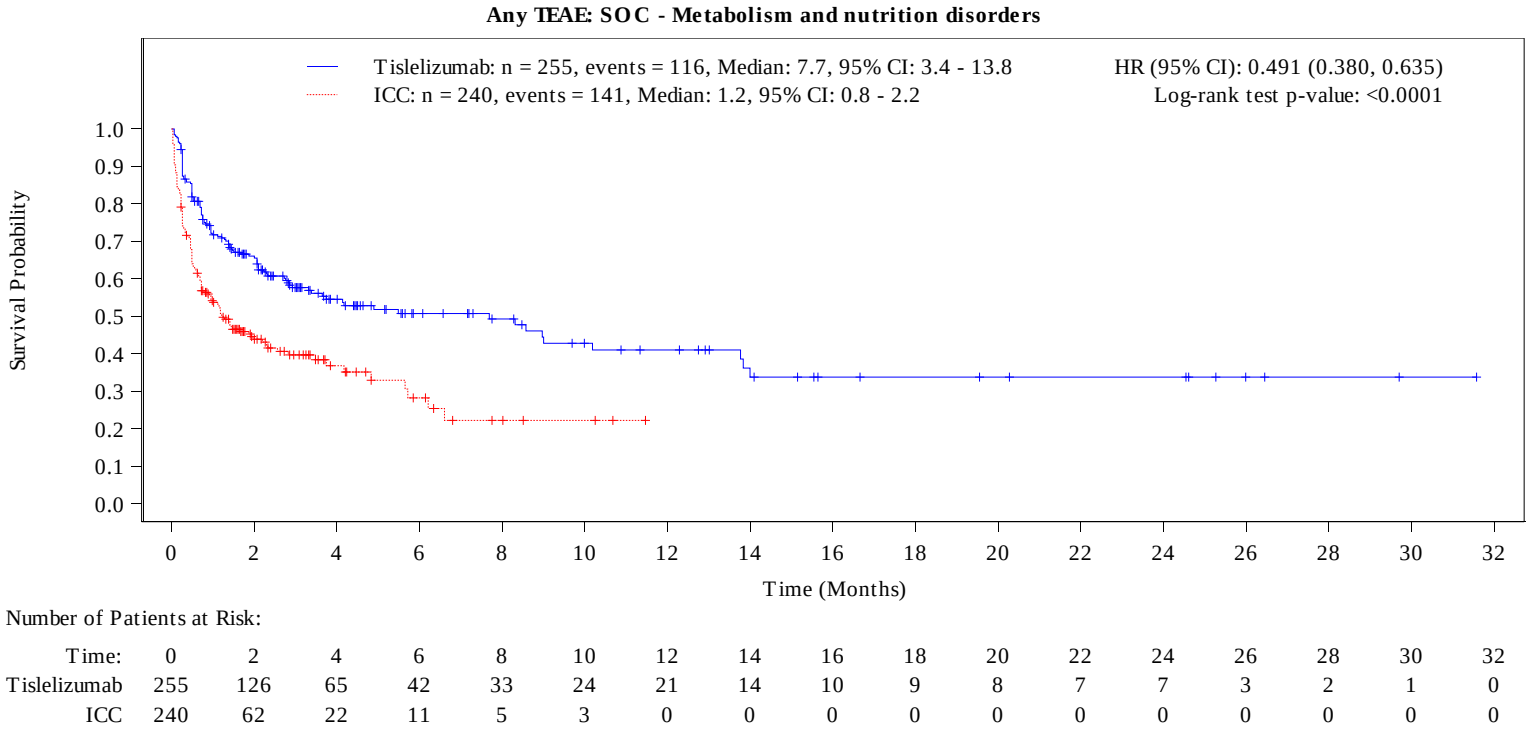
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	126	65	42	33	24	21	14	10	9	8	7	7	3	2	1	0
ICC	240	62	22	11	5	3	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-km-aesocpt-safety-sa.rtf

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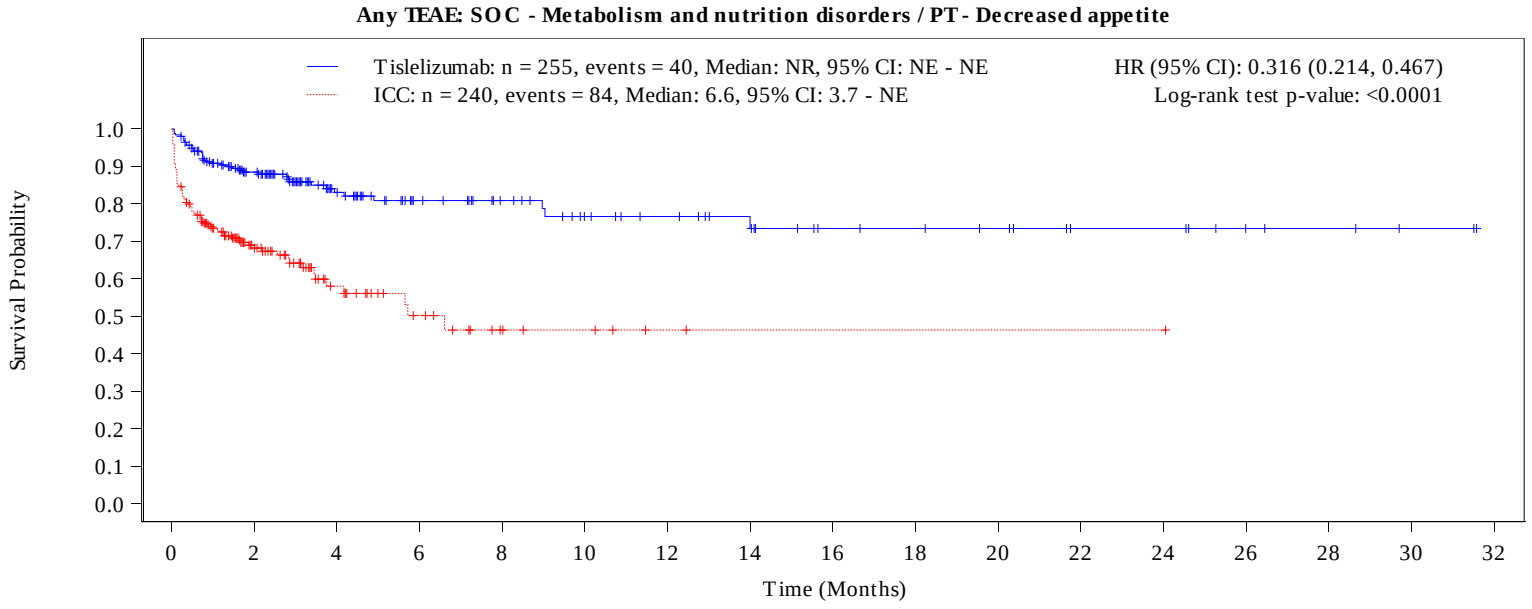
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	157	84	55	42	32	28	23	17	16	14	10	10	5	4	2	0
ICC	240	87	30	15	7	5	2	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-km-aesocpt-safety-sa.rtf

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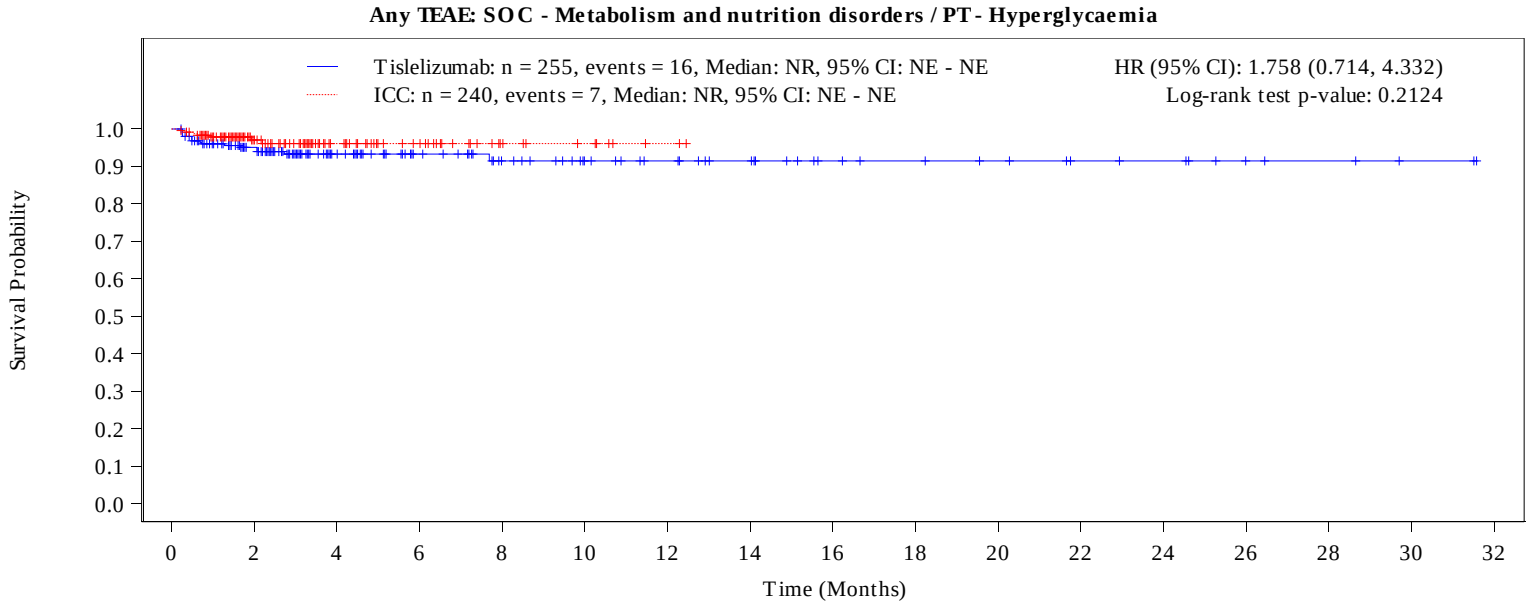
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	169	91	60	46	36	30	25	17	15	13	10	9	5	4	2	0
ICC	240	109	44	25	11	7	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-km-aesocpt-safety-sa.rtf

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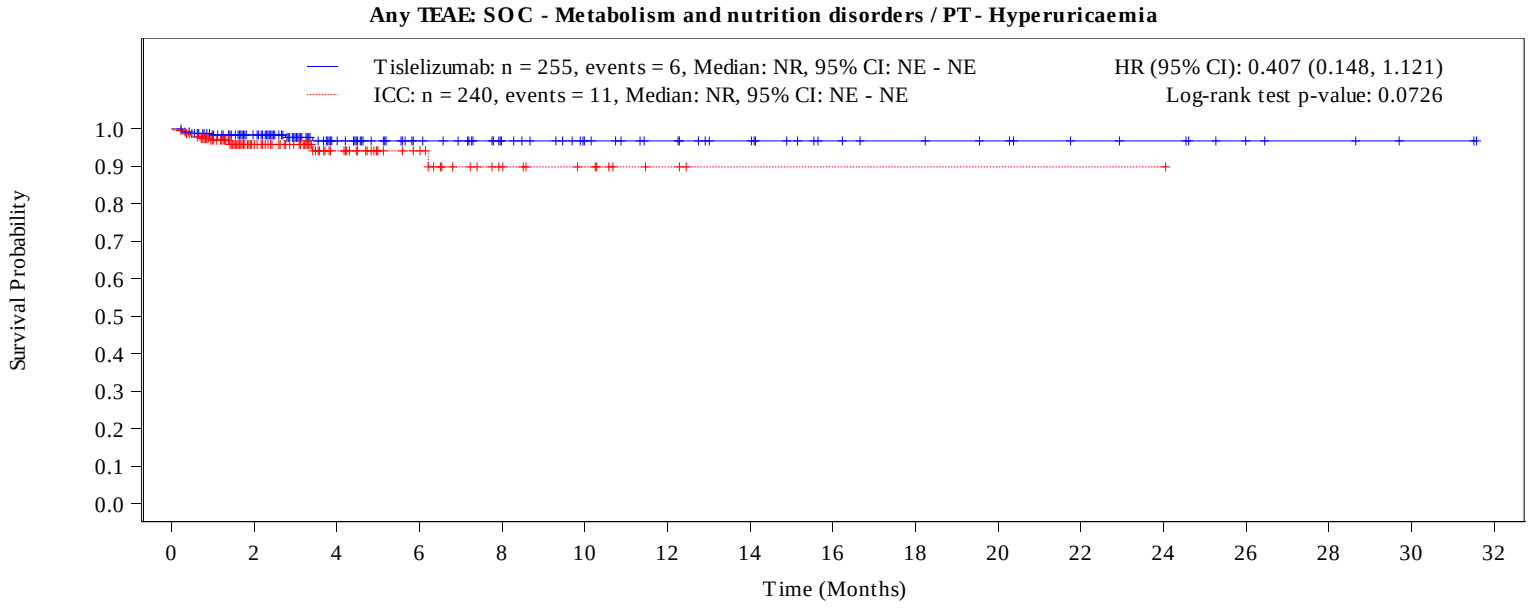
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

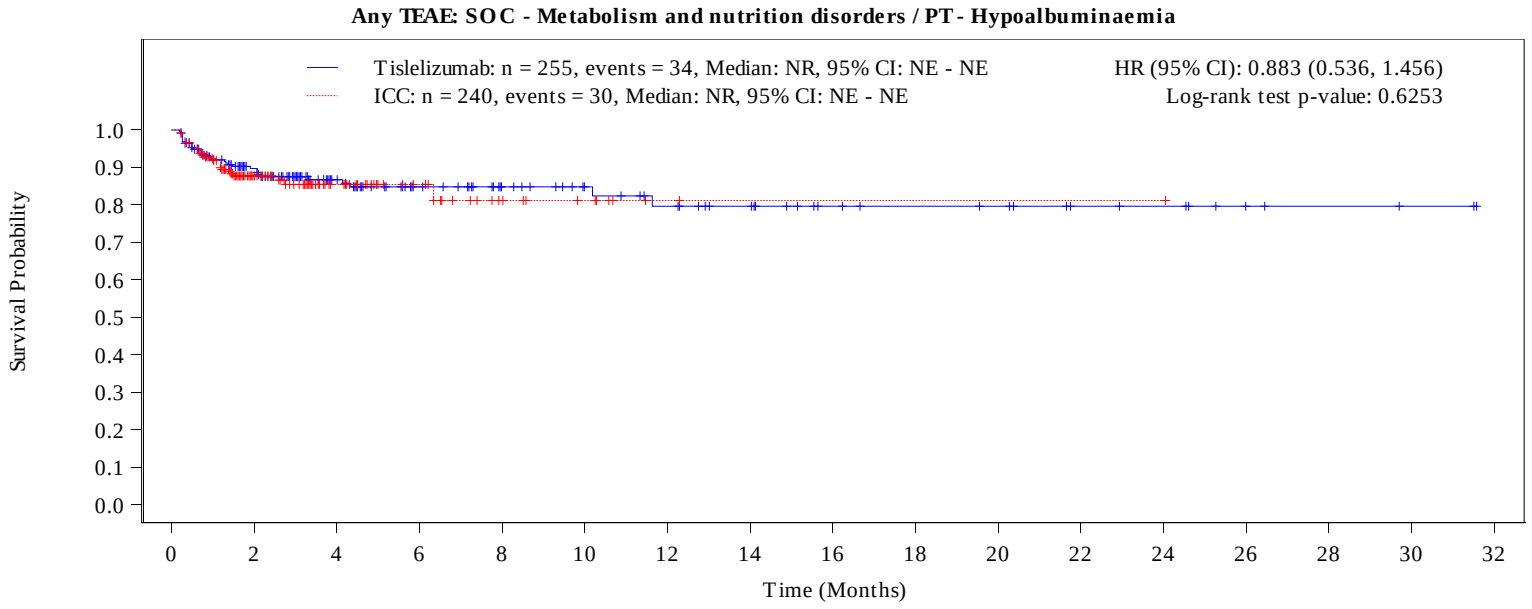


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	175	95	64	48	37	31	26	18	16	14	11	10	5	4	2	0
ICC	240	108	42	24	12	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-km-aesocpt-safety-sa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	165	93	61	45	35	29	24	17	15	14	10	9	4	3	2	0
ICC	240	102	41	22	11	7	2	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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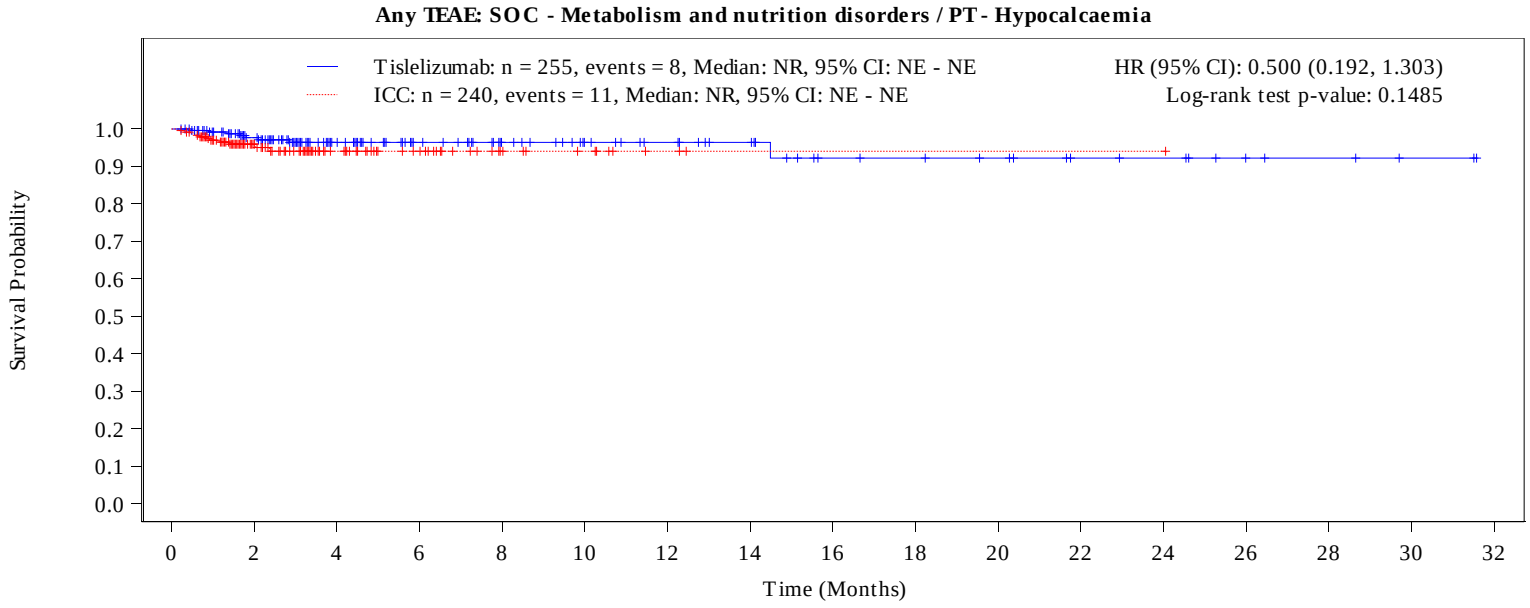
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	172	97	65	49	38	32	27	18	17	15	11	10	5	4	2	0
ICC	240	109	43	25	12	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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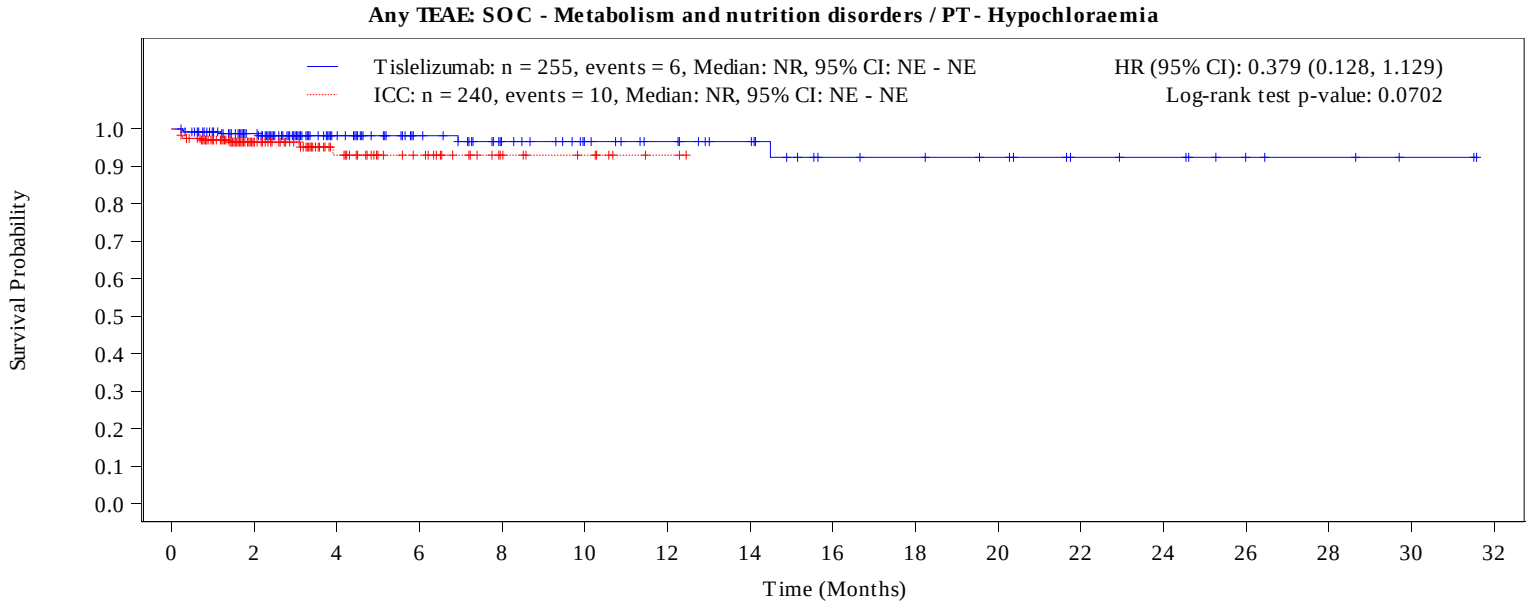
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	174	97	65	48	37	31	26	18	17	15	11	10	5	4	2	0
ICC	240	110	43	24	11	7	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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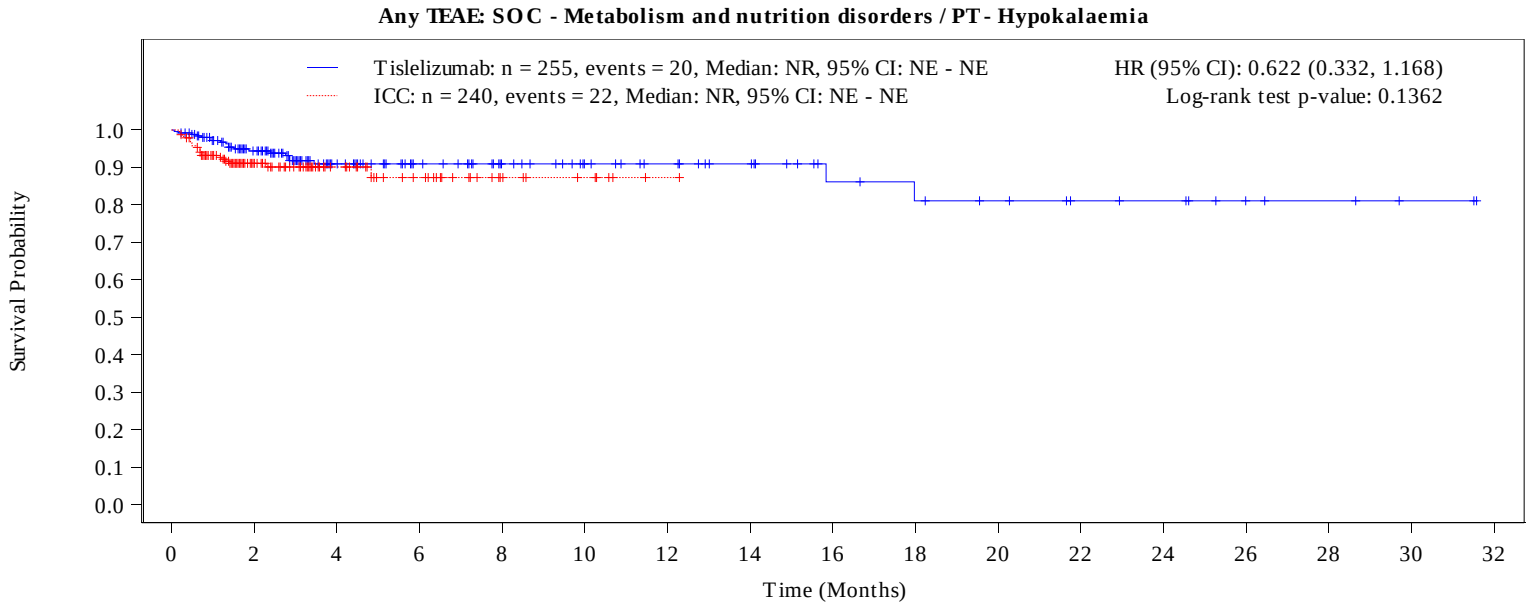
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	169	96	65	49	38	32	27	18	16	14	11	10	5	4	2	0
ICC	240	106	41	23	10	6	1	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-km-aesocpt-safety-sa.rtf

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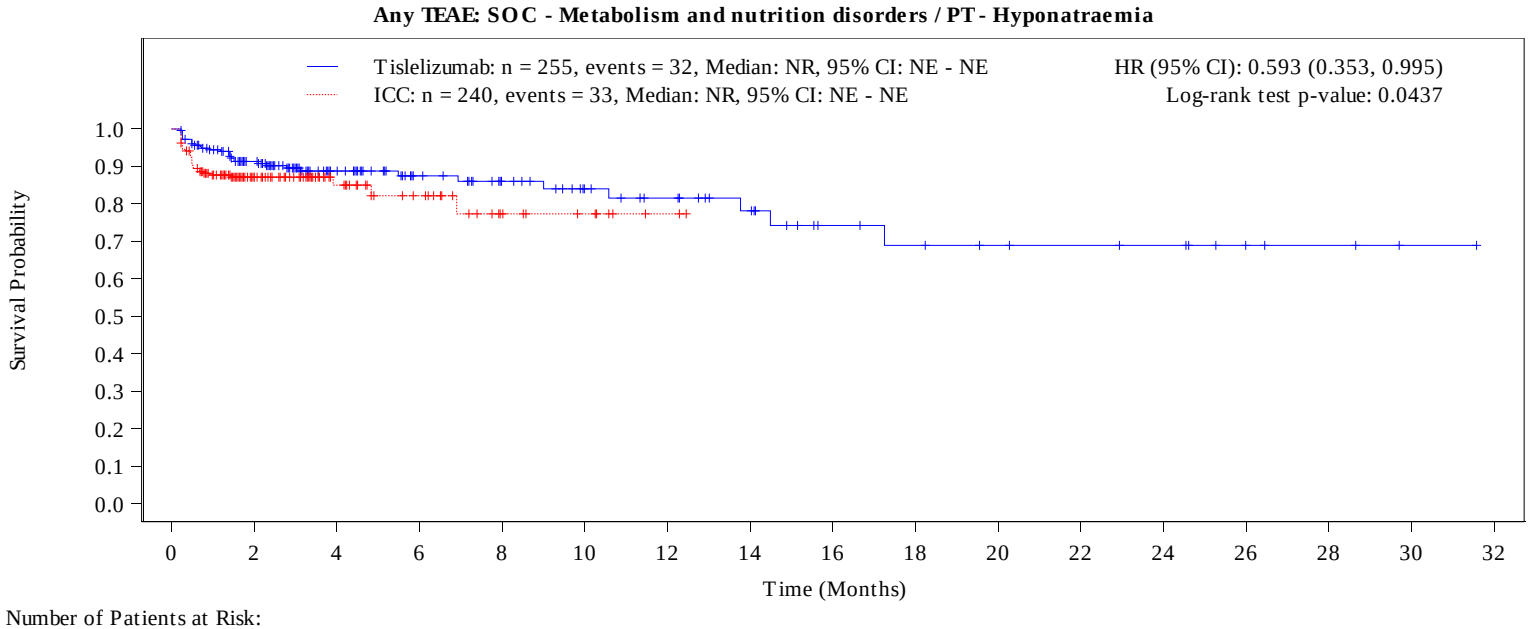

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	166	93	62	47	35	29	23	15	13	11	10	9	4	3	1	0
ICC	240	103	40	23	11	7	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-km-aesocpt-safety-sa.rtf

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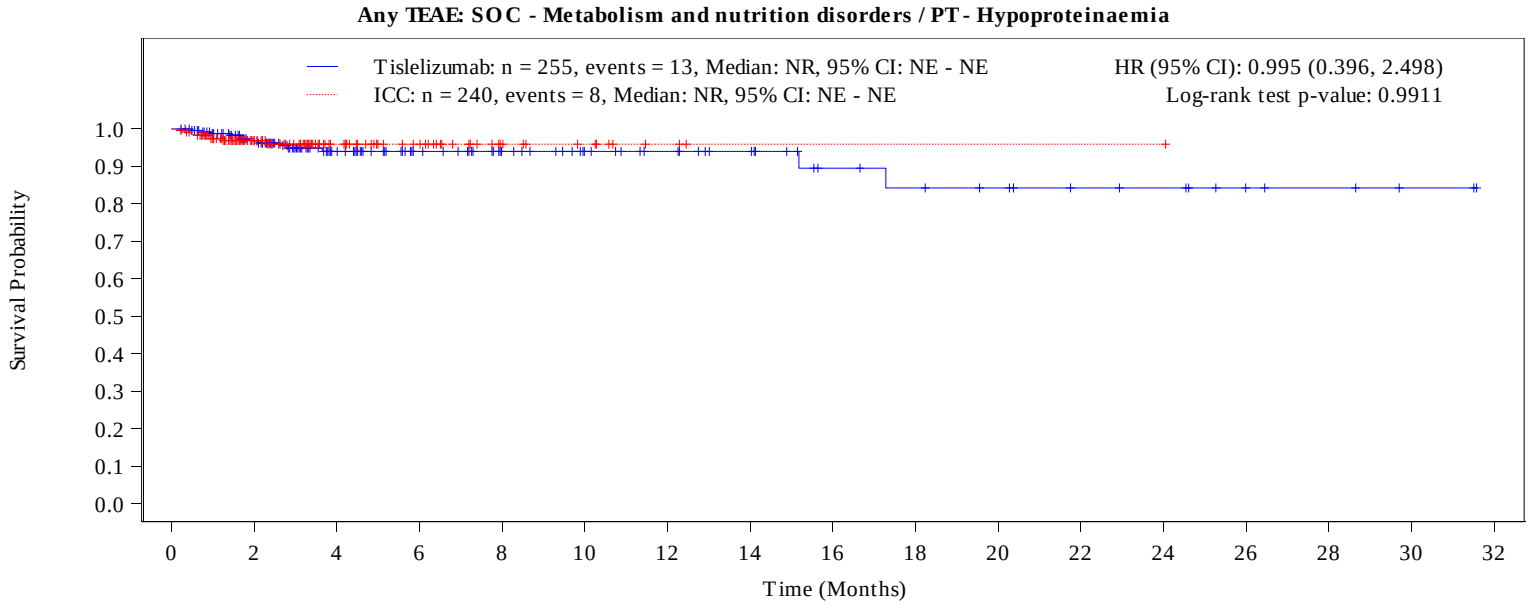

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	174	96	65	49	38	32	27	18	16	14	11	10	5	4	2	0
ICC	240	112	44	26	12	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-km-aesocpt-safety-sa.rtf

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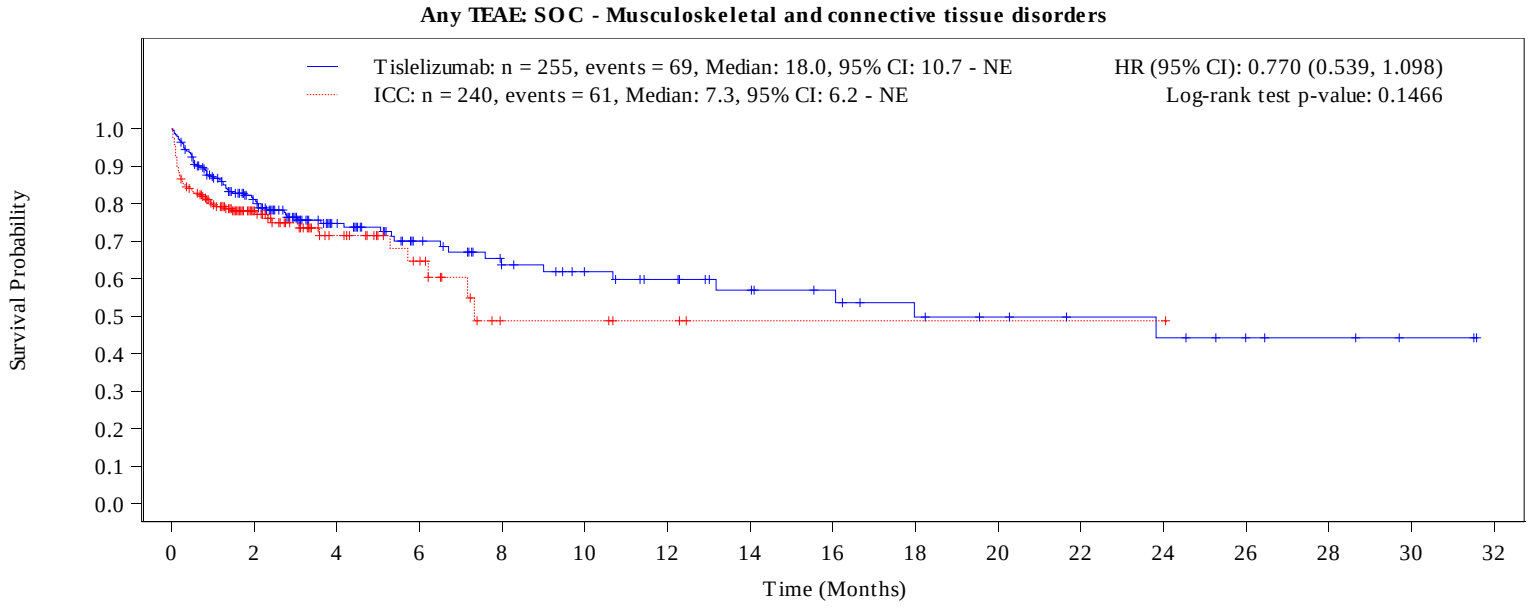
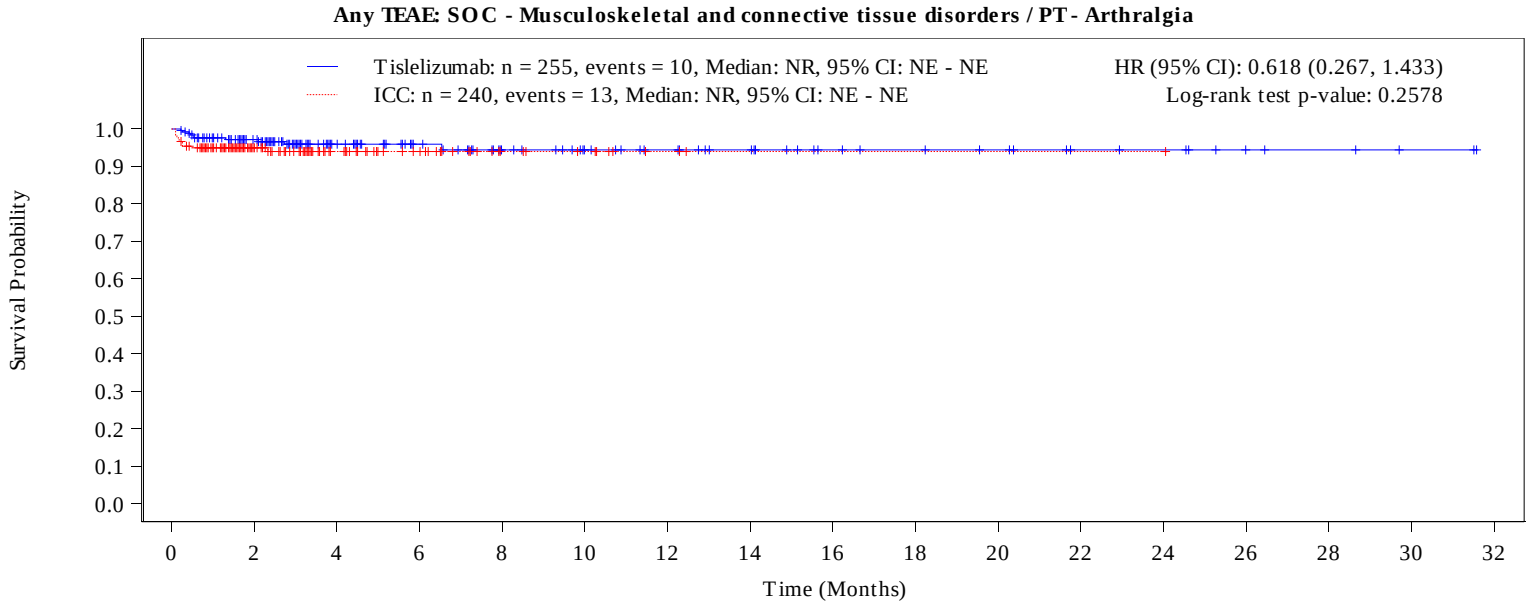


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	145	76	49	36	30	25	20	17	13	11	9	8	5	4	2	0
ICC	240	86	30	17	5	5	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-km-aesocpt-safety-sa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	172	93	64	48	38	32	27	19	17	15	11	10	5	4	2	0
ICC	240	108	42	24	11	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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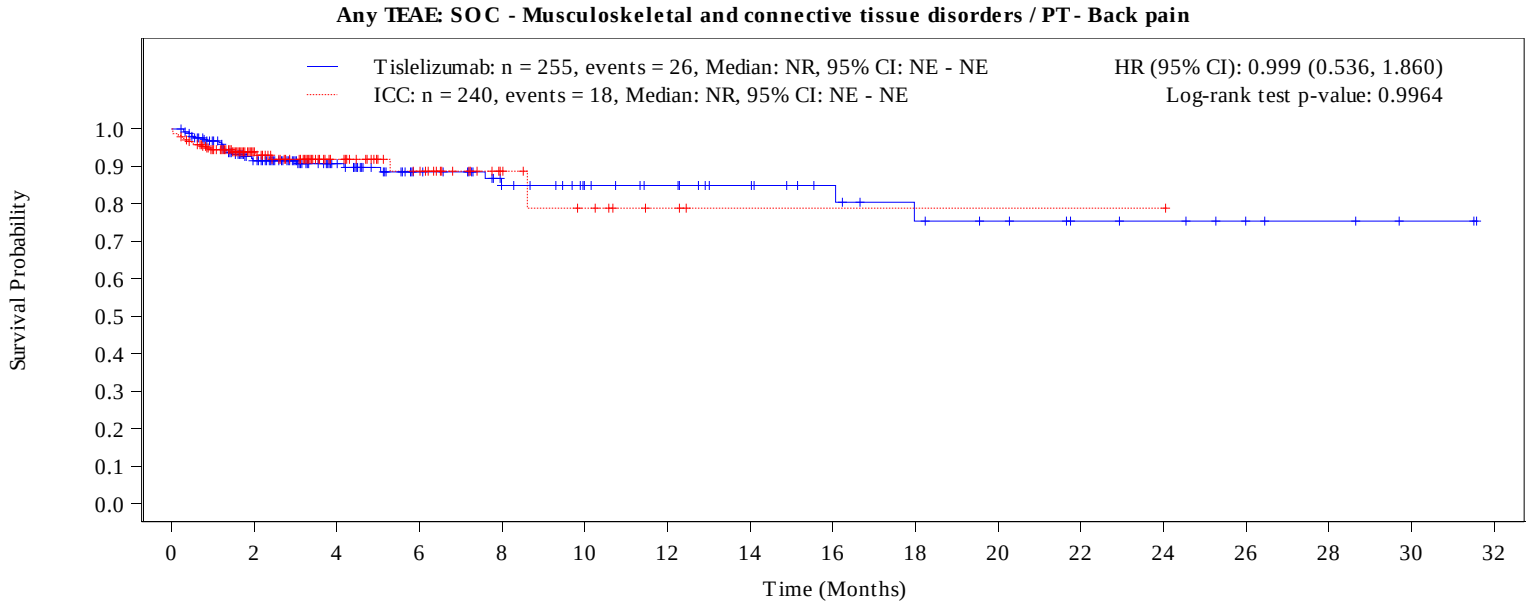
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	160	91	60	44	35	30	25	19	15	13	10	9	5	4	2	0
ICC	240	106	43	25	11	7	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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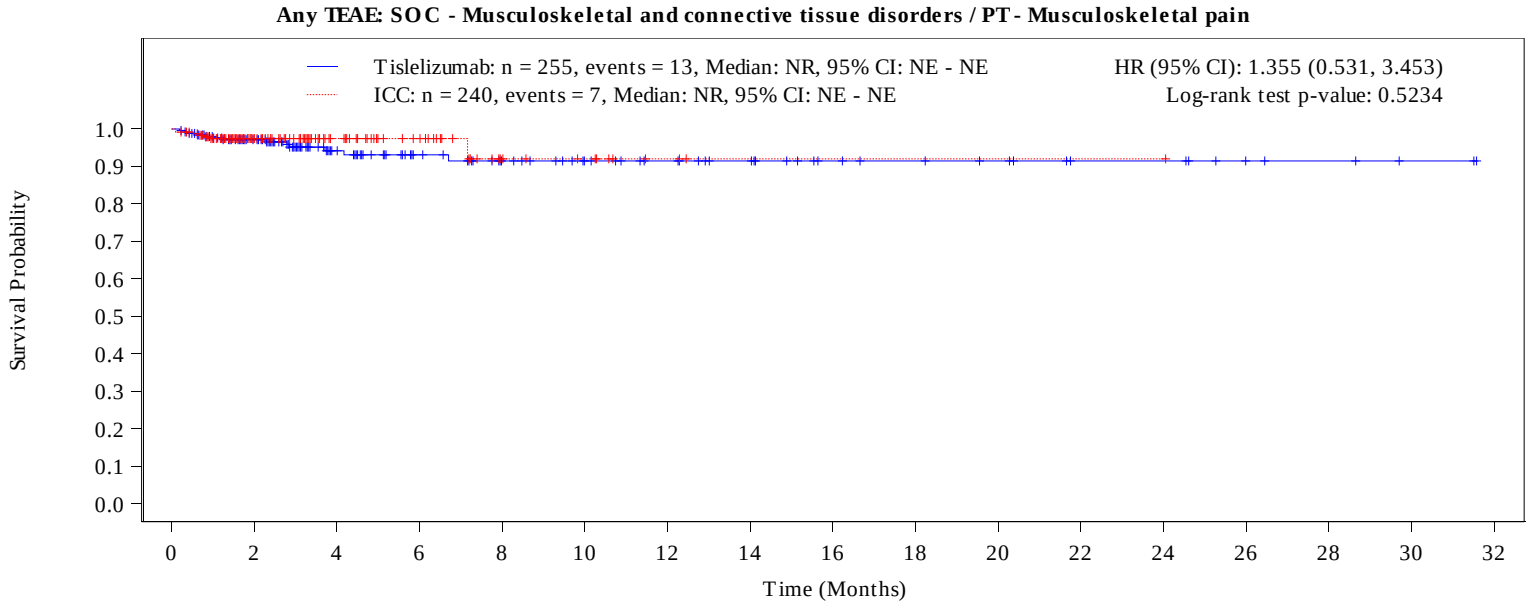
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	170	89	59	45	36	30	25	18	16	14	10	10	5	4	2	0
ICC	240	111	44	26	11	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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Figure 14.3.1.2:
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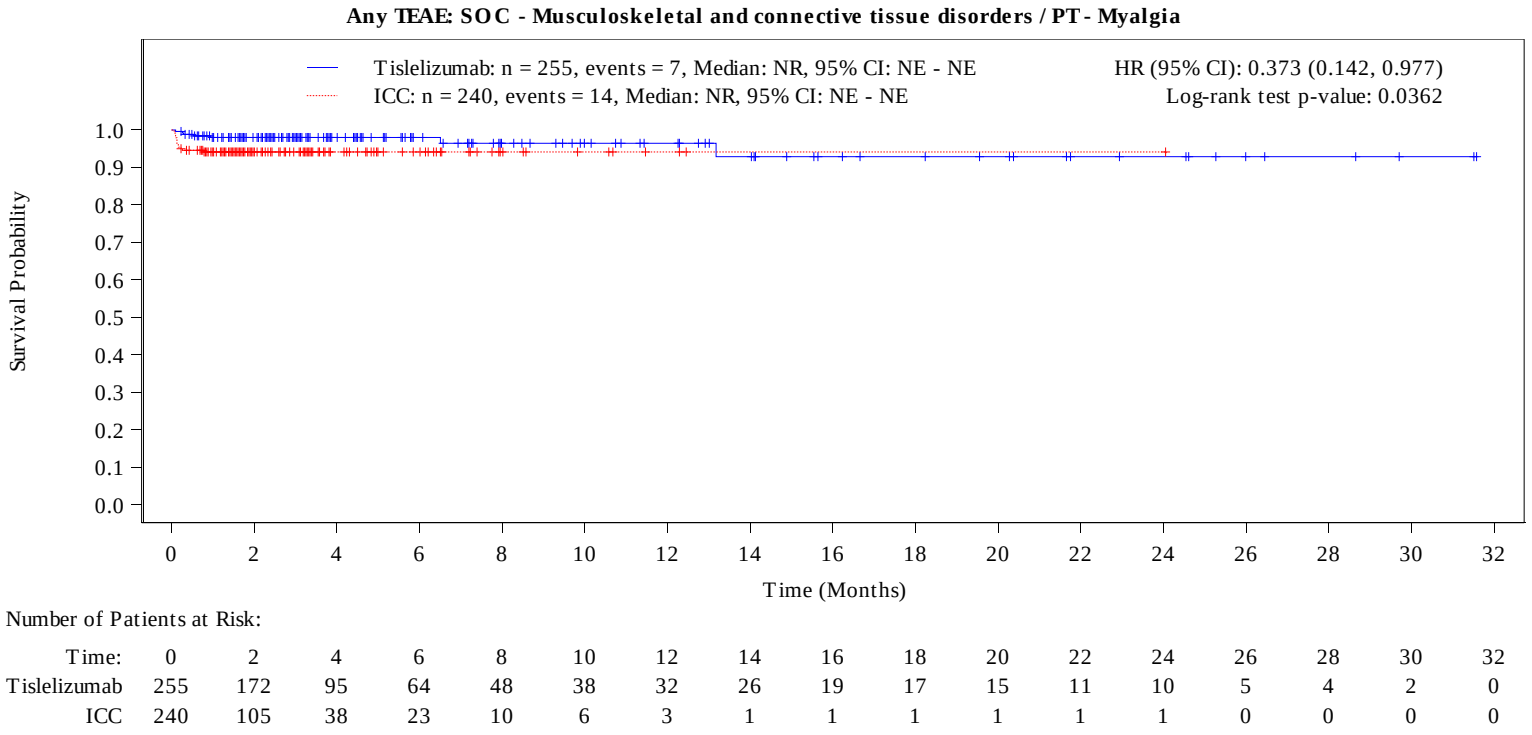
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	172	95	64	48	38	32	26	19	17	15	11	10	5	4	2	0
ICC	240	105	38	23	10	6	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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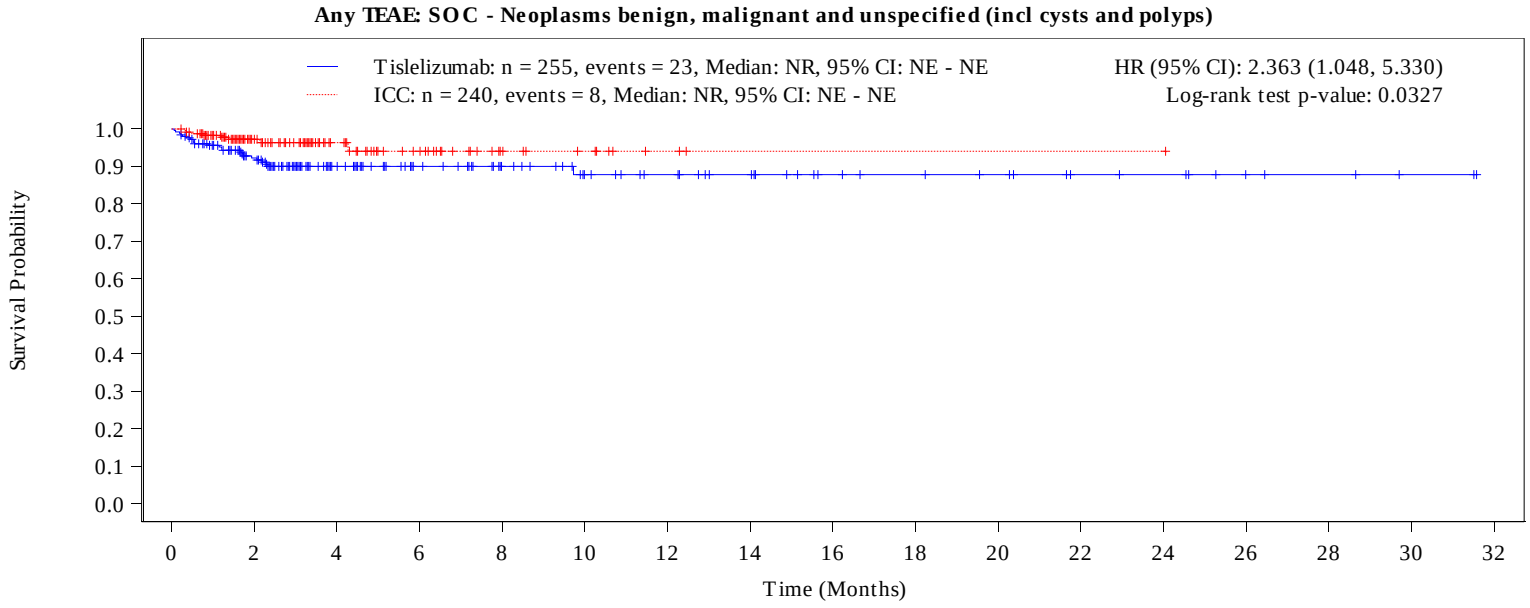

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	168	93	63	48	37	32	27	19	17	15	11	10	5	4	2	0
ICC	240	113	45	26	12	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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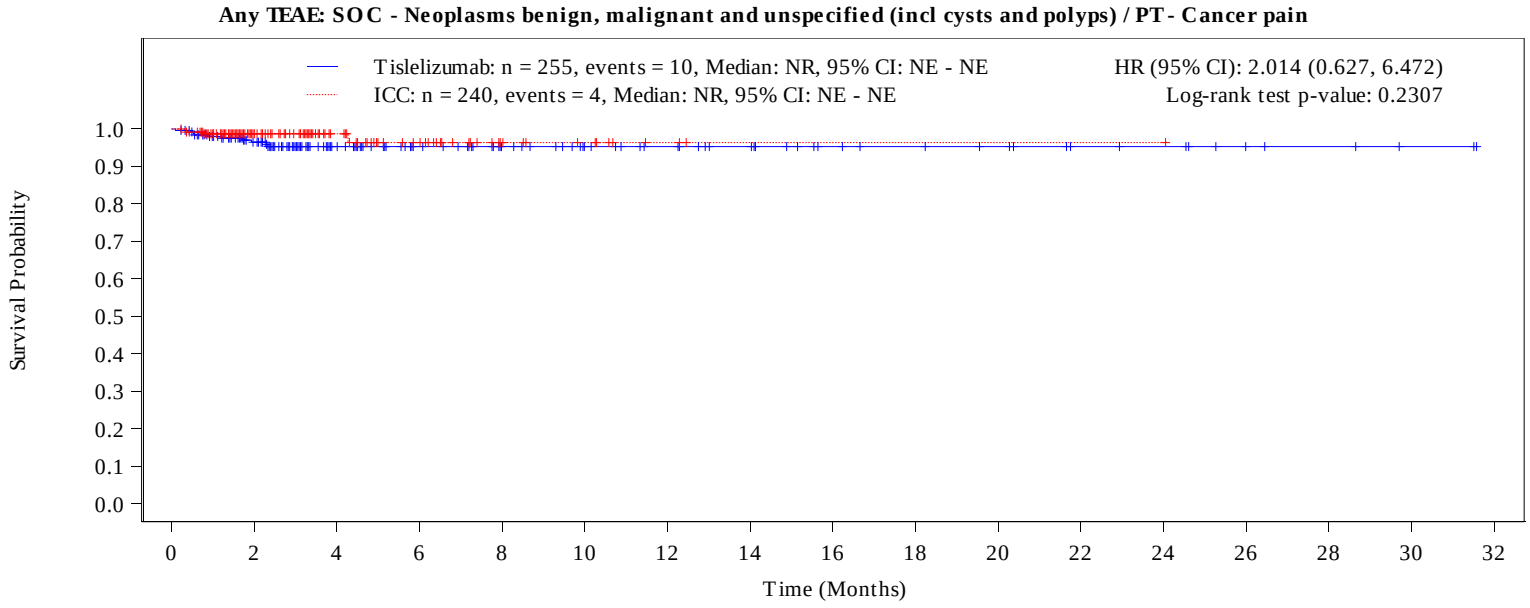
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	171	95	65	49	38	32	27	19	17	15	11	10	5	4	2	0
ICC	240	113	45	26	12	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-km-aesocpt-safety-sa.rtf

Figure 14.3.1.2:
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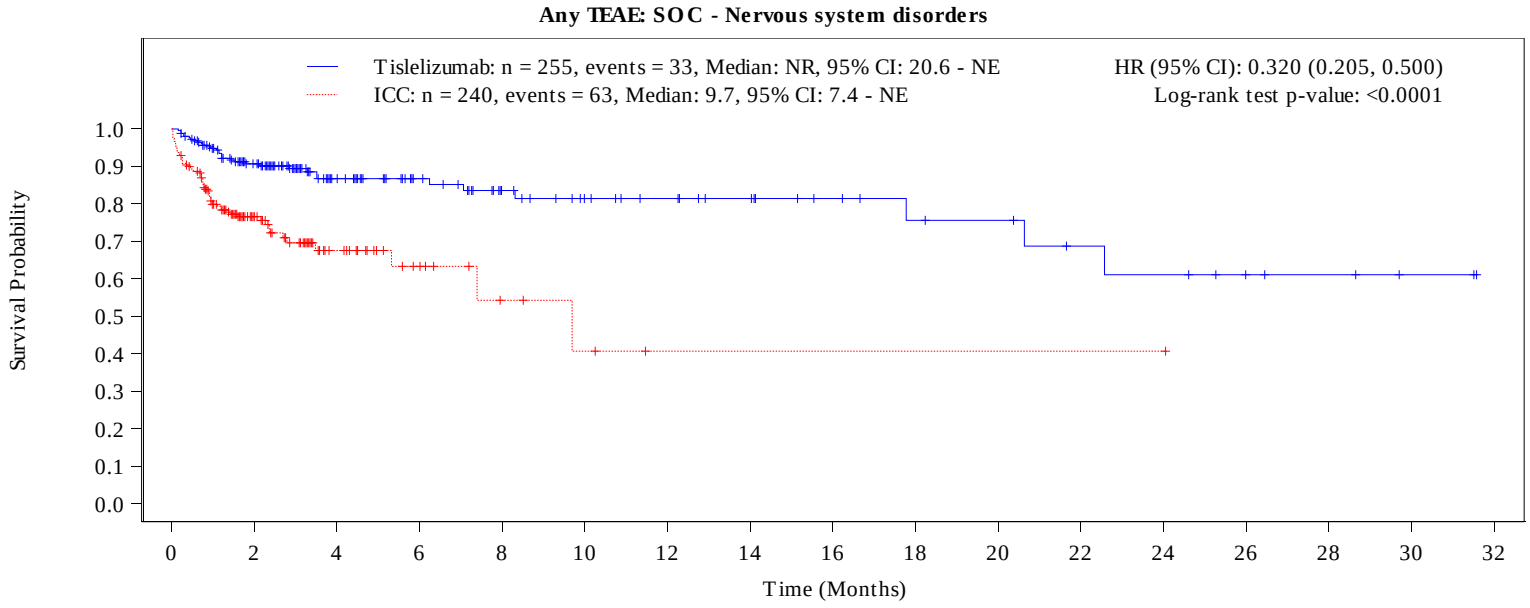
Safety Analysis Set

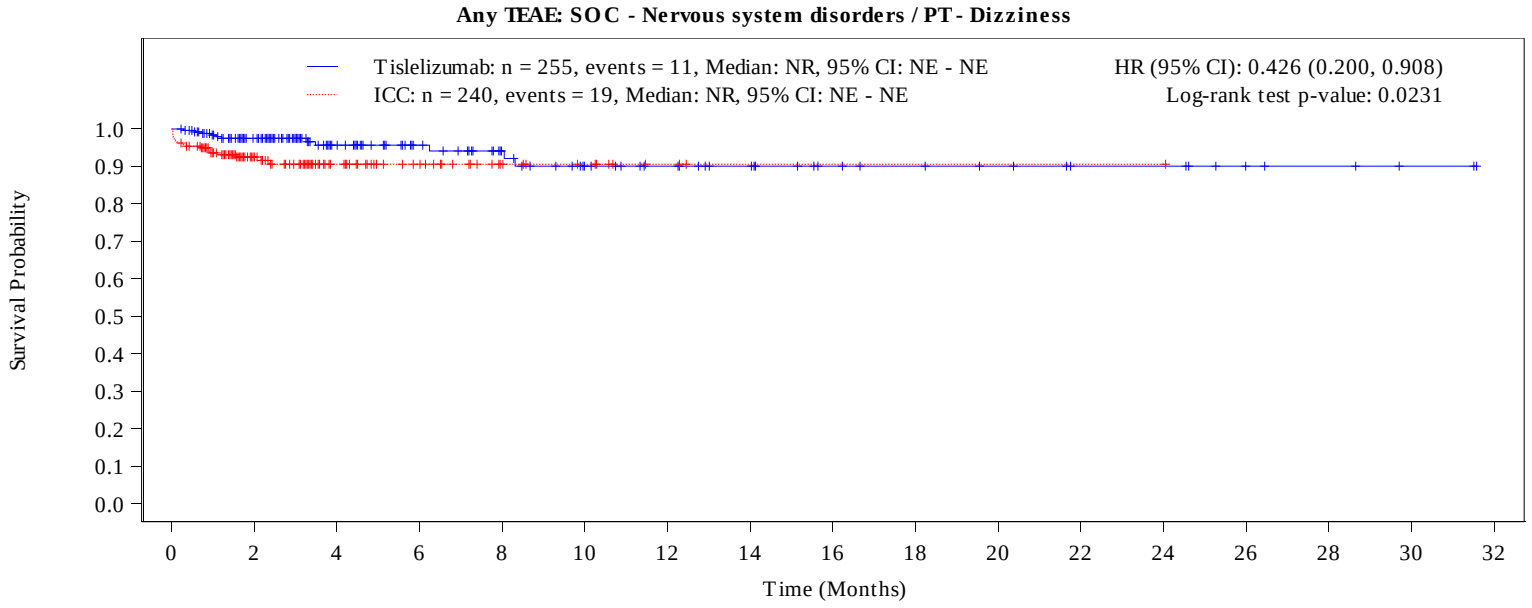


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	162	86	57	40	31	26	22	16	13	12	9	8	5	4	2	0
ICC	240	81	27	11	5	3	1	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-km-aesocpt-safety-sa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

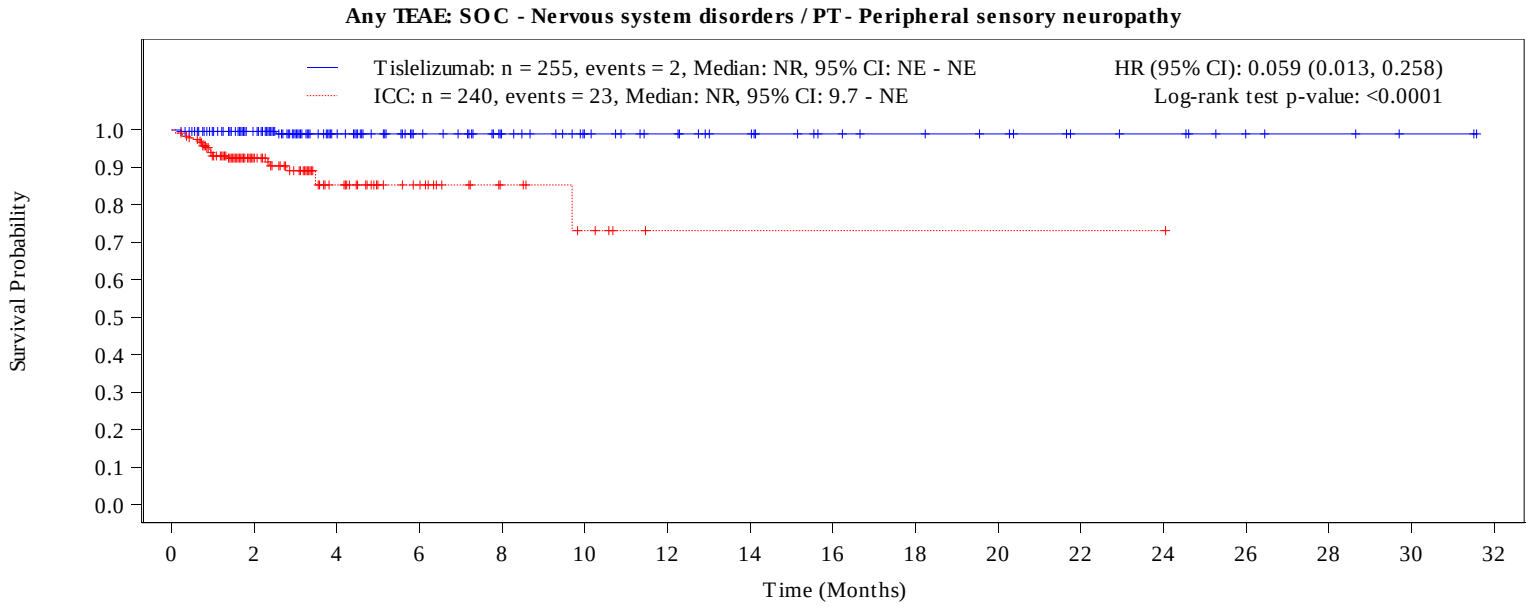


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	171	94	63	47	35	29	24	17	15	13	10	10	5	4	2	0
ICC	240	105	41	24	12	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-km-aesocpt-safety-sa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	174	95	64	48	37	31	26	19	17	15	11	10	5	4	2	0
ICC	240	101	37	19	9	5	1	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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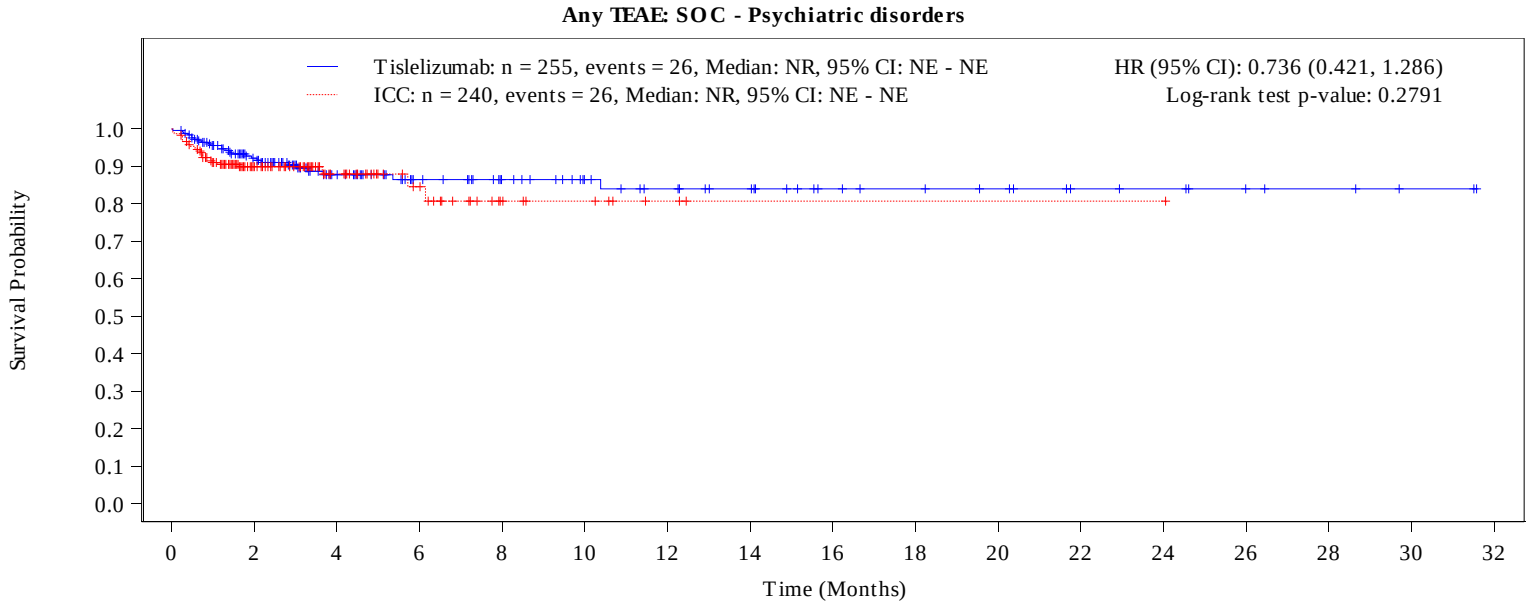
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	161	89	60	47	36	30	26	18	16	14	10	9	5	4	2	0
ICC	240	103	41	23	10	7	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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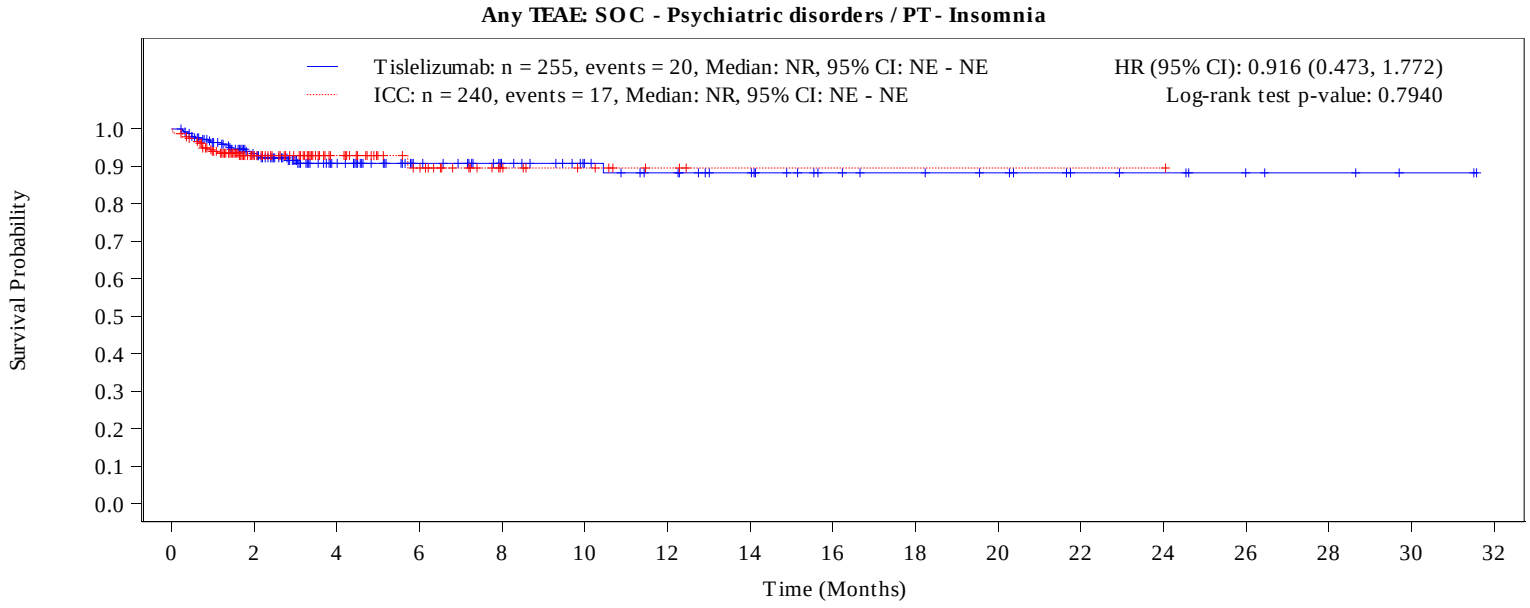
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	162	90	62	48	37	31	26	18	16	14	10	9	5	4	2	0
ICC	240	106	43	24	11	7	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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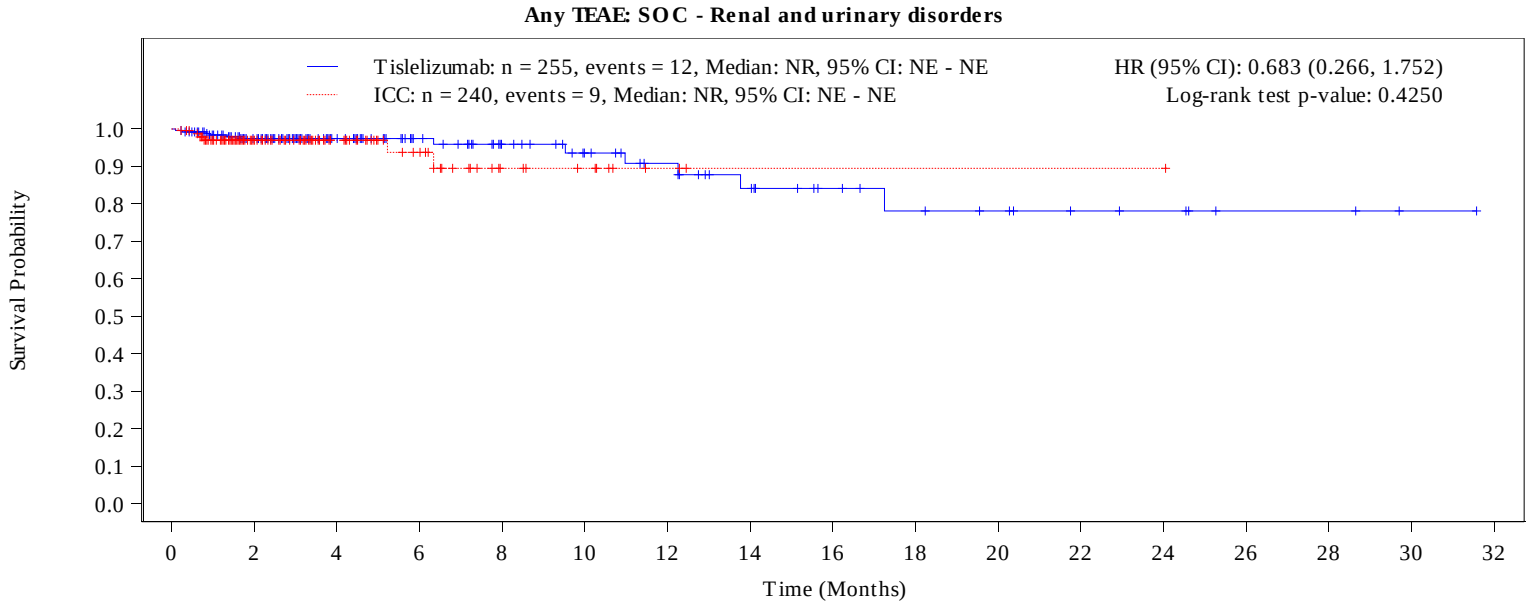

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	170	96	65	48	37	30	23	16	13	11	8	7	3	3	1	0
ICC	240	111	45	25	11	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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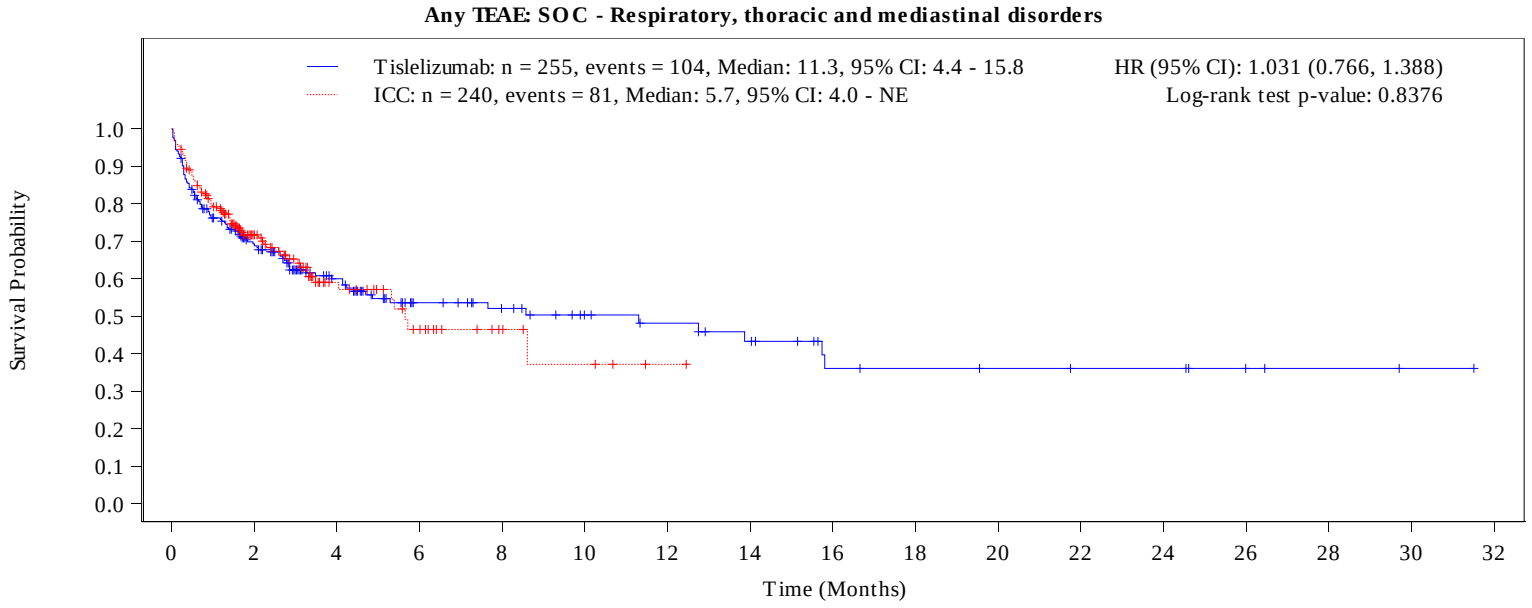

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	131	73	42	33	24	21	17	10	9	8	7	7	3	2	1	0
ICC	240	92	31	16	7	4	1	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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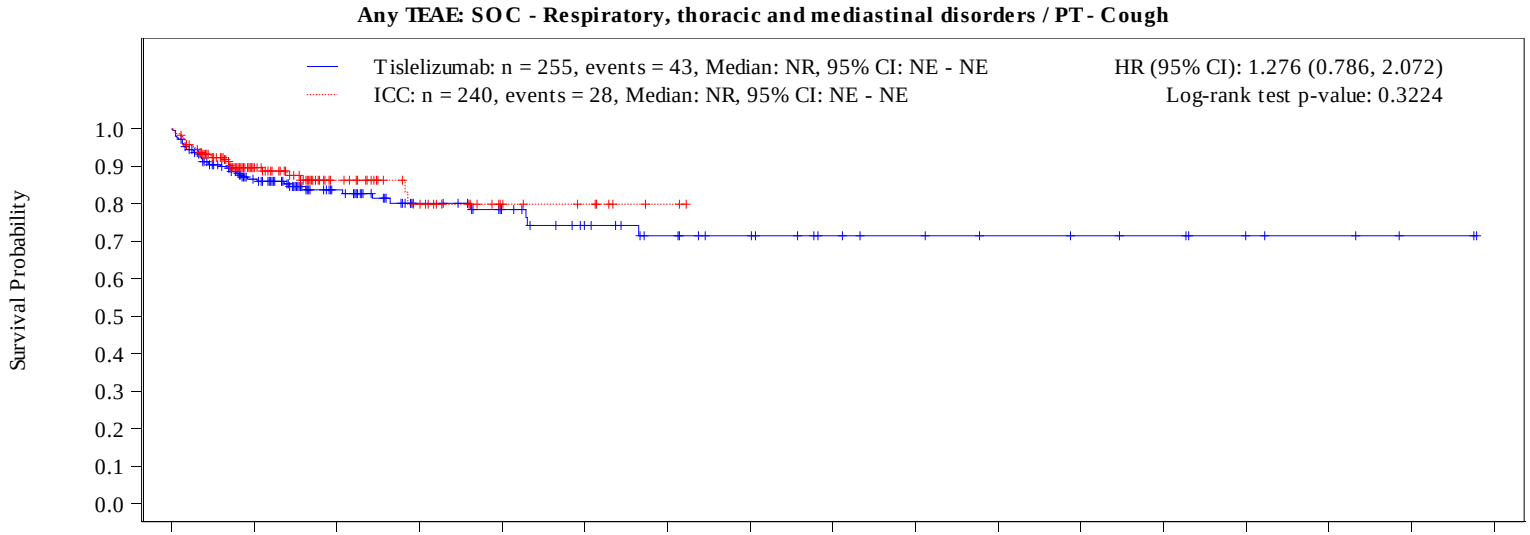

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	150	83	52	40	30	24	20	15	13	11	10	9	5	4	2	0
ICC	240	108	41	22	10	7	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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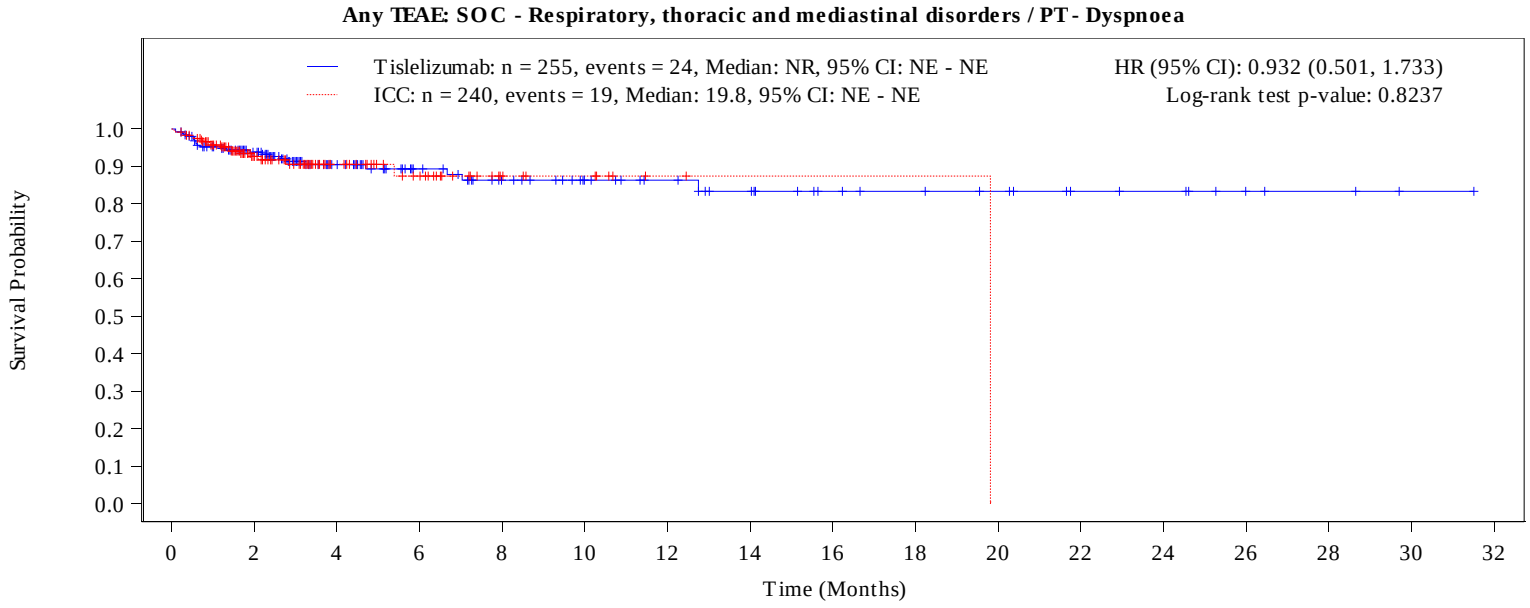

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	169	95	62	47	36	30	25	18	16	14	10	9	4	3	1	0
ICC	240	106	41	24	10	7	2	1	1	1	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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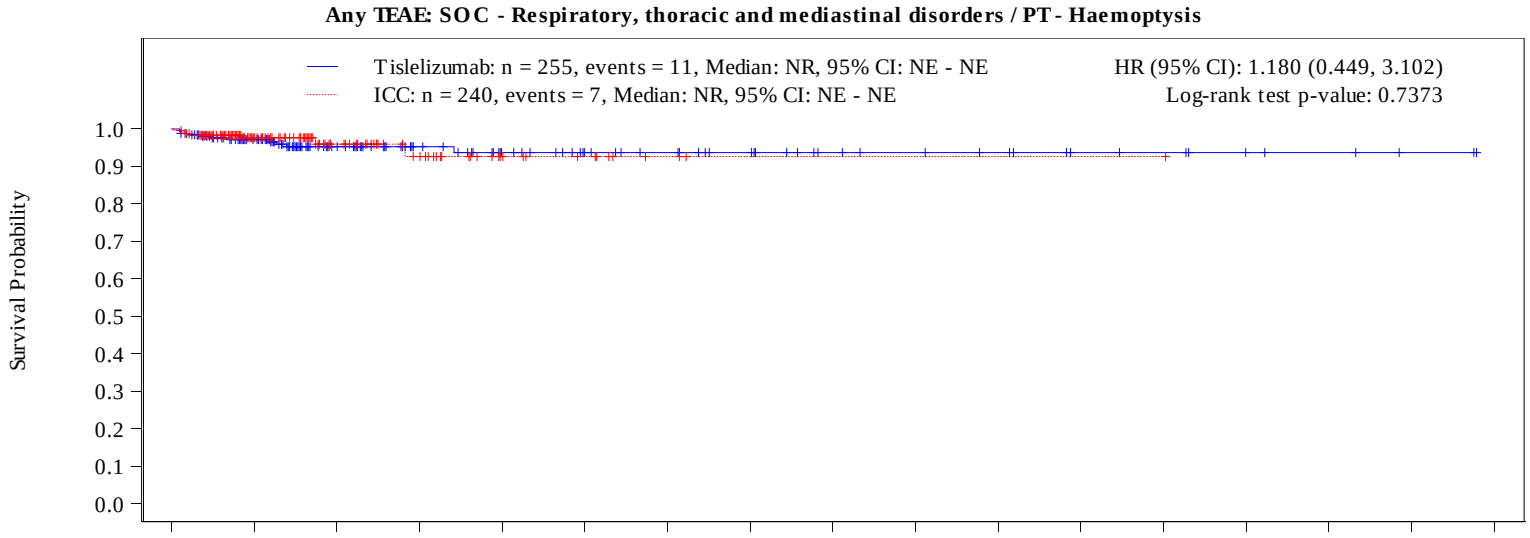

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	173	95	63	47	36	31	26	18	16	14	10	9	5	4	2	0
ICC	240	112	44	25	12	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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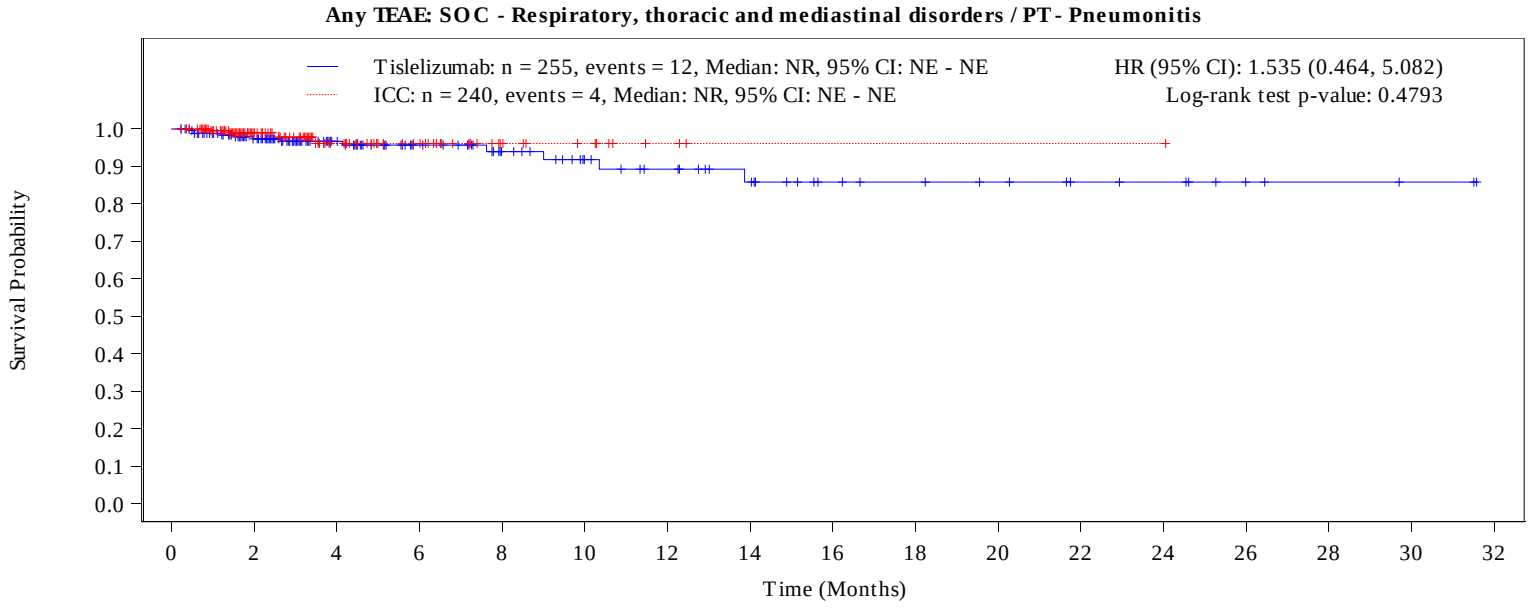
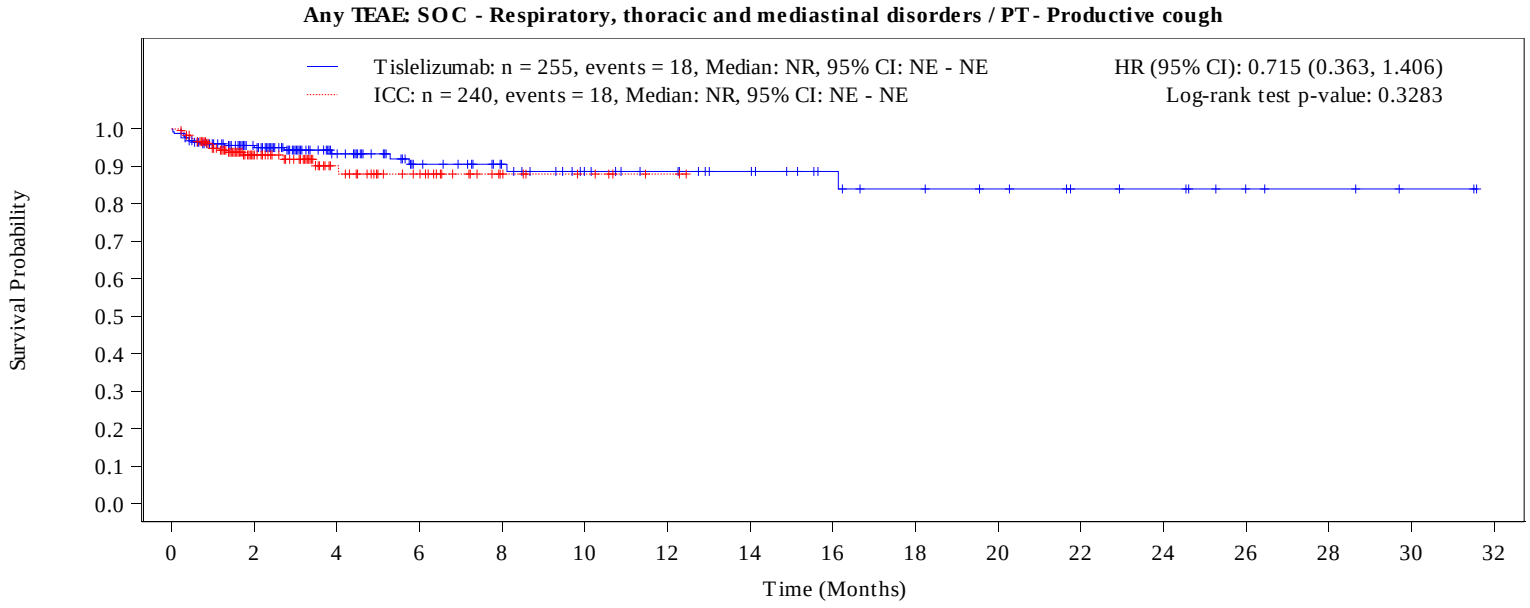


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	174	97	64	48	37	31	25	17	15	13	10	9	4	3	2	0
ICC	240	112	44	26	12	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-km-aesocpt-safety-sa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	168	92	60	47	36	31	26	19	16	14	11	10	5	4	2	0
ICC	240	107	41	24	10	6	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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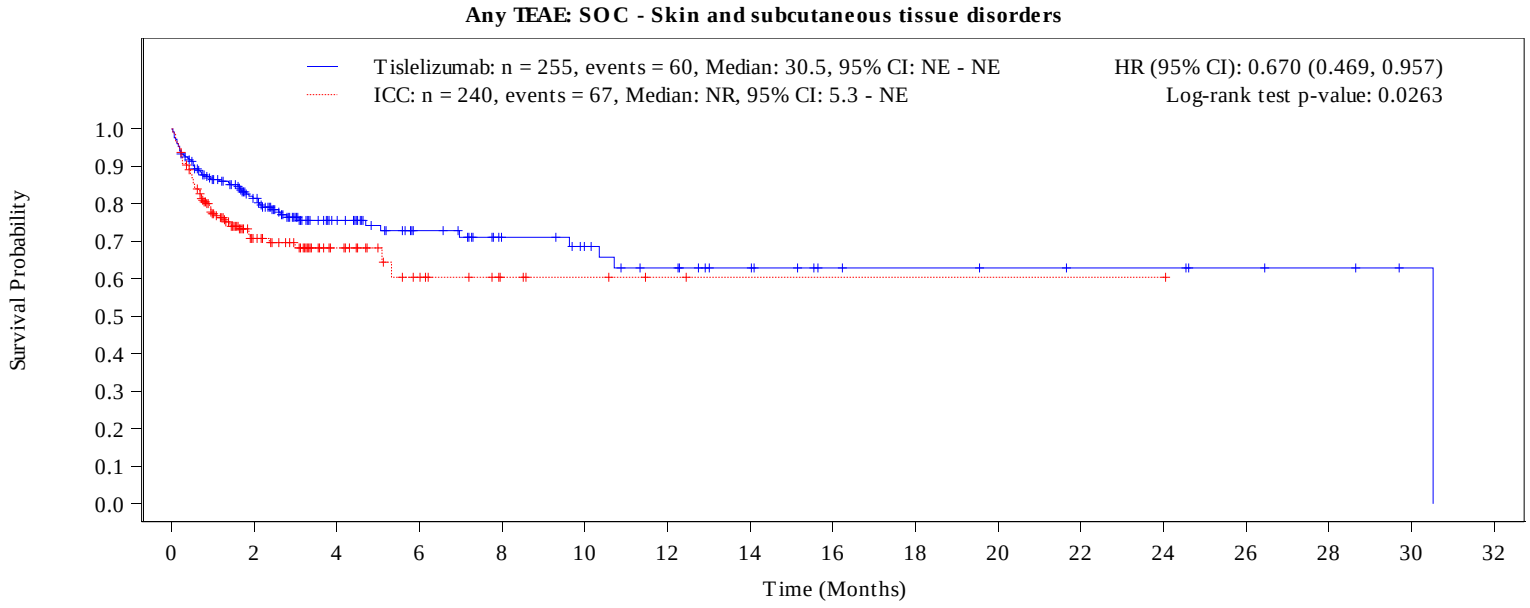
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	140	68	43	30	25	19	14	9	8	7	6	6	4	3	1	0
ICC	240	72	26	13	6	4	2	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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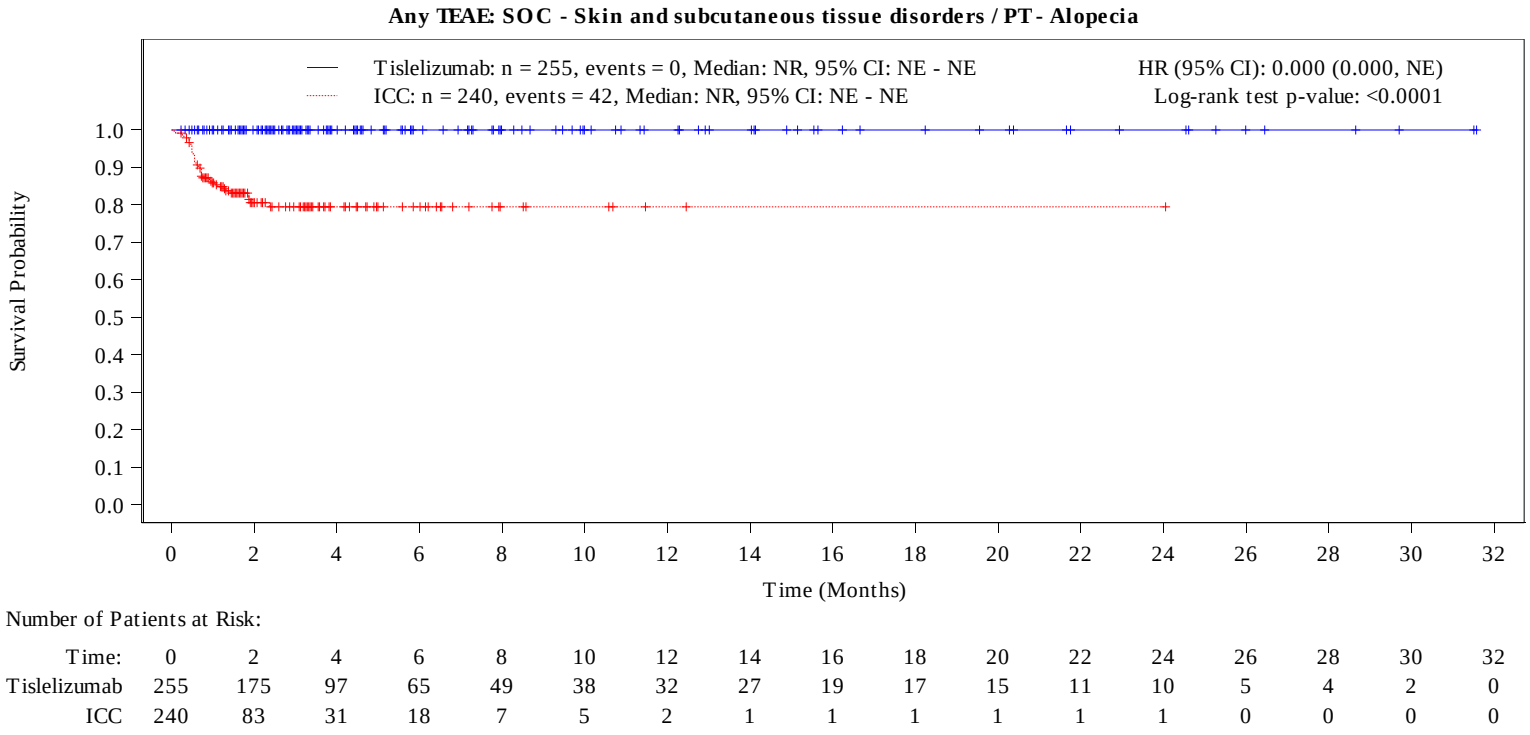
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

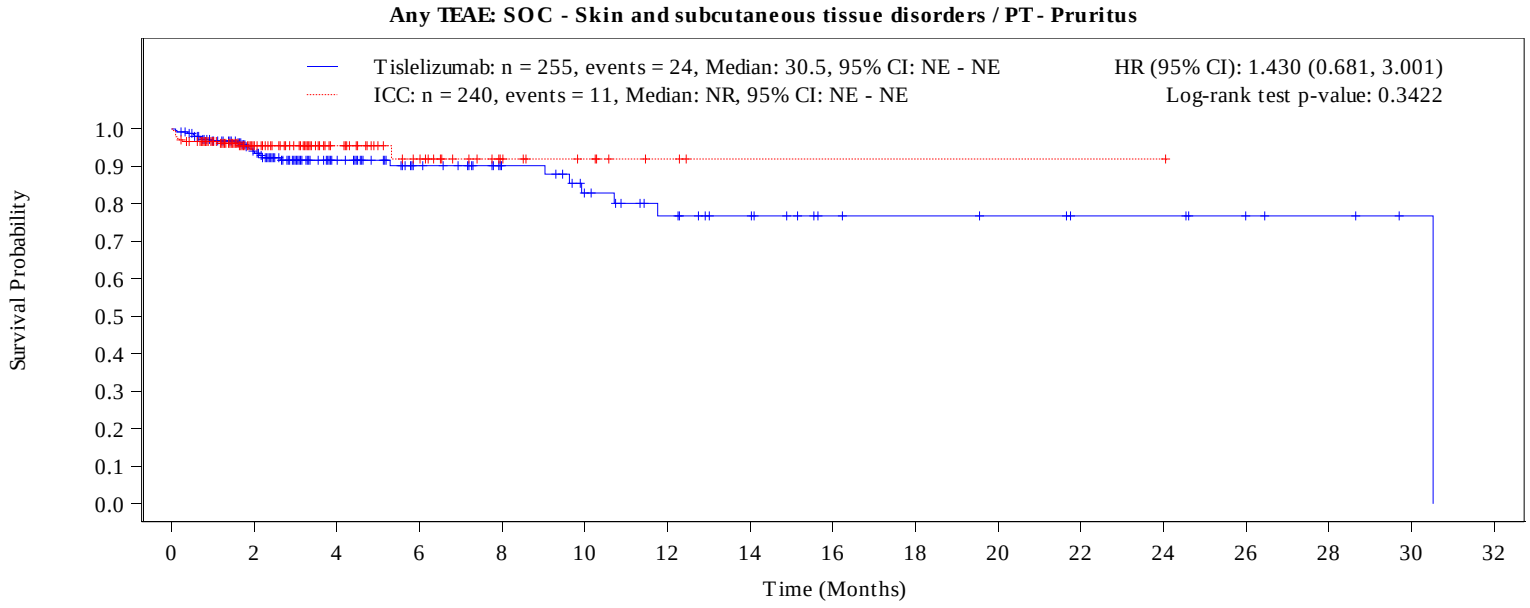


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	175	97	65	49	38	32	27	19	17	15	11	10	5	4	2	0
ICC	240	83	31	18	7	5	2	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-km-aesocpt-safety-sa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

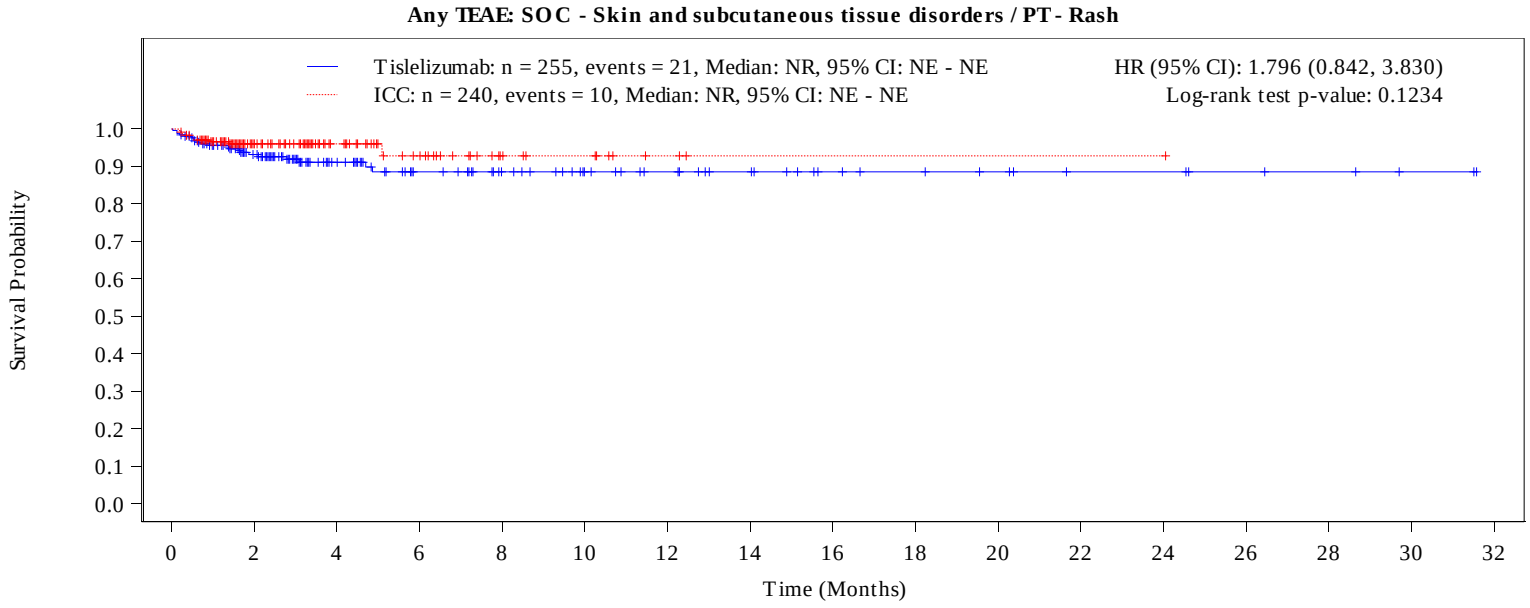


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	162	86	55	40	31	23	18	12	11	10	8	8	4	3	1	0
ICC	240	105	41	23	11	7	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-km-aesocpt-safety-sa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

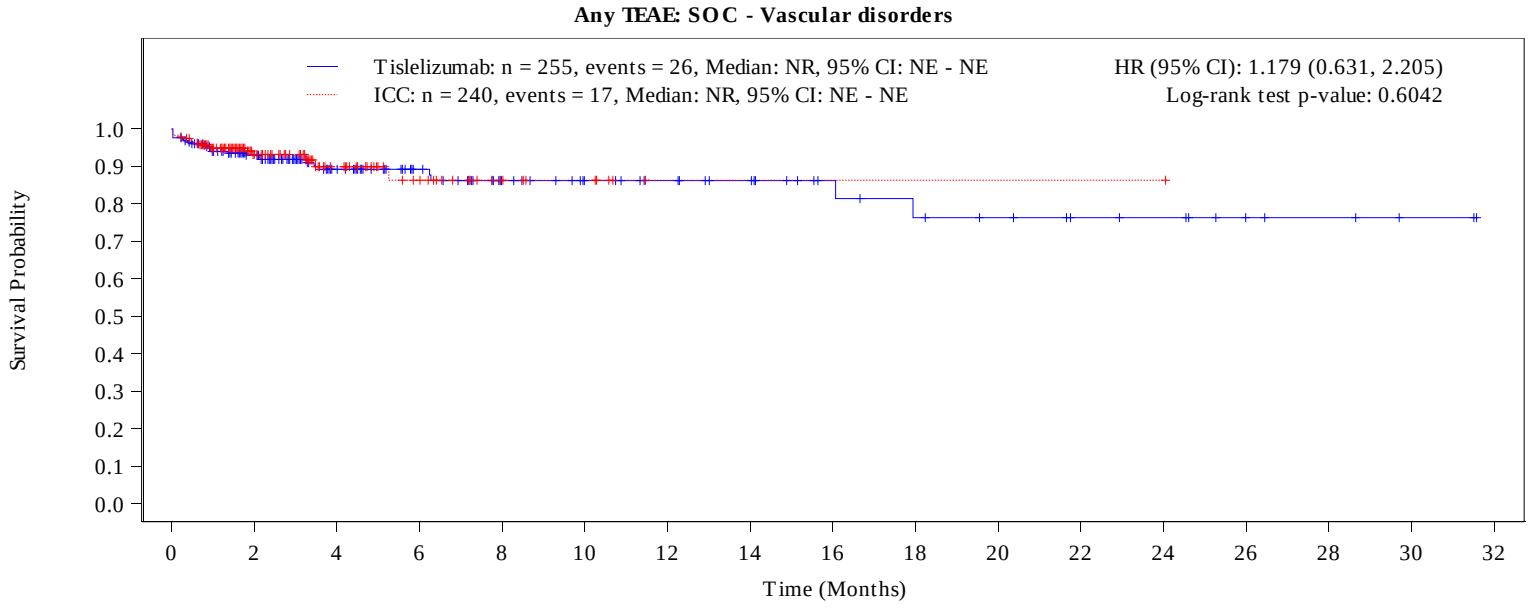


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	163	87	57	44	33	27	22	15	13	11	8	8	5	4	2	0
ICC	240	106	43	24	11	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-km-aesocpt-safety-sa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

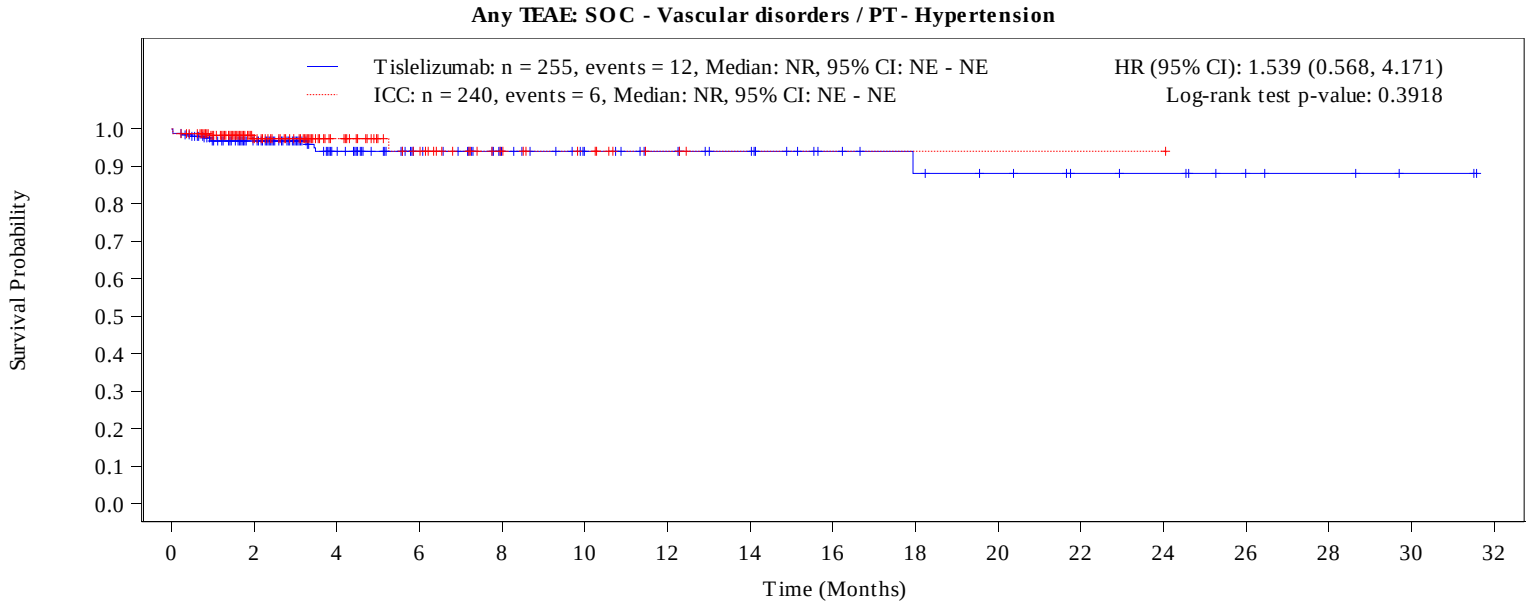


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	166	92	60	43	34	29	25	18	15	13	10	9	5	4	2	0
ICC	240	102	40	20	9	6	1	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-km-aesocpt-safety-sa.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

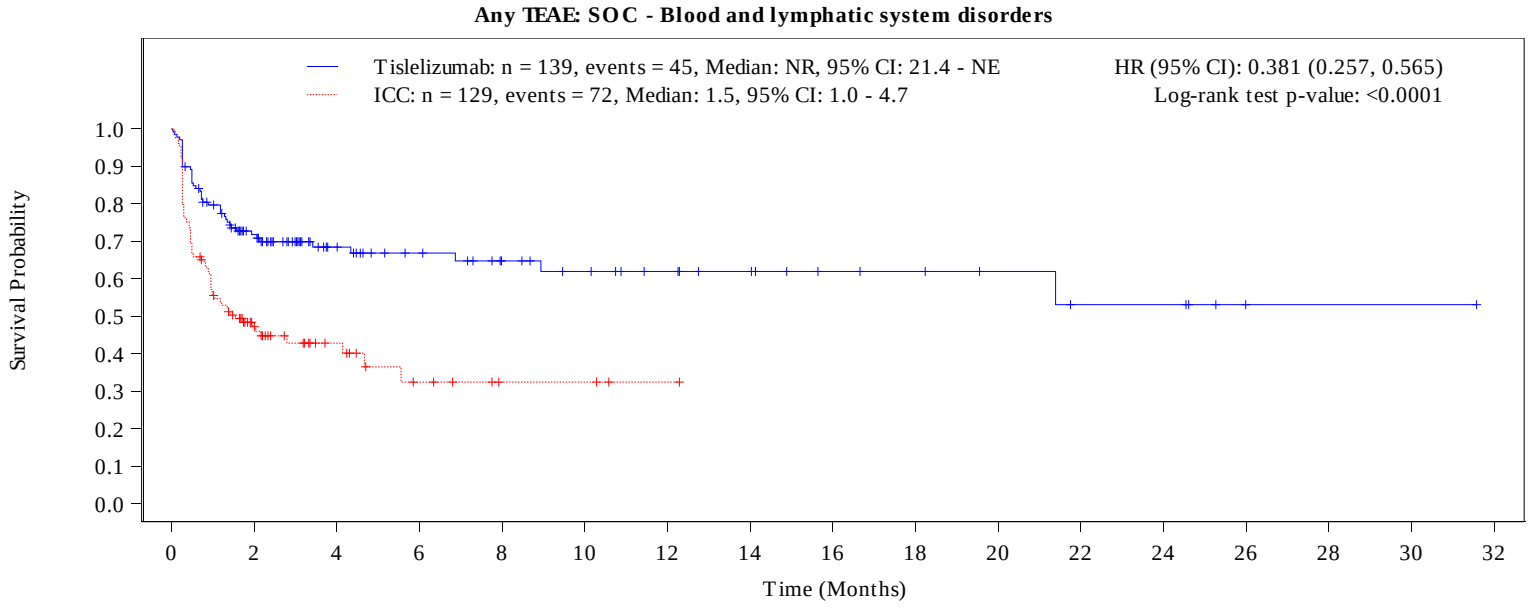


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	170	92	60	44	35	30	26	18	15	13	10	9	5	4	2	0
ICC	240	109	44	24	12	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-km-aesocpt-safety-sa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

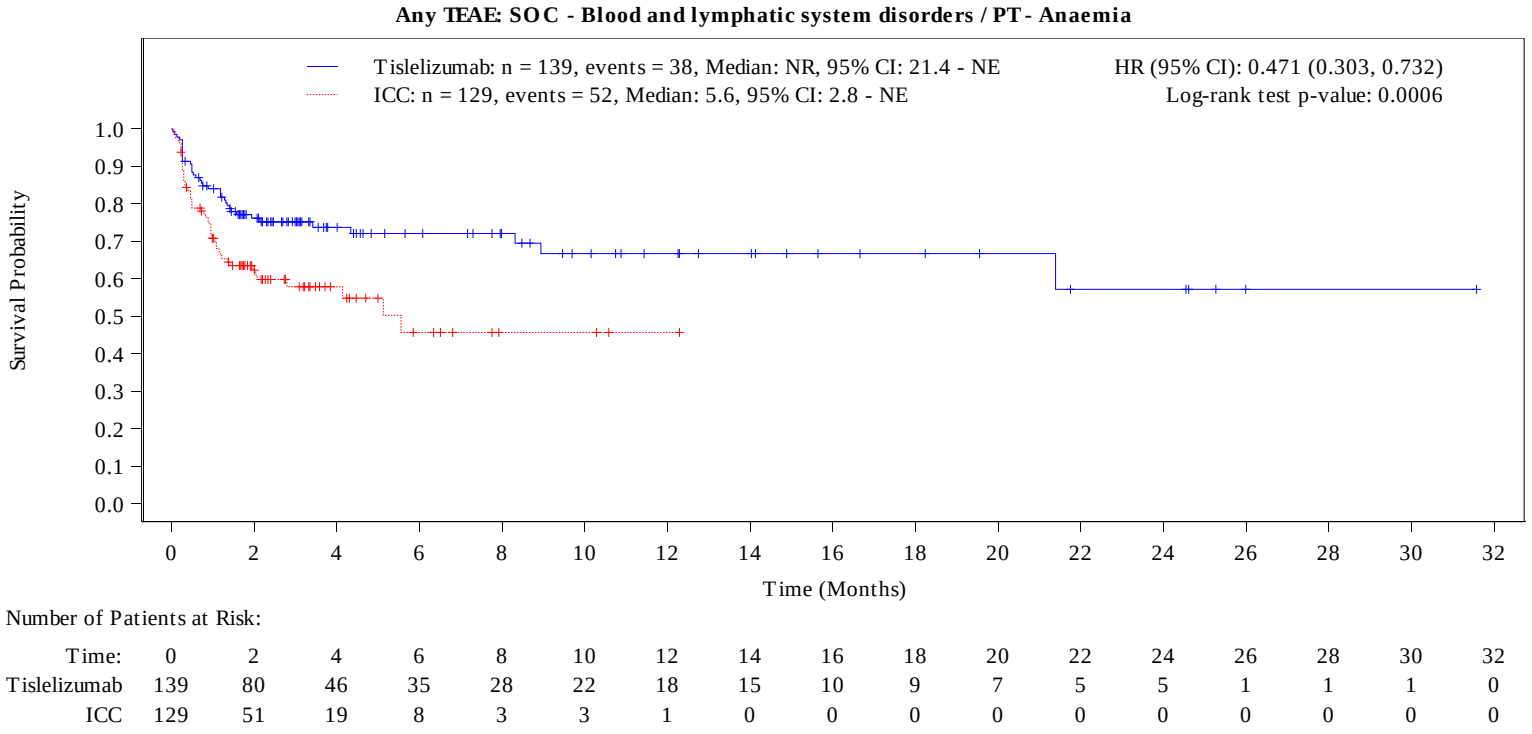


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	76	44	33	25	21	17	14	10	9	7	5	5	1	1	1	0
ICC	129	40	16	7	3	3	1	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-b-km-aesocpt-safetys-sa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

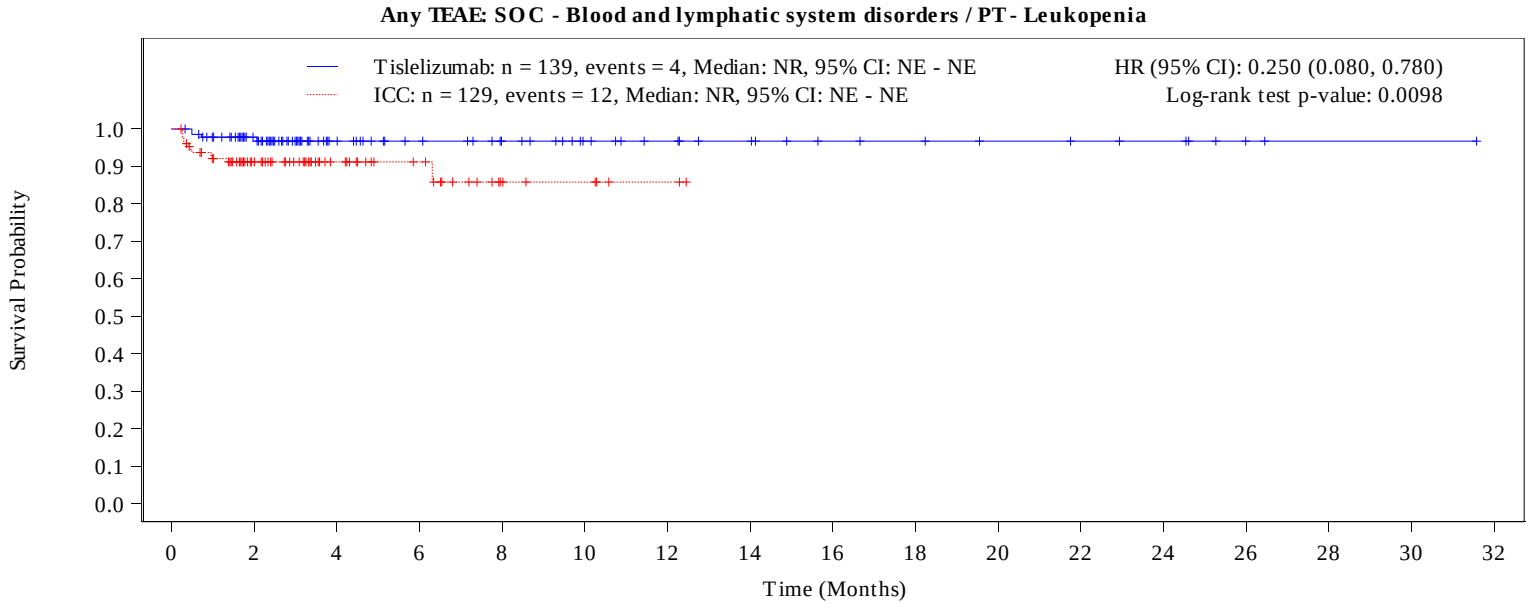


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	80	46	35	28	22	18	15	10	9	7	5	5	1	1	1	0
ICC	129	51	19	8	3	3	1	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-b-km-aesocpt-safetys-sa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

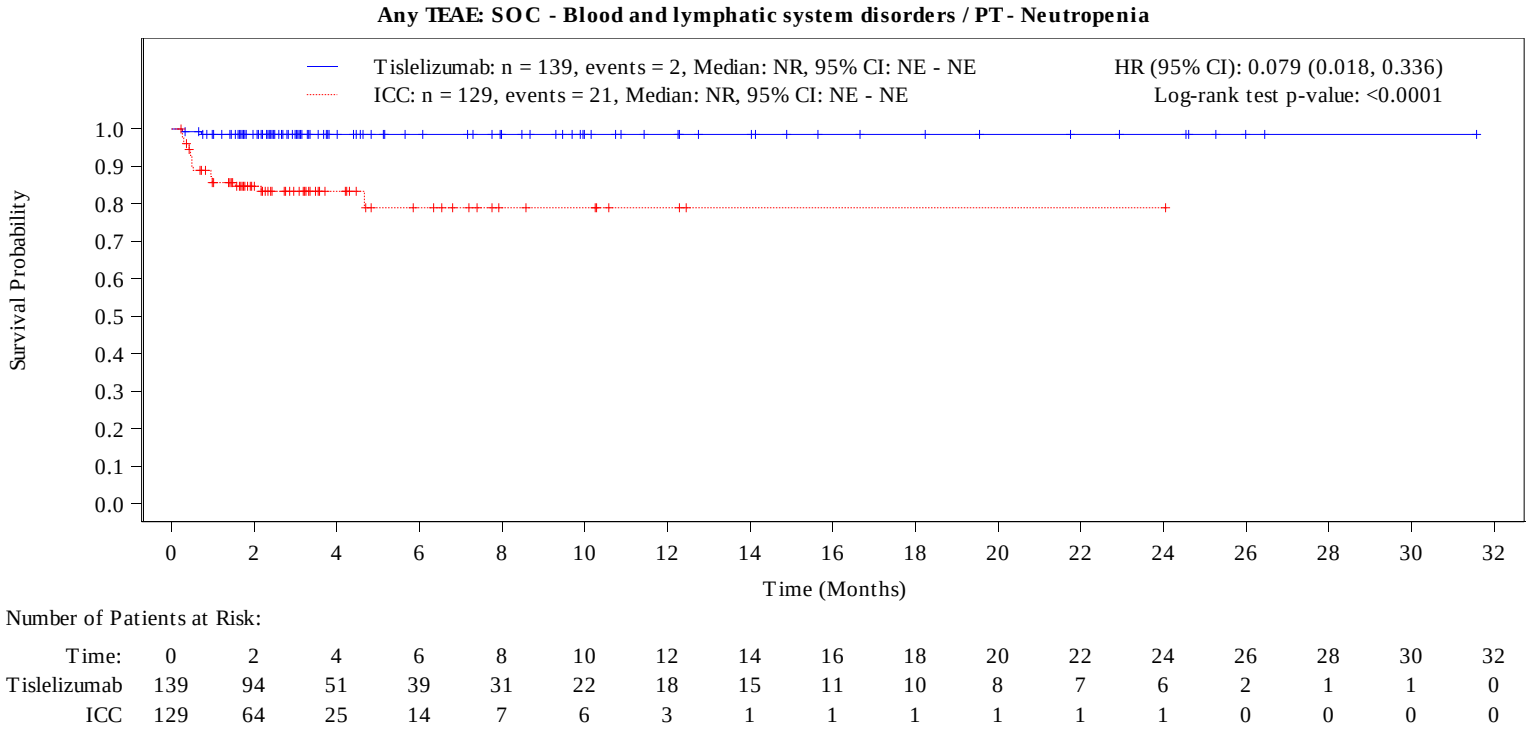


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	92	50	38	30	22	18	15	11	10	8	7	6	2	1	1	0
ICC	129	71	30	18	7	5	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-b-km-aesocpt-safetys-sa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

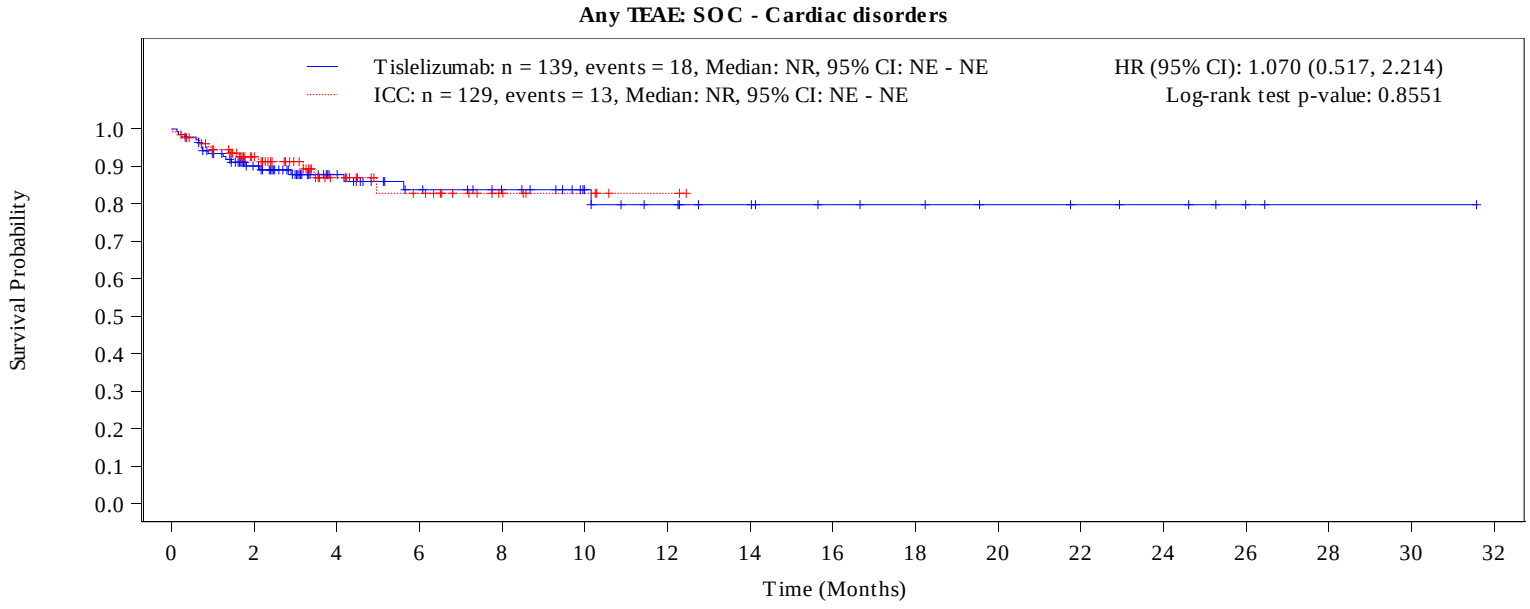


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	94	51	39	31	22	18	15	11	10	8	7	6	2	1	1	0
ICC	129	64	25	14	7	6	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-b-km-aesocpt-safetys-sa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	88	49	37	30	21	17	14	10	9	7	6	5	2	1	1	0
ICC	129	73	30	17	8	5	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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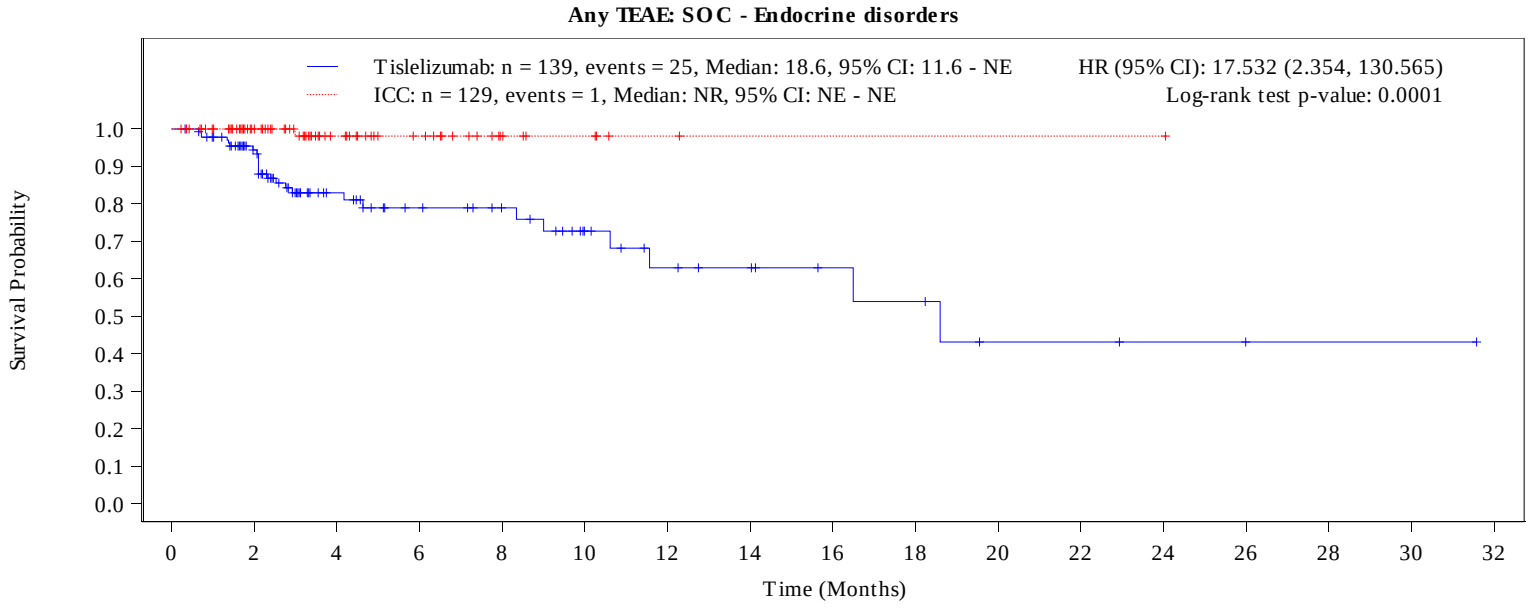
Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

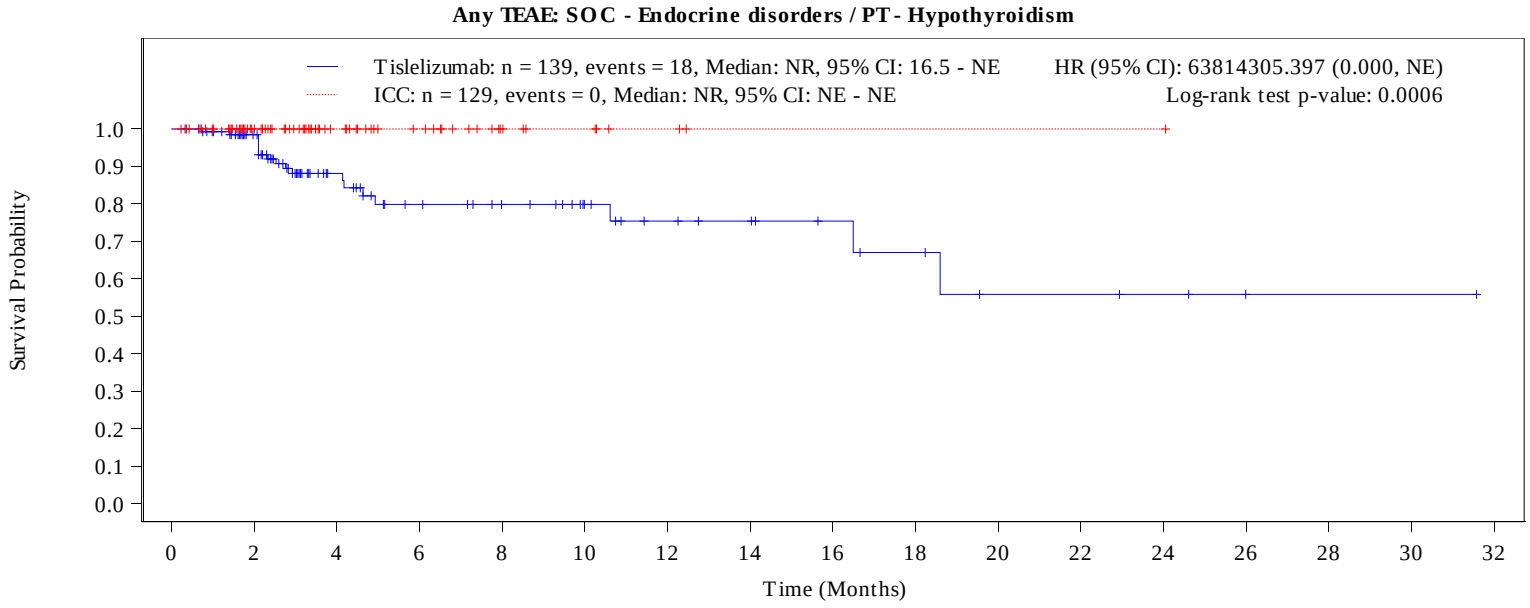


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	89	44	31	26	17	12	10	7	6	3	3	2	1	1	1	0
ICC	129	75	32	18	8	5	2	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-b-km-aesocpt-safetys-sa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

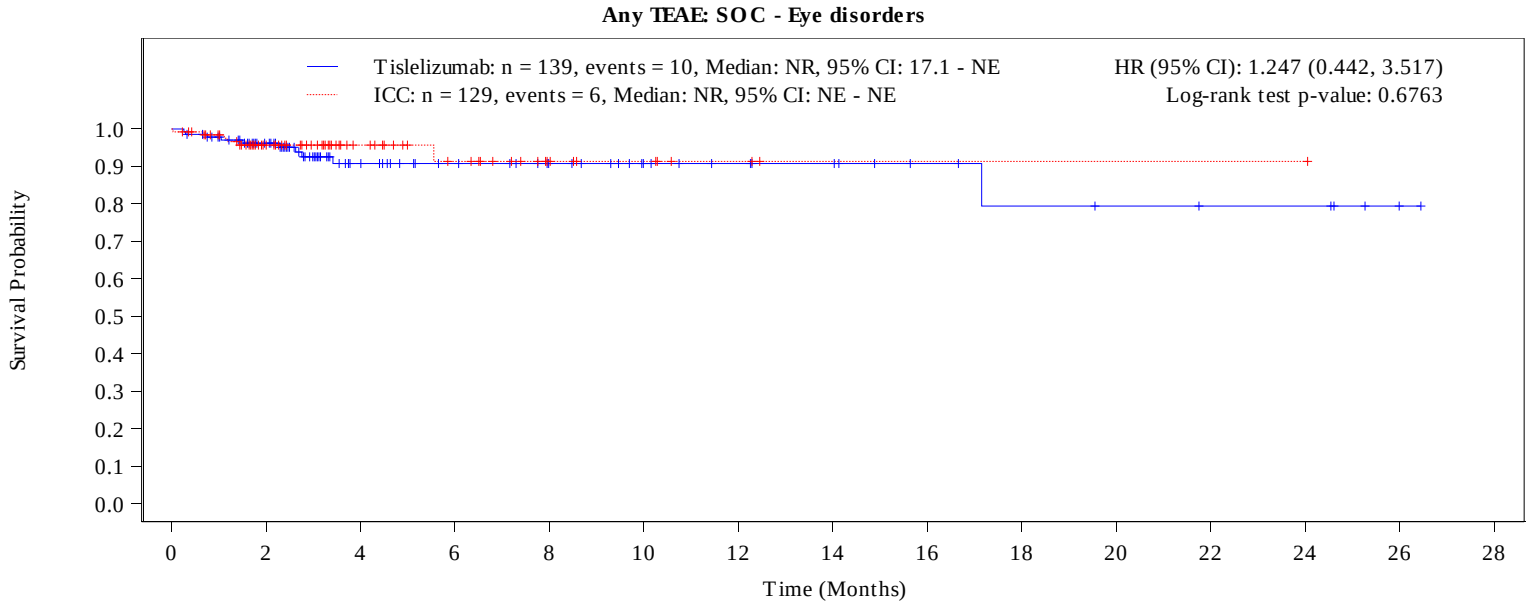


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	93	46	31	26	19	14	12	9	7	4	4	3	1	1	1	0
ICC	129	75	33	19	9	6	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-b-km-aesocpt-safetys-sa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

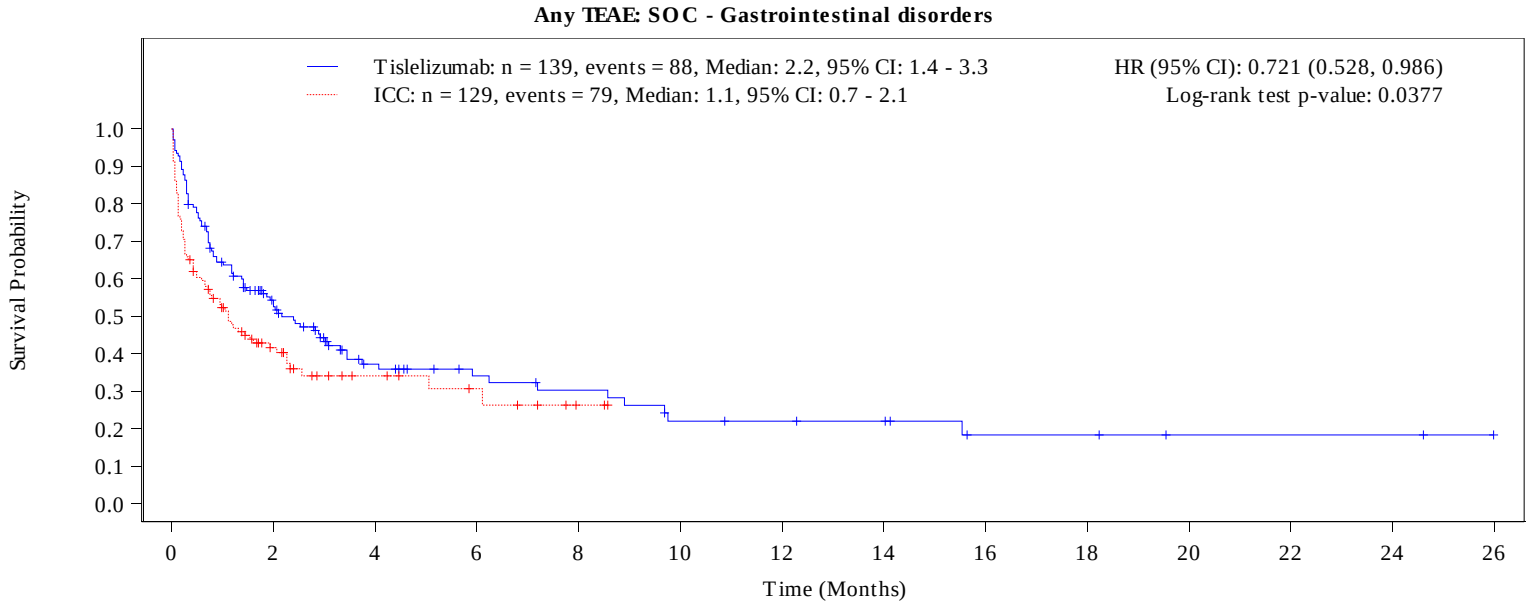


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28
Tislelizumab	139	92	47	35	27	19	16	14	9	7	6	5	5	1	0
ICC	129	73	31	18	9	6	3	1	1	1	1	1	1	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-b-km-aesocpt-safetys-sa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

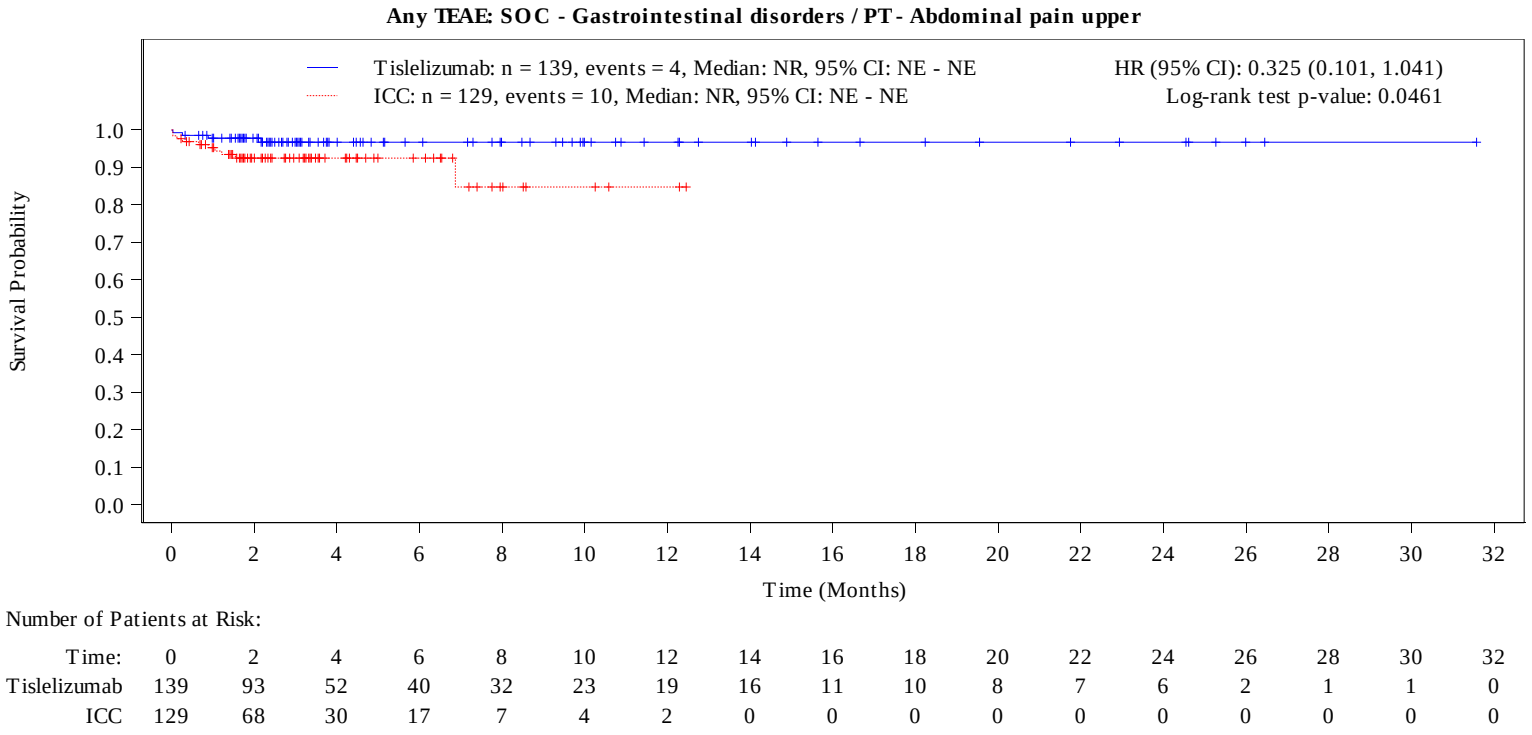


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	139	62	28	19	15	10	9	8	4	4	2	2	2	0
ICC	129	32	13	7	2	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-b-km-aesocpt-safetys-sa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

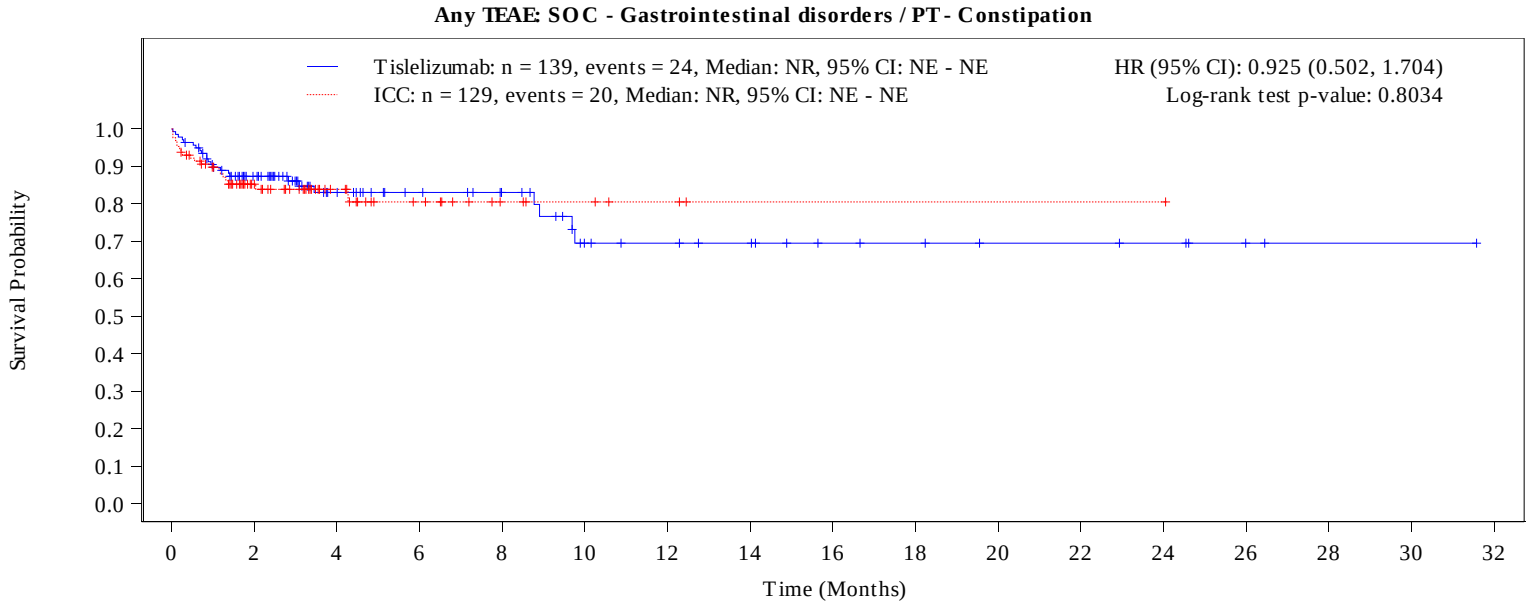


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	93	52	40	32	23	19	16	11	10	8	7	6	2	1	1	0
ICC	129	68	30	17	7	4	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-b-km-aesocpt-safetys-sa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

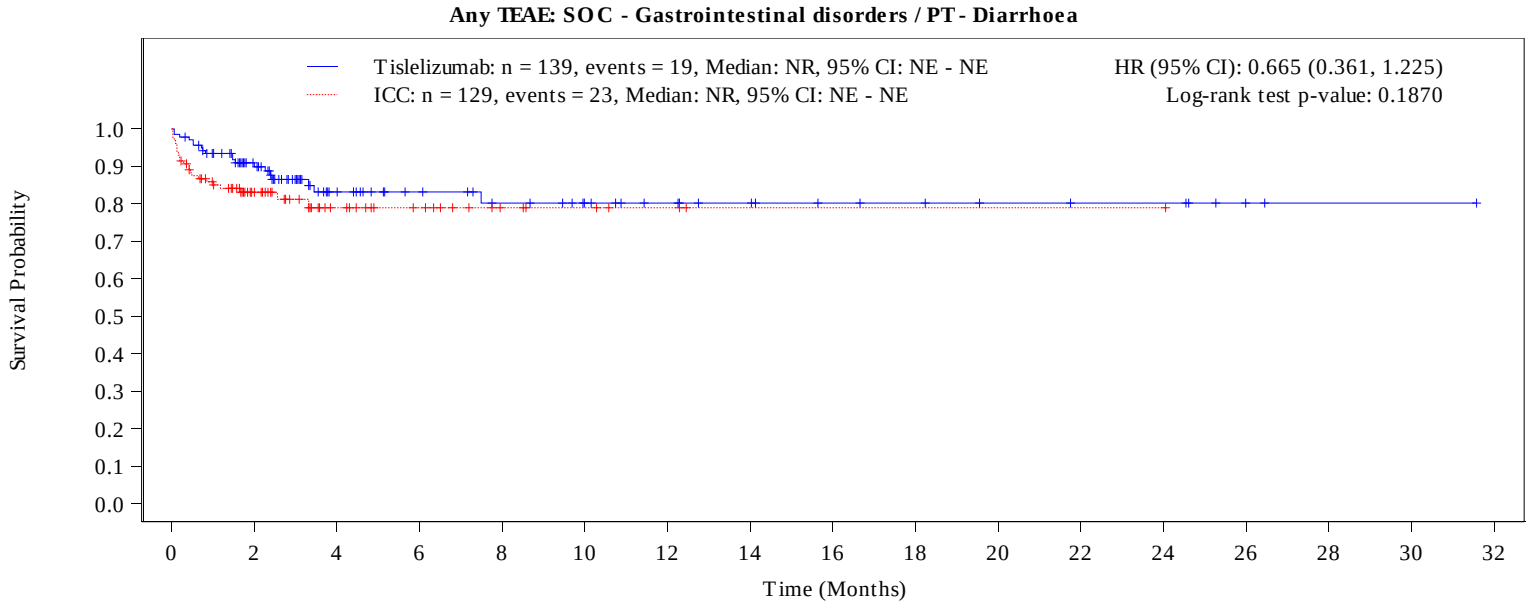


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	86	47	35	28	17	15	13	9	8	6	6	5	2	1	1	0
ICC	129	63	27	14	7	5	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-b-km-aesocpt-safetys-sa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	86	44	32	26	21	17	14	10	9	7	6	6	2	1	1	0
ICC	129	60	24	14	7	5	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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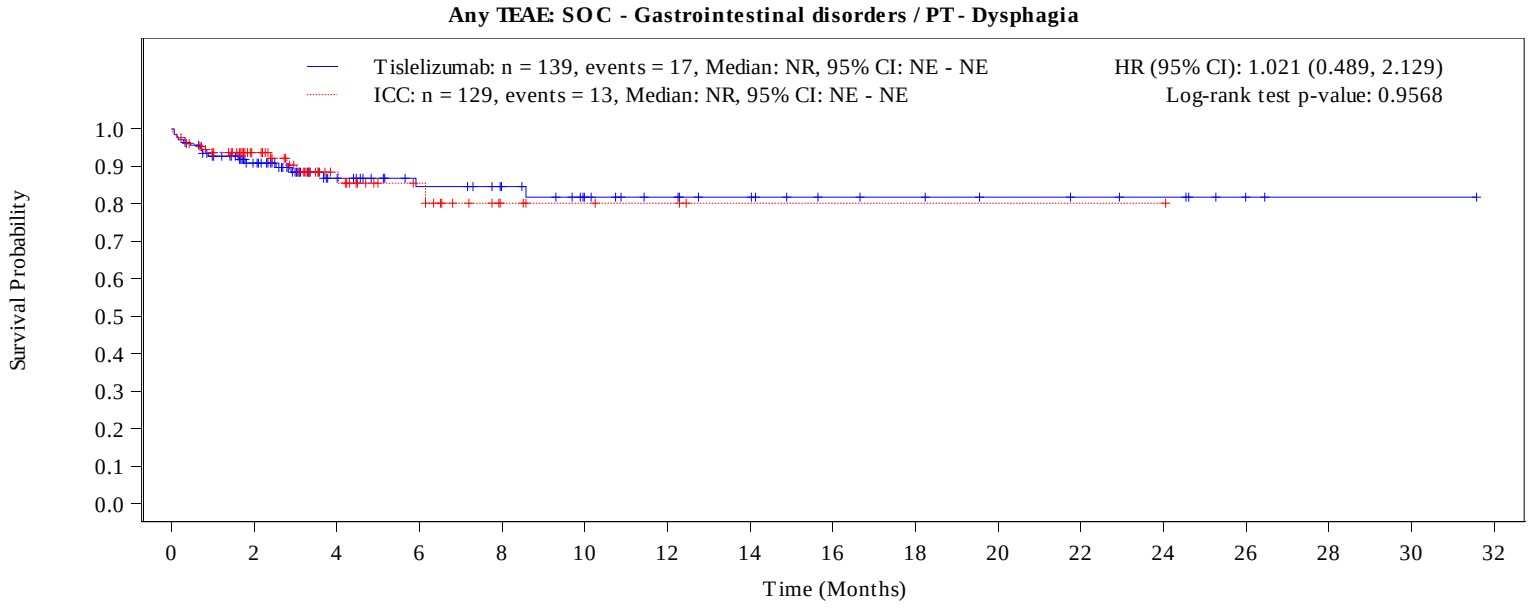
Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	90	51	38	31	23	19	16	11	10	8	7	6	2	1	1	0
ICC	129	70	30	16	6	4	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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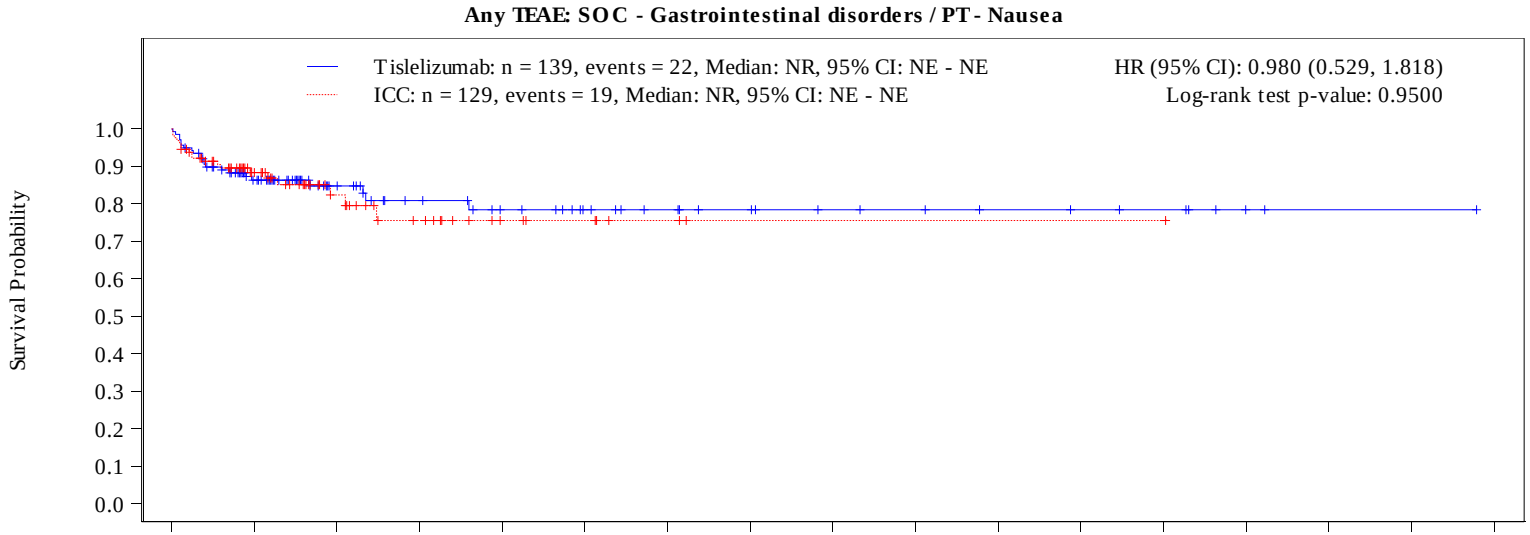
Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

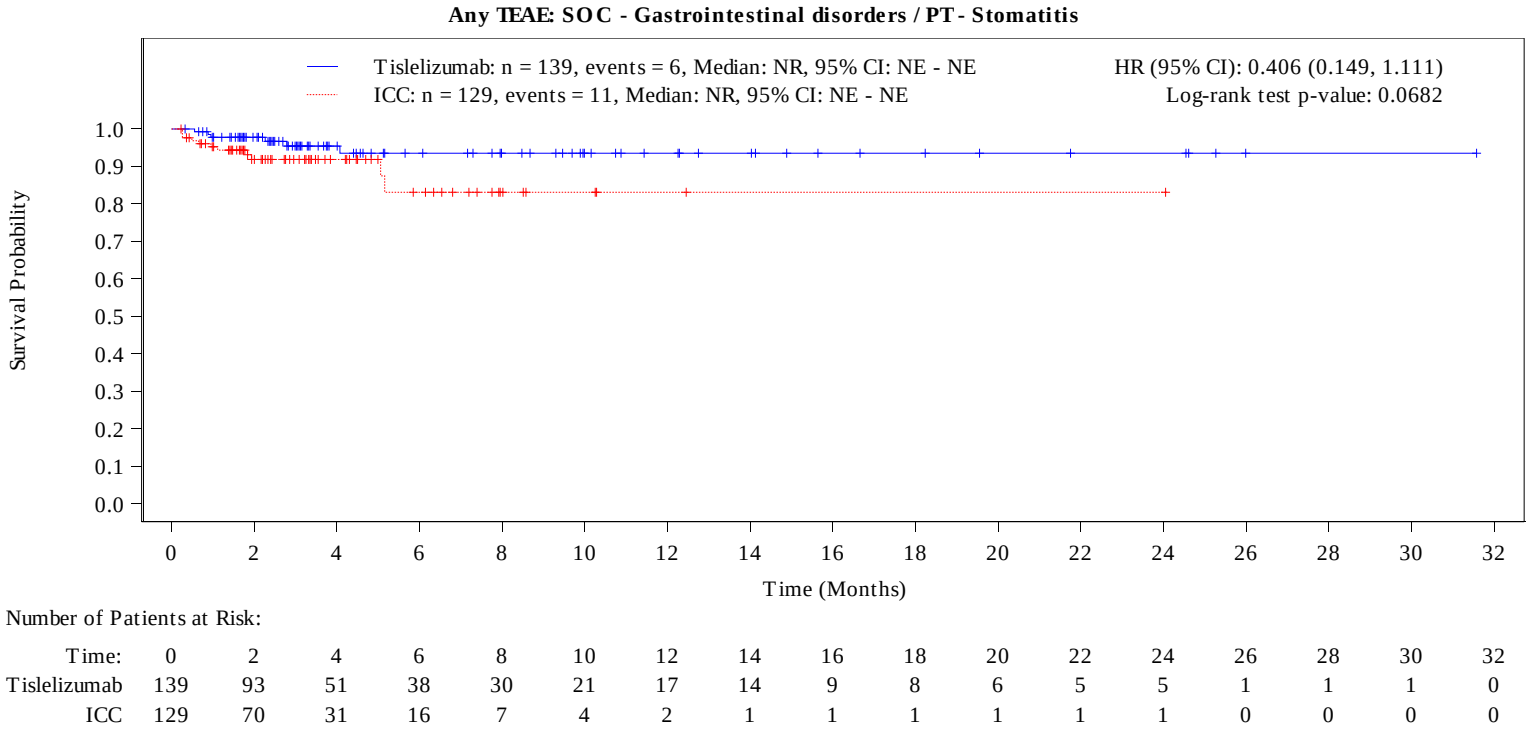


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	87	49	36	29	22	18	15	11	10	8	7	6	2	1	1	0
ICC	129	67	29	16	8	6	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-b-km-aesocpt-safetys-sa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	93	51	38	30	21	17	14	9	8	6	5	5	1	1	1	0
ICC	129	70	31	16	7	4	2	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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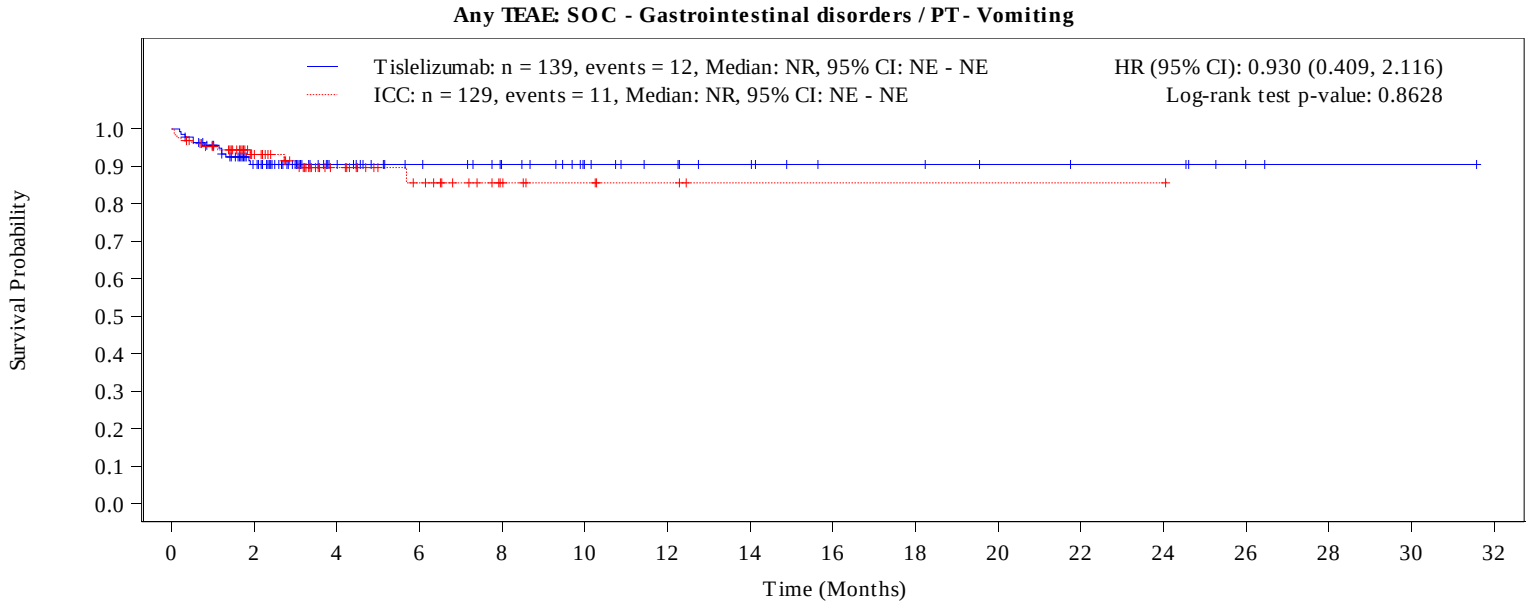
Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	89	49	37	30	21	17	14	9	9	7	6	6	2	1	1	0
ICC	129	72	32	18	8	5	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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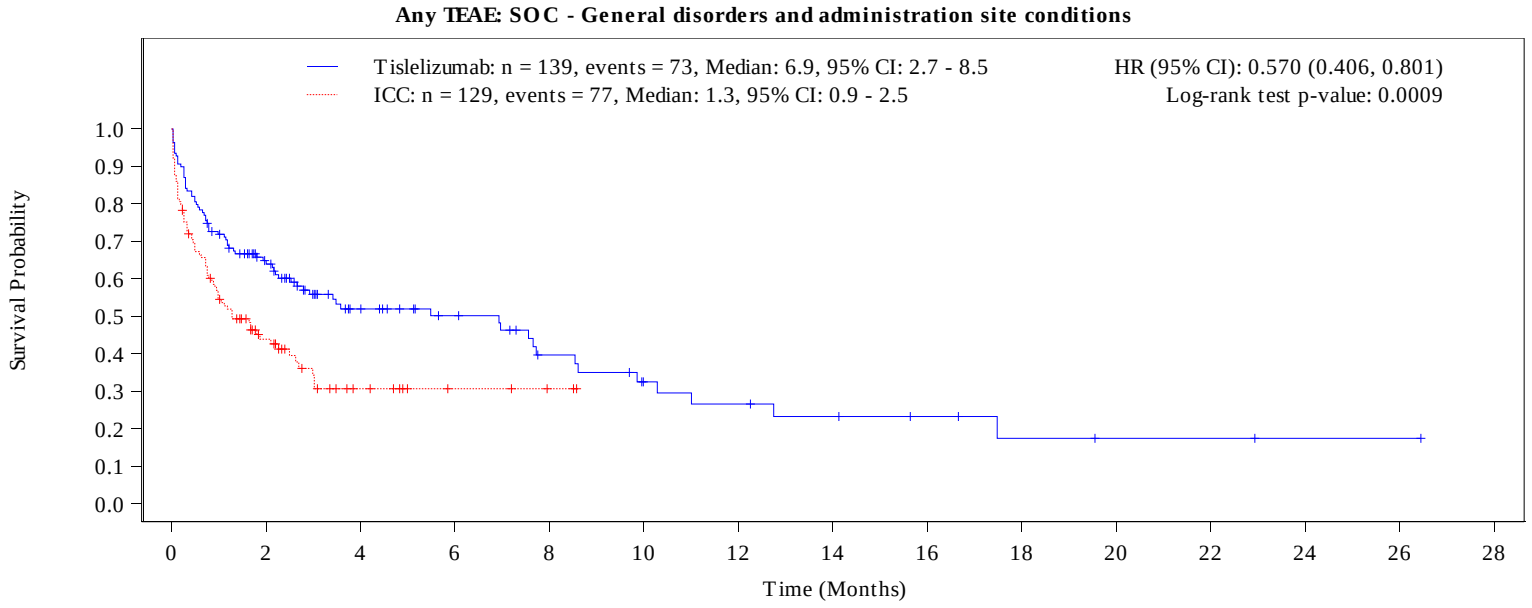
Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28
Tislelizumab	139	70	37	27	17	11	9	7	5	3	2	2	1	1	0
ICC	129	35	10	4	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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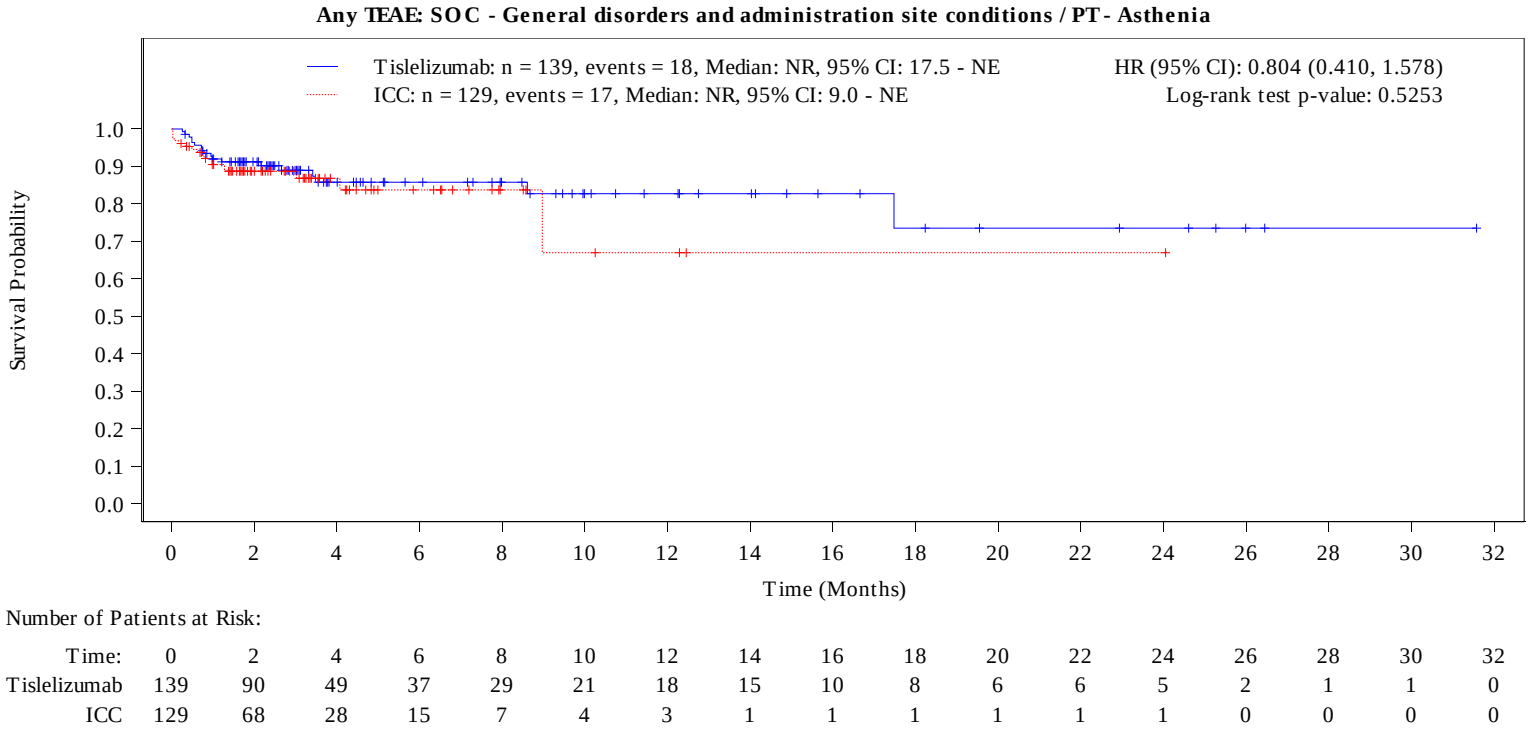
Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	90	49	37	29	21	18	15	10	8	6	6	5	2	1	1	0
ICC	129	68	28	15	7	4	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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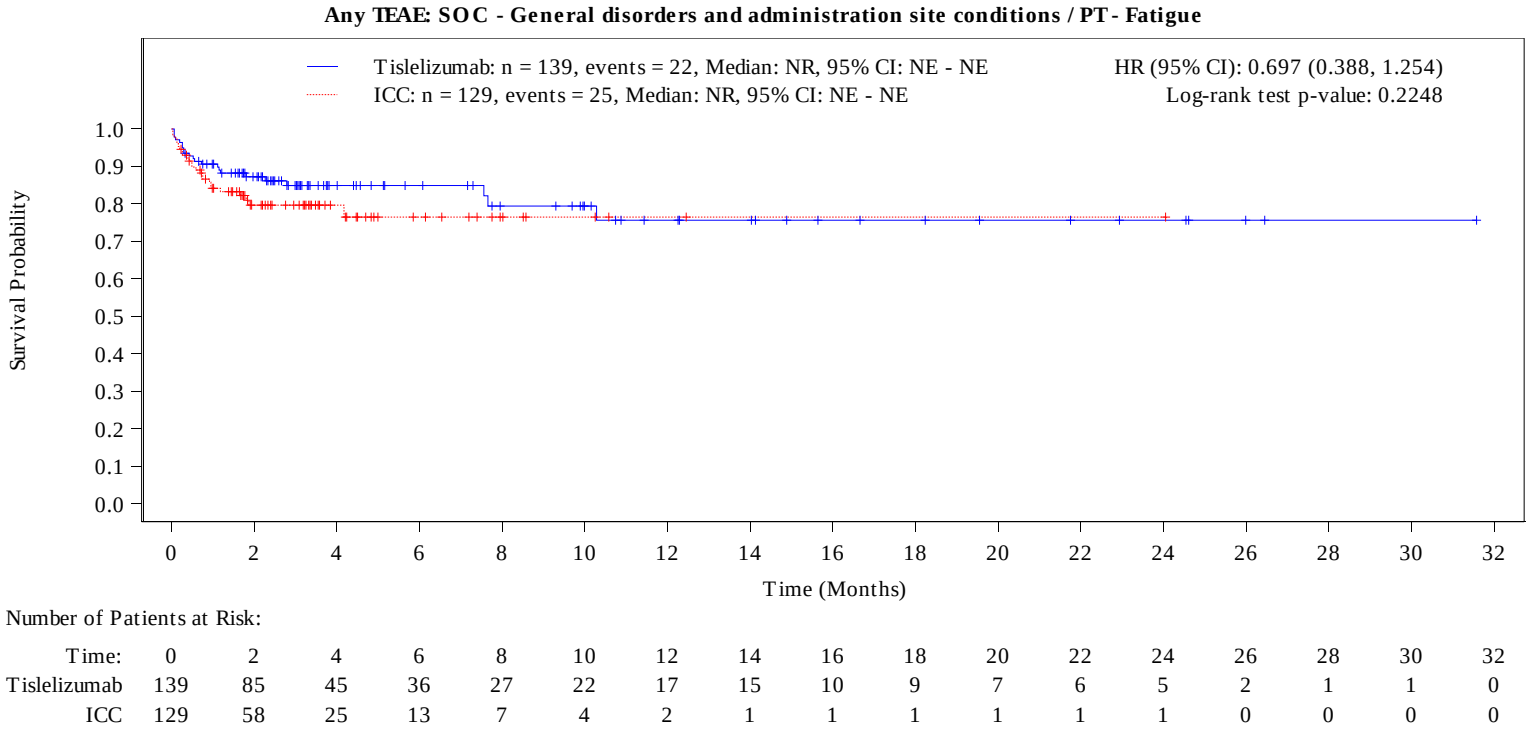
Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	85	45	36	27	22	17	15	10	9	7	6	5	2	1	1	0
ICC	129	58	25	13	7	4	2	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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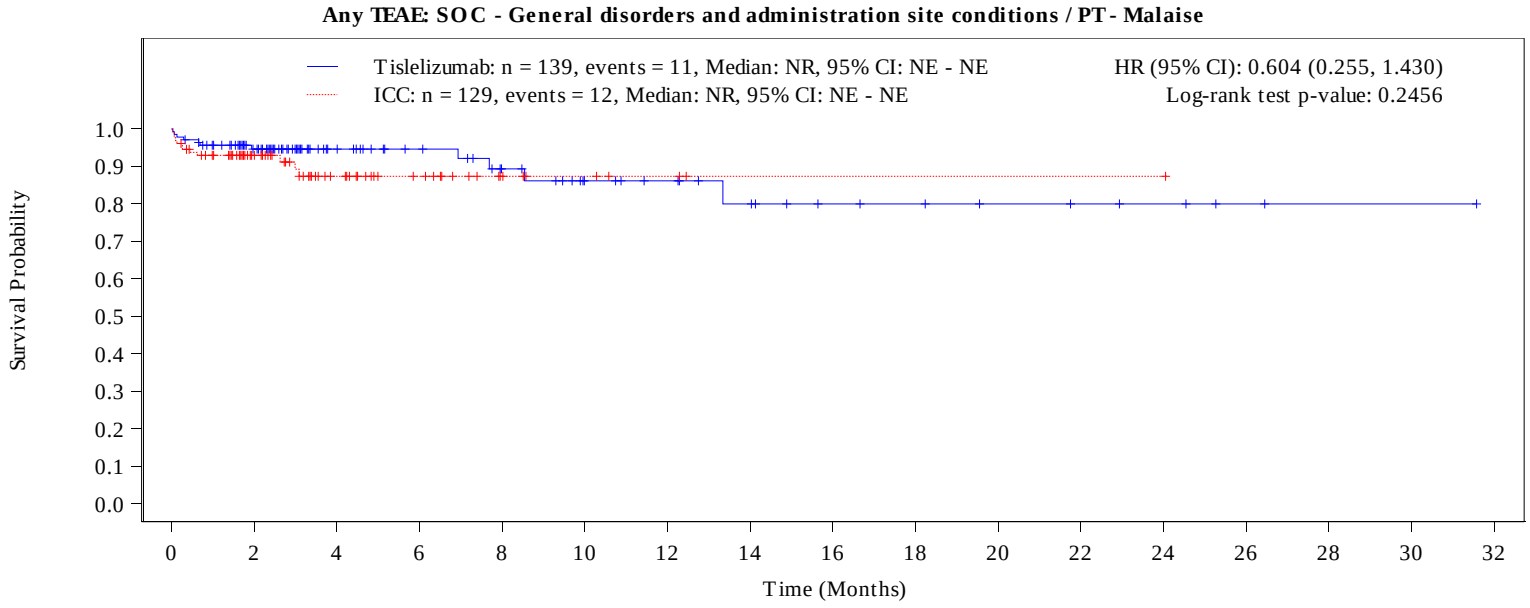
Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	91	51	39	29	20	17	13	9	8	6	5	4	2	1	1	0
ICC	129	70	30	17	8	5	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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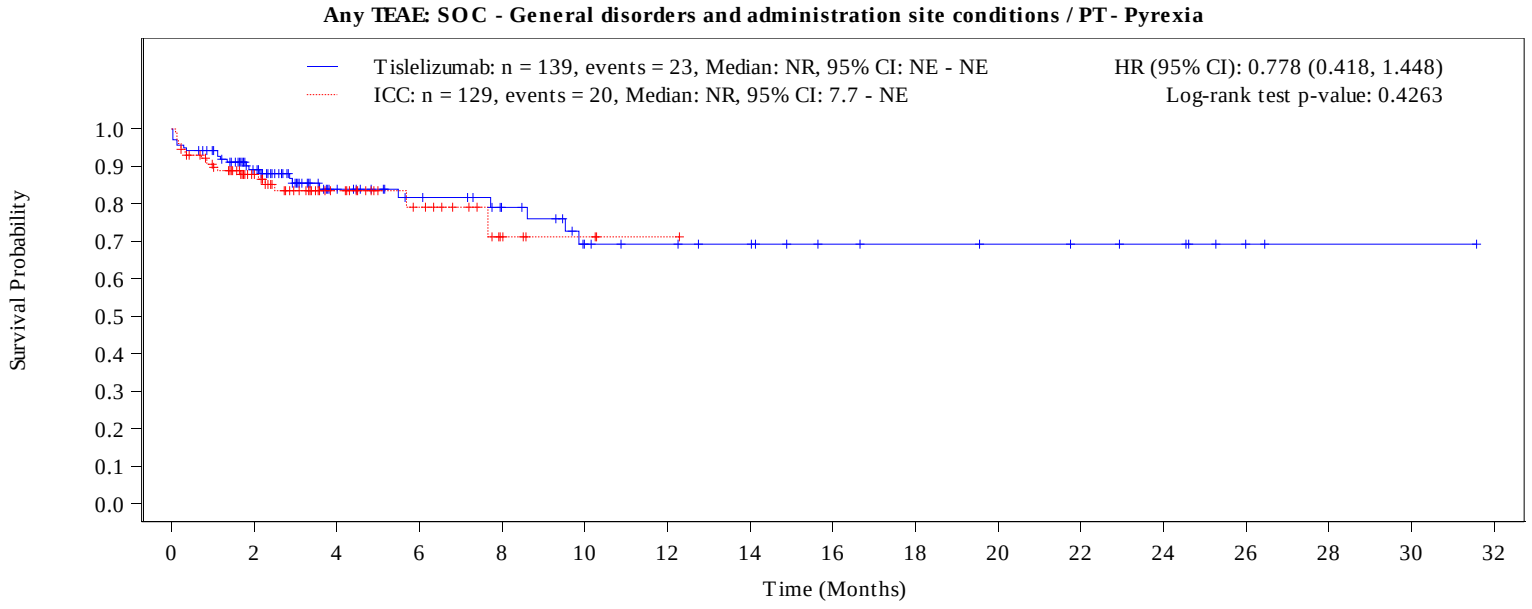
Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	87	48	36	27	18	16	14	10	9	8	7	6	2	1	1	0
ICC	129	69	29	16	6	3	1	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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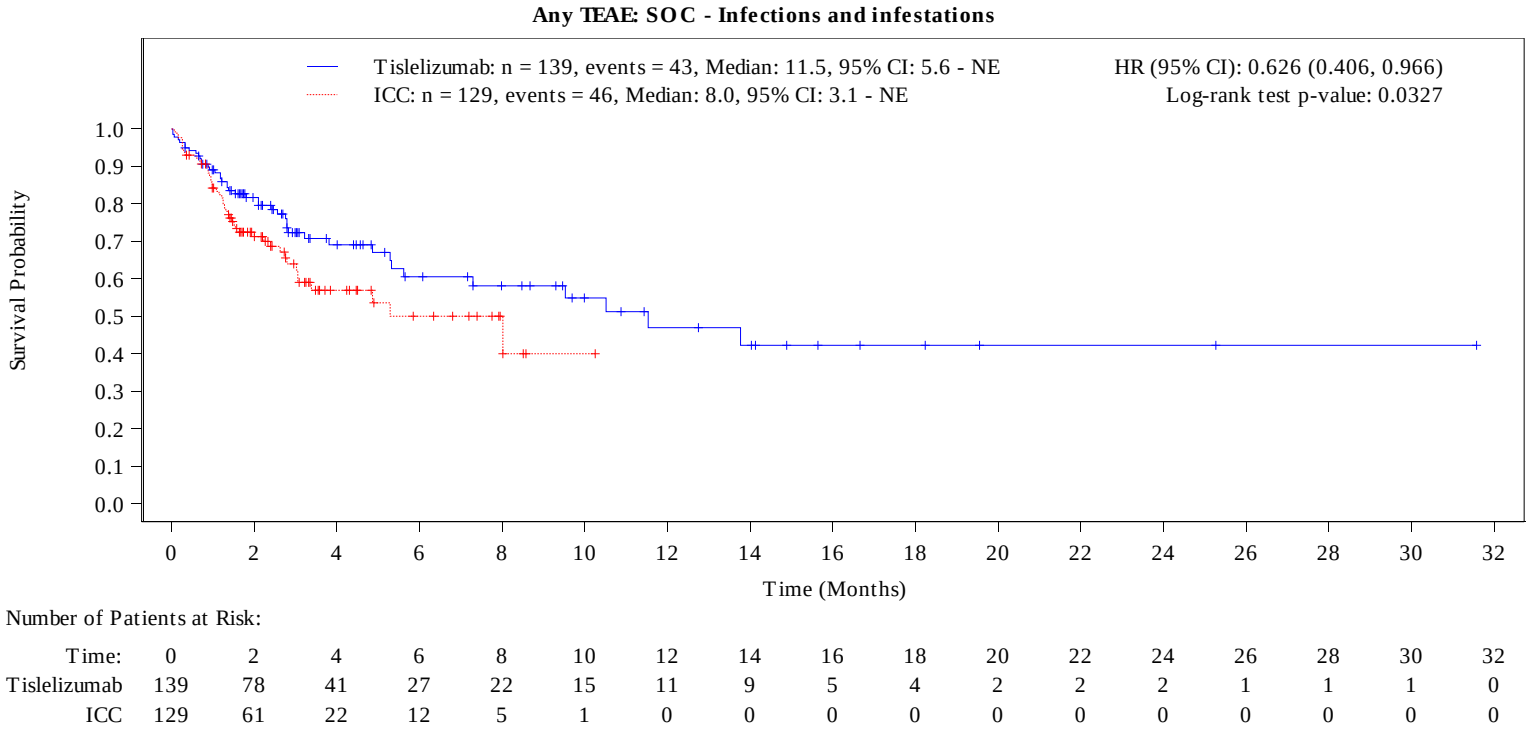
Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	78	41	27	22	15	11	9	5	4	2	2	2	1	1	1	0
ICC	129	61	22	12	5	1	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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Figure 14.3.1.2.b:
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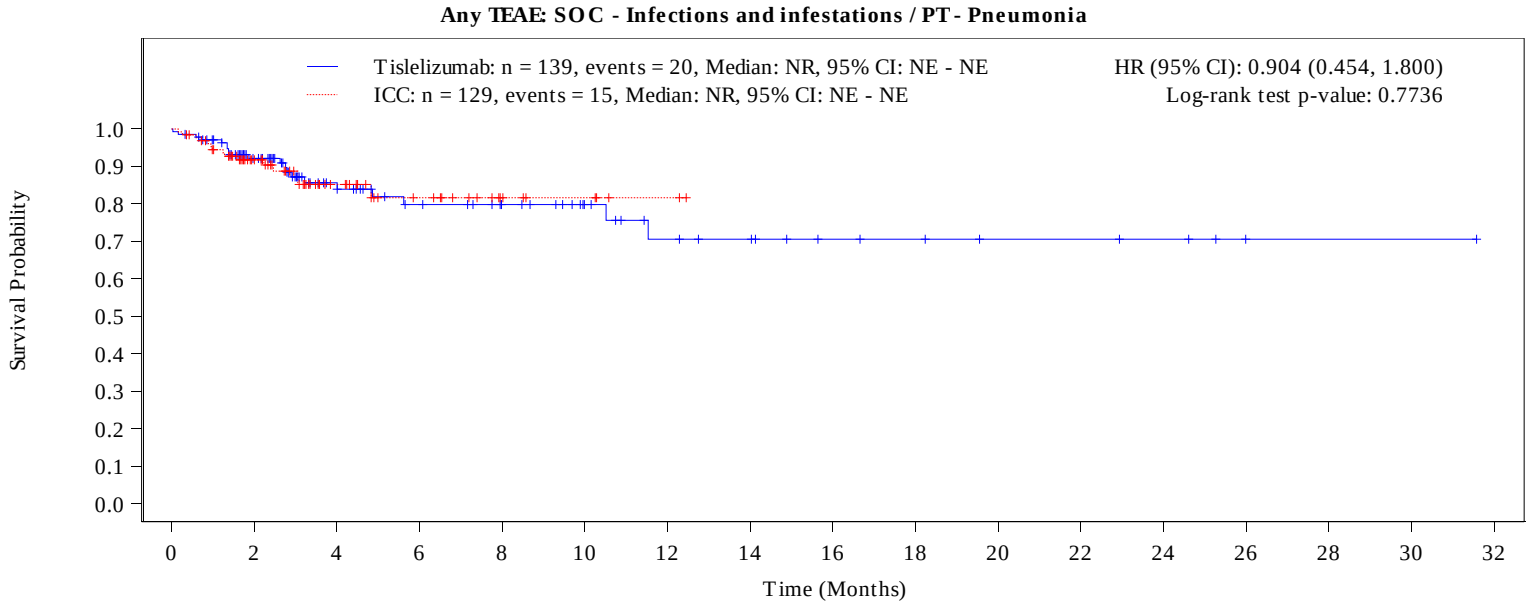
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	89	50	37	29	20	14	12	8	7	5	5	4	1	1	1	0
ICC	129	73	32	17	8	5	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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Figure 14.3.1.2.b:
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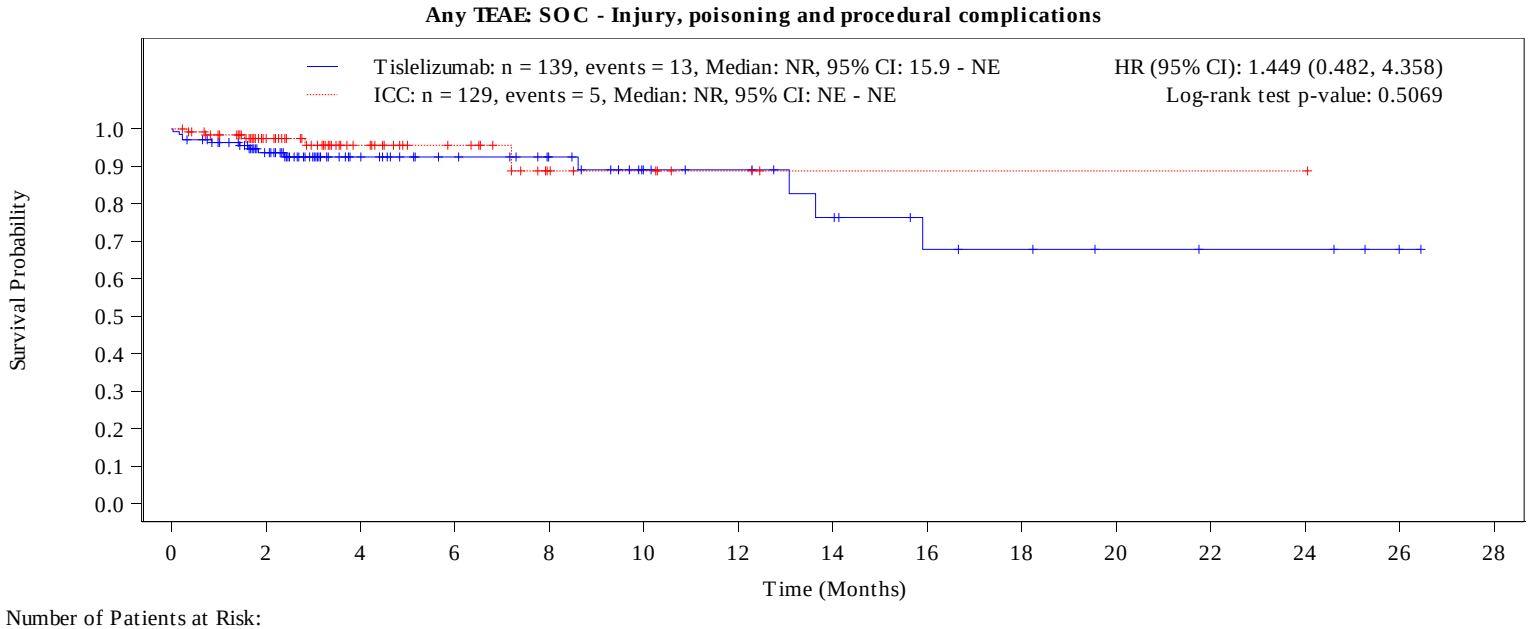
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28
Tislelizumab	139	89	48	36	28	18	16	12	8	7	5	4	4	1	0
ICC	129	73	32	18	8	6	3	1	1	1	1	1	1	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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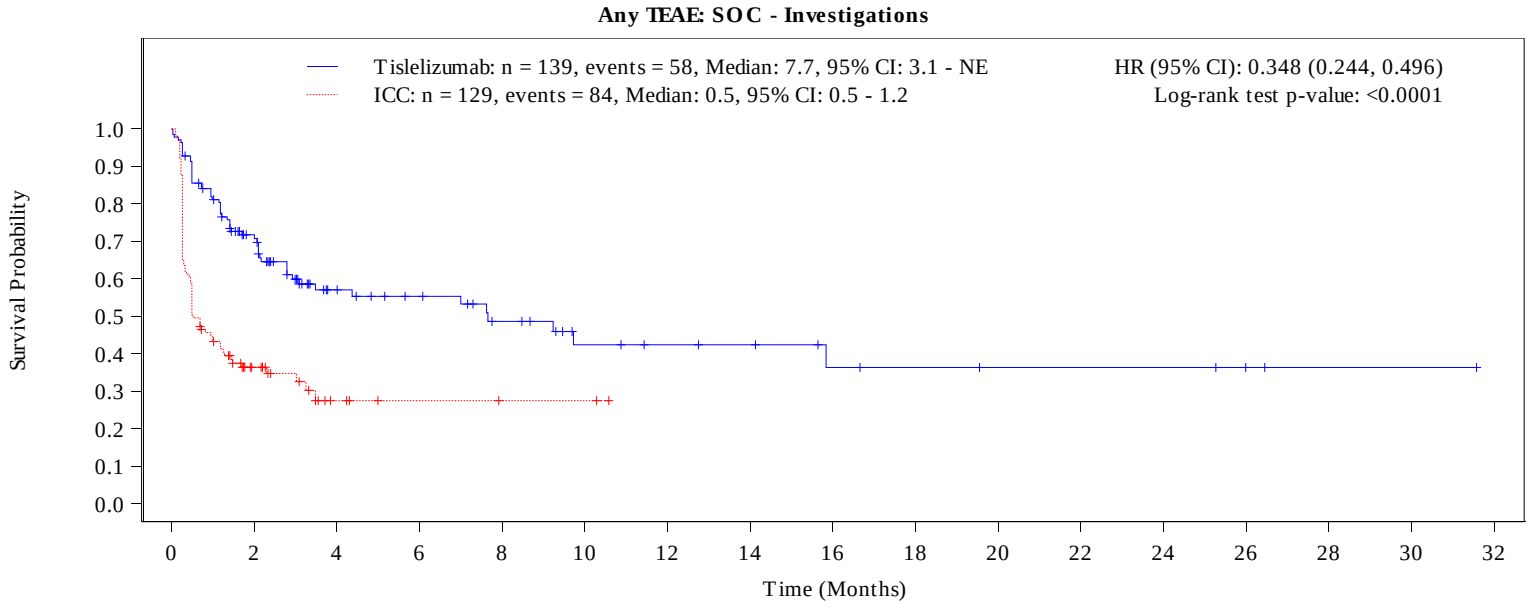
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	71	34	28	20	12	10	9	6	5	4	4	4	2	1	1	0
ICC	129	25	6	3	2	2	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-b-km-aesocpt-safetys-sa.rtf

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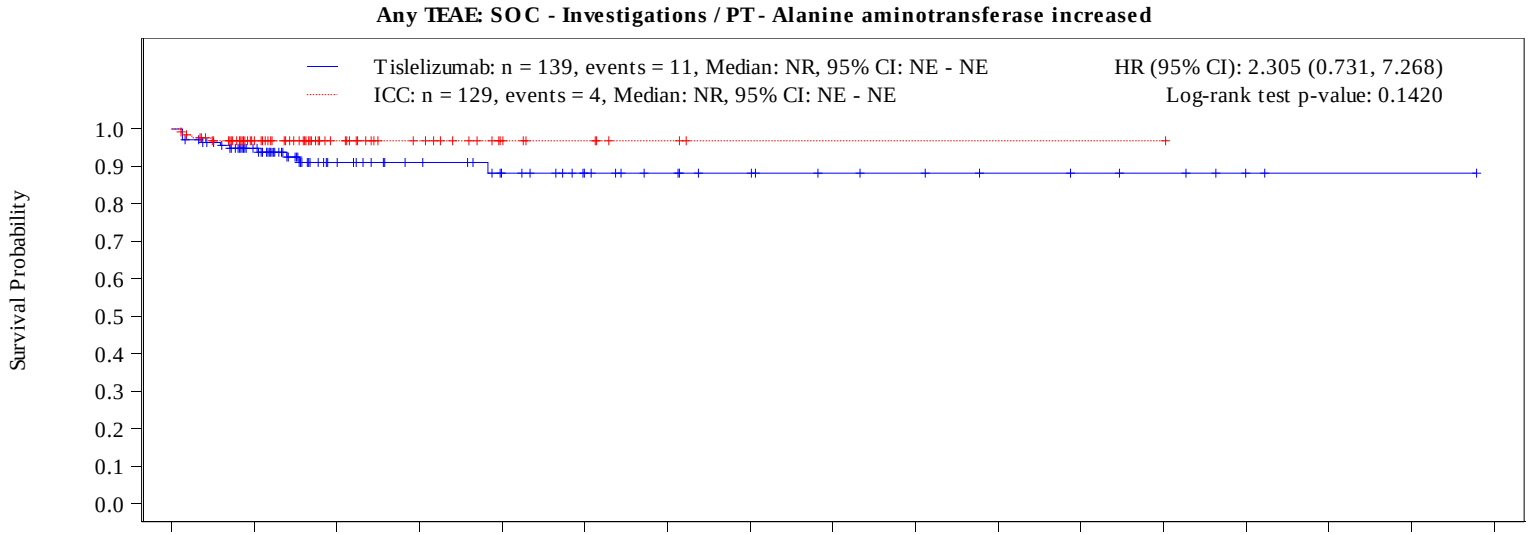
Safety Analysis Set - Subpopulation without Irinotecan

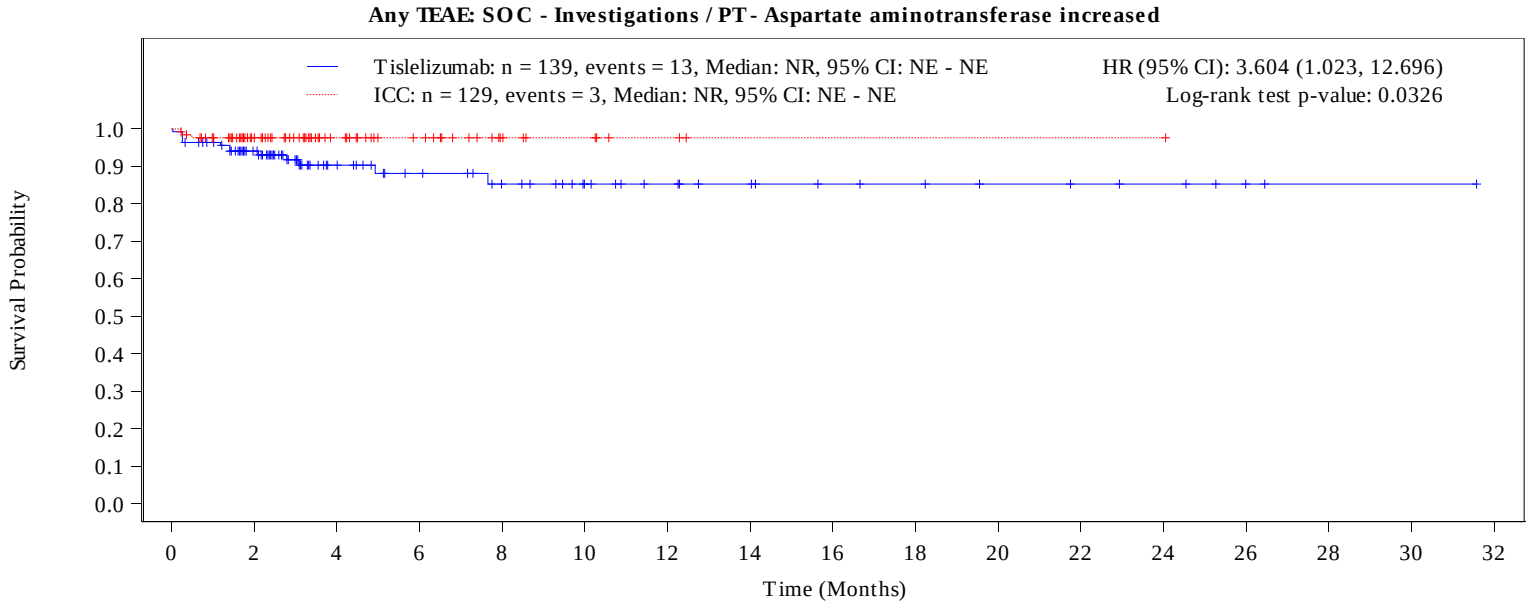


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	91	48	37	28	20	16	13	10	9	7	6	5	2	1	1	0
ICC	129	74	32	18	9	6	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-b-km-aesocpt-safetys-sa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	92	48	36	28	20	16	13	10	9	7	6	5	2	1	1	0
ICC	129	75	33	19	9	6	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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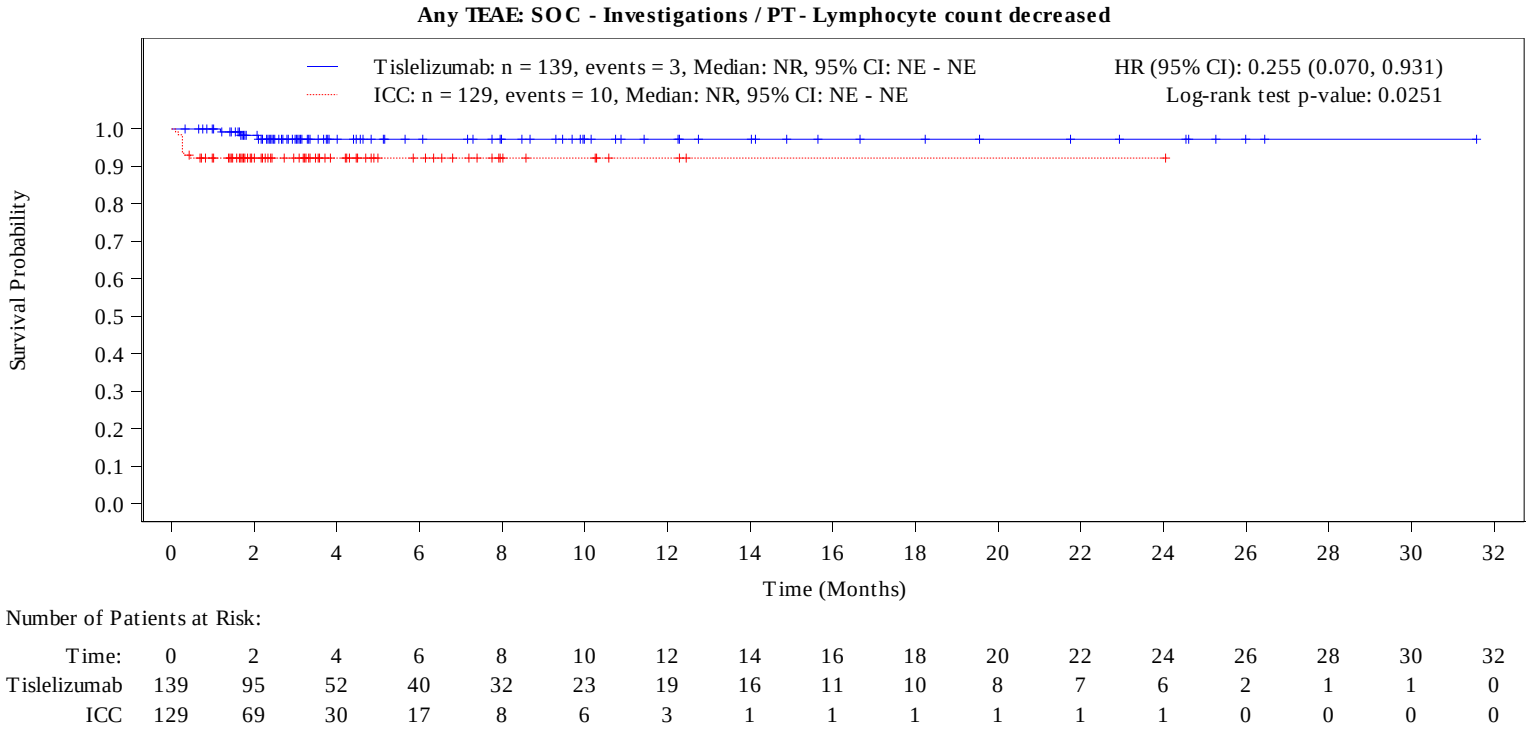
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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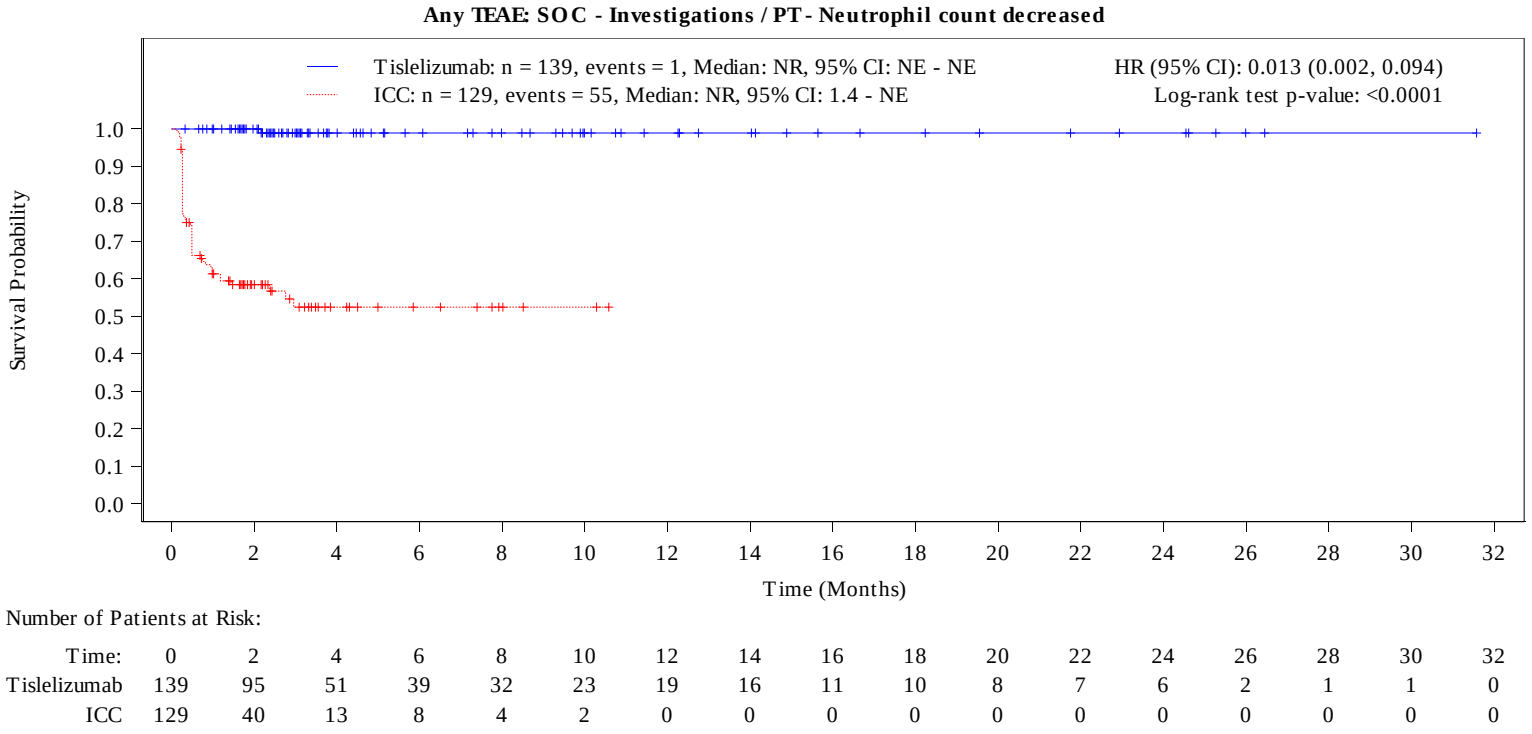
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	95	51	39	32	23	19	16	11	10	8	7	6	2	1	1	0
ICC	129	40	13	8	4	2	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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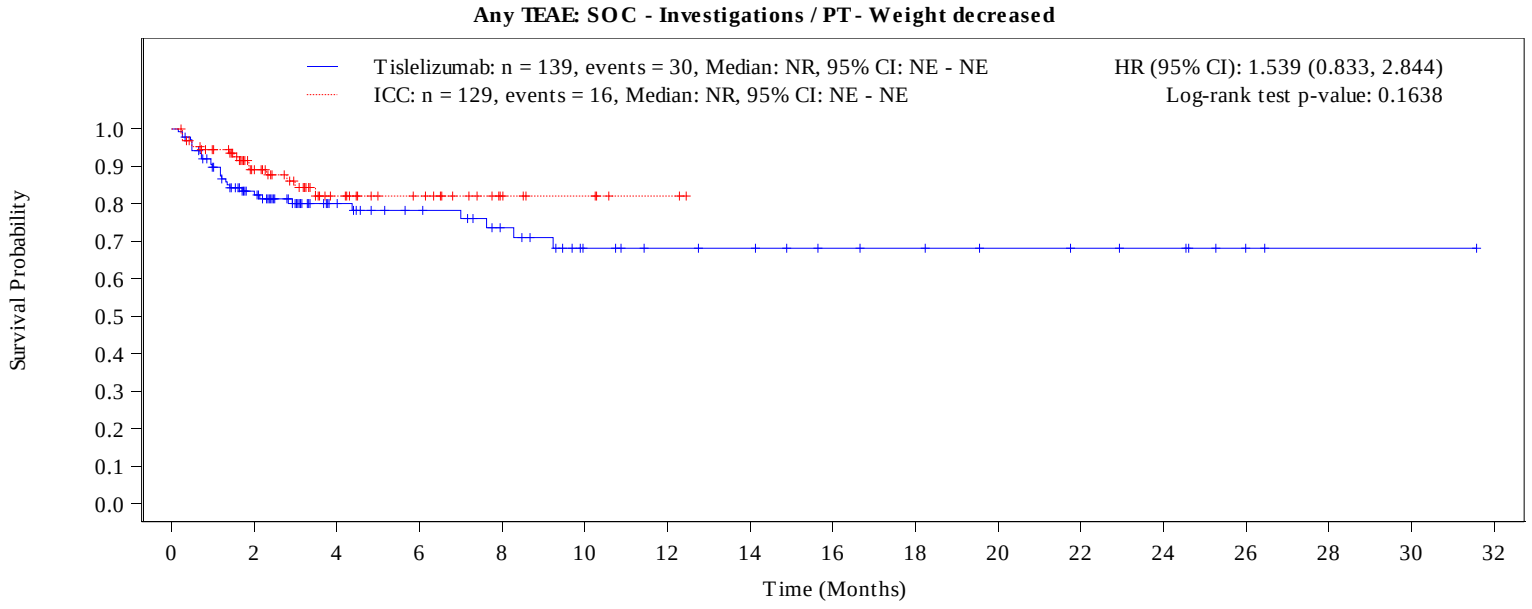
Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	82	45	37	28	18	15	14	11	10	8	7	6	2	1	1	0
ICC	129	71	30	18	8	5	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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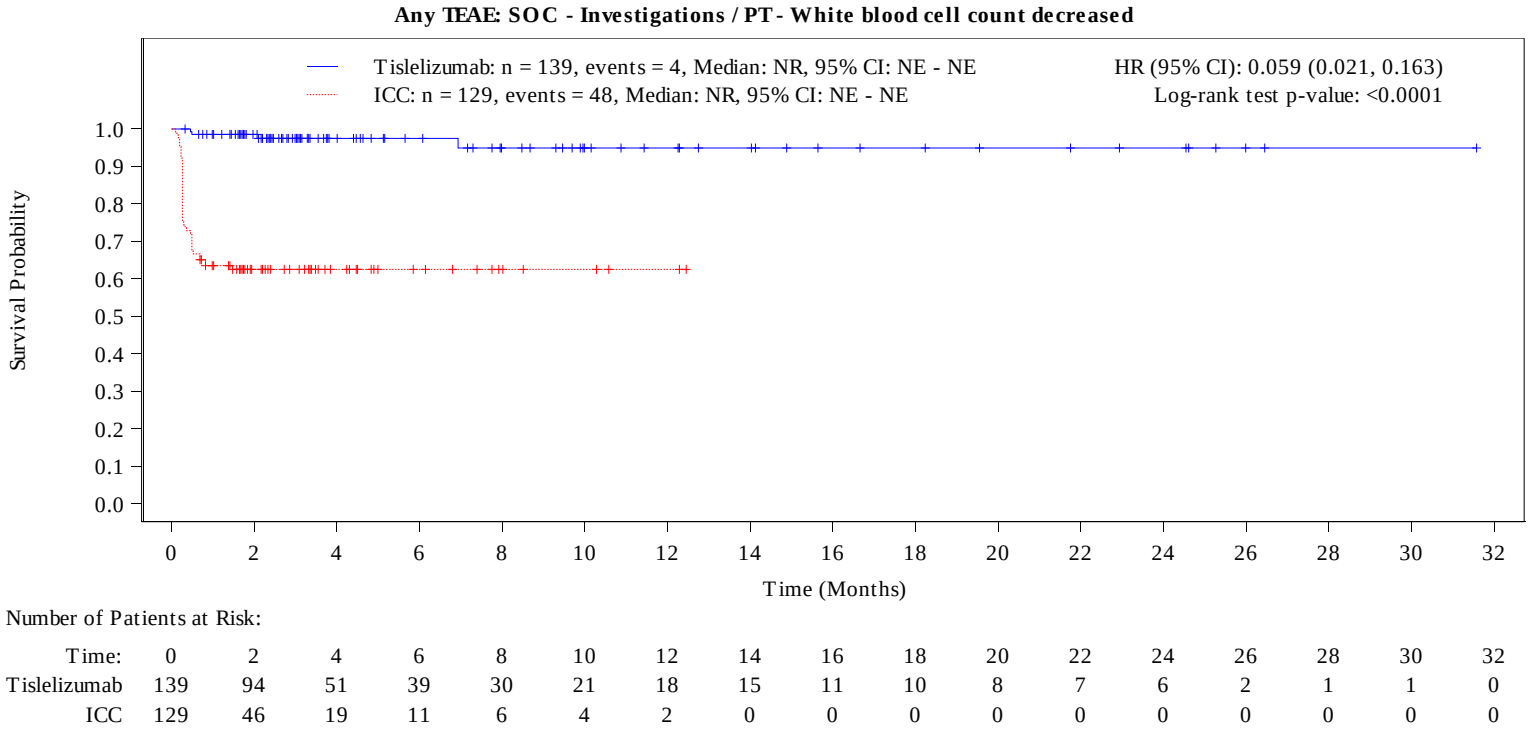
Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-b-km-aesocpt-safetys-sa.rtf

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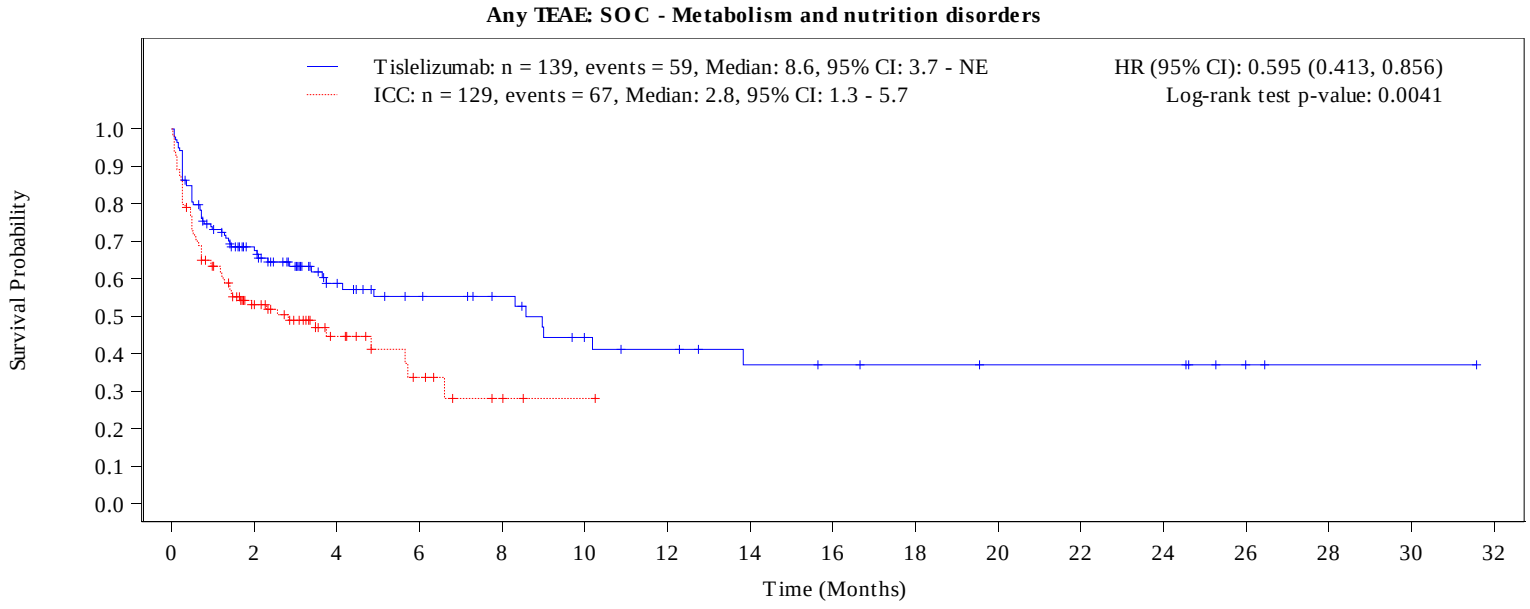
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	69	37	27	21	14	12	9	8	7	6	6	6	2	1	1	0
ICC	129	46	18	8	3	1	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-b-km-aesocpt-safetys-sa.rtf

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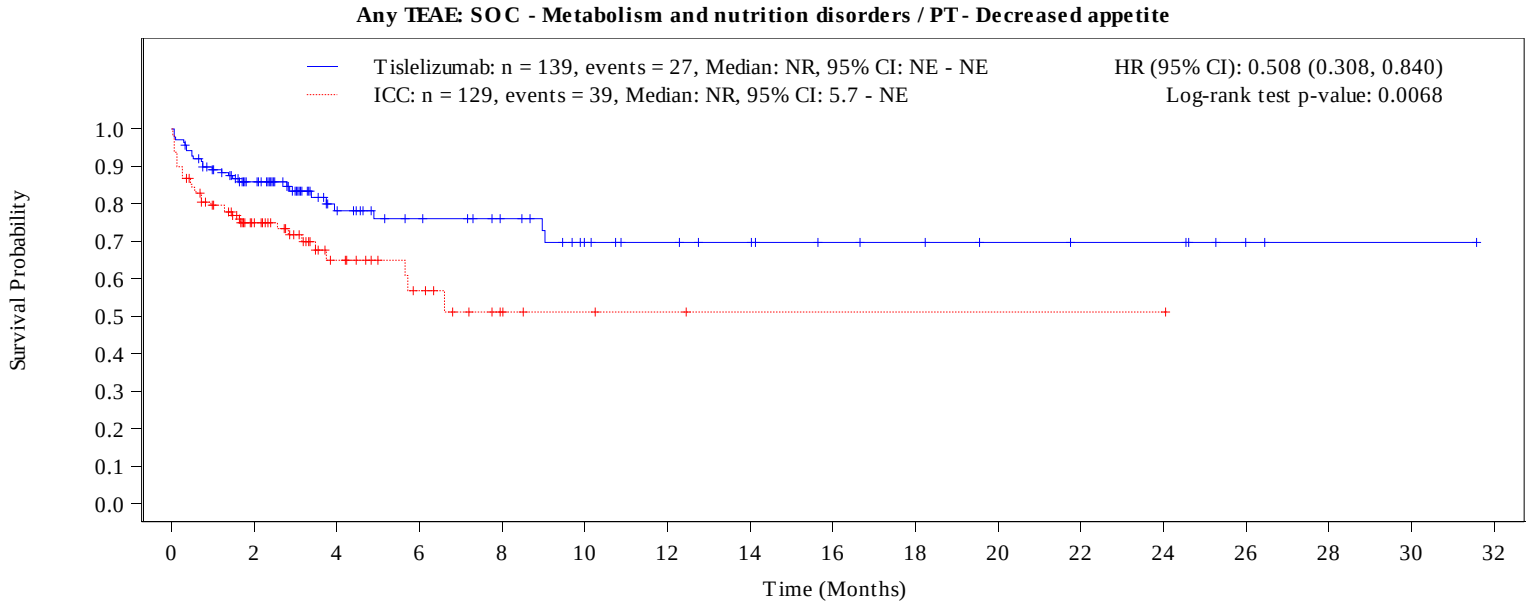
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	84	43	33	26	18	15	13	10	9	7	6	6	2	1	1	0
ICC	129	61	23	12	5	3	2	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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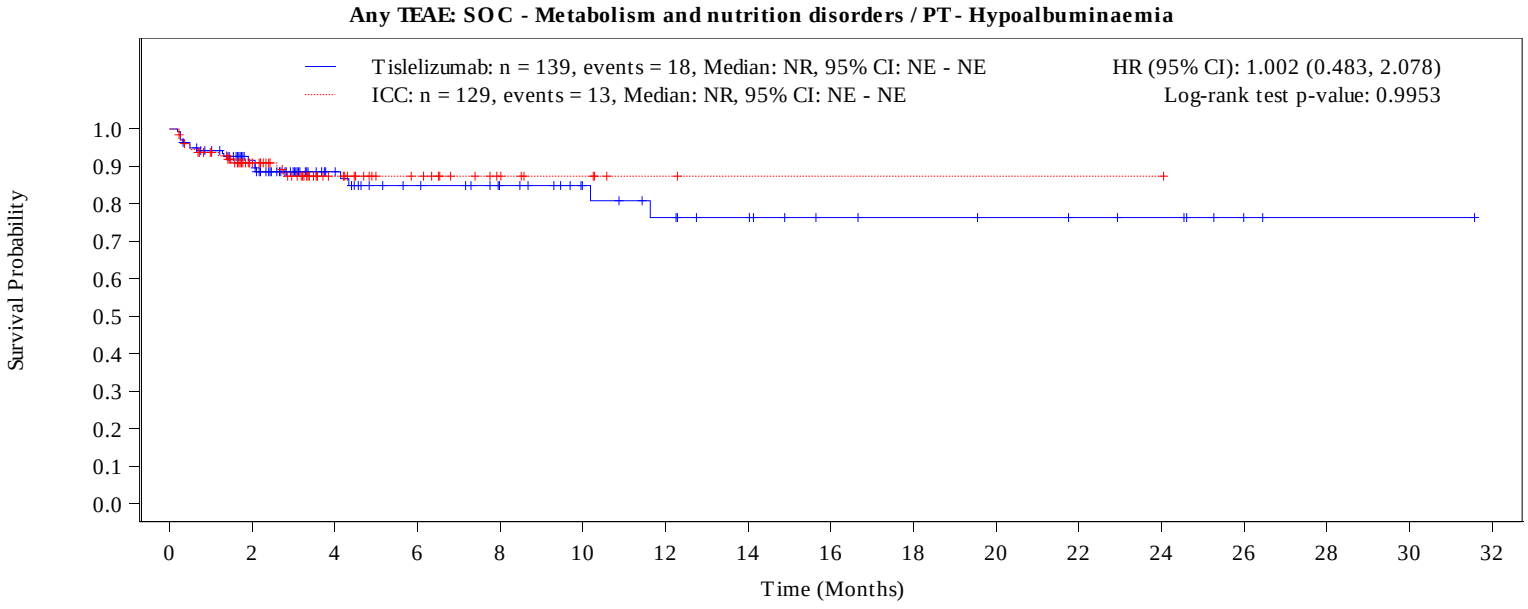
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	90	49	37	29	21	17	14	10	9	8	7	6	2	1	1	0
ICC	129	68	30	16	8	5	2	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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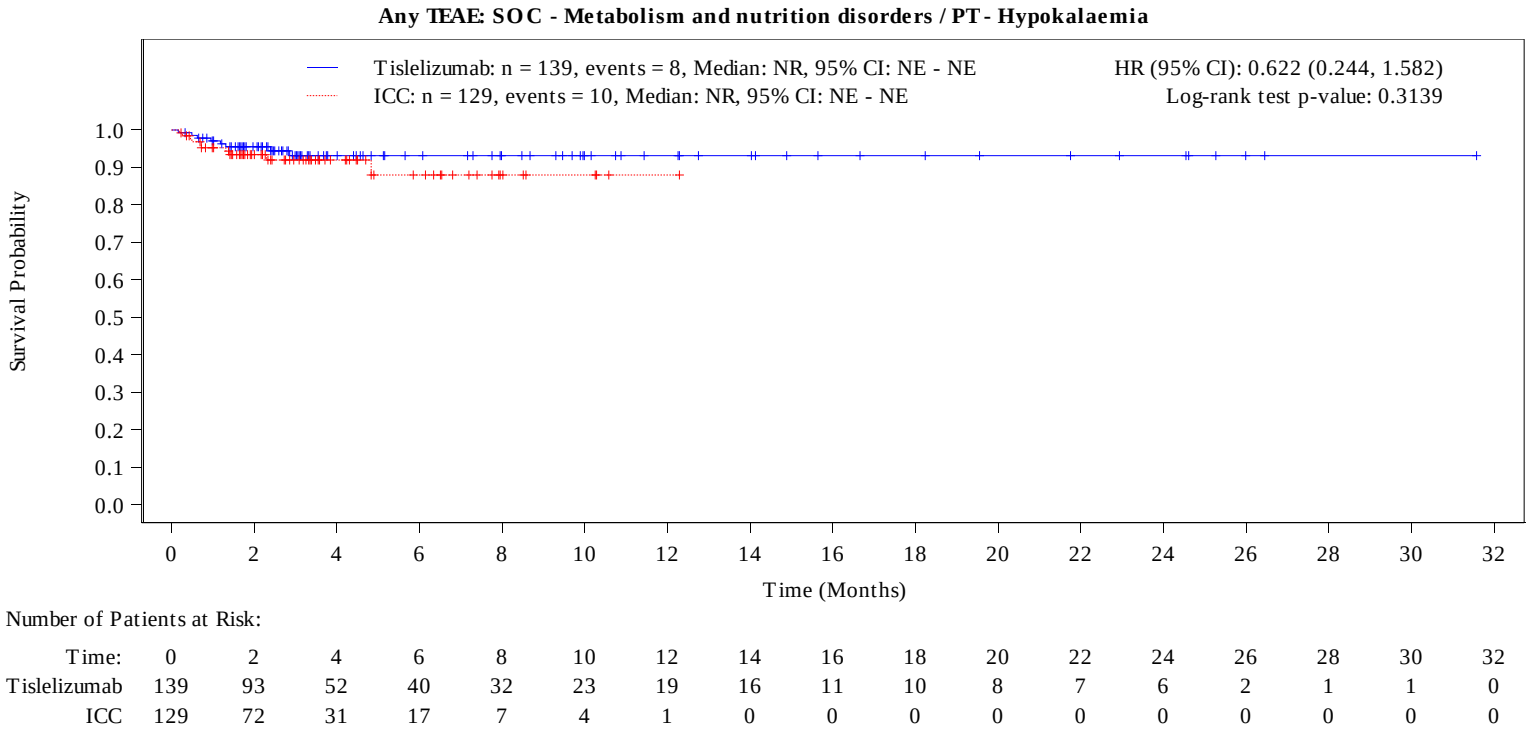
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	93	52	40	32	23	19	16	11	10	8	7	6	2	1	1	0
ICC	129	72	31	17	7	4	1	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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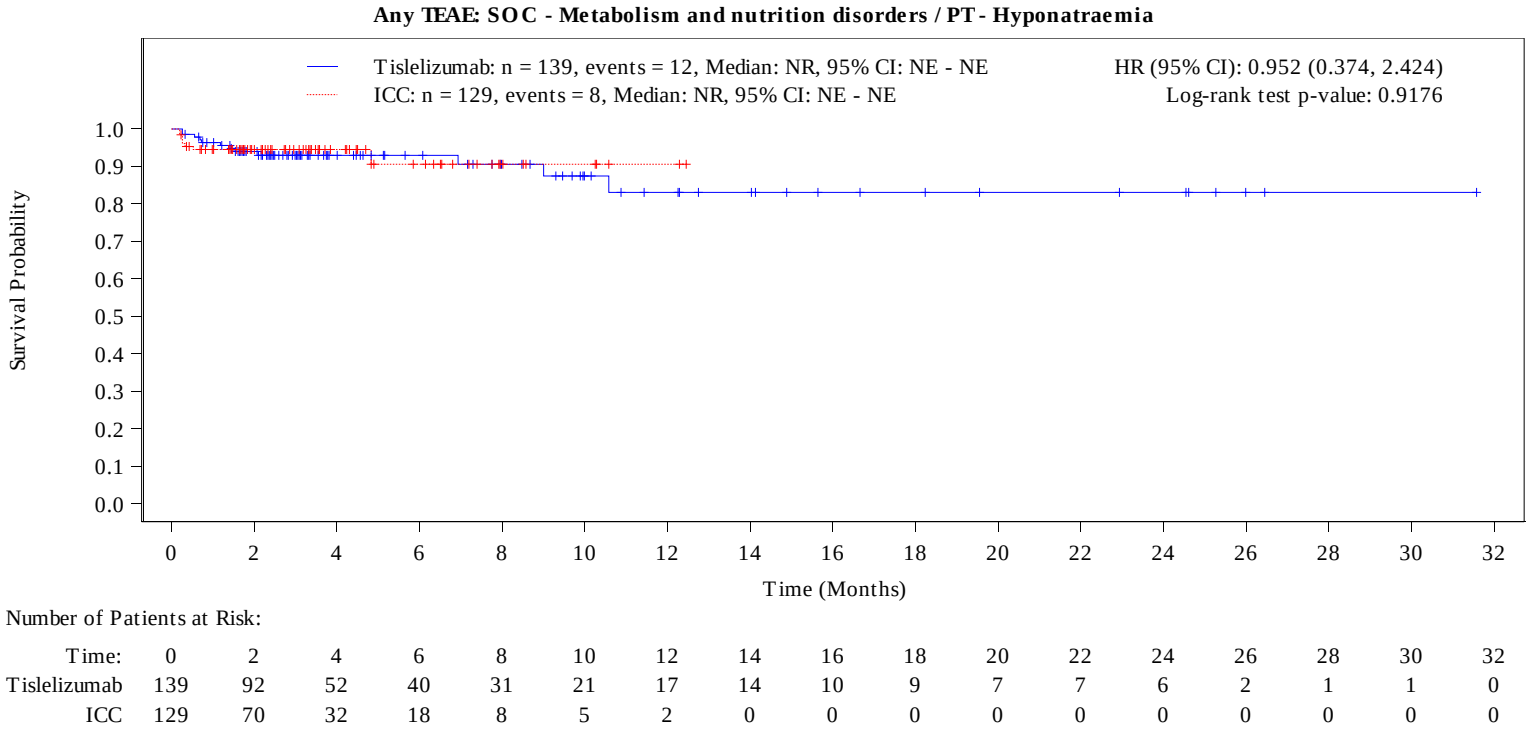
Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	92	52	40	31	21	17	14	10	9	7	7	6	2	1	1	0
ICC	129	70	32	18	8	5	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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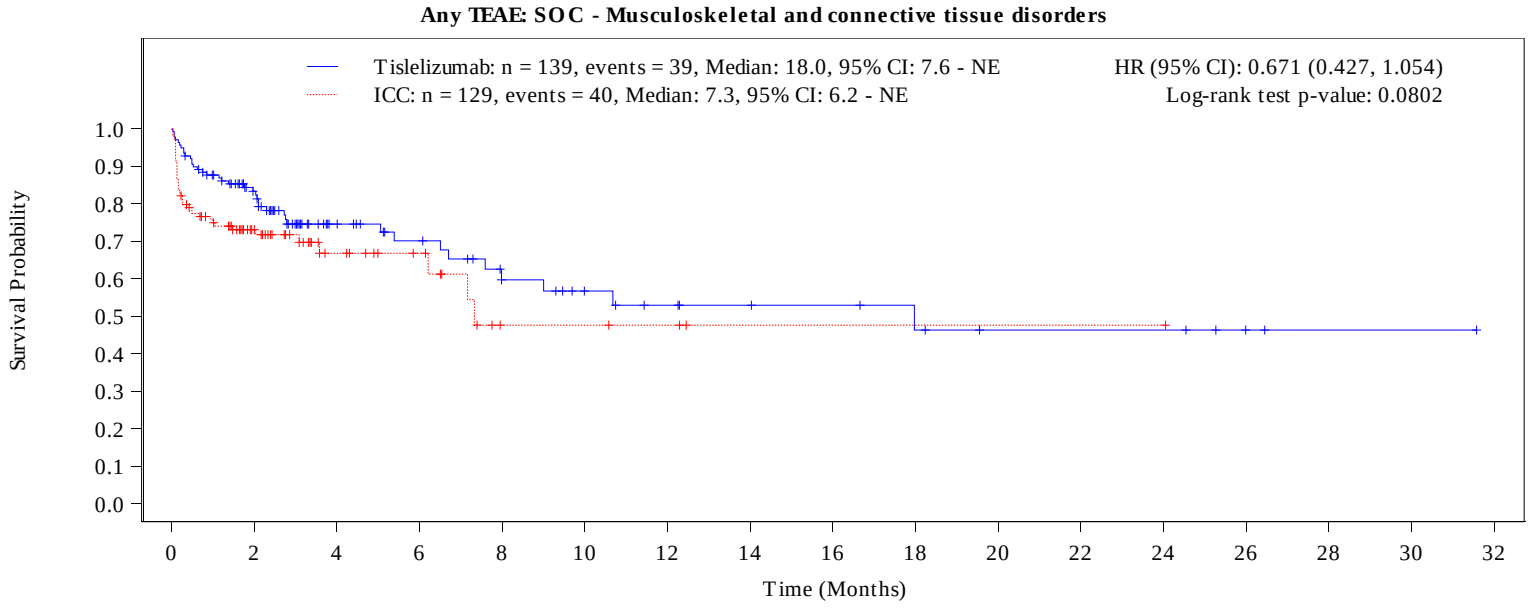
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	82	40	30	20	15	12	10	9	7	5	5	5	2	1	1	0
ICC	129	56	20	13	4	4	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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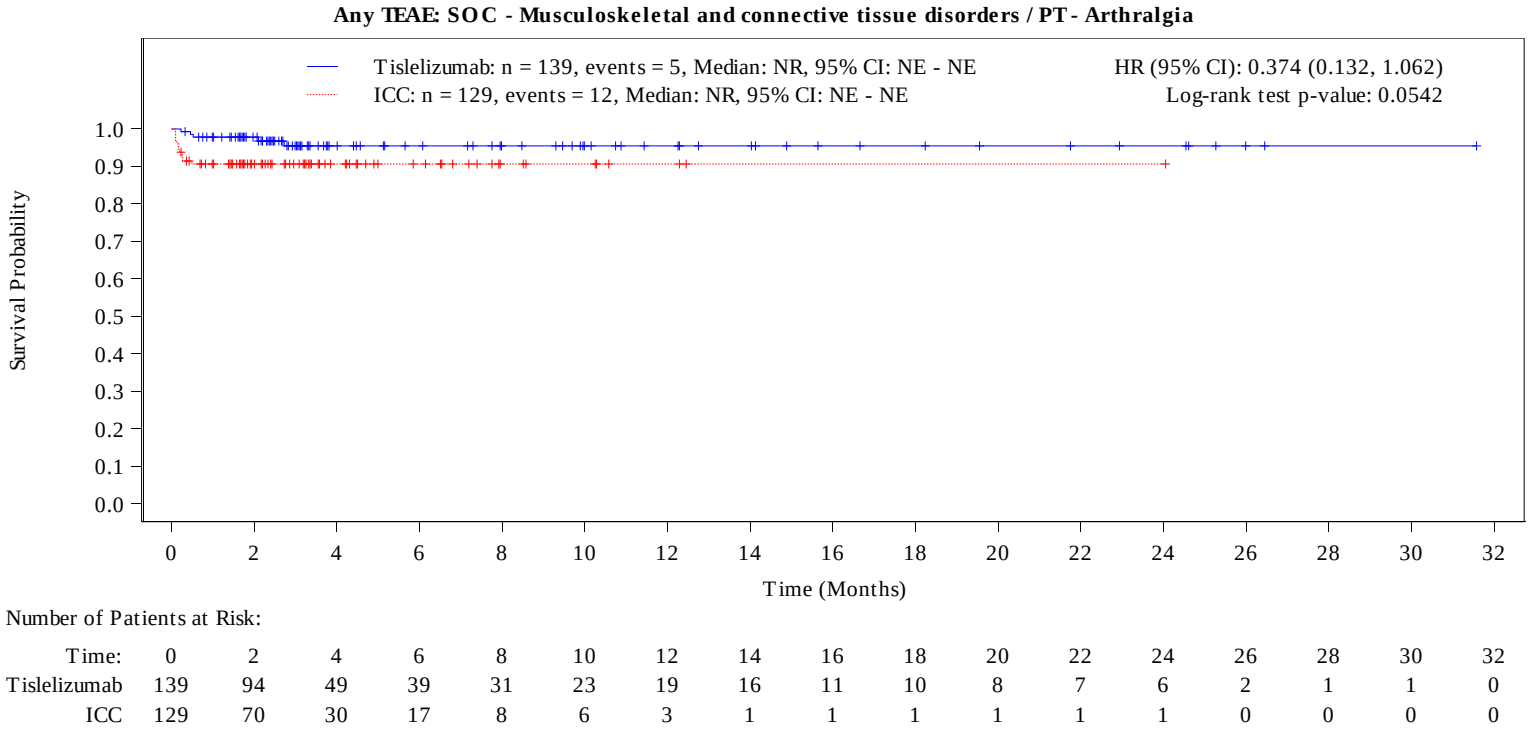
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	94	49	39	31	23	19	16	11	10	8	7	6	2	1	1	0
ICC	129	70	30	17	8	6	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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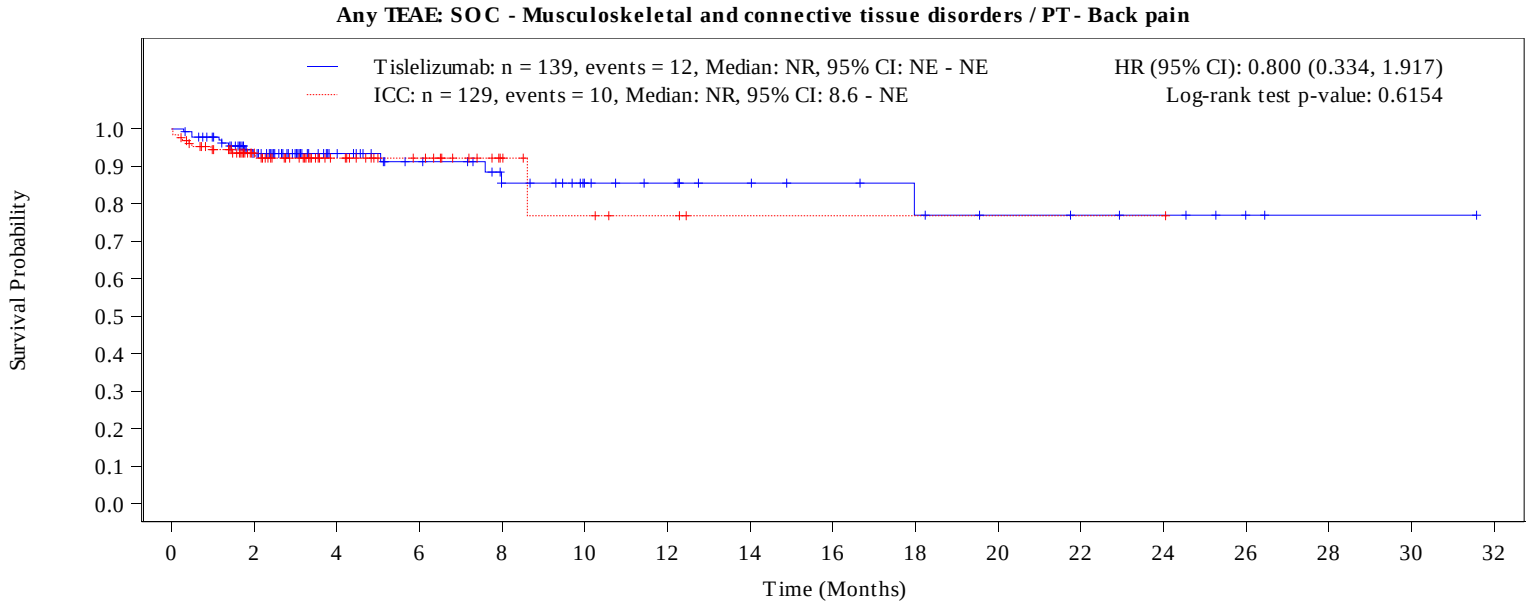
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	90	51	38	28	20	17	14	11	9	7	6	5	2	1	1	0
ICC	129	71	31	18	8	5	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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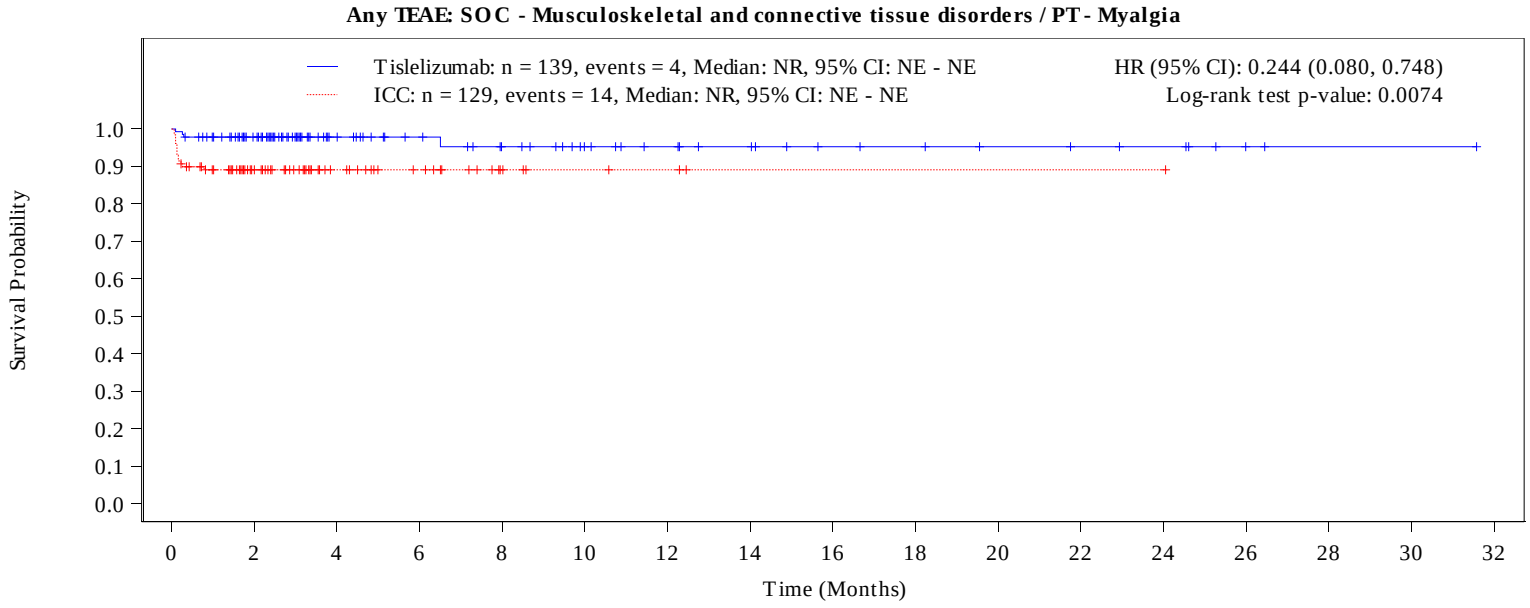

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	94	51	39	31	23	19	16	11	10	8	7	6	2	1	1	0
ICC	129	67	26	16	7	4	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-b-km-aesocpt-safetys-sa.rtf

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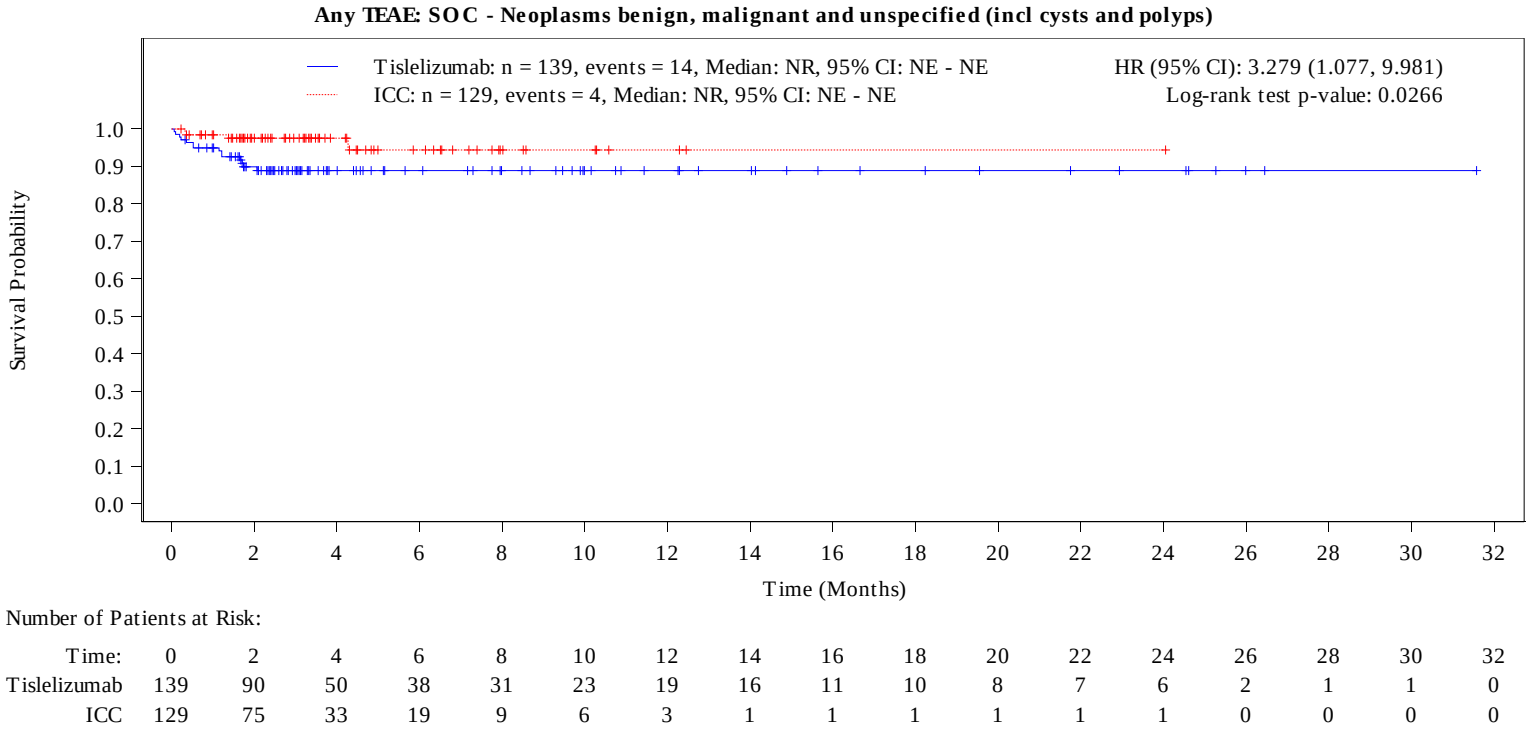

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	90	50	38	31	23	19	16	11	10	8	7	6	2	1	1	0
ICC	129	75	33	19	9	6	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-b-km-aesocpt-safetys-sa.rtf

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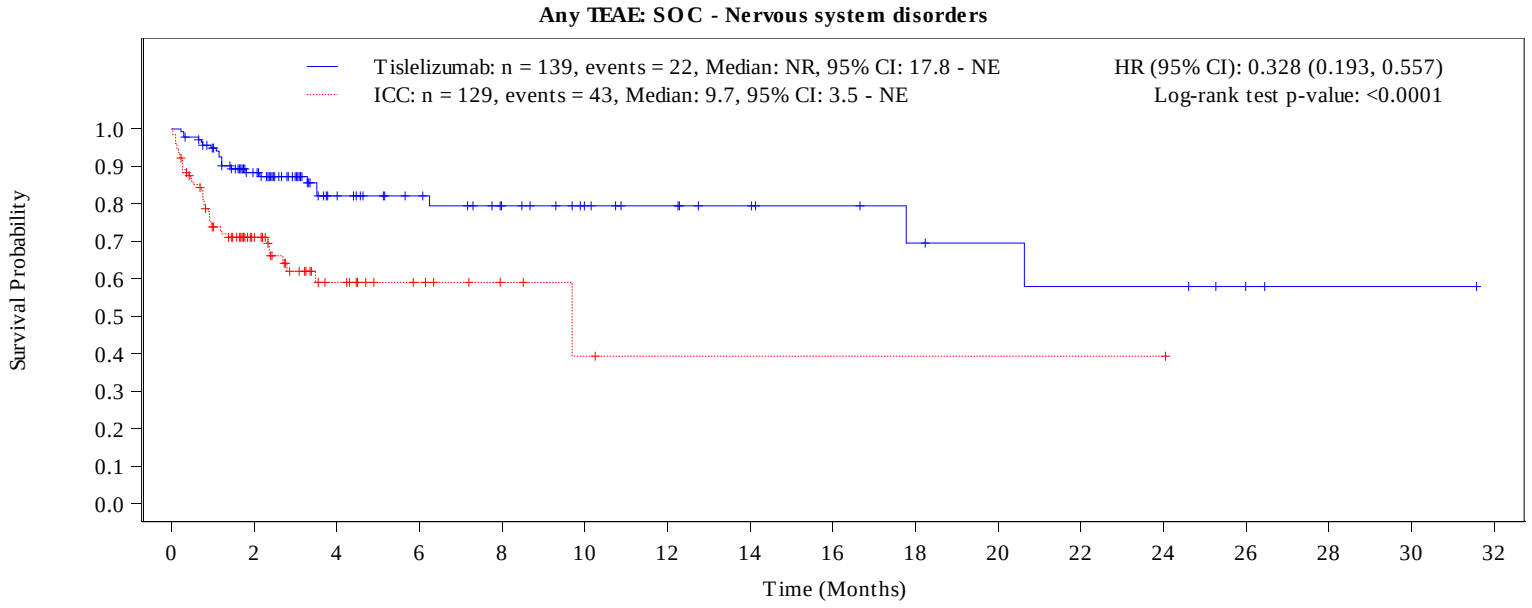

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	85	43	32	24	18	15	12	9	7	6	5	5	2	1	1	0
ICC	129	50	18	8	4	2	1	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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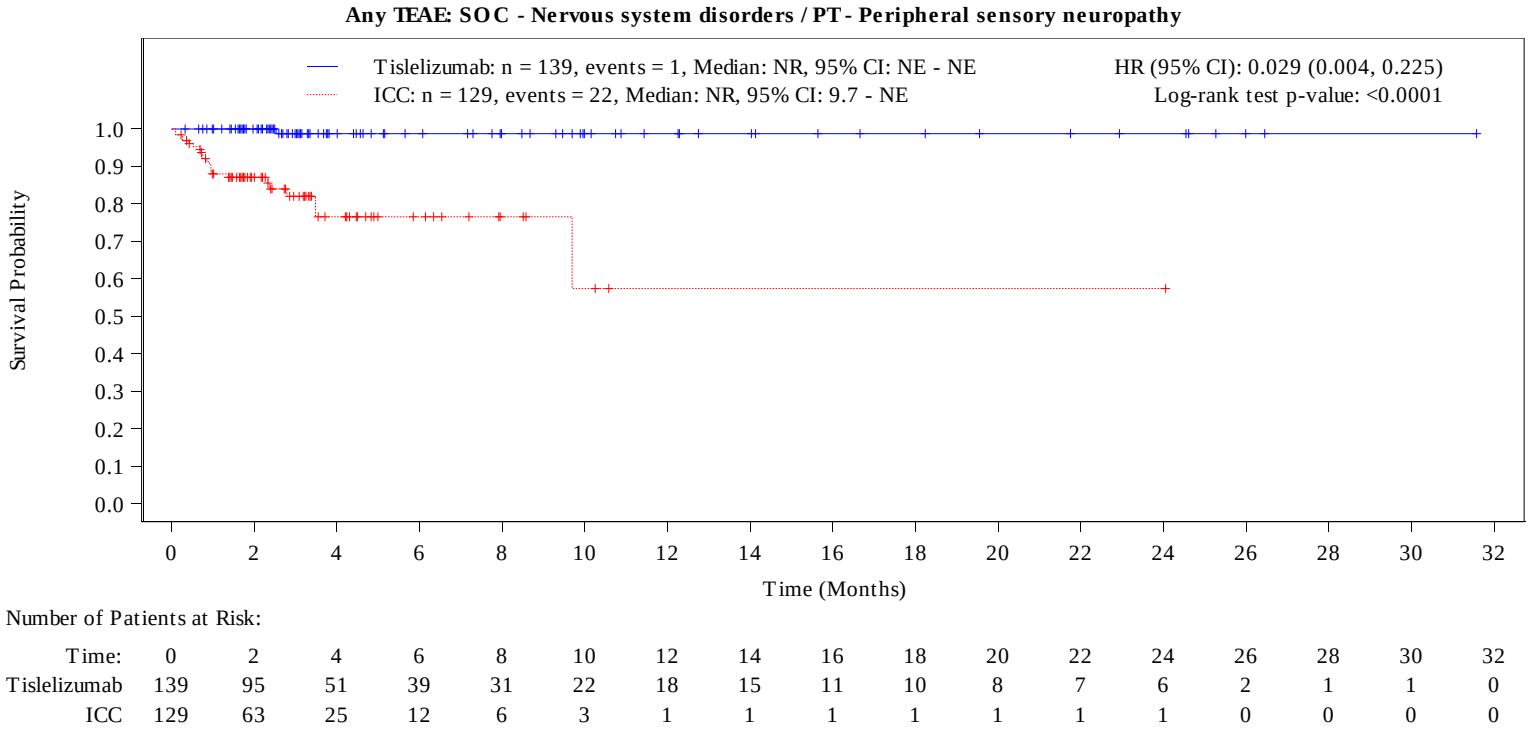
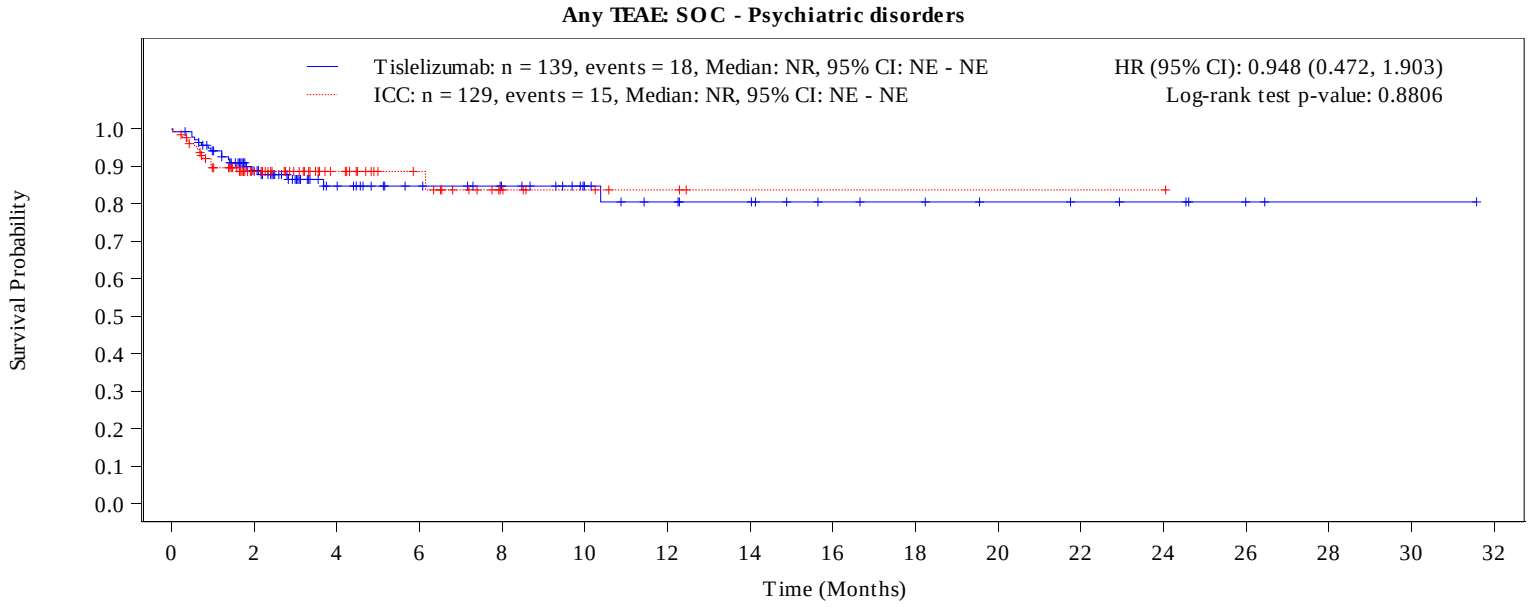


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	95	51	39	31	22	18	15	11	10	8	7	6	2	1	1	0
ICC	129	63	25	12	6	3	1	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-b-km-aesocpt-safetys-sa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

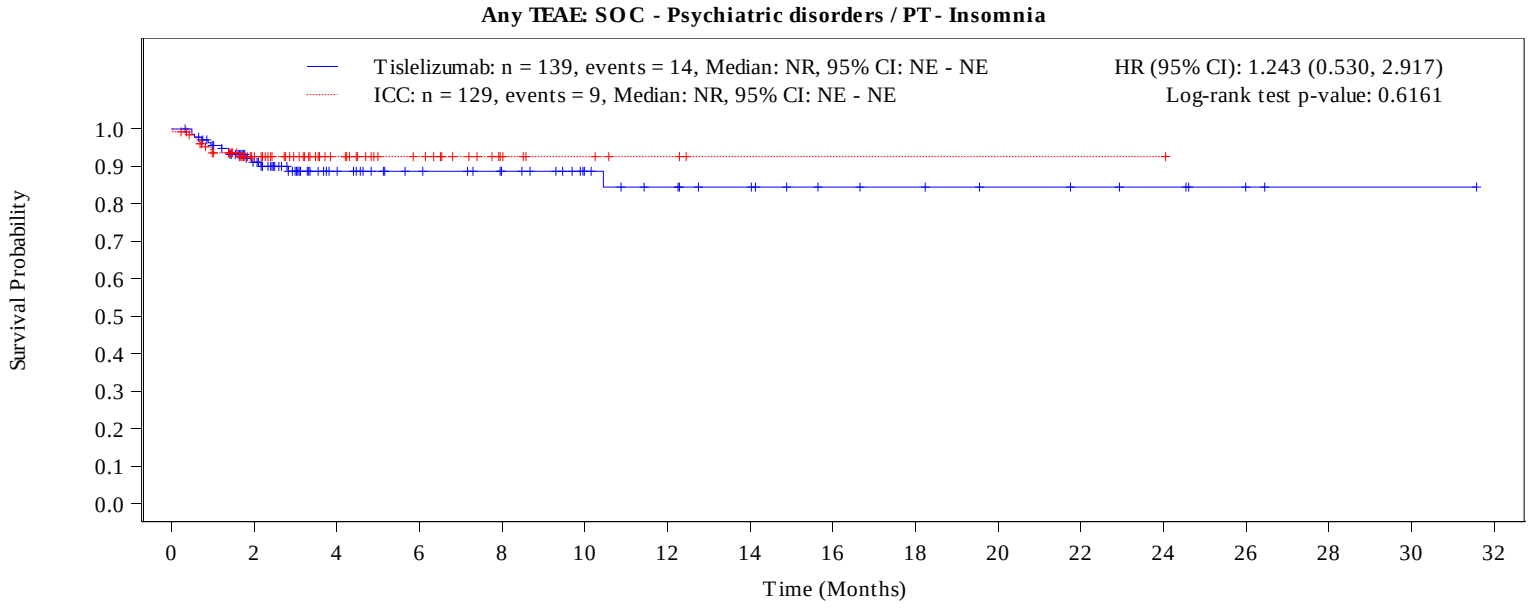


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	84	46	36	30	21	17	15	10	9	7	6	5	2	1	1	0
ICC	129	66	30	18	8	5	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-b-km-aesocpt-safetys-sa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

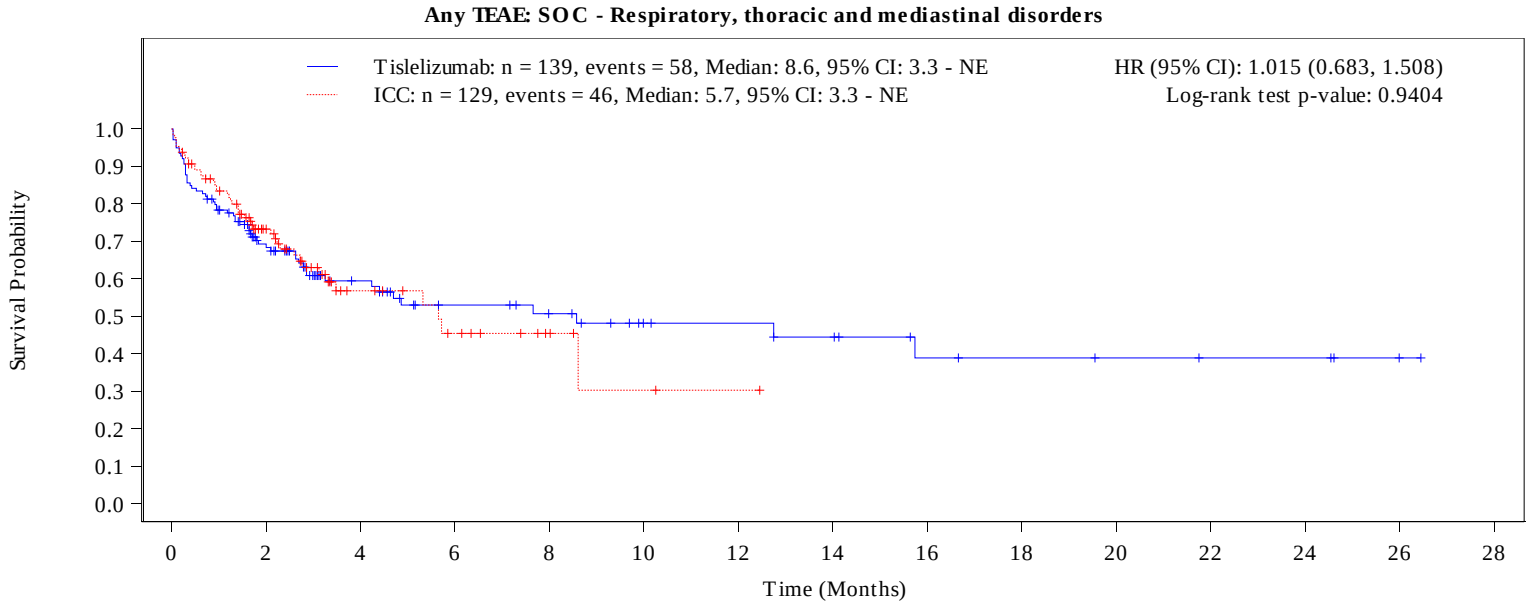


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	85	47	37	31	22	18	15	10	9	7	6	5	2	1	1	0
ICC	129	68	31	18	8	5	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-b-km-aesocpt-safetys-sa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

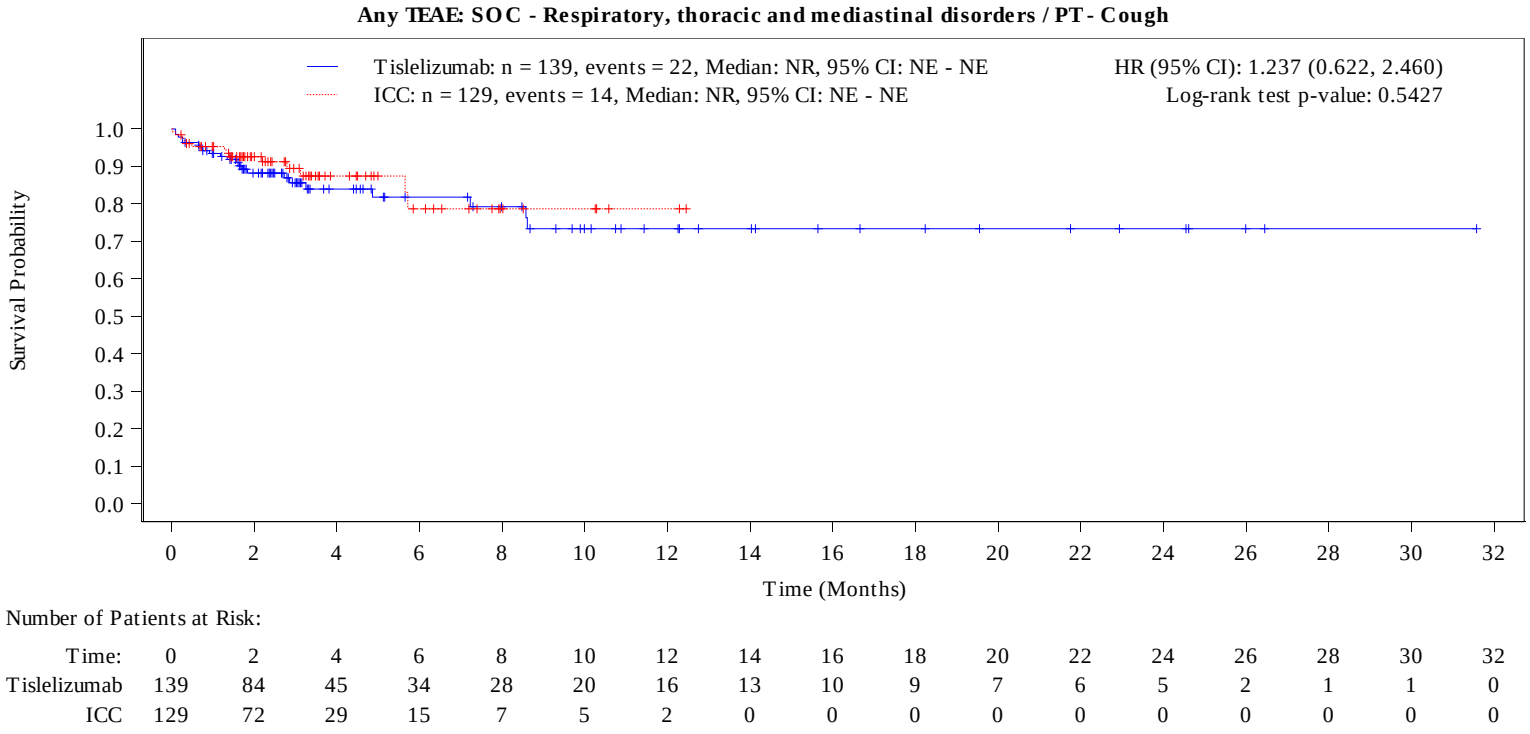


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28
Tislelizumab	139	74	40	27	21	14	13	11	7	6	5	4	4	1	0
ICC	129	59	20	11	5	2	1	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-b-km-aesocpt-safetys-sa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

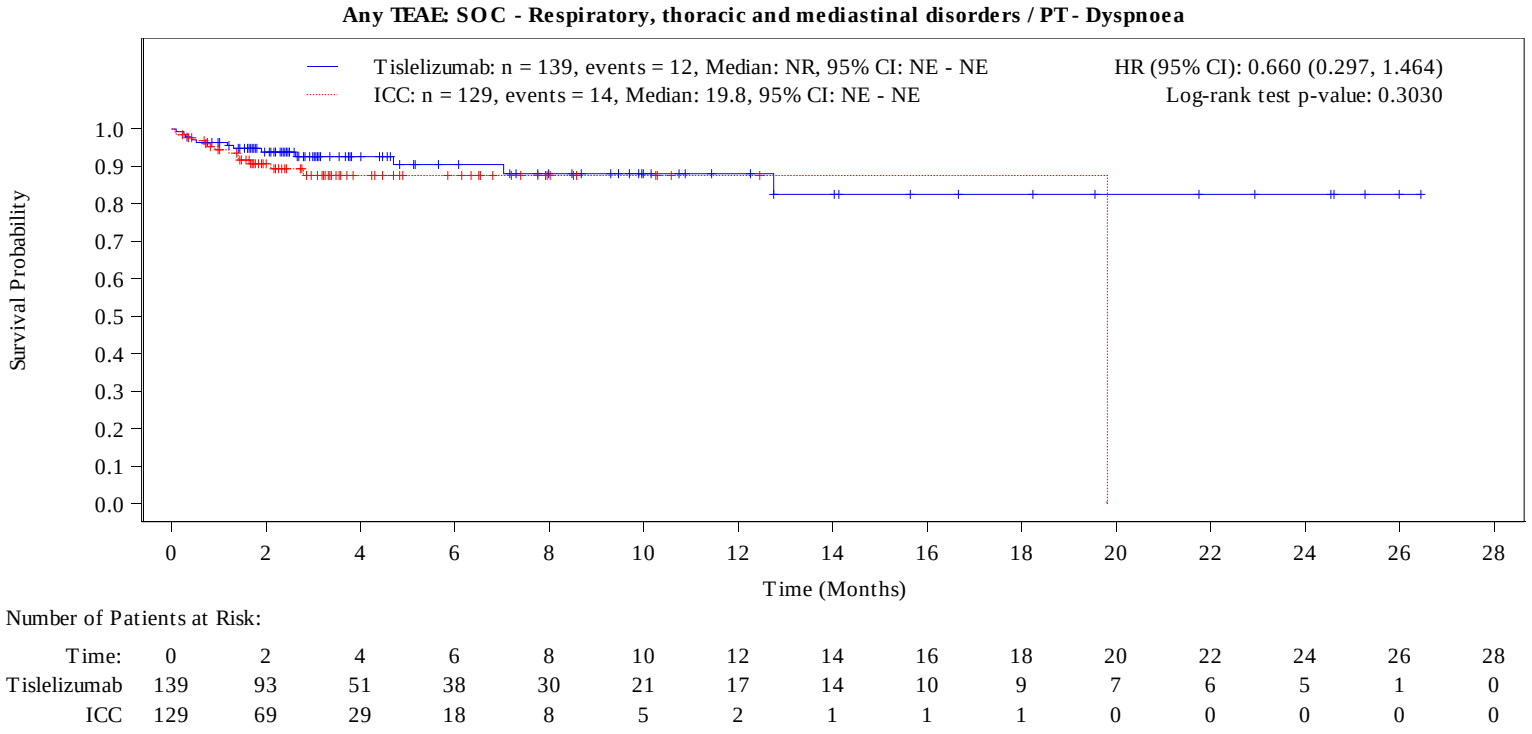


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	84	45	34	28	20	16	13	10	9	7	6	5	2	1	1	0
ICC	129	72	29	15	7	5	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-b-km-aesocpt-safetys-sa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28
Tislelizumab	139	93	51	38	30	21	17	14	10	9	7	6	5	1	0
ICC	129	69	29	18	8	5	2	1	1	1	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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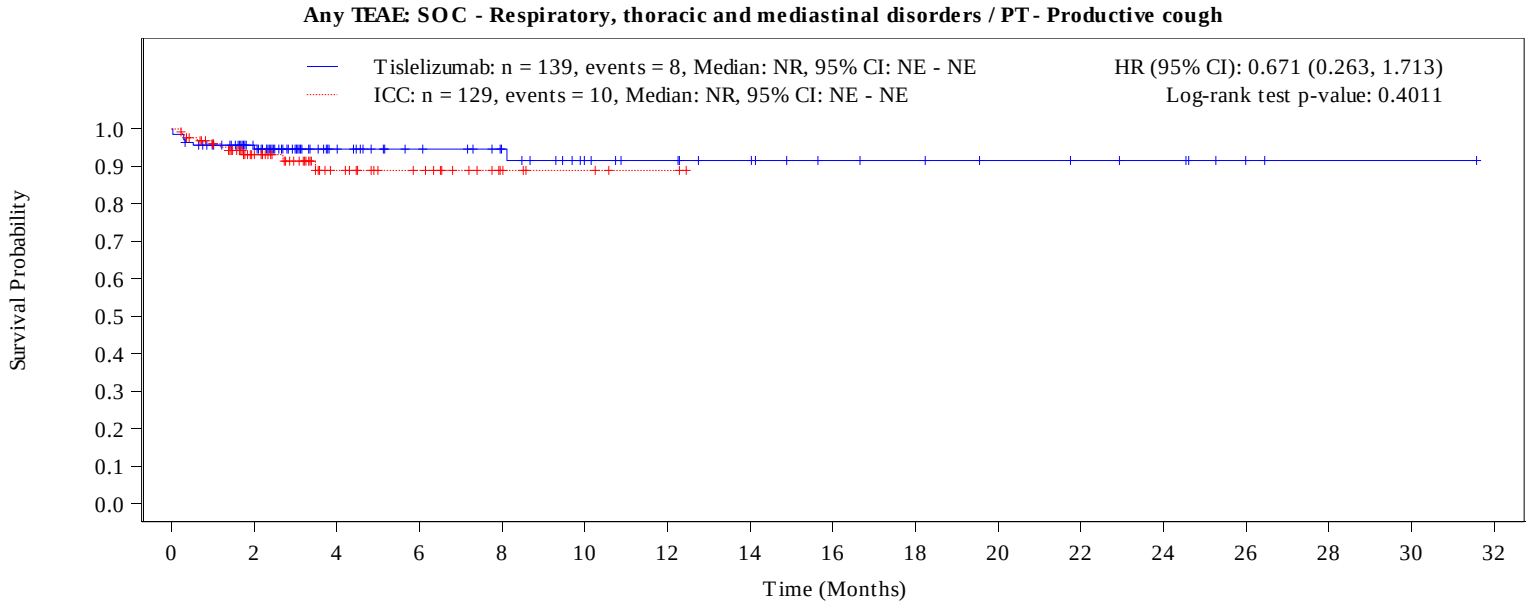
Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

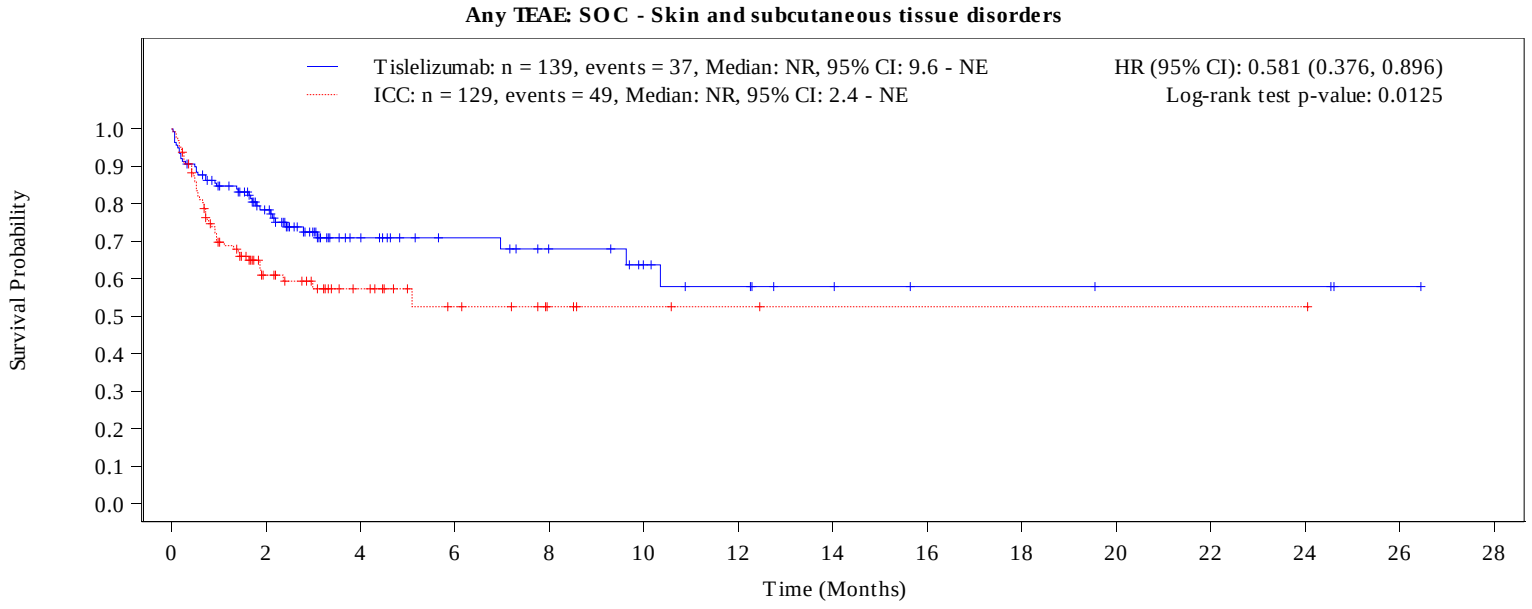


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	92	50	39	31	22	19	16	11	10	8	7	6	2	1	1	0
ICC	129	72	29	17	7	4	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-b-km-aesocpt-safetys-sa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

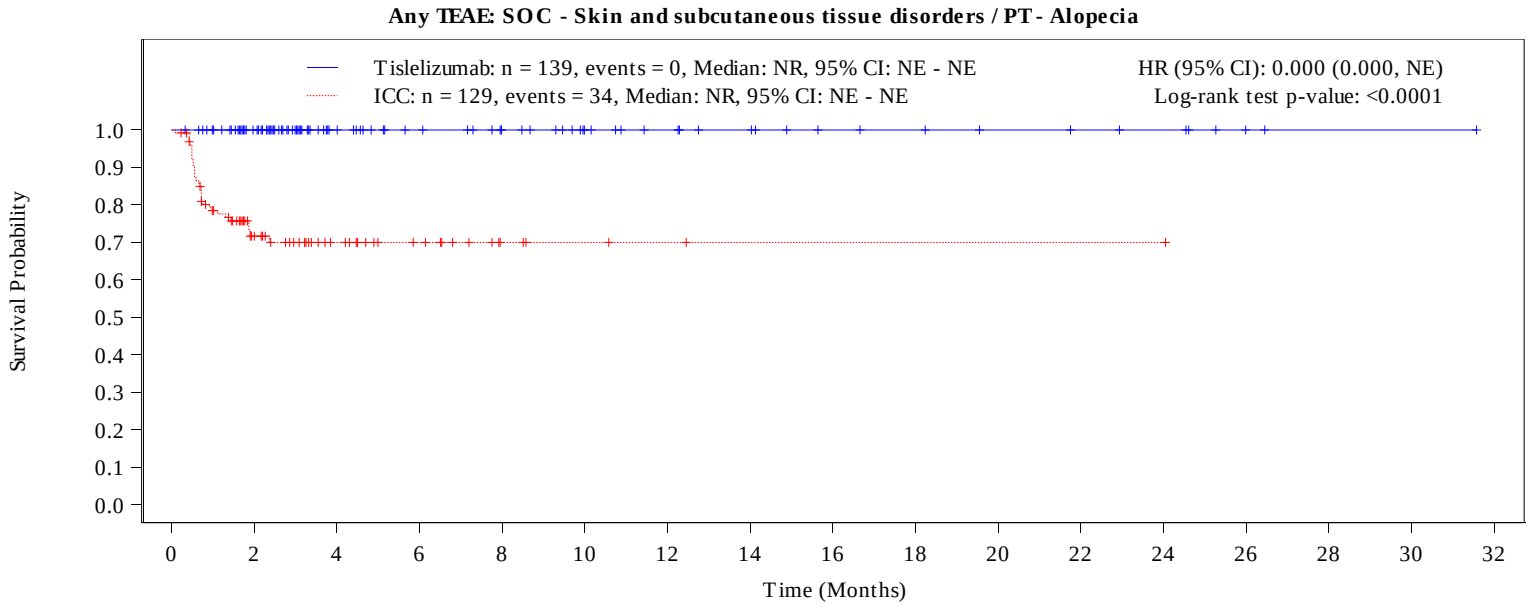


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28
Tislelizumab	139	73	33	24	17	12	9	6	4	4	3	3	3	1	0
ICC	129	43	18	10	5	3	2	1	1	1	1	1	1	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-b-km-aesocpt-safetys-sa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

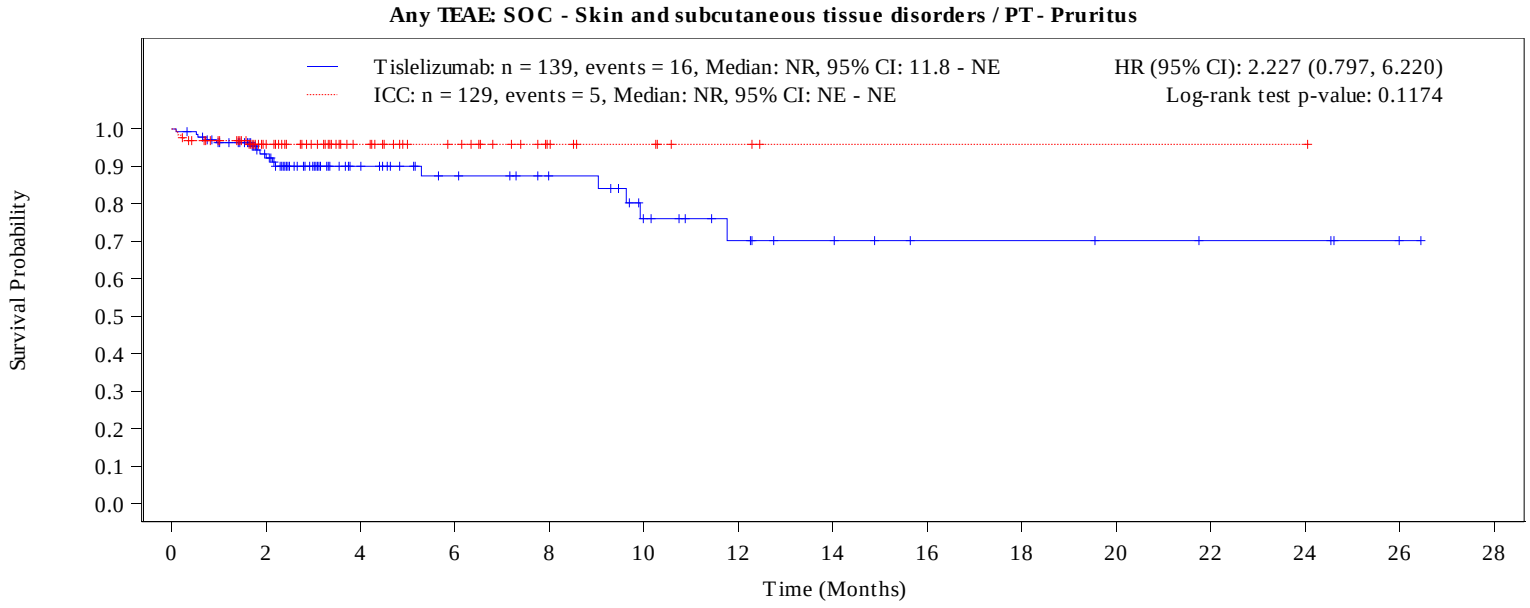


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	95	52	40	32	23	19	16	11	10	8	7	6	2	1	1	0
ICC	129	50	21	13	5	3	2	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-b-km-aesocpt-safetys-sa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

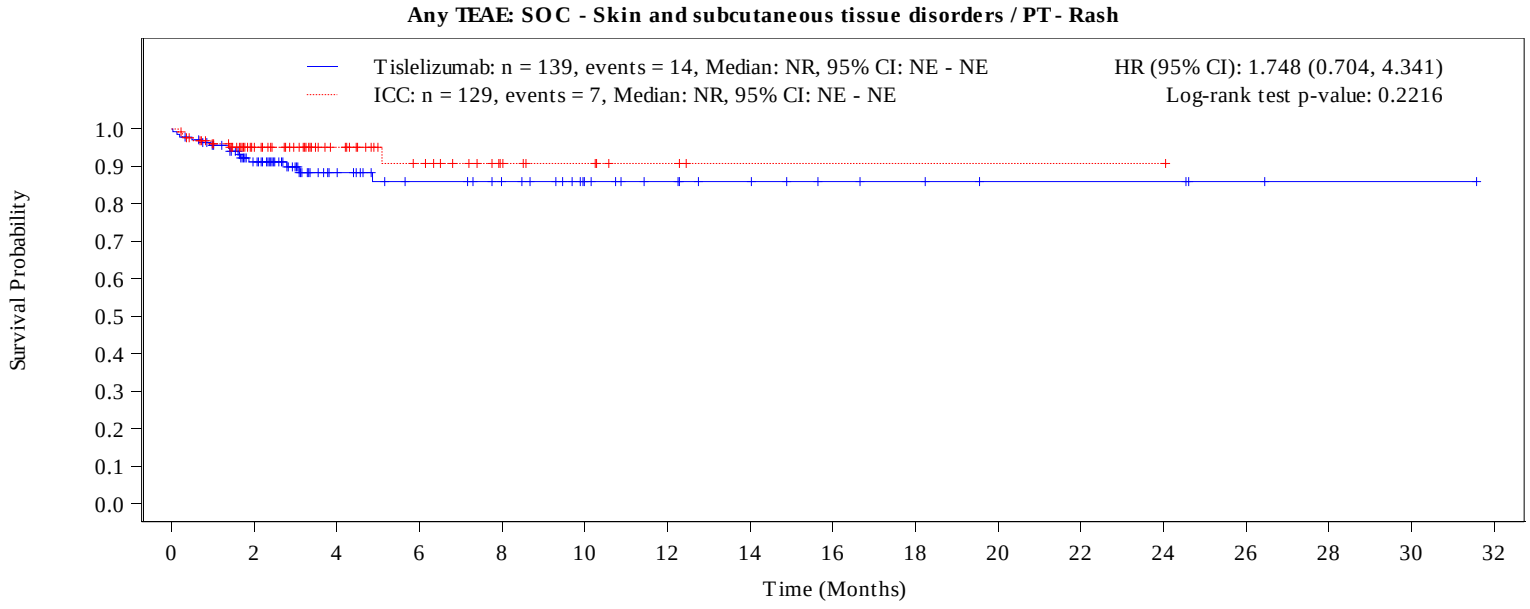


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28
Tislelizumab	139	87	45	33	26	17	12	9	6	6	5	4	4	1	0
ICC	129	71	32	19	9	6	3	1	1	1	1	1	1	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-b-km-aesocpt-safetys-sa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	86	44	33	27	18	14	11	7	6	4	4	4	2	1	1	0
ICC	129	69	32	18	9	6	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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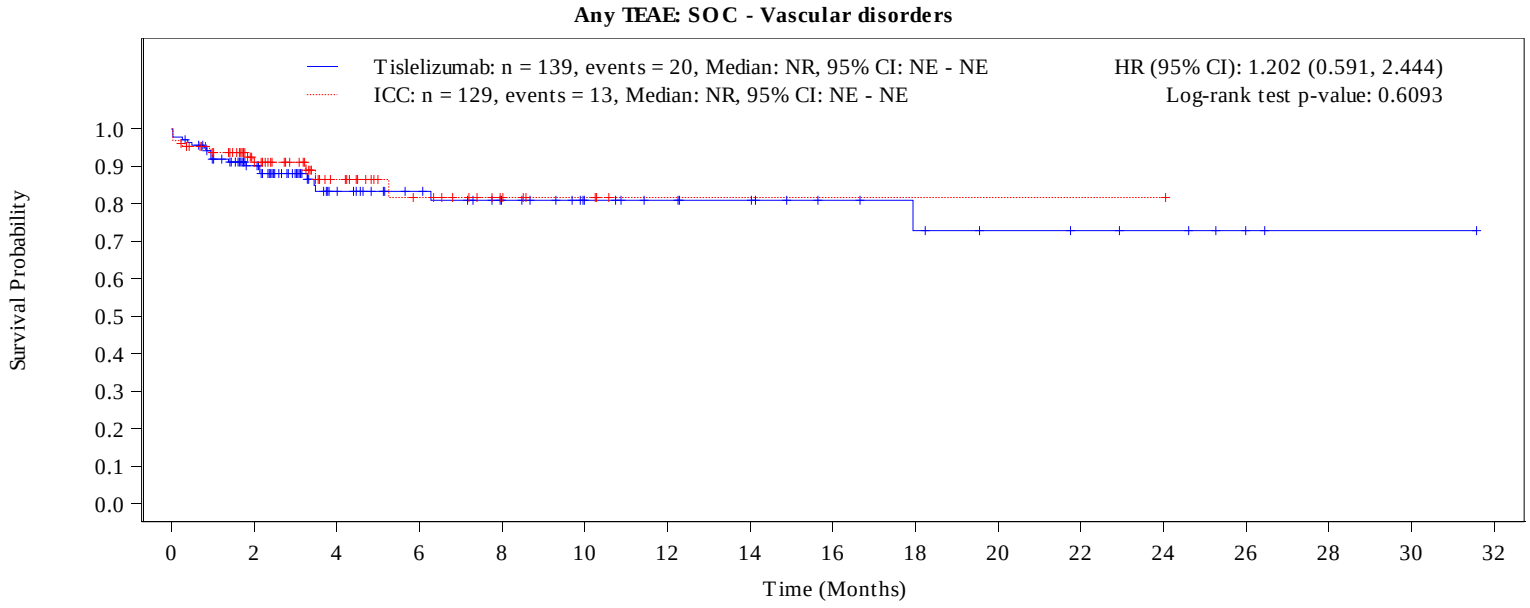
Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

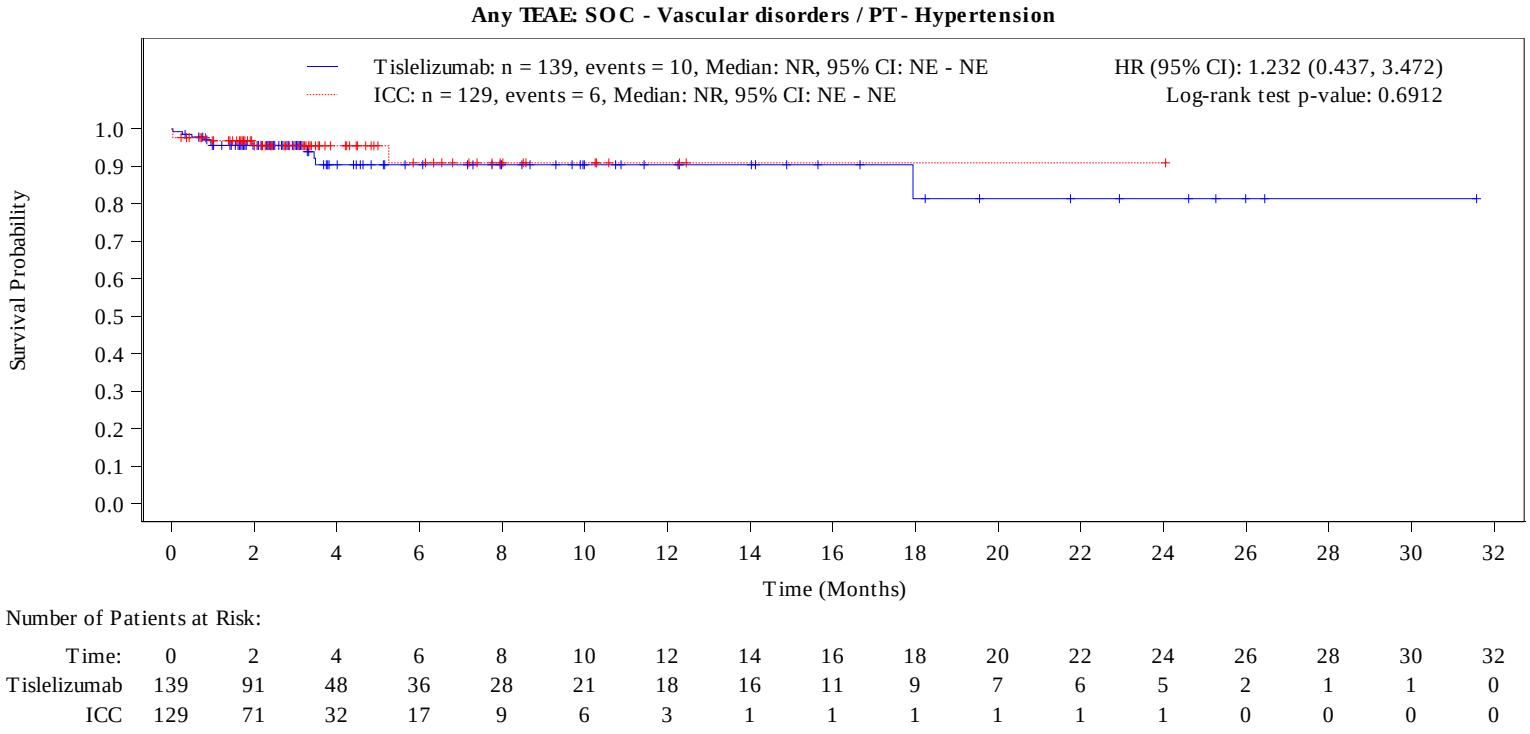


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	89	48	36	27	20	17	15	11	9	7	6	5	2	1	1	0
ICC	129	67	29	14	7	4	1	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-02-b-km-aesocpt-safetys-sa.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	91	48	36	28	21	18	16	11	9	7	6	5	2	1	1	0
ICC	129	71	32	17	9	6	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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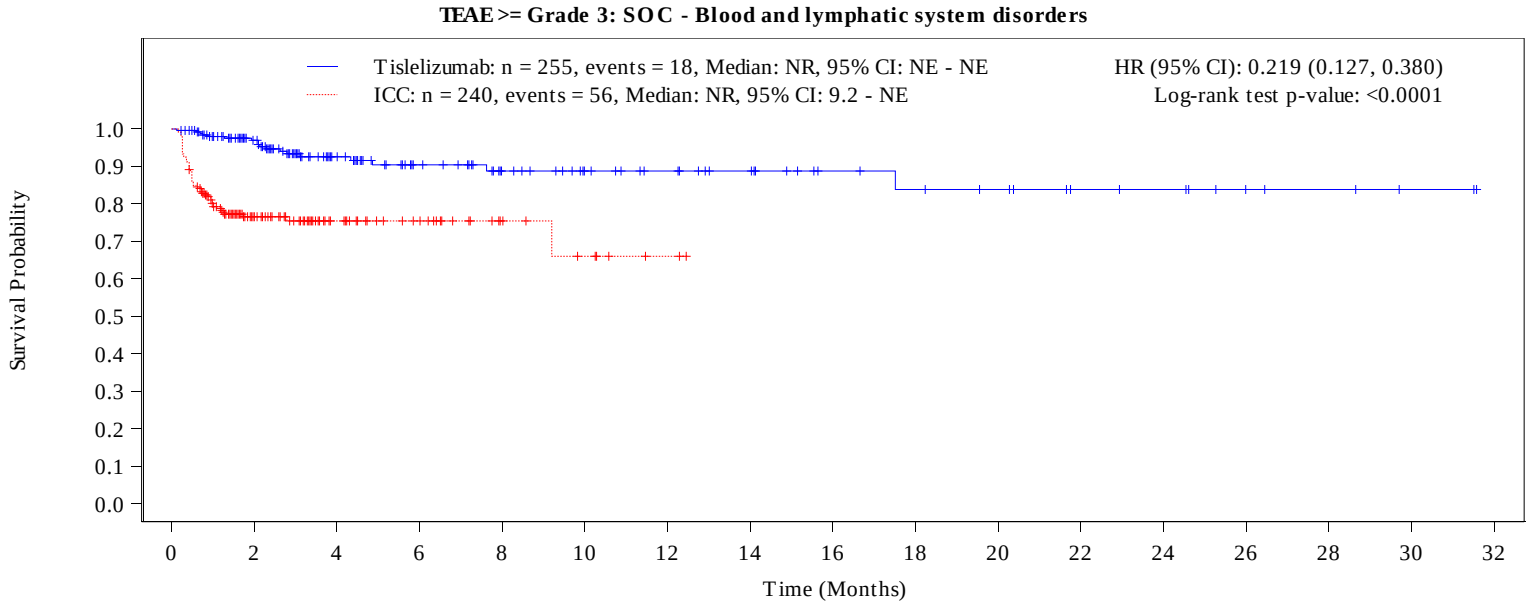
Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	172	96	65	48	37	31	26	19	17	15	11	10	5	4	2	0
ICC	240	95	37	22	10	6	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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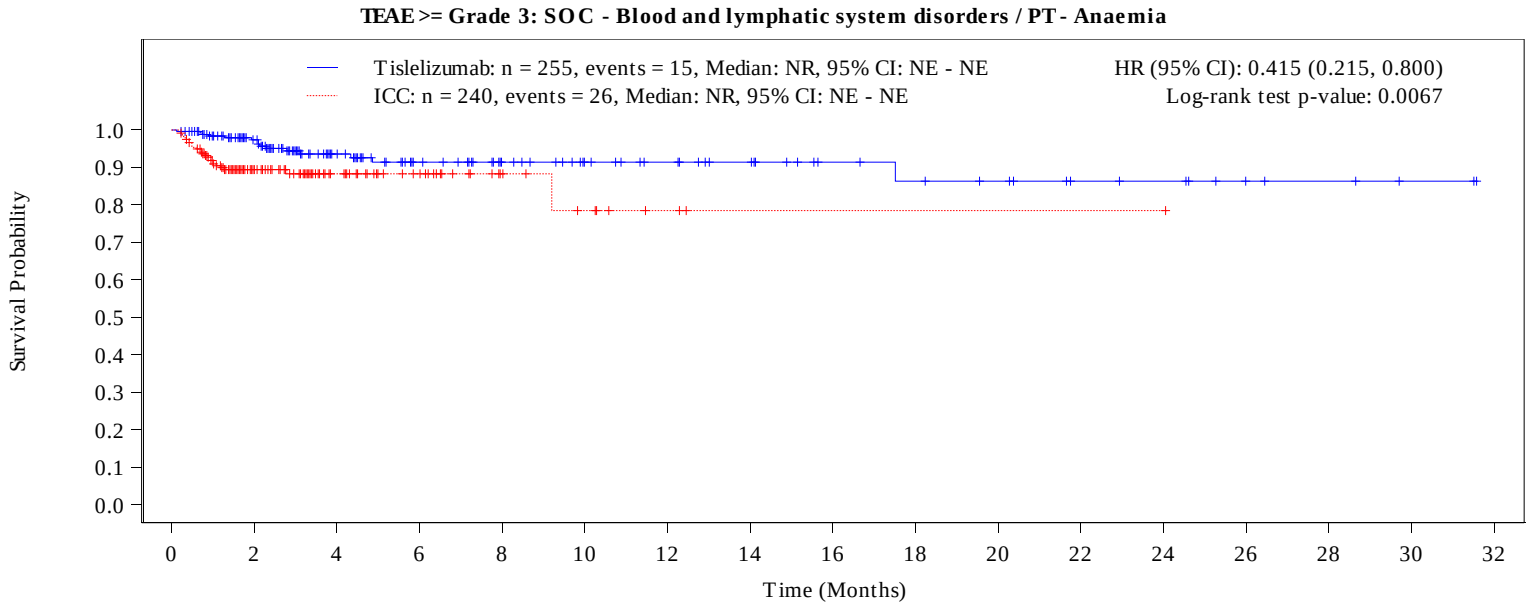
Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

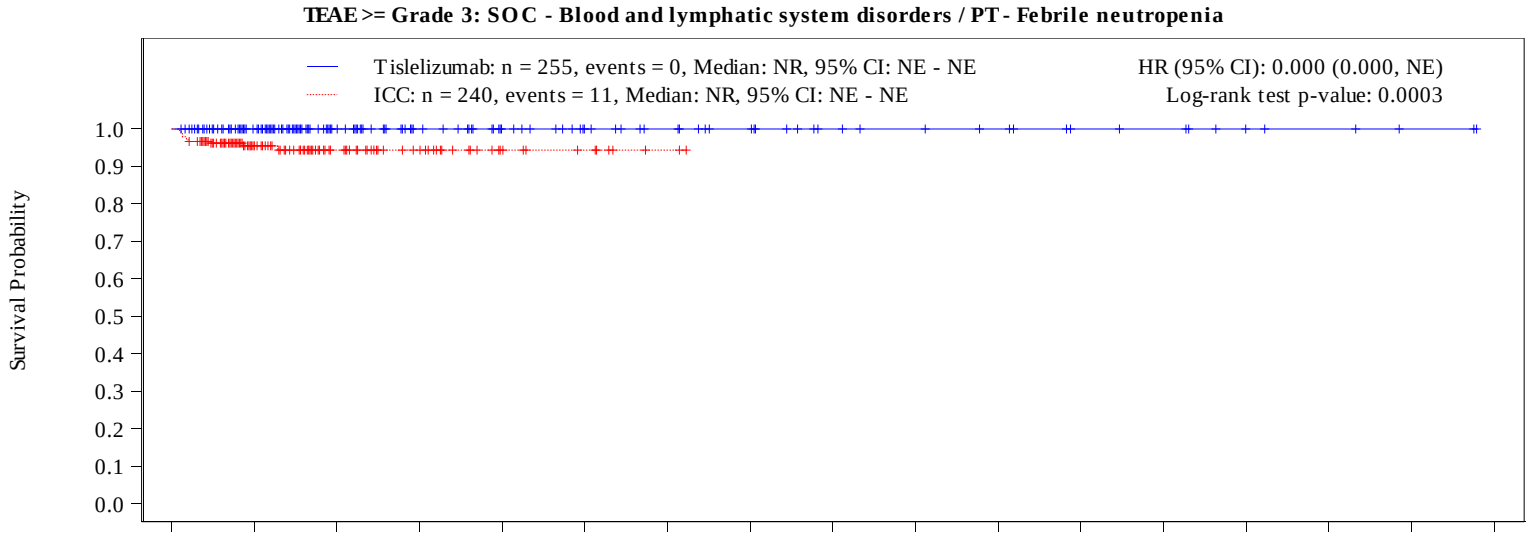


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	172	96	65	49	38	32	27	19	17	15	11	10	5	4	2	0
ICC	240	109	42	24	11	7	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-03-km-aesocpt-g3-safety-sa.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

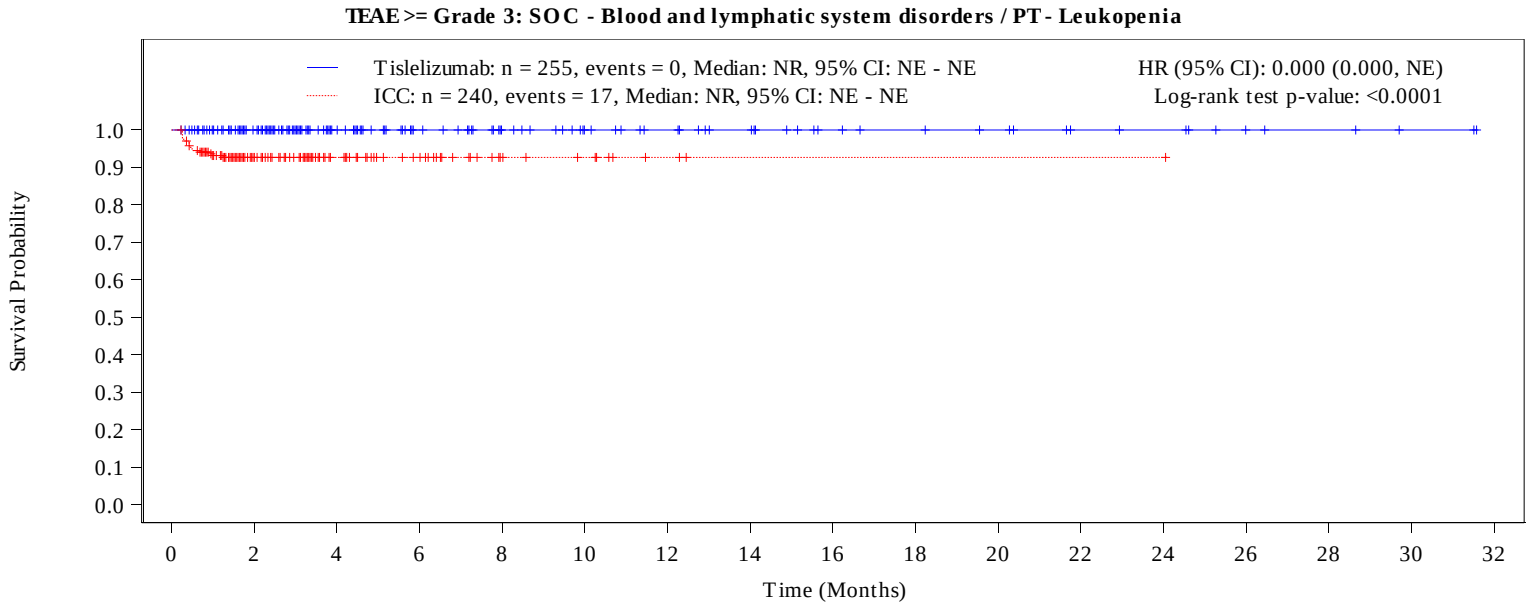


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	175	97	65	49	38	32	27	19	17	15	11	10	5	4	2	0
ICC	240	110	44	25	11	7	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-03-km-aesocpt-g3-safety-sa.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

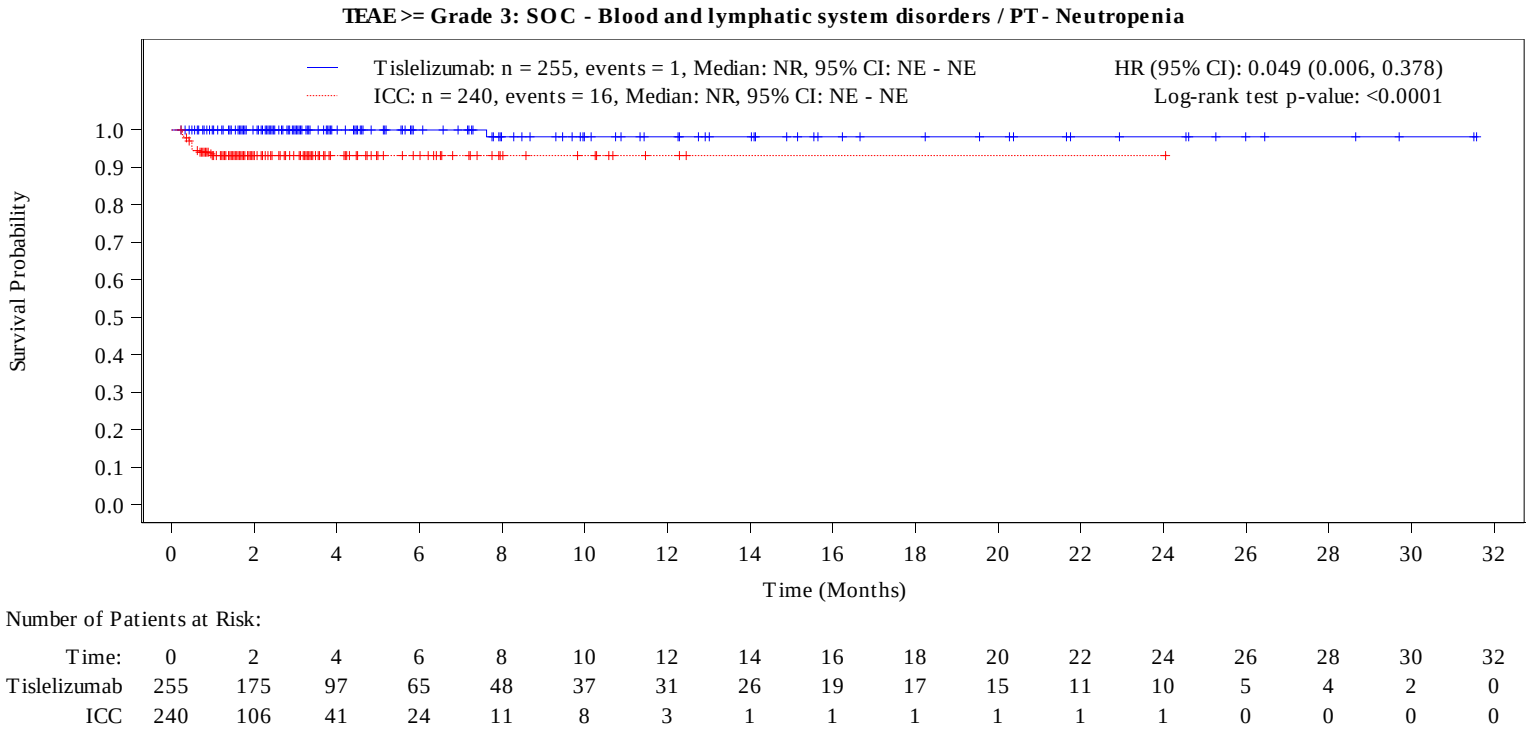


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	175	97	65	49	38	32	27	19	17	15	11	10	5	4	2	0
ICC	240	106	42	25	11	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-03-km-aesocpt-g3-safety-sa.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

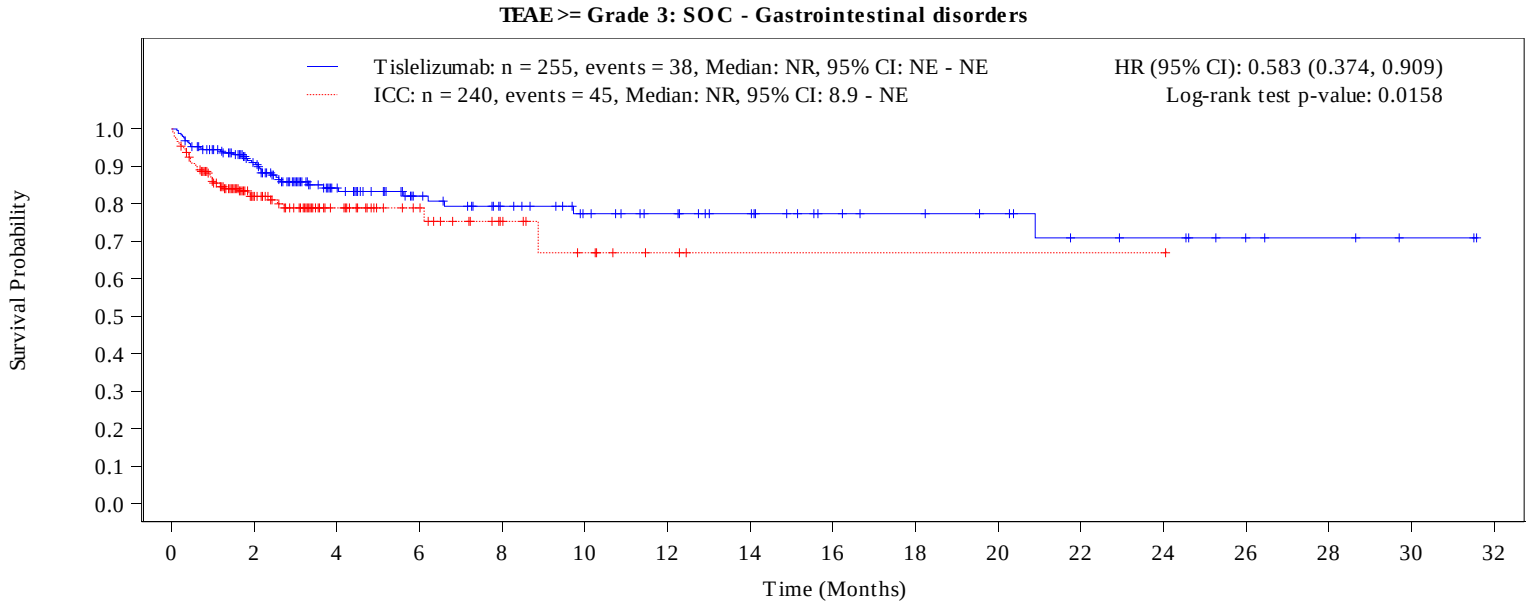


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	175	97	65	48	37	31	26	19	17	15	11	10	5	4	2	0
ICC	240	106	41	24	11	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-03-km-aesocpt-g3-safety-sa.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

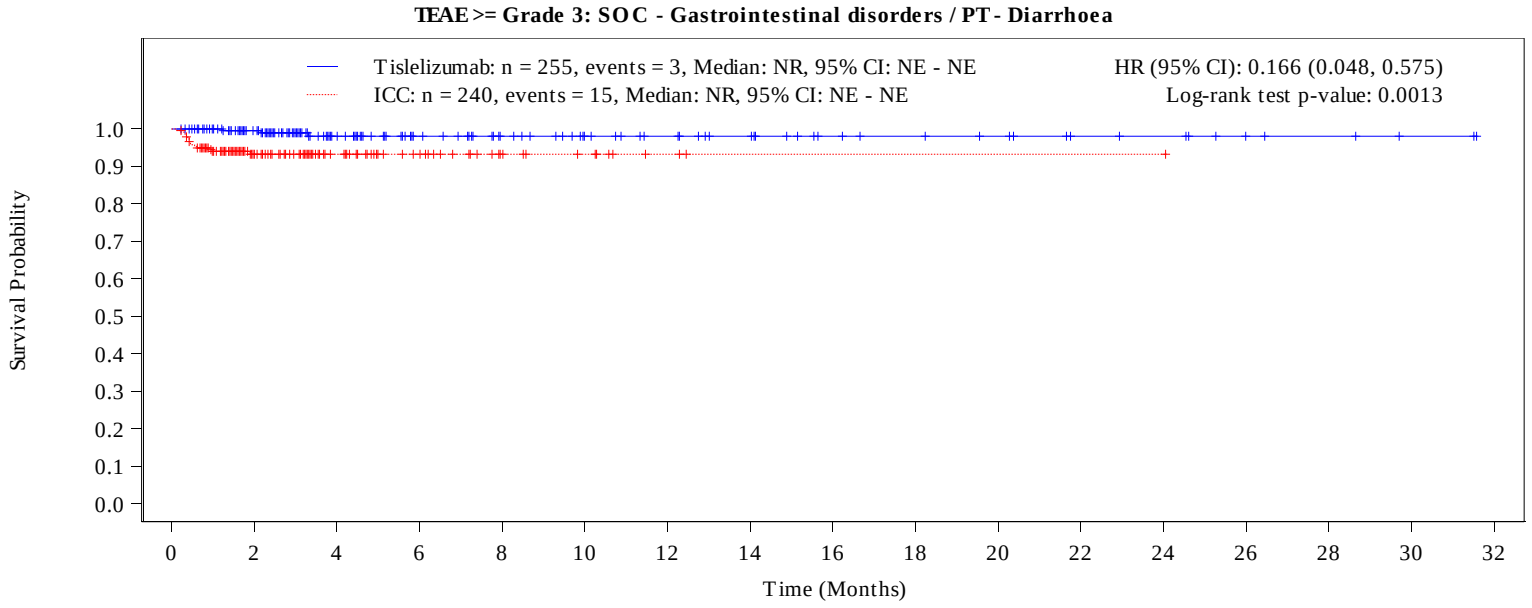


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	167	92	62	48	37	31	26	18	16	14	10	9	5	4	2	0
ICC	240	100	41	23	12	7	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-03-km-aesocpt-g3-safety-sa.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	174	95	64	49	38	32	27	19	17	15	11	10	5	4	2	0
ICC	240	108	43	24	12	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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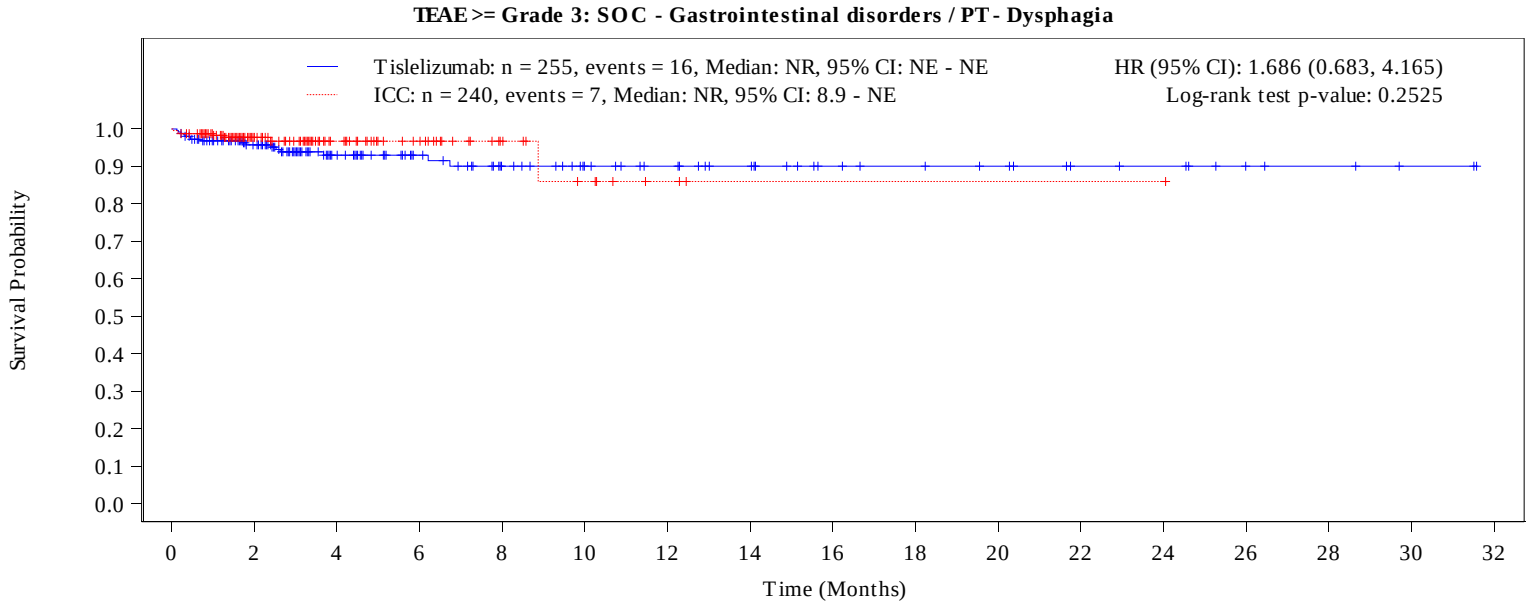
Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	171	96	65	49	38	32	27	19	17	15	11	10	5	4	2	0
ICC	240	108	44	25	12	7	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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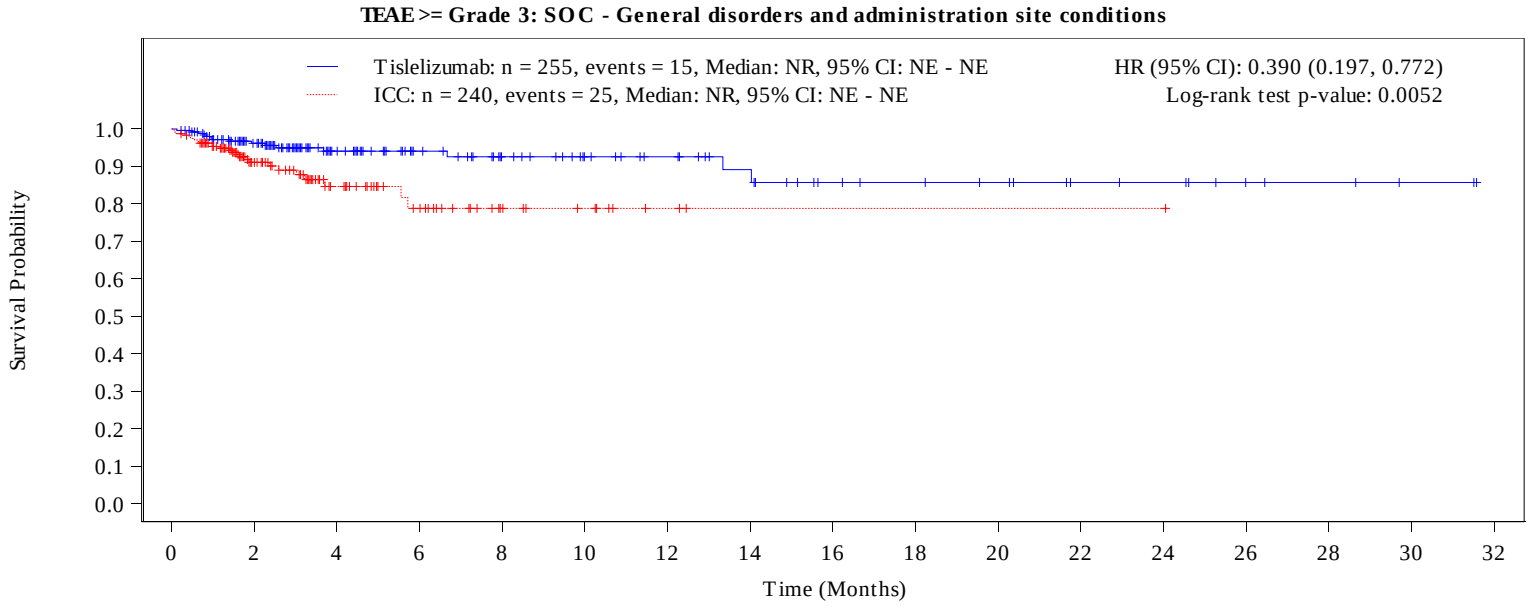
Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

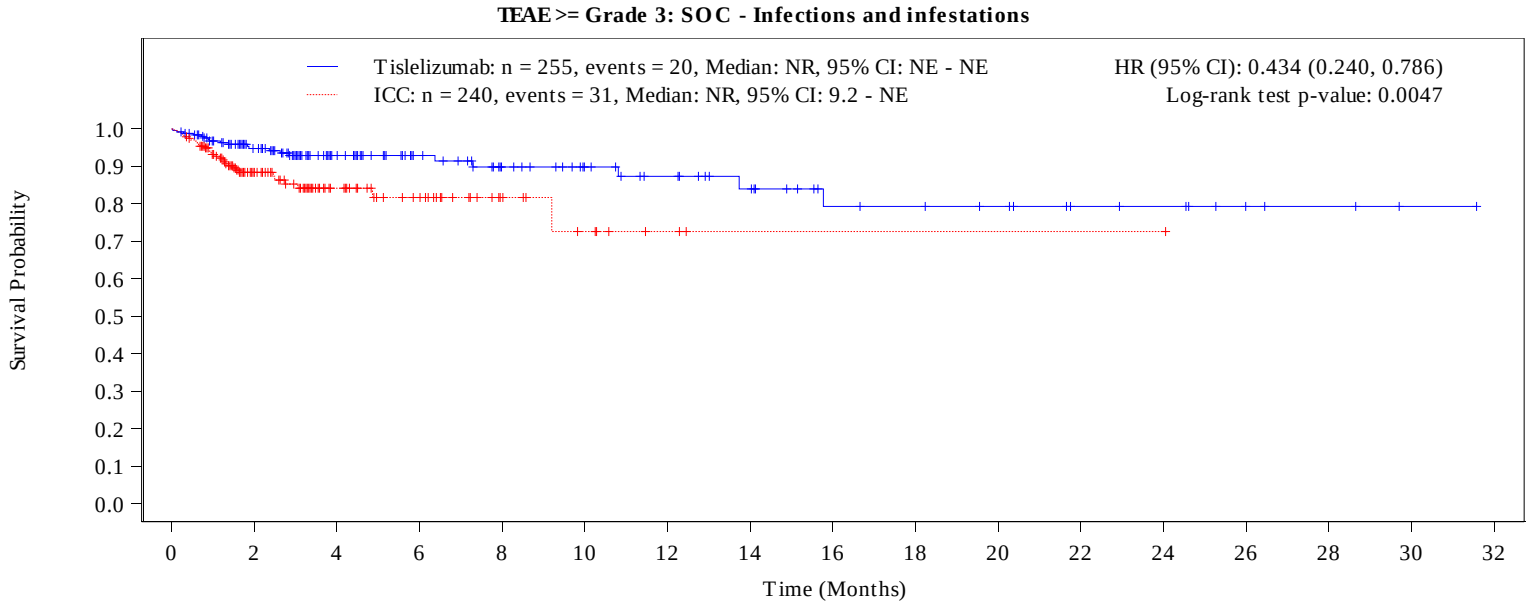


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	173	97	65	49	38	32	26	19	17	15	11	10	5	4	2	0
ICC	240	108	43	25	12	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-03-km-aesocpt-g3-safety-sa.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

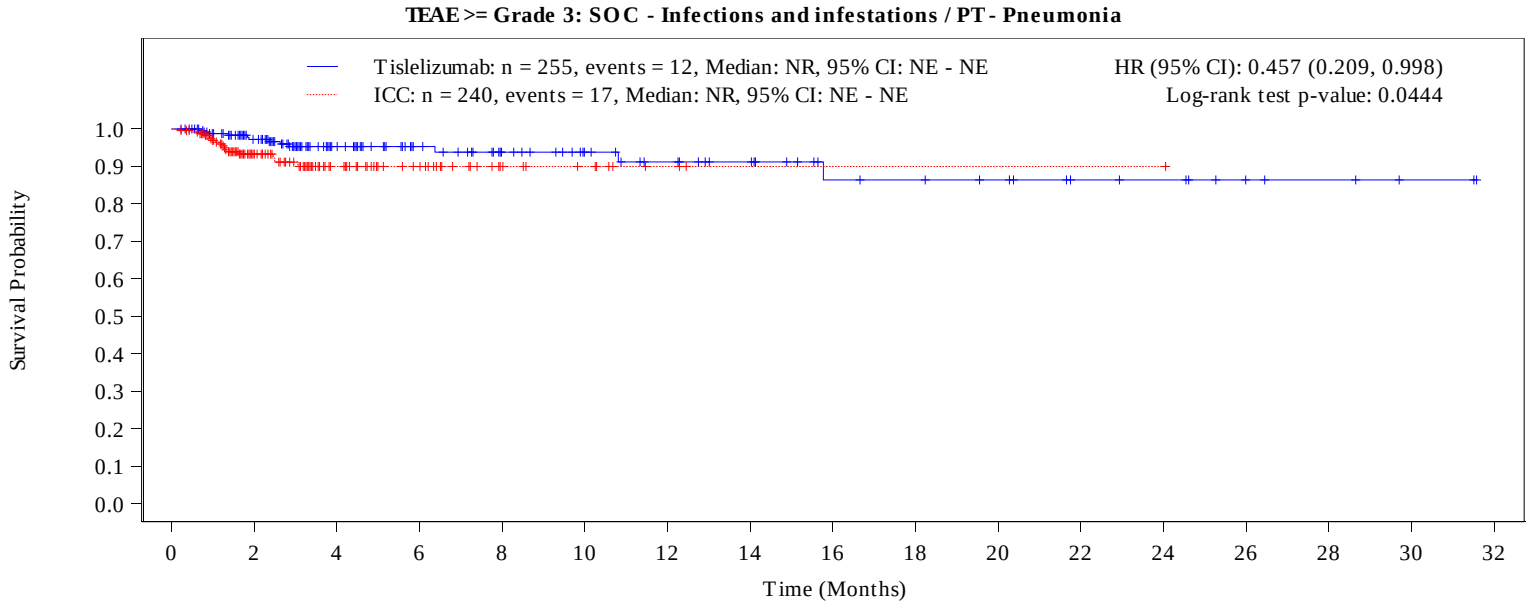


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	169	97	65	49	38	31	25	17	16	14	10	9	4	3	1	0
ICC	240	110	44	26	12	7	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-03-km-aesocpt-g3-safety-sa.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

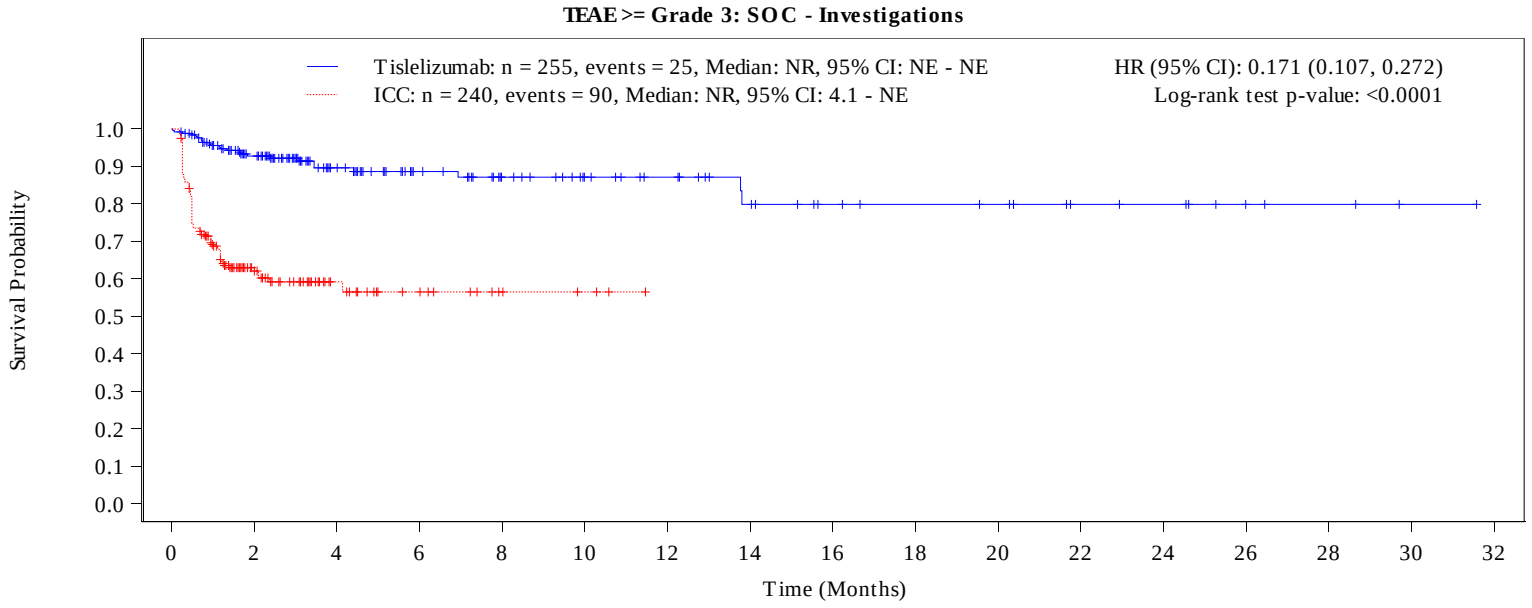


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	173	97	65	49	38	31	26	18	17	15	11	10	5	4	2	0
ICC	240	112	45	26	12	8	3	1	1	1	1	1	1	0	0	0	0

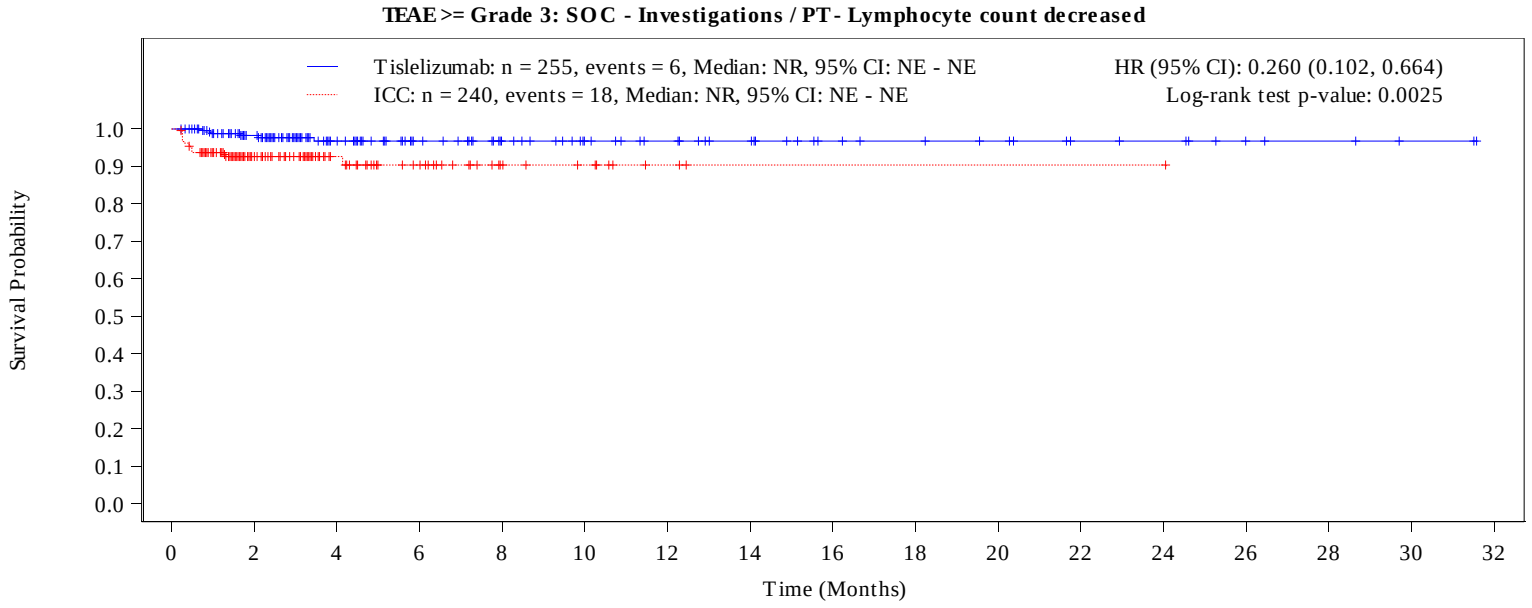
Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-03-km-aesocpt-g3-safety-sa.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set



Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-03-km-aesocpt-g3-safety-sa.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

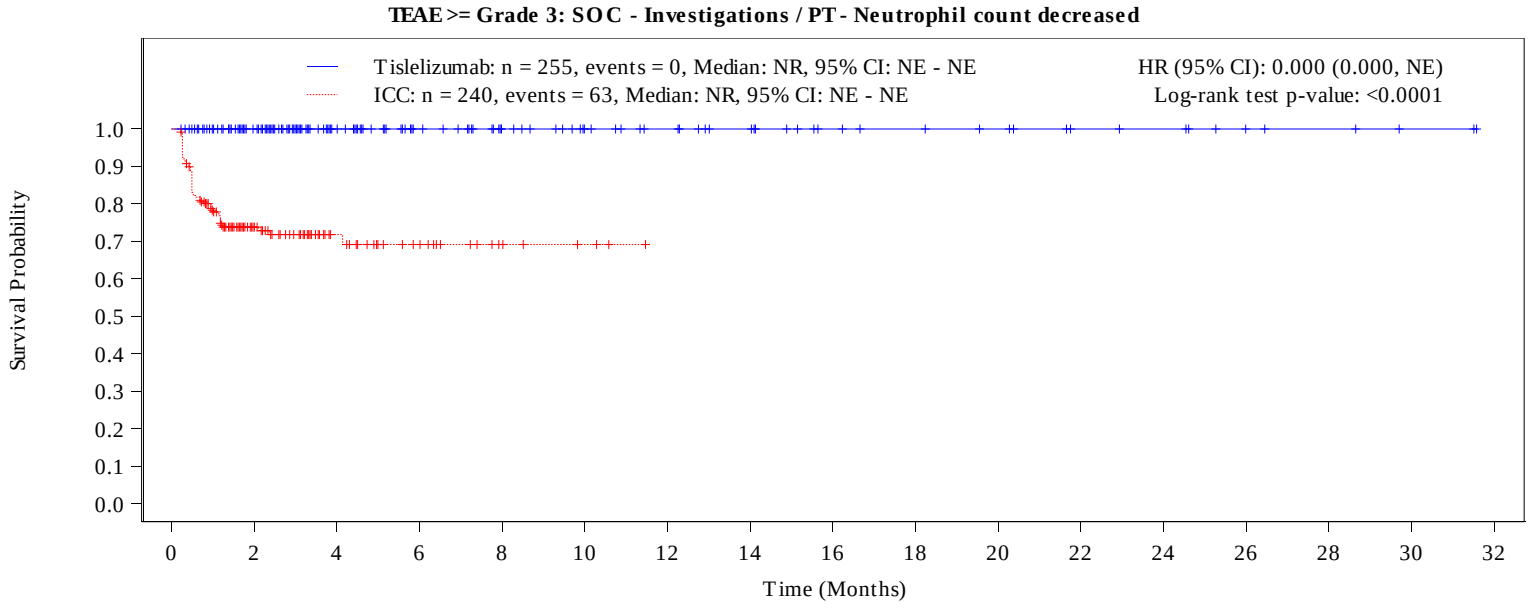


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	172	97	65	49	38	32	27	19	17	15	11	10	5	4	2	0
ICC	240	107	41	24	11	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-03-km-aesocpt-g3-safety-sa.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

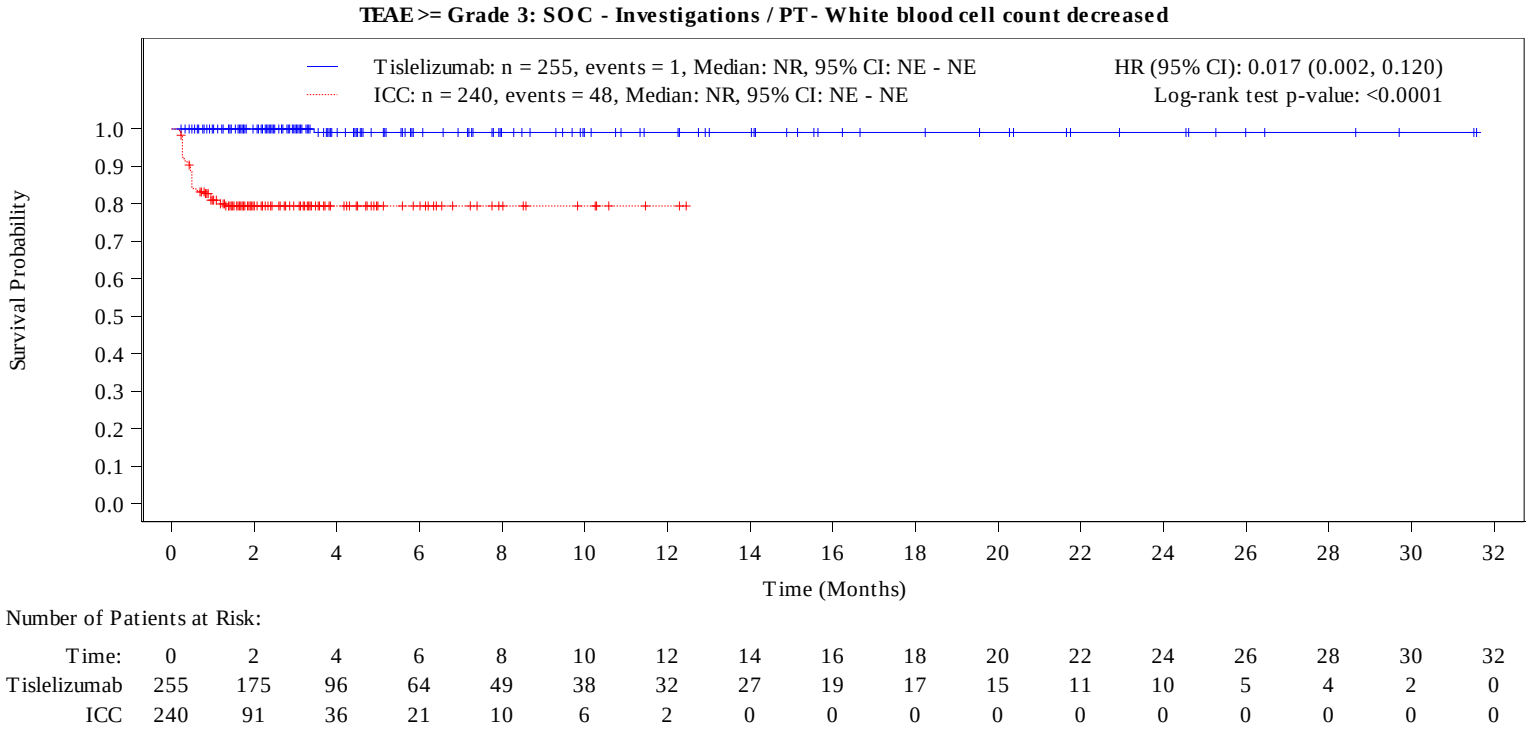


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	175	97	65	49	38	32	27	19	17	15	11	10	5	4	2	0
ICC	240	81	27	15	6	3	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-03-km-aesocpt-g3-safety-sa.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

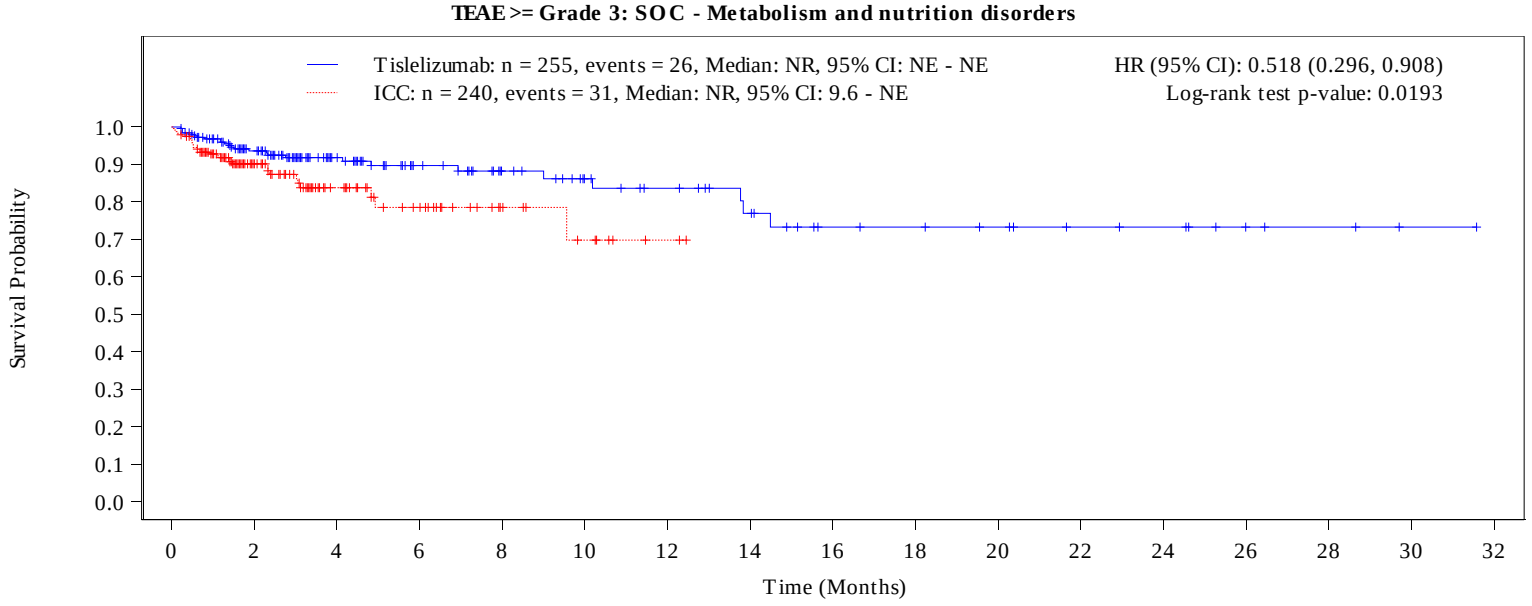


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	175	96	64	49	38	32	27	19	17	15	11	10	5	4	2	0
ICC	240	91	36	21	10	6	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-03-km-aesocpt-g3-safety-sa.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

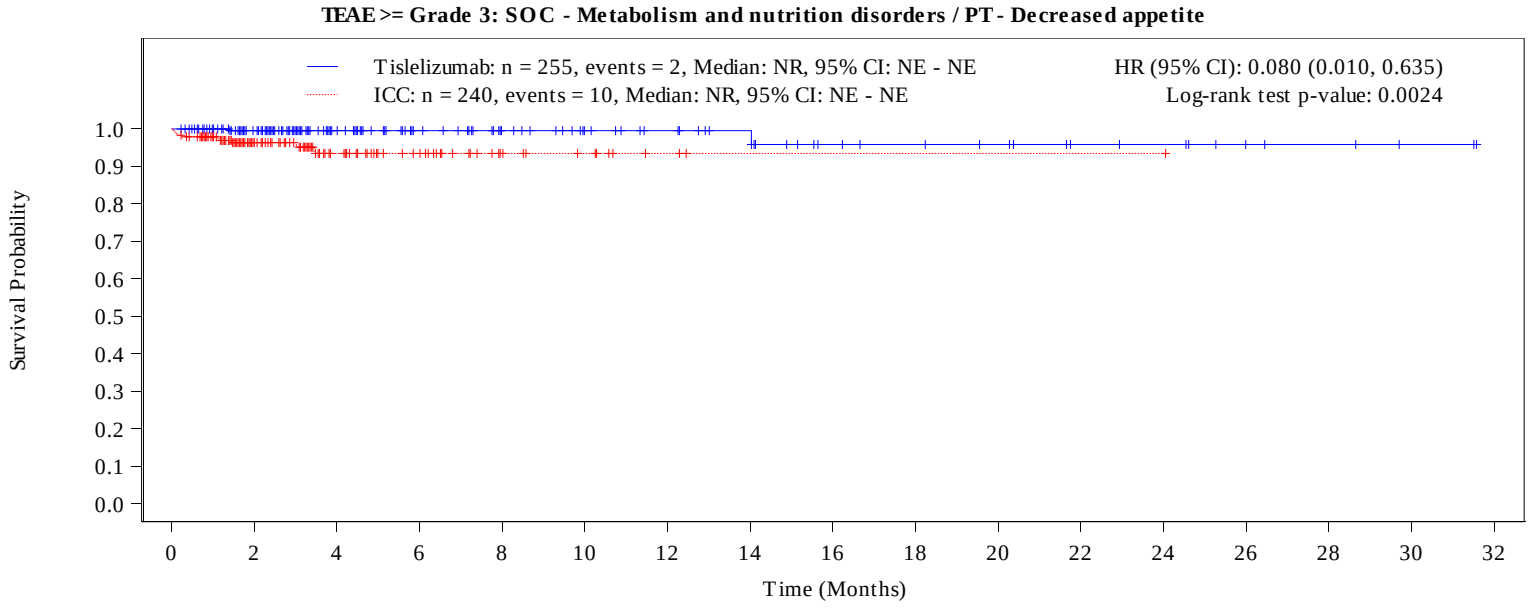


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	169	96	63	46	35	29	23	16	15	13	10	9	4	3	1	0
ICC	240	108	43	25	12	7	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-03-km-aesocpt-g3-safety-sa.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	174	97	65	49	38	32	27	19	17	15	11	10	5	4	2	0
ICC	240	112	45	26	12	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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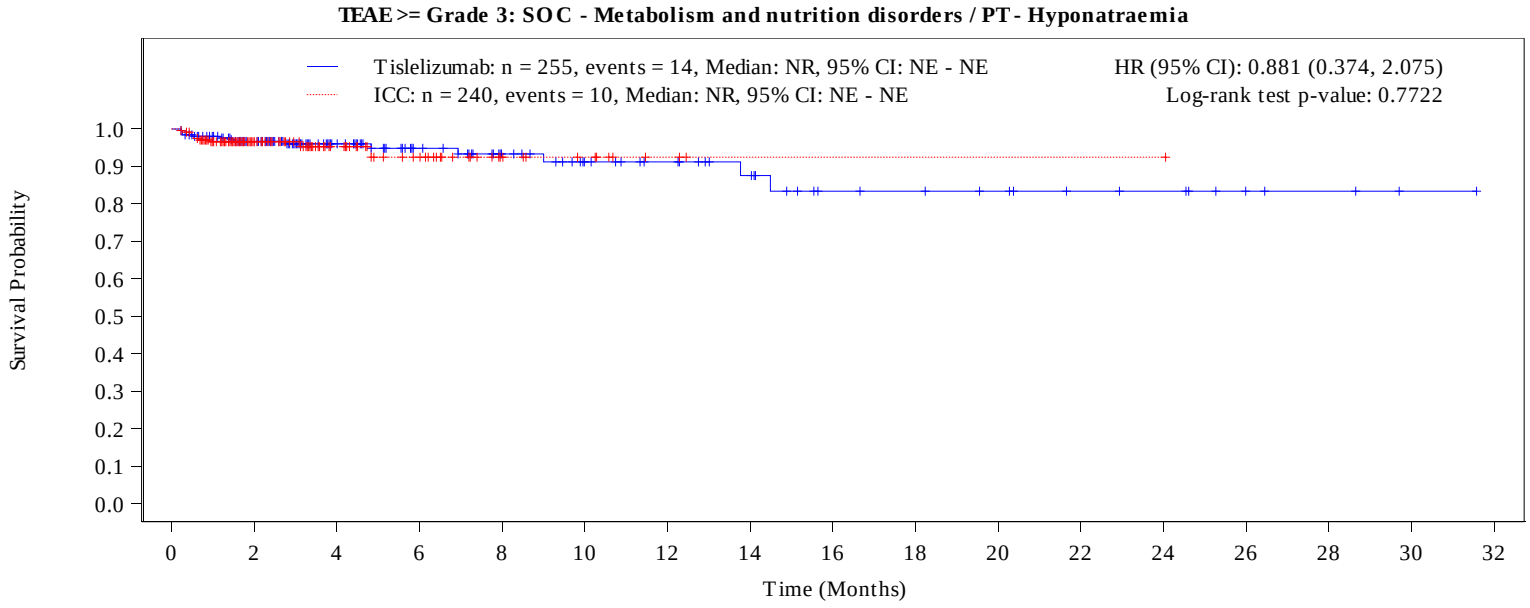
Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

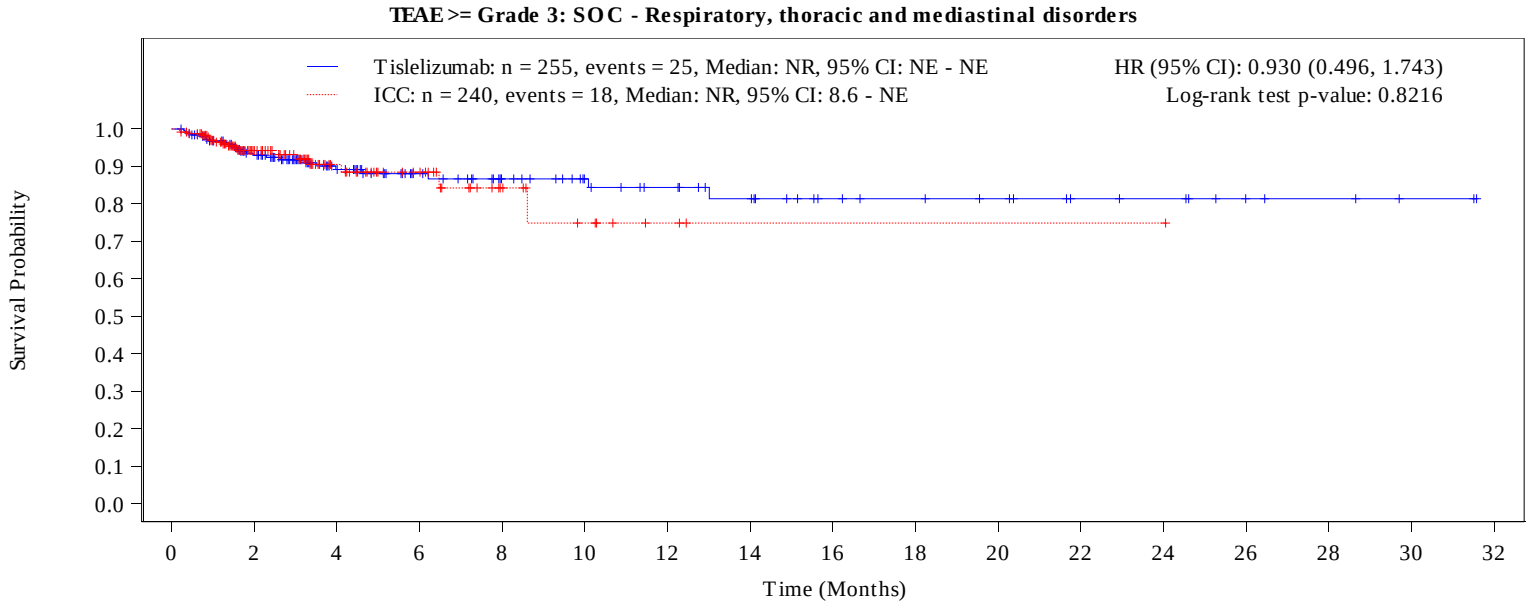


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	173	97	65	48	36	30	24	16	15	13	10	9	4	3	1	0
ICC	240	111	44	26	12	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-03-km-aesocpt-g3-safety-sa.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

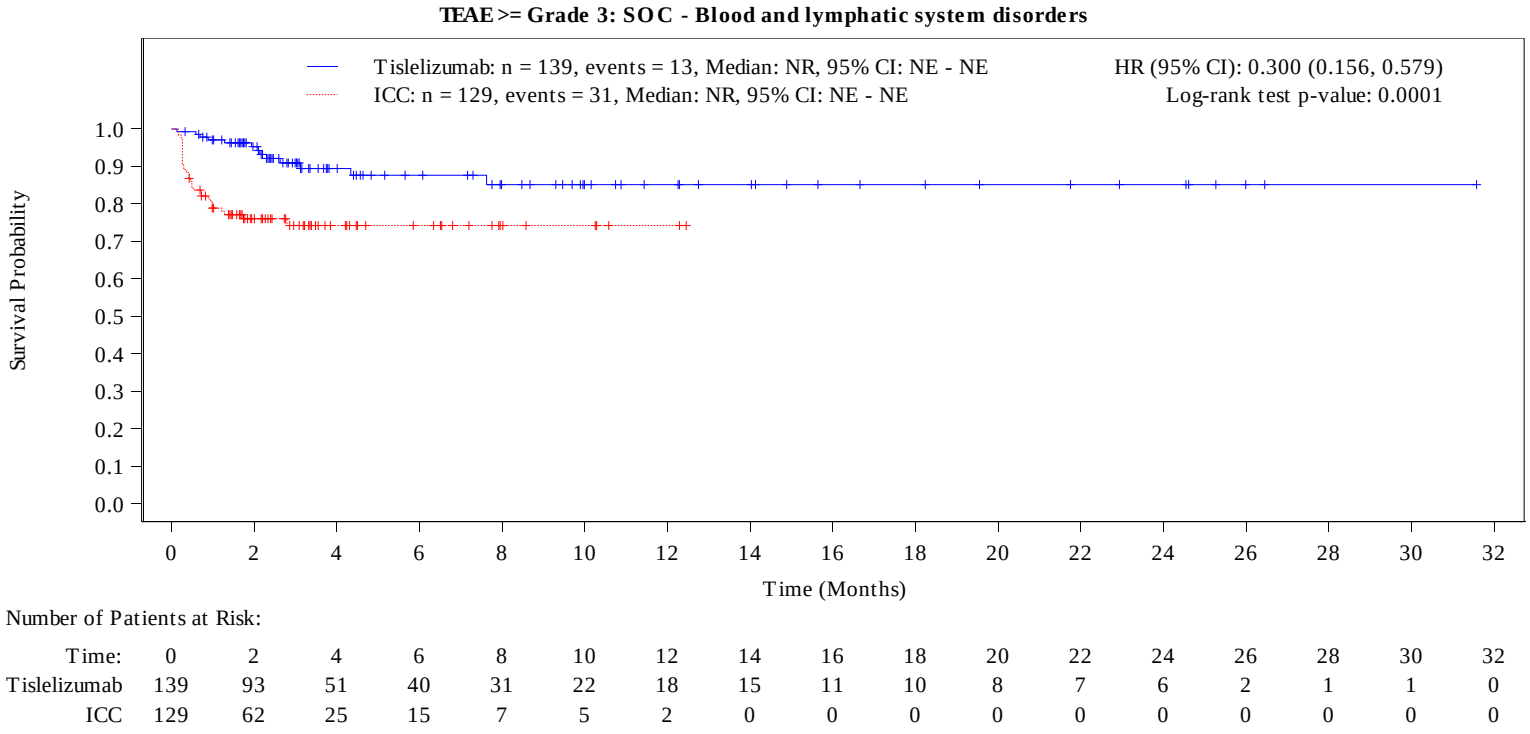


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	170	96	64	49	38	32	27	19	17	15	11	10	5	4	2	0
ICC	240	112	44	26	12	7	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-03-km-aesocpt-g3-safety-sa.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

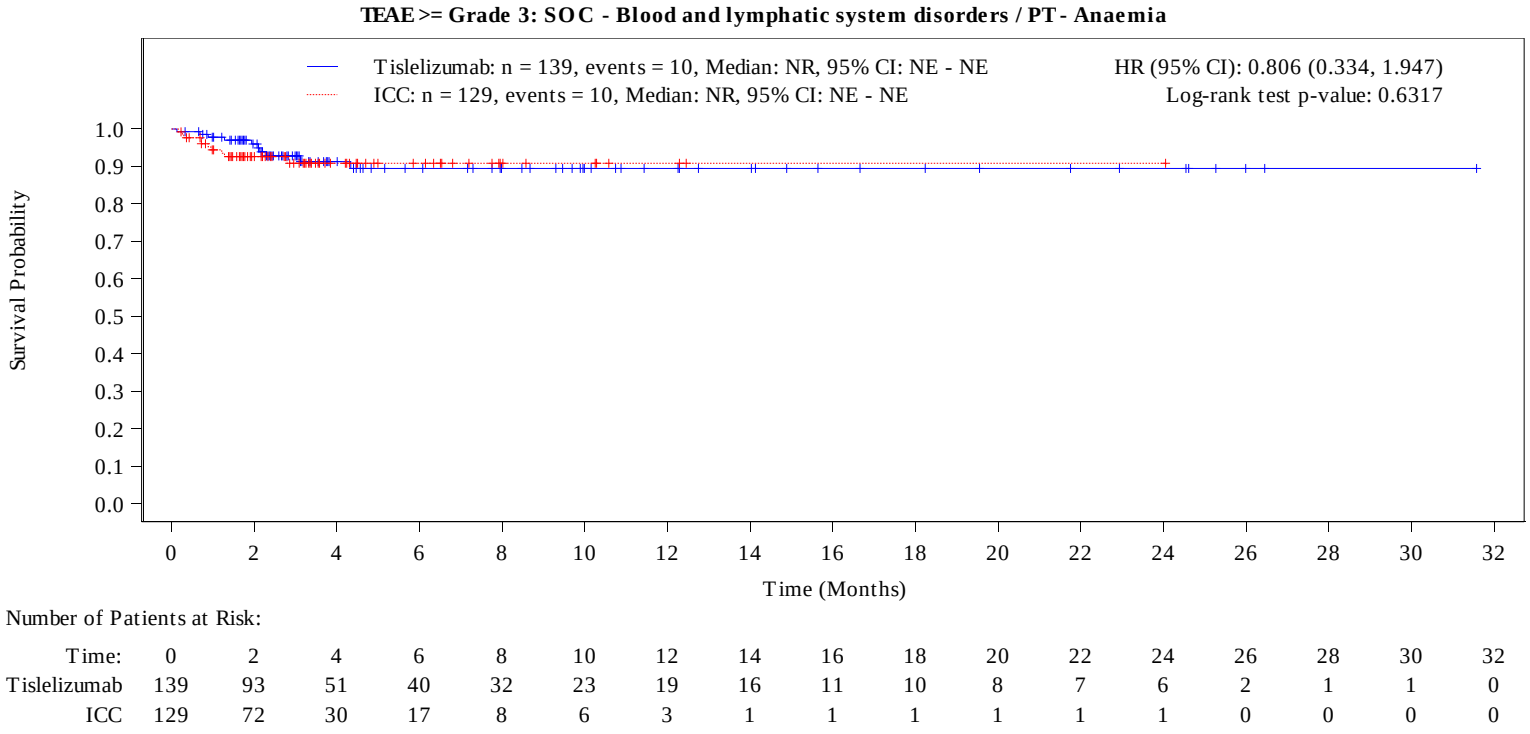


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	93	51	40	31	22	18	15	11	10	8	7	6	2	1	1	0
ICC	129	62	25	15	7	5	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-03-b-km-aesocpt-g3-safetys-sa.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

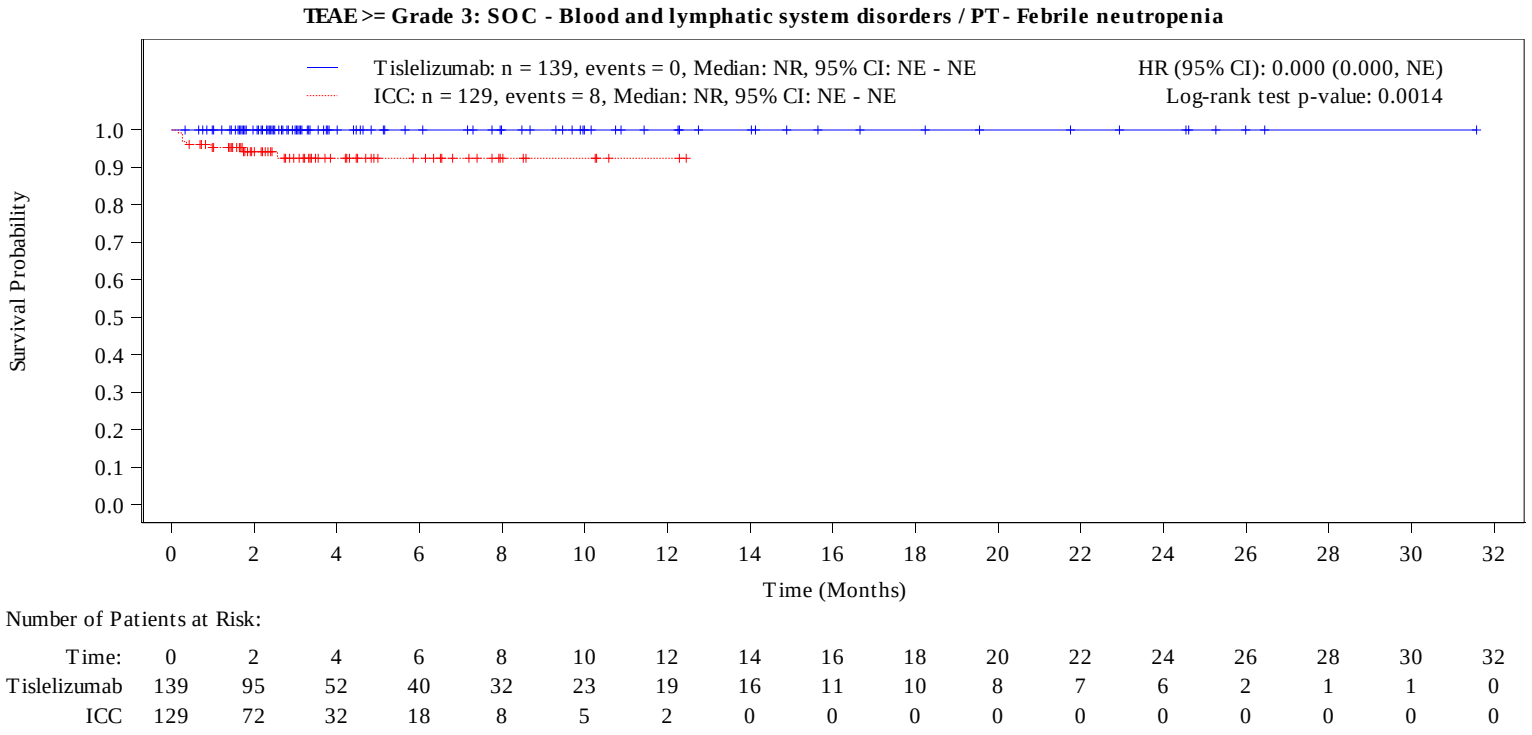


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	93	51	40	32	23	19	16	11	10	8	7	6	2	1	1	0
ICC	129	72	30	17	8	6	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-03-b-km-aesocpt-g3-safetys-sa.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

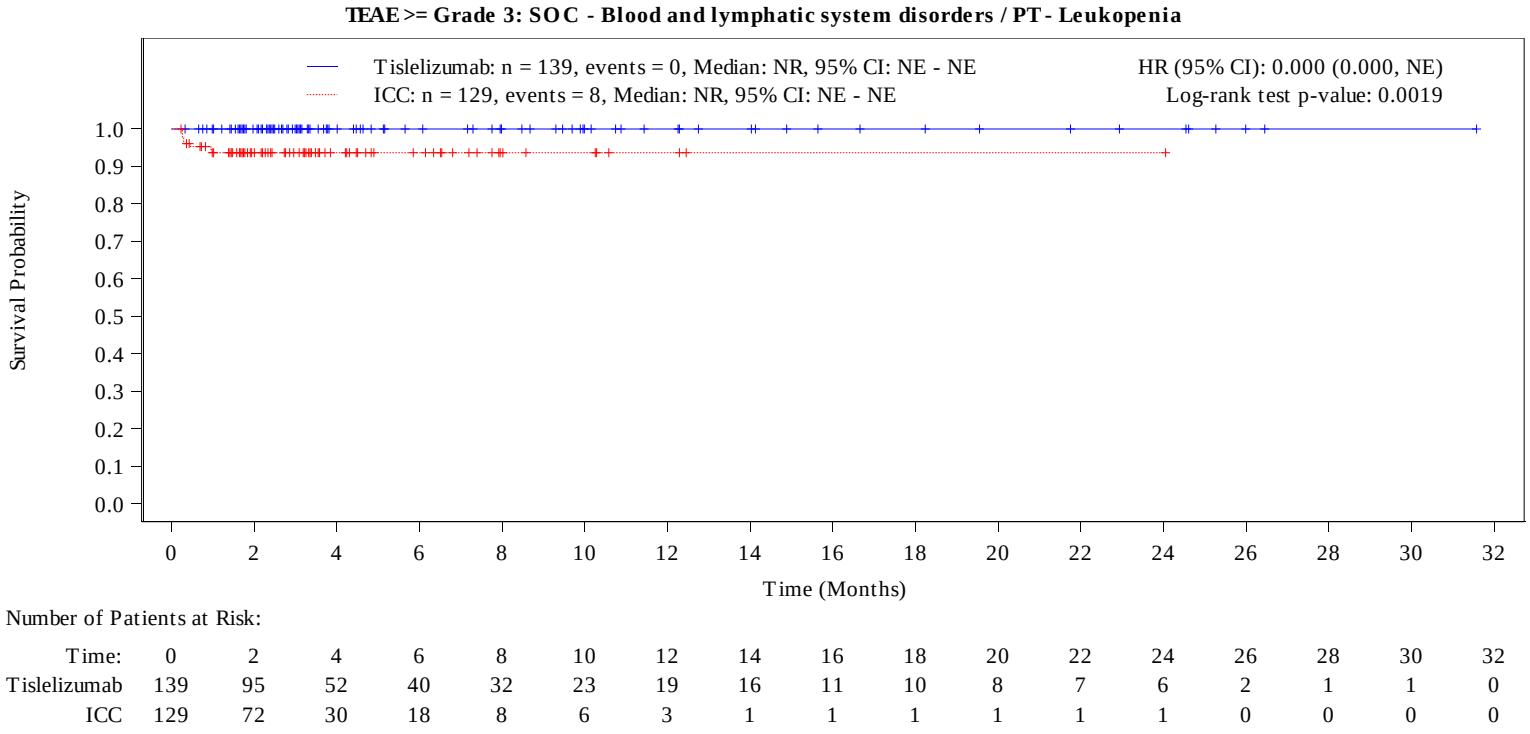


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	95	52	40	32	23	19	16	11	10	8	7	6	2	1	1	0
ICC	129	72	32	18	8	5	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-03-b-km-aesocpt-g3-safetys-sa.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

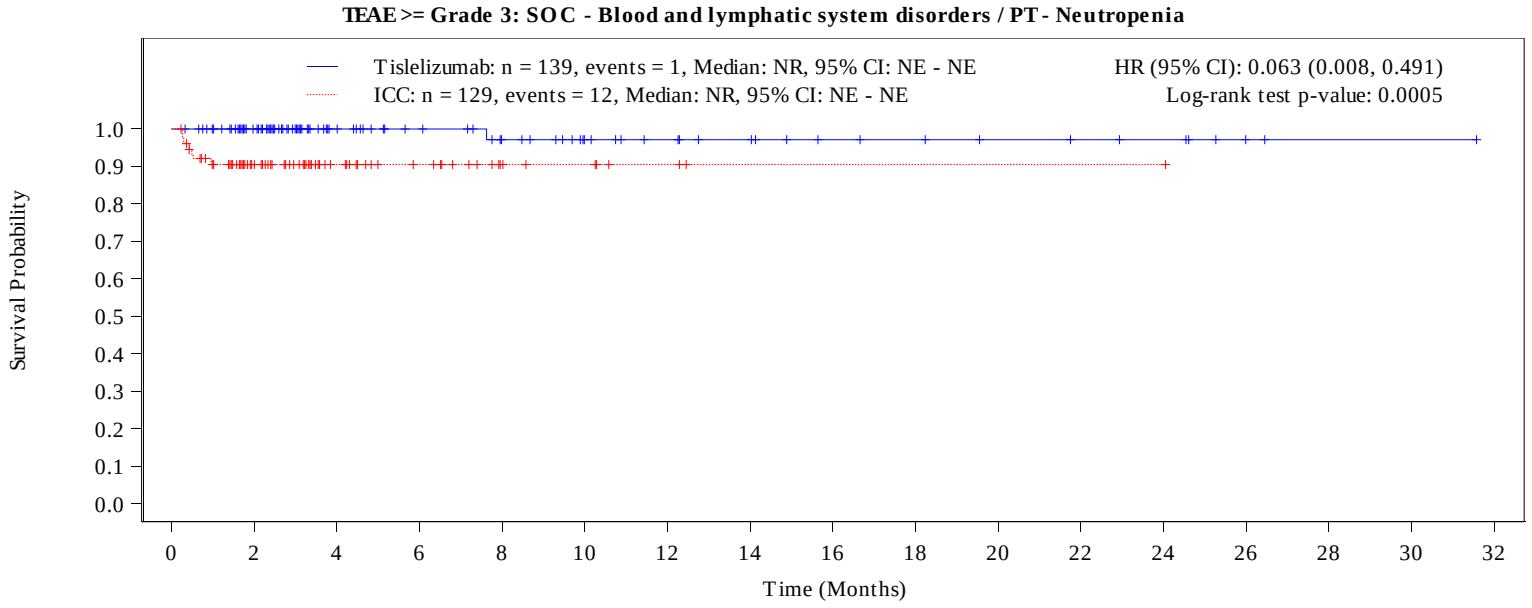


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	95	52	40	32	23	19	16	11	10	8	7	6	2	1	1	0
ICC	129	72	30	18	8	6	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-03-b-km-aesocpt-g3-safetys-sa.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

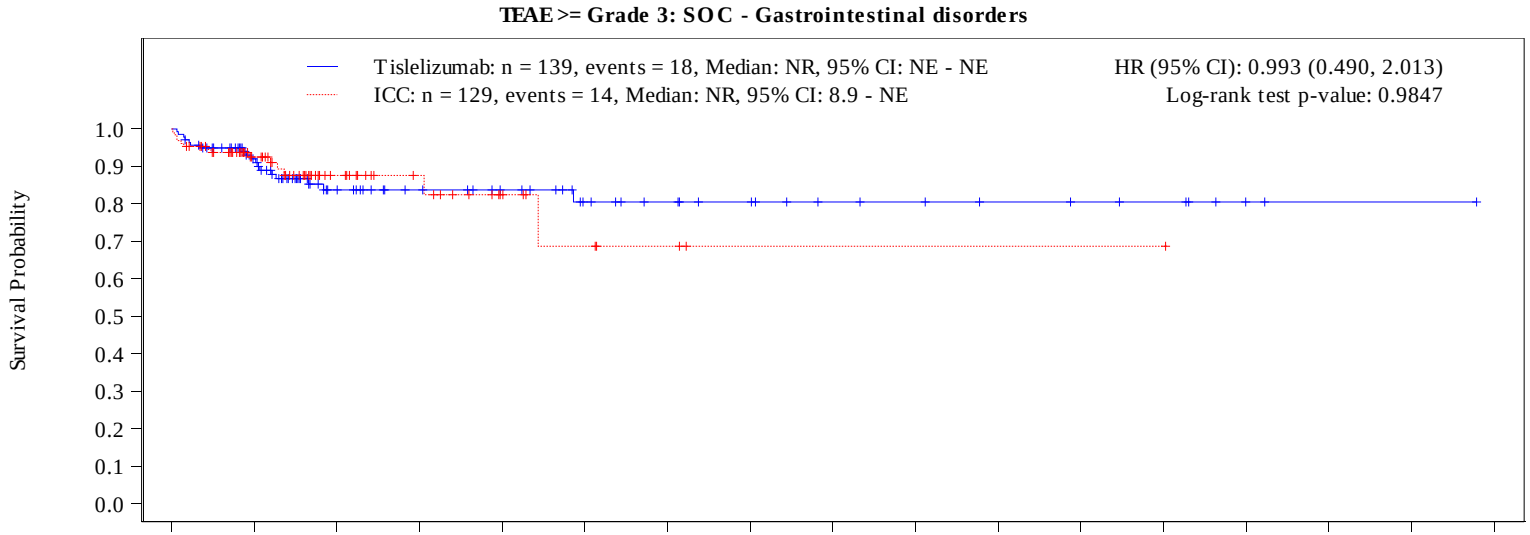


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	95	52	40	31	22	18	15	11	10	8	7	6	2	1	1	0
ICC	129	70	29	17	8	6	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-03-b-km-aesocpt-g3-safetys-sa.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

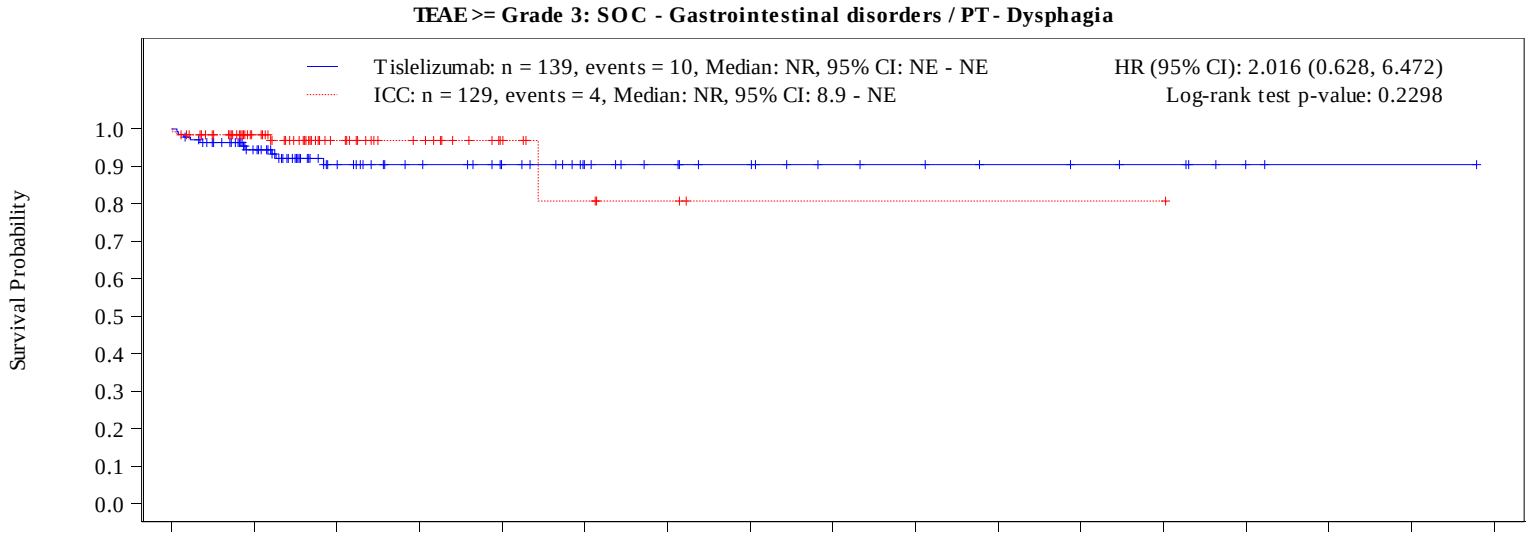


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	91	51	39	32	23	19	16	11	10	8	7	6	2	1	1	0
ICC	129	71	30	17	9	5	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-03-b-km-aesocpt-g3-safetys-sa.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

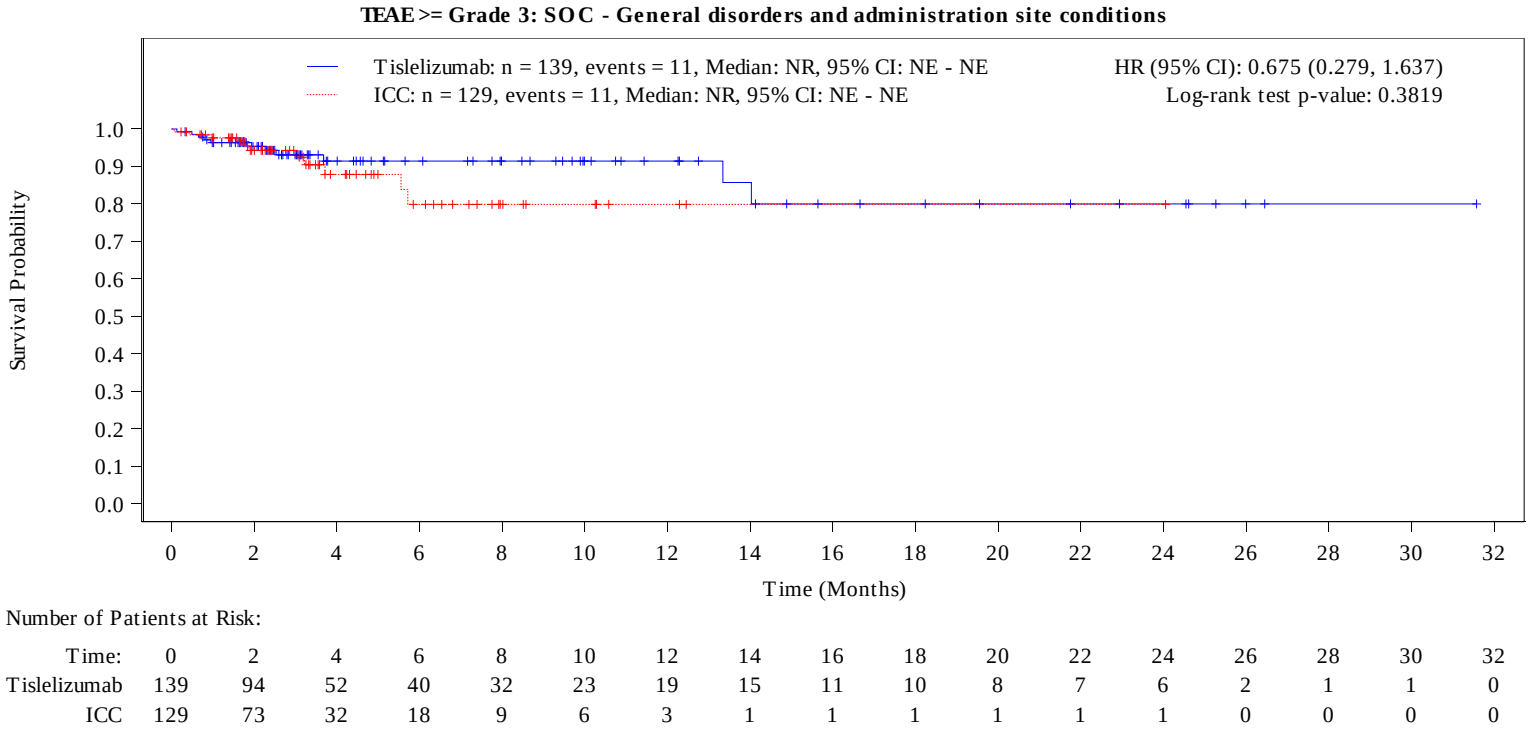


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	92	52	40	32	23	19	16	11	10	8	7	6	2	1	1	0
ICC	129	73	32	18	9	5	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-03-b-km-aesocpt-g3-safetys-sa.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

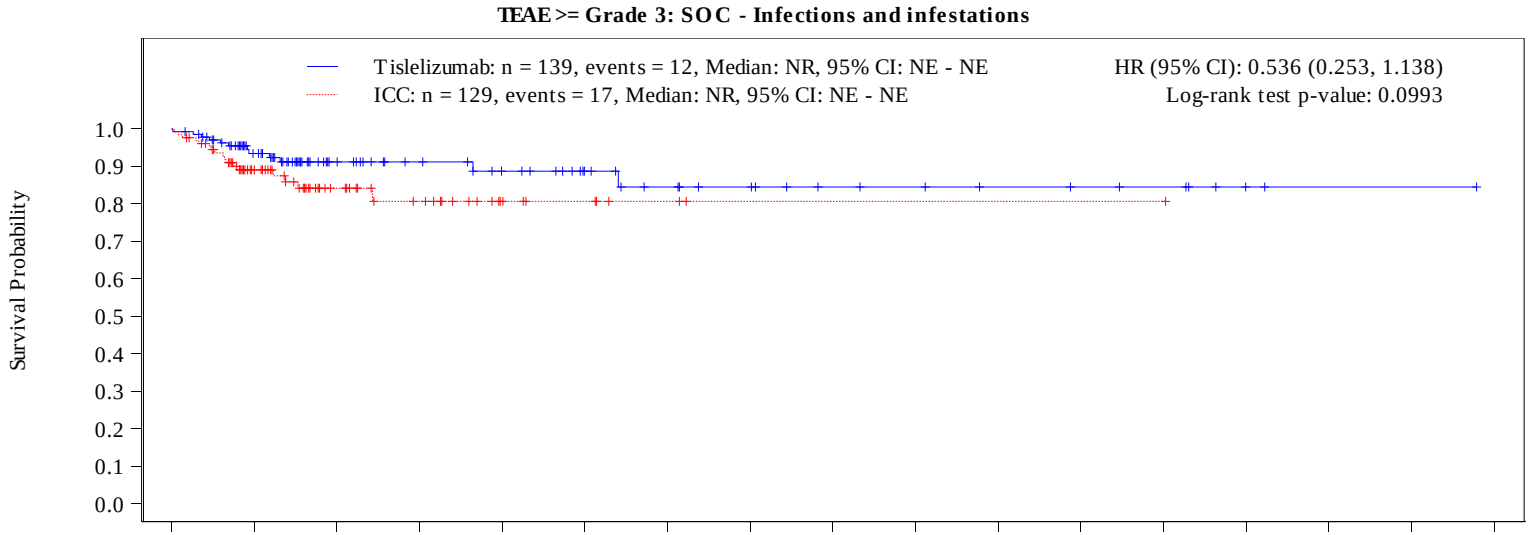


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	94	52	40	32	23	19	15	11	10	8	7	6	2	1	1	0
ICC	129	73	32	18	9	6	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-03-b-km-aesocpt-g3-safetys-sa.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

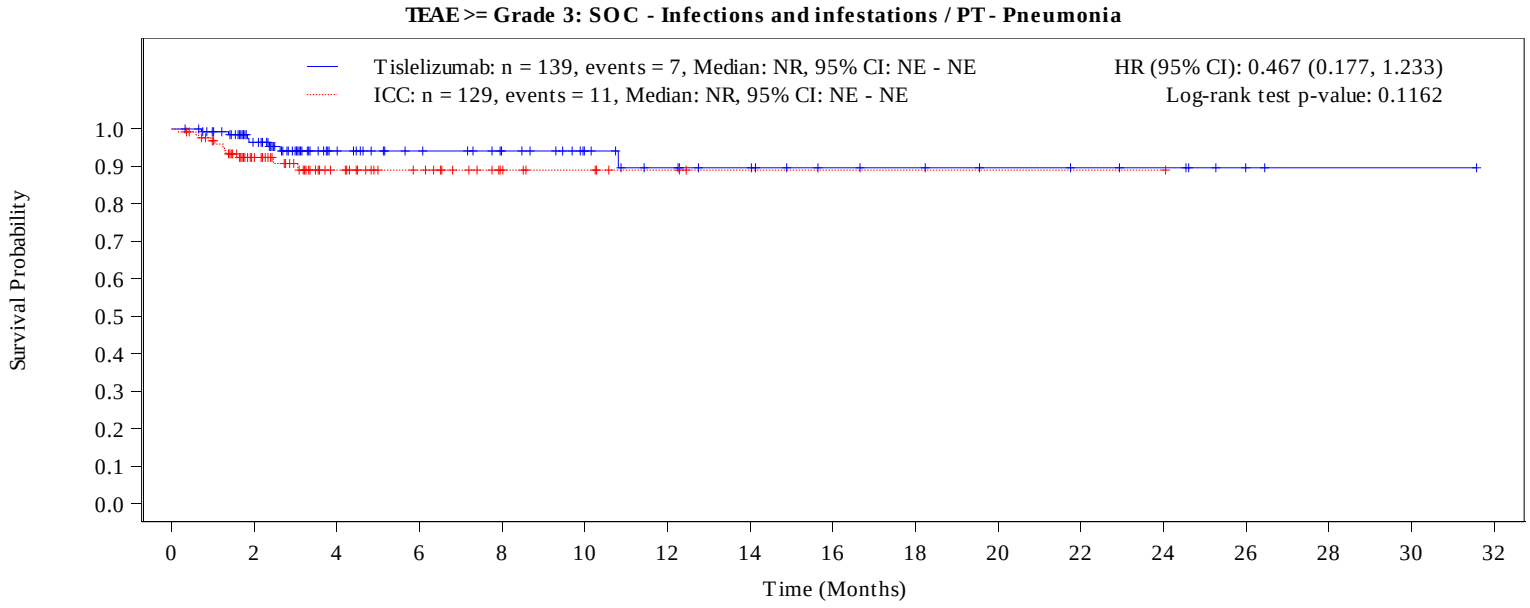


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	90	52	40	32	23	18	15	11	10	8	7	6	2	1	1	0
ICC	129	73	32	19	9	6	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-03-b-km-aesocpt-g3-safetys-sa.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

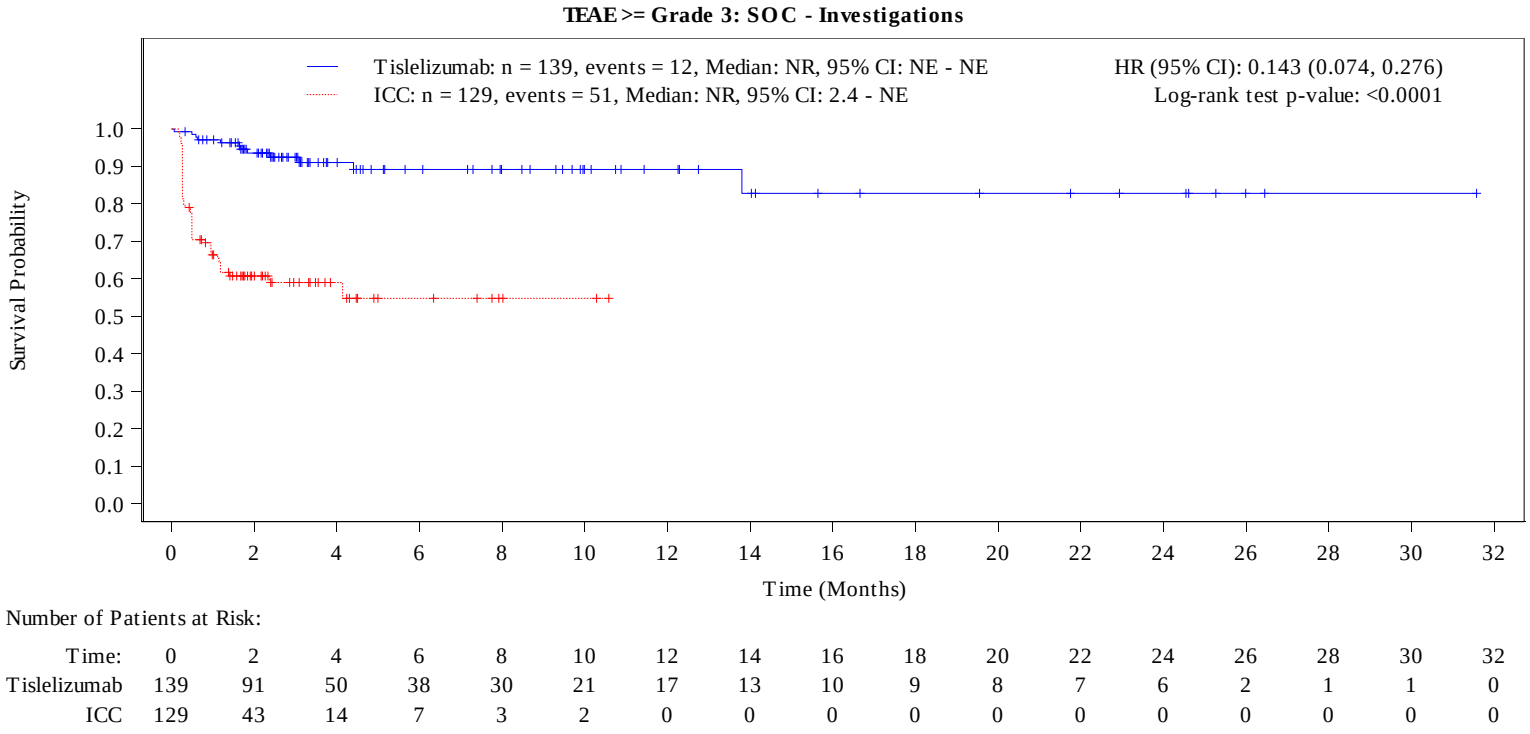


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	93	52	40	32	23	18	15	11	10	8	7	6	2	1	1	0
ICC	129	74	33	19	9	6	3	1	1	1	1	1	1	0	0	0	0

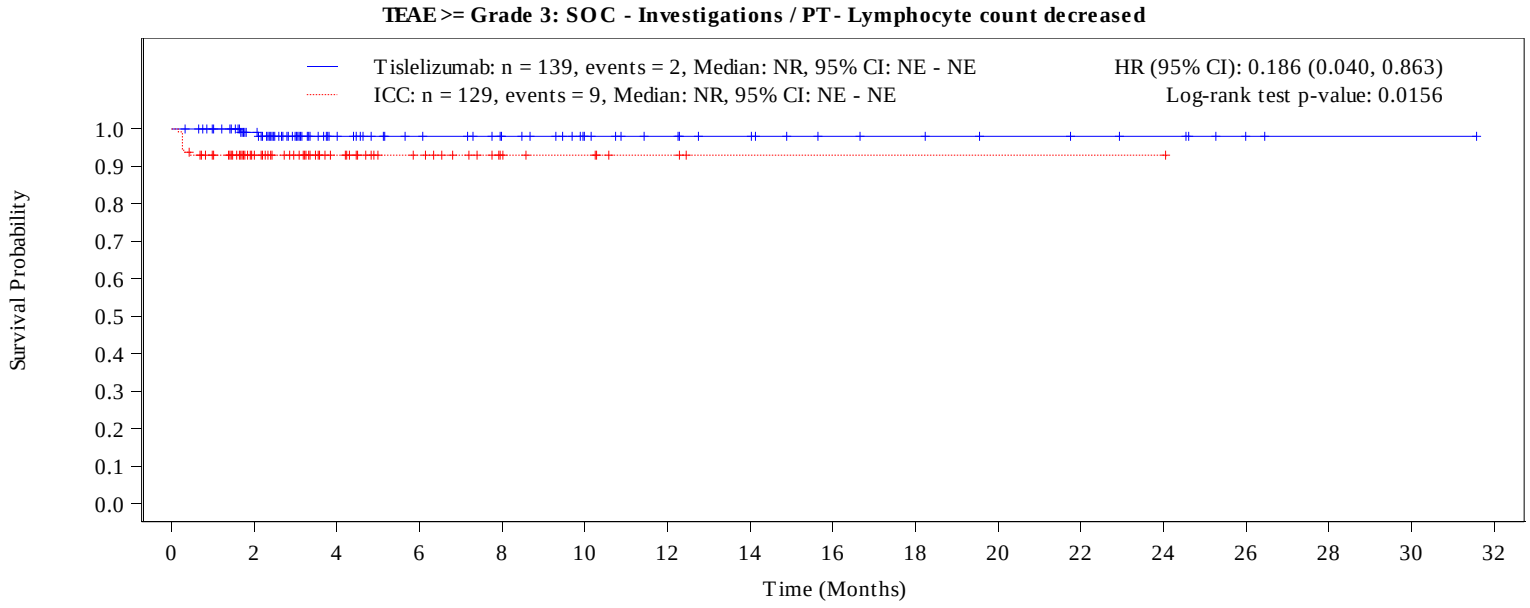
Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-03-b-km-aesocpt-g3-safetys-sa.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-03-b-km-aesocpt-g3-safetys-sa.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

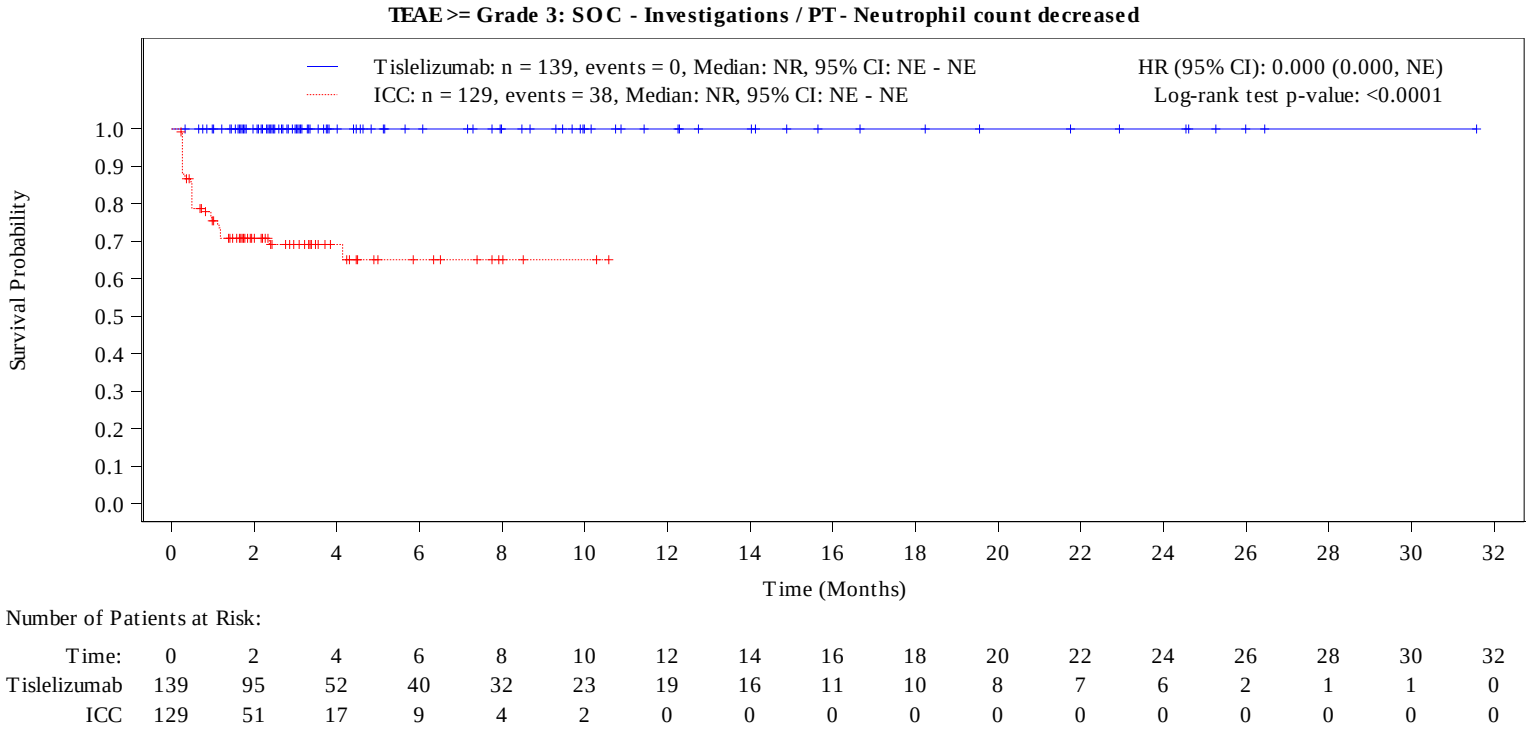


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	95	52	40	32	23	19	16	11	10	8	7	6	2	1	1	0
ICC	129	70	30	17	8	6	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-03-b-km-aesocpt-g3-safetys-sa.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

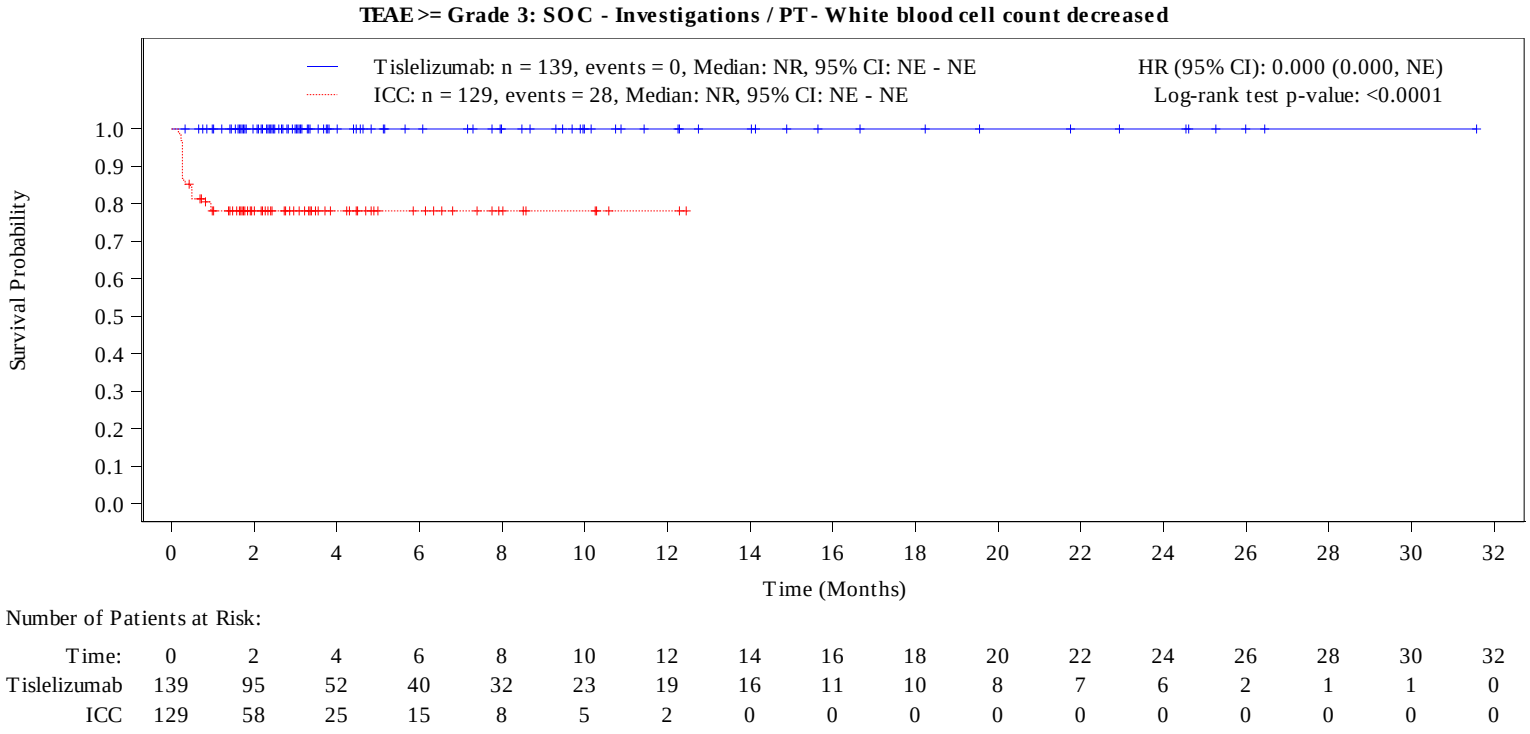


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	95	52	40	32	23	19	16	11	10	8	7	6	2	1	1	0
ICC	129	51	17	9	4	2	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-03-b-km-aesocpt-g3-safetys-sa.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

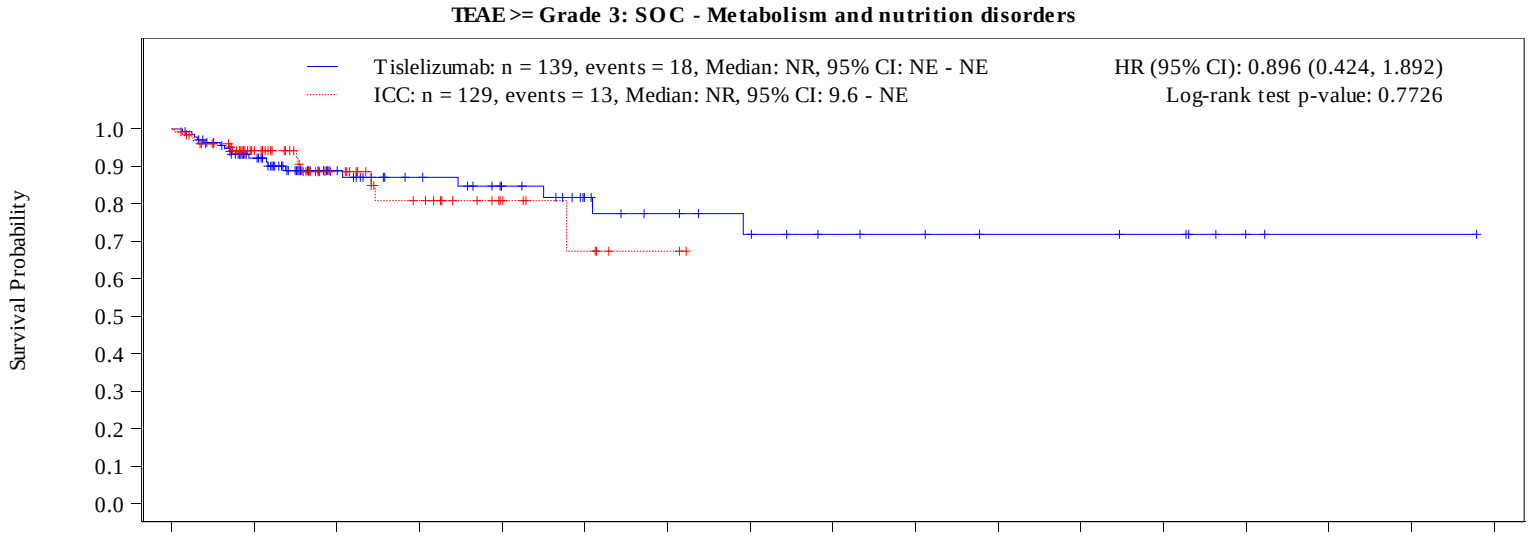


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	95	52	40	32	23	19	16	11	10	8	7	6	2	1	1	0
ICC	129	58	25	15	8	5	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-03-b-km-aesocpt-g3-safetys-sa.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

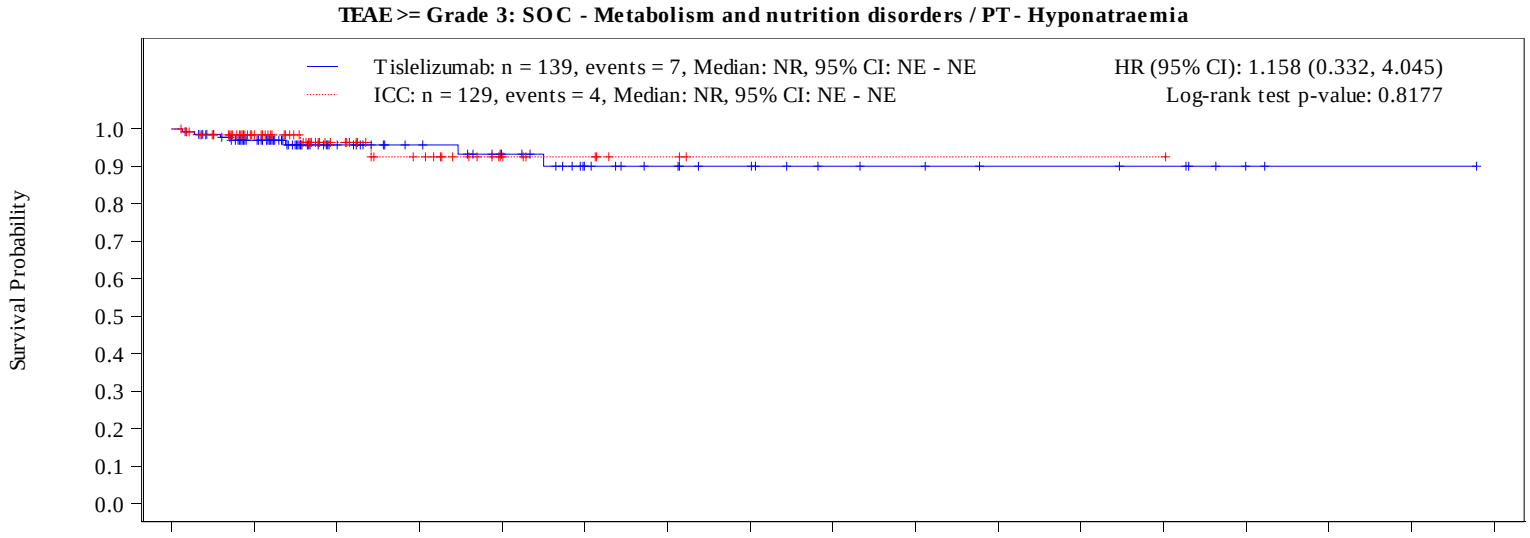


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	90	51	38	29	20	16	13	10	9	7	7	6	2	1	1	0
ICC	129	72	32	18	9	5	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-03-b-km-aesocpt-g3-safetys-sa.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

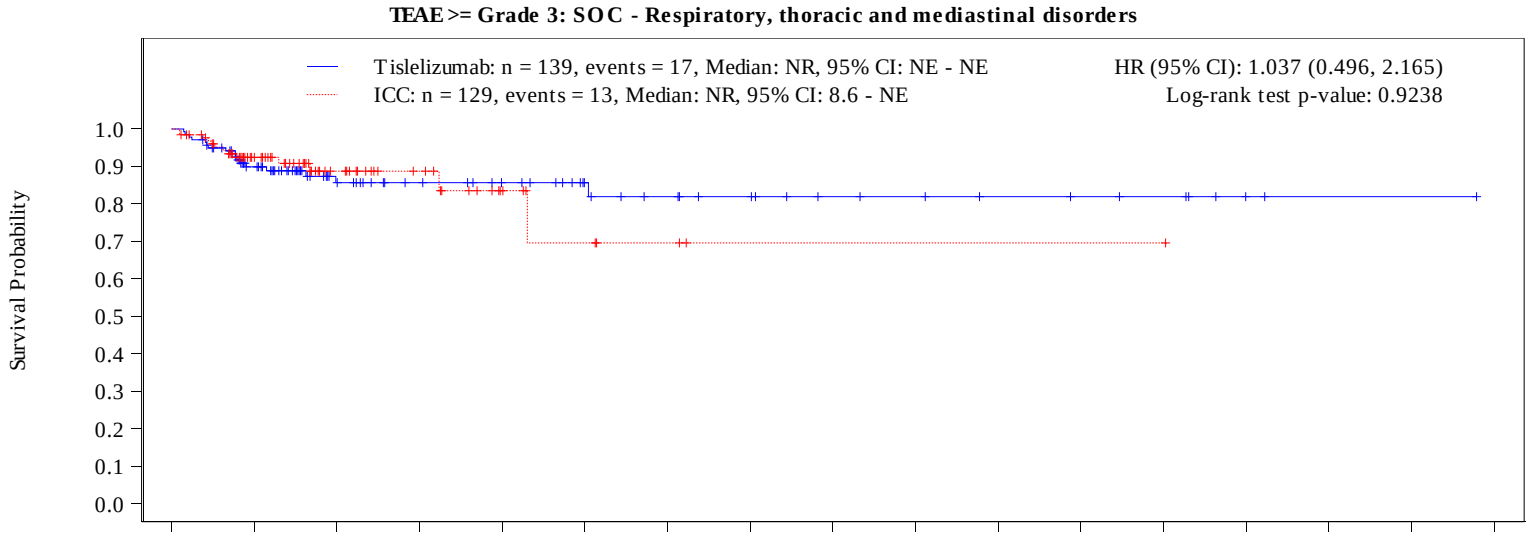


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	94	52	40	31	21	17	14	10	9	7	7	6	2	1	1	0
ICC	129	74	33	19	9	6	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-03-b-km-aesocpt-g3-safetys-sa.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

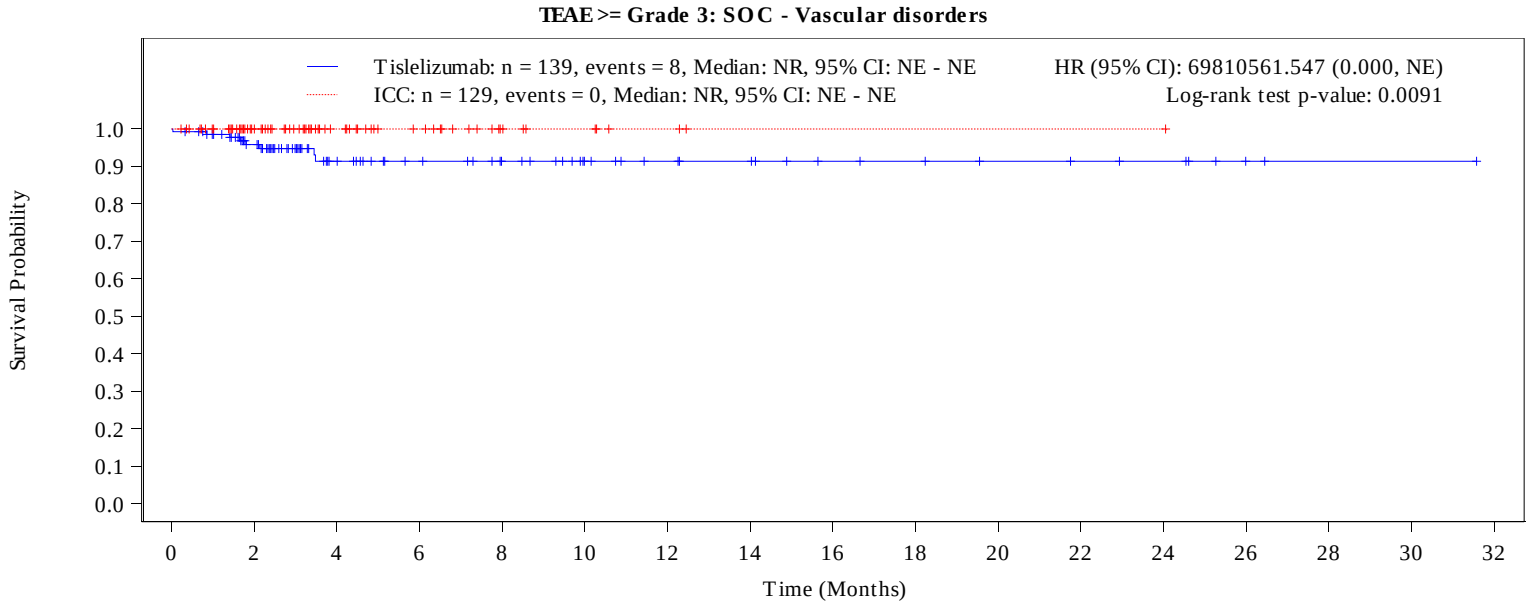


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	91	51	39	32	23	19	16	11	10	8	7	6	2	1	1	0
ICC	129	75	32	19	9	5	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-03-b-km-aesocpt-g3-safetys-sa.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

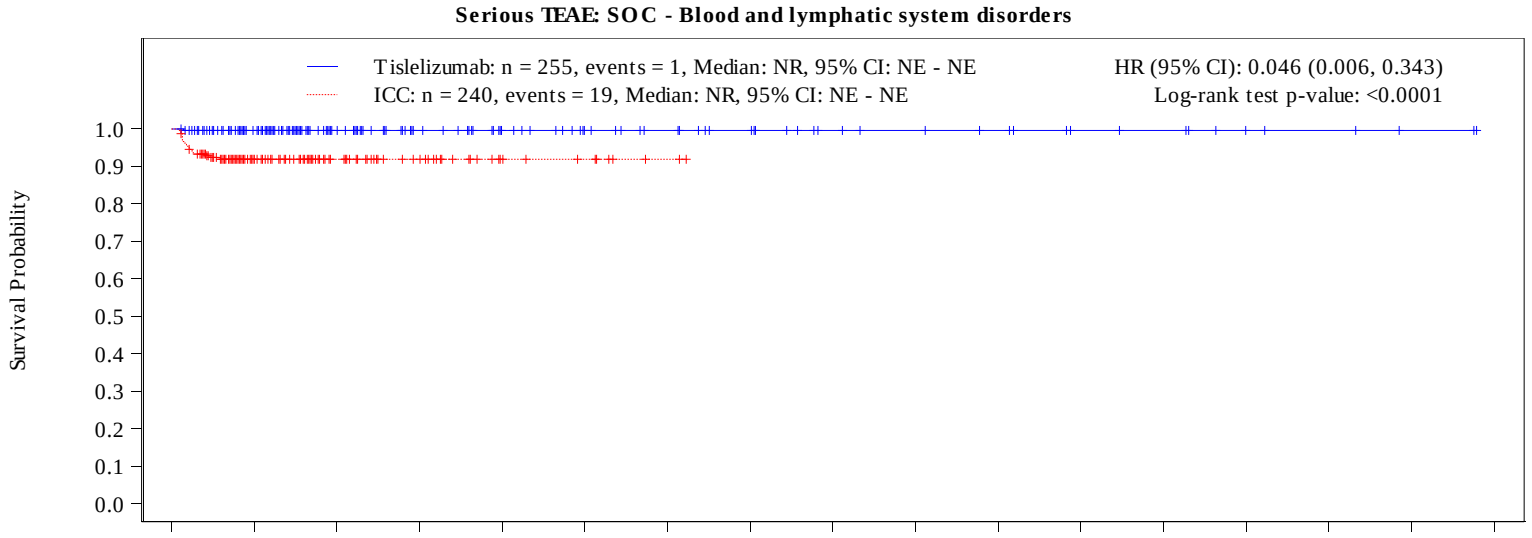


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	92	50	38	30	22	18	16	11	10	8	7	6	2	1	1	0
ICC	129	75	33	19	9	6	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-03-b-km-aesocpt-g3-safetys-sa.rtf

Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	175	97	65	49	38	32	27	19	17	15	11	10	5	4	2	0
ICC	240	107	43	24	10	7	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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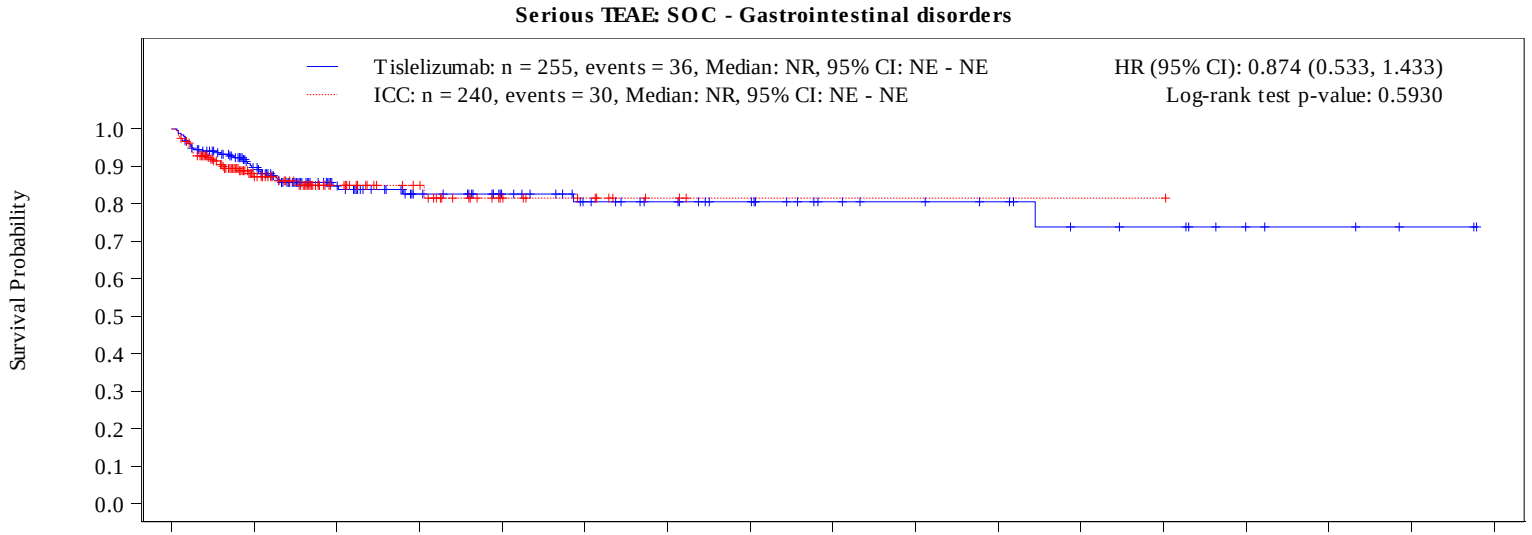
Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	167	91	63	48	37	31	26	18	16	14	10	9	5	4	2	0
ICC	240	103	42	26	12	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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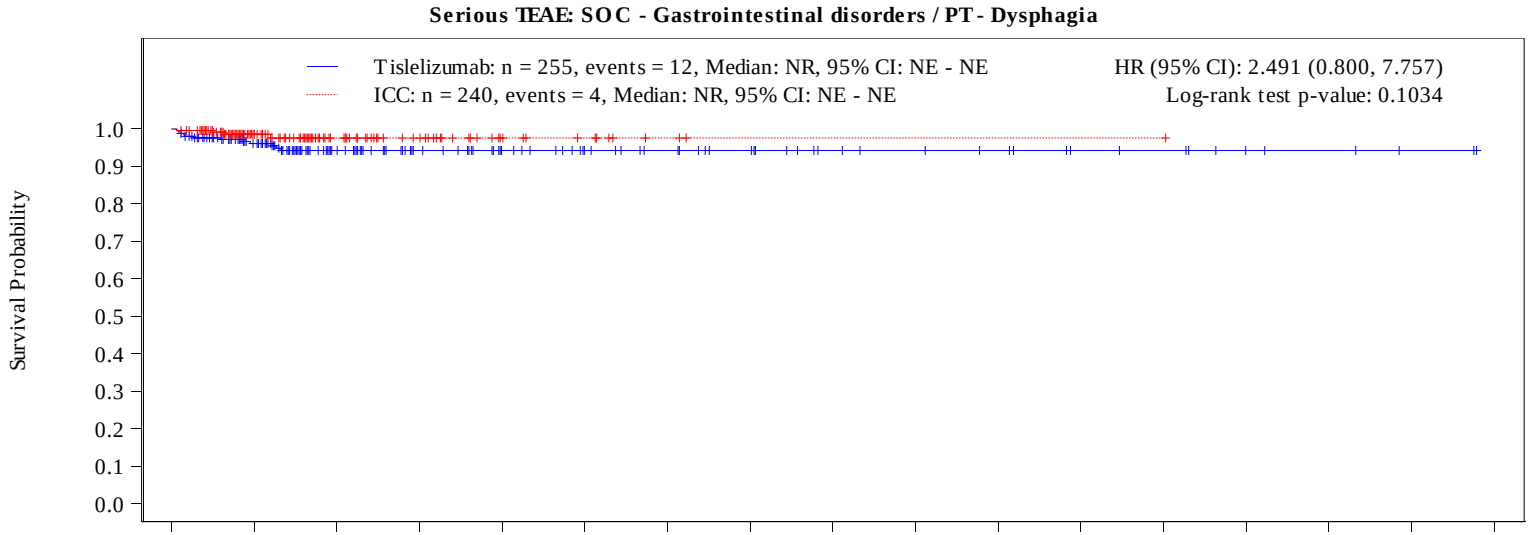
Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	172	96	65	49	38	32	27	19	17	15	11	10	5	4	2	0
ICC	240	110	45	26	12	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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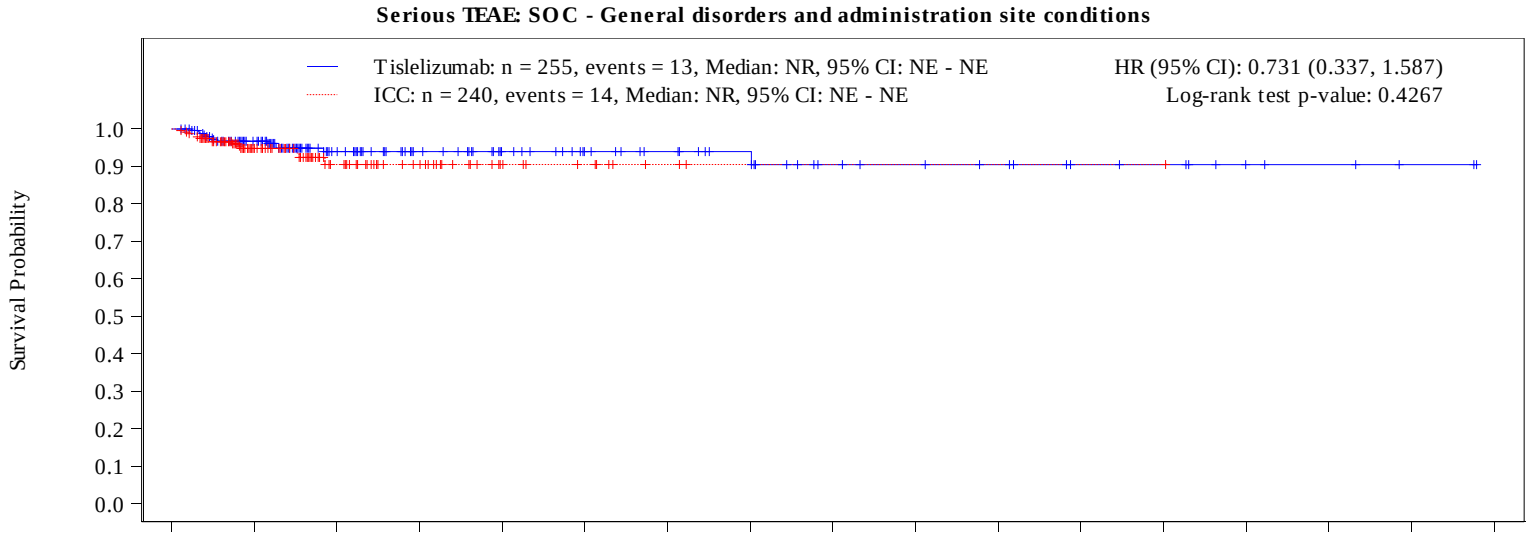
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	174	96	65	49	38	32	27	19	17	15	11	10	5	4	2	0
ICC	240	112	45	26	12	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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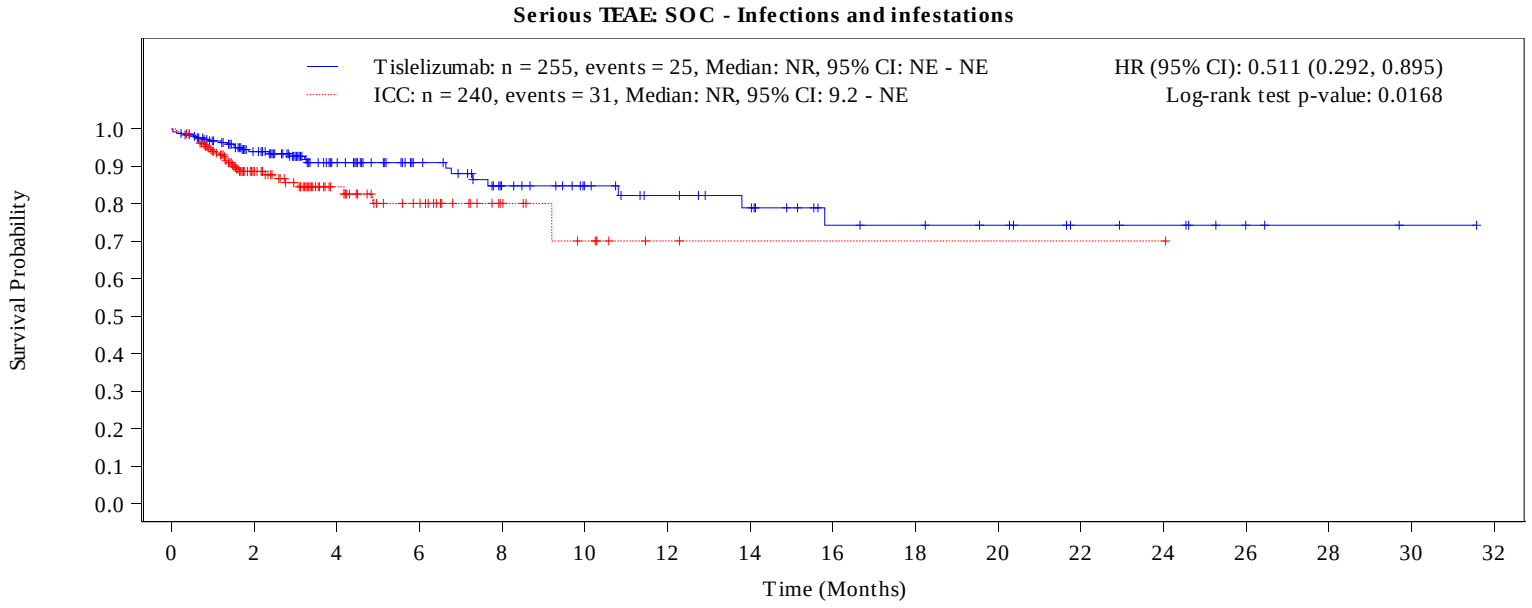
Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	168	96	64	46	35	28	24	16	15	13	9	8	3	2	1	0
ICC	240	109	44	25	11	6	2	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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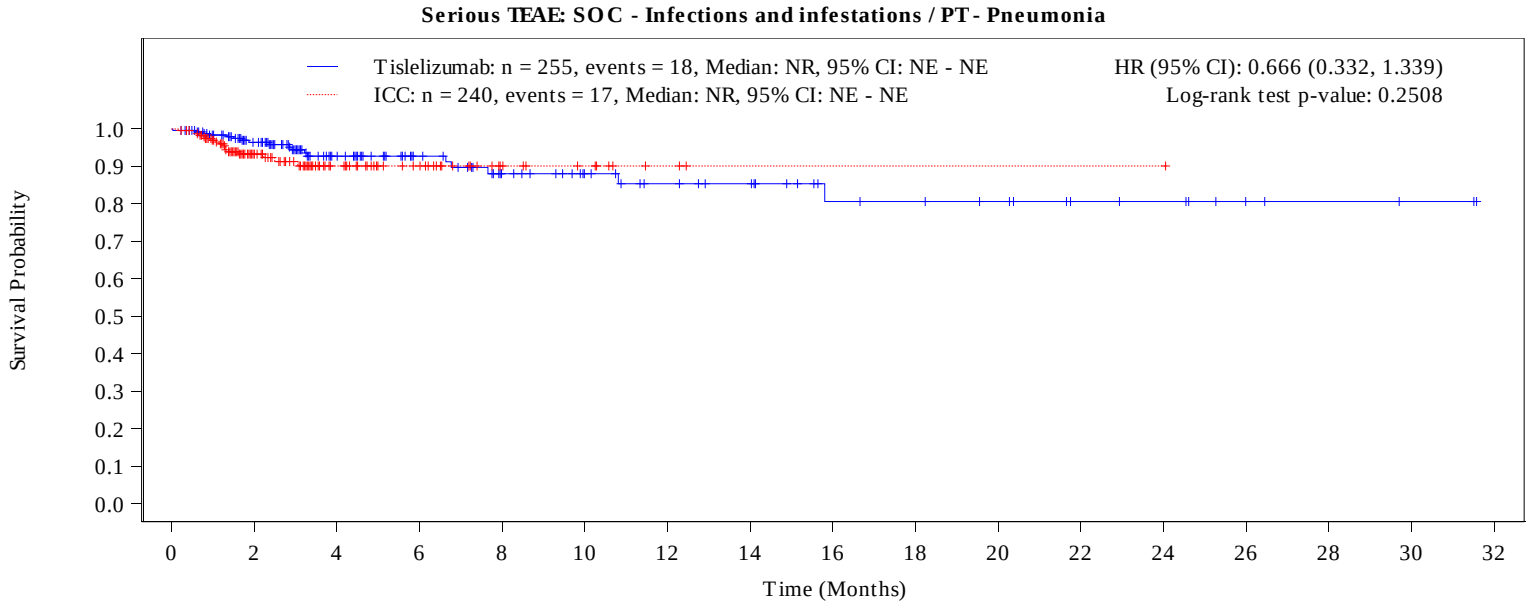
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	172	96	64	46	35	28	25	17	16	14	10	9	4	3	2	0
ICC	240	112	45	26	12	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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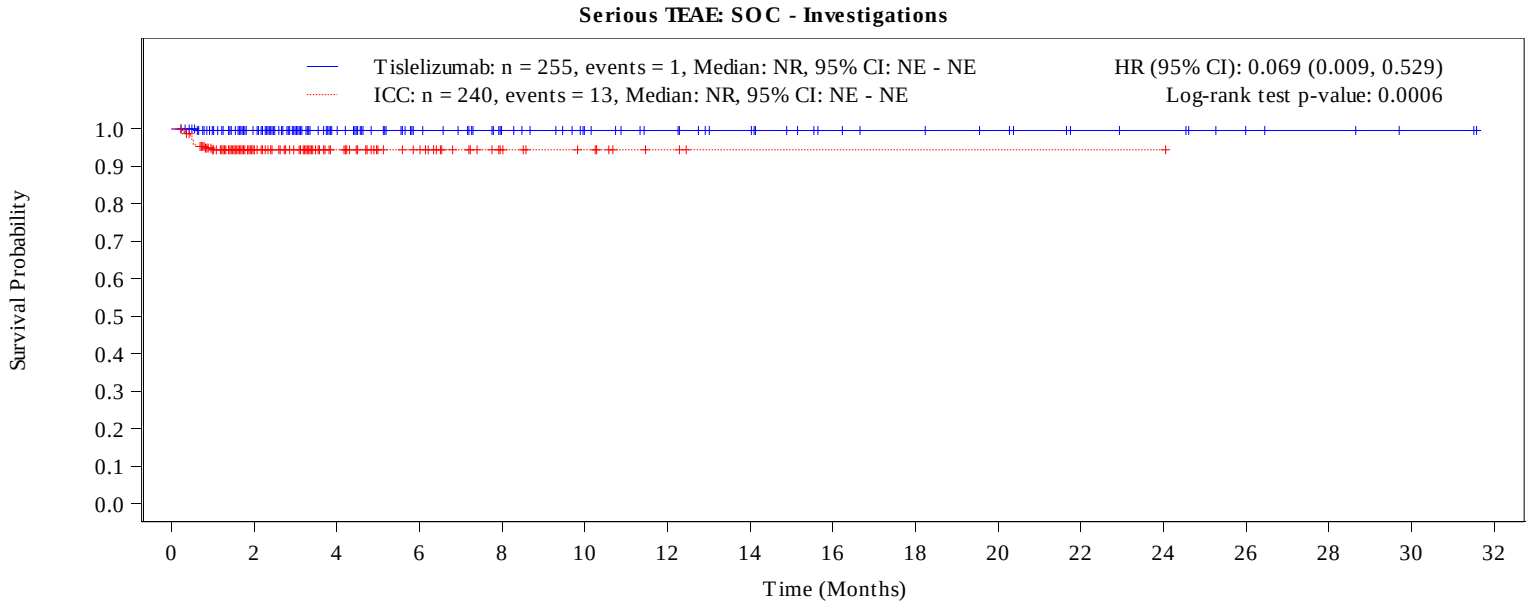

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	175	97	65	49	38	32	27	19	17	15	11	10	5	4	2	0
ICC	240	111	45	26	12	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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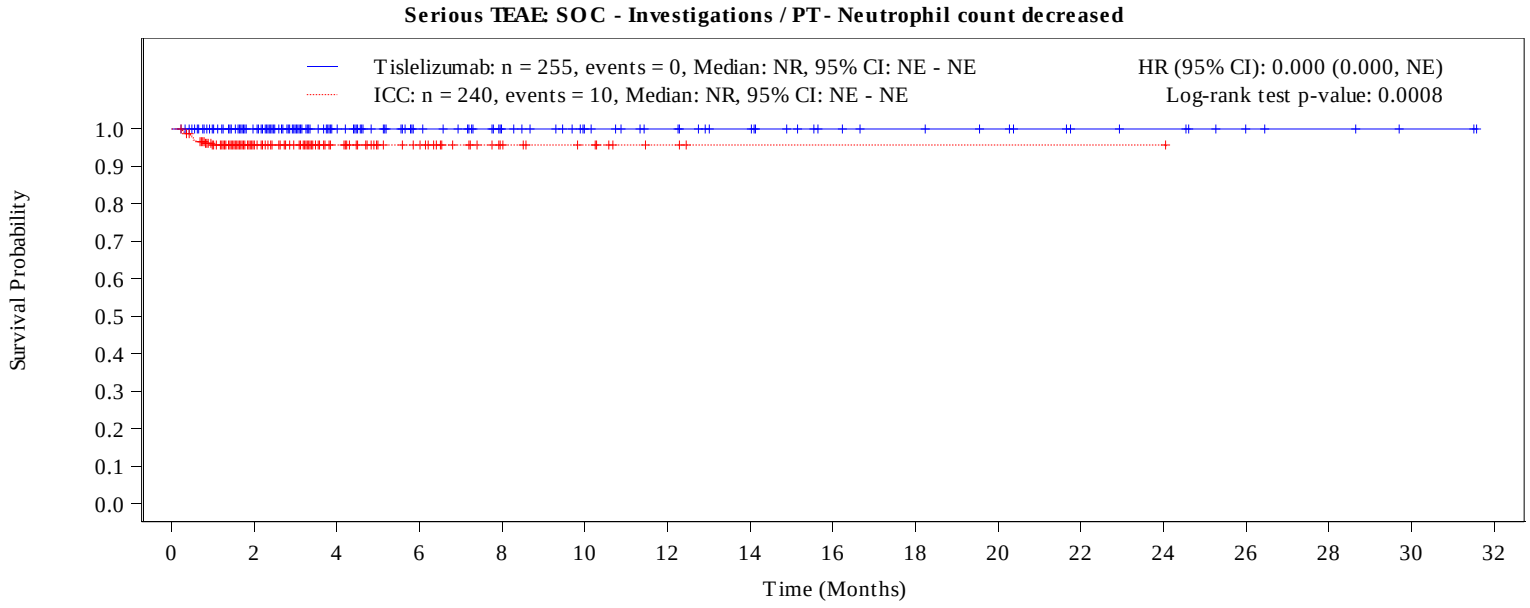
Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

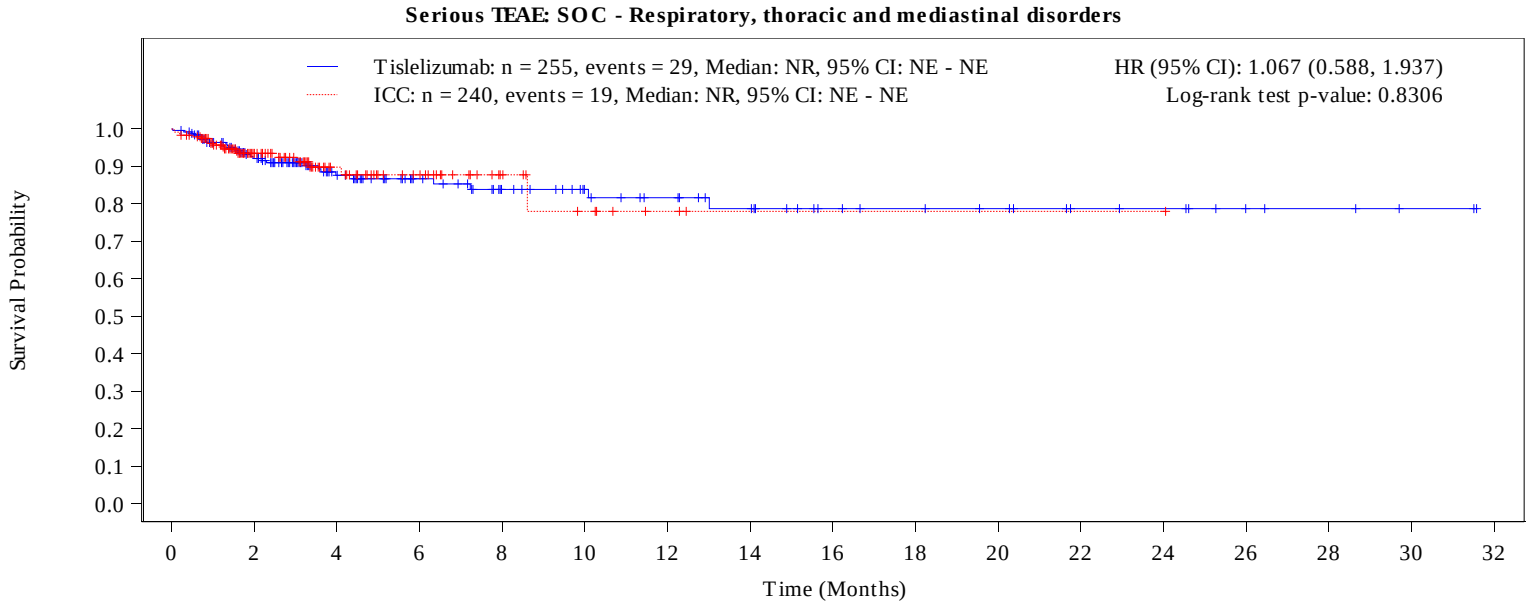


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	175	97	65	49	38	32	27	19	17	15	11	10	5	4	2	0
ICC	240	112	45	26	12	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-04-km-aesocpt-sae-safety-sa.rtf

Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

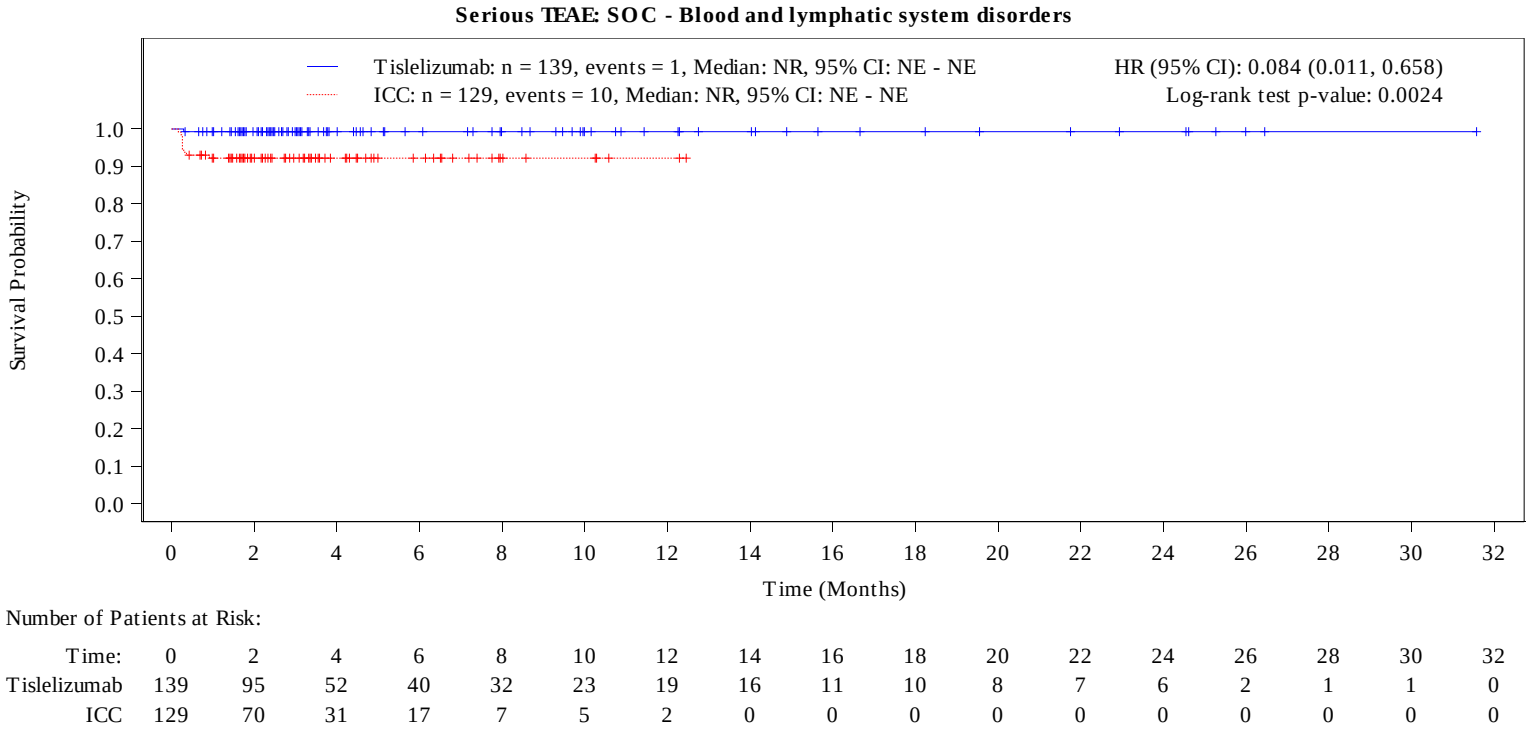


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	172	97	64	48	38	32	27	19	17	15	11	10	5	4	2	0
ICC	240	112	44	26	12	7	3	1	1	1	1	1	1	0	0	0	0

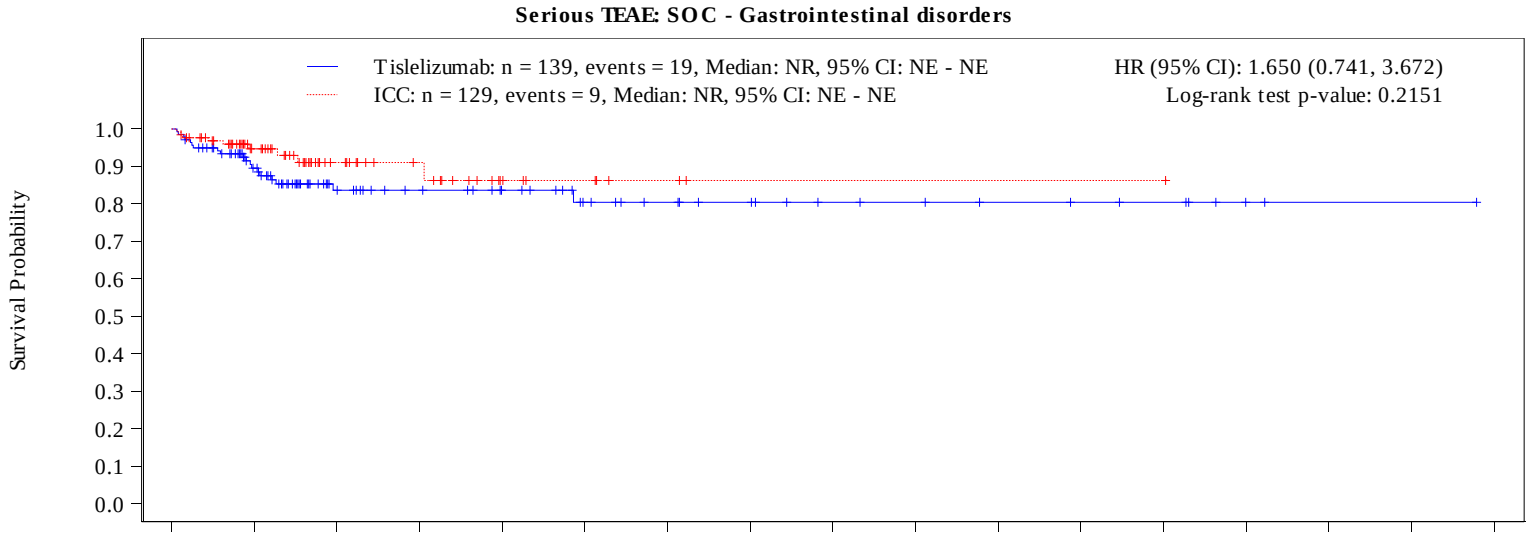
Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-04-km-aesocpt-sae-safety-sa.rtf

Figure 14.3.1.4.b:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-04-b-km-aesocpt-sae-safetys-sa.rtf

Figure 14.3.1.4.b:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

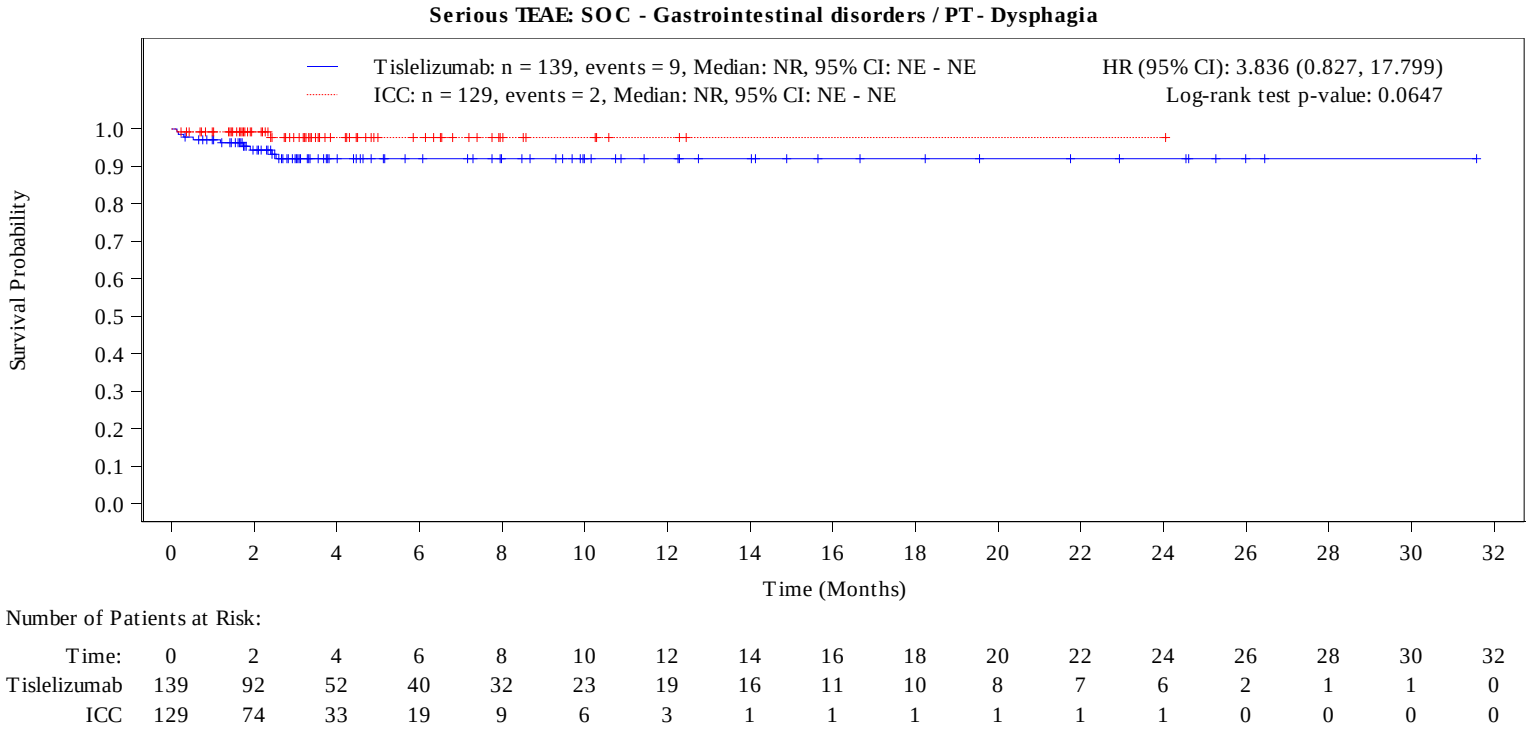


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	90	50	40	32	23	19	16	11	10	8	7	6	2	1	1	0
ICC	129	71	31	19	9	6	3	1	1	1	1	1	1	0	0	0	0

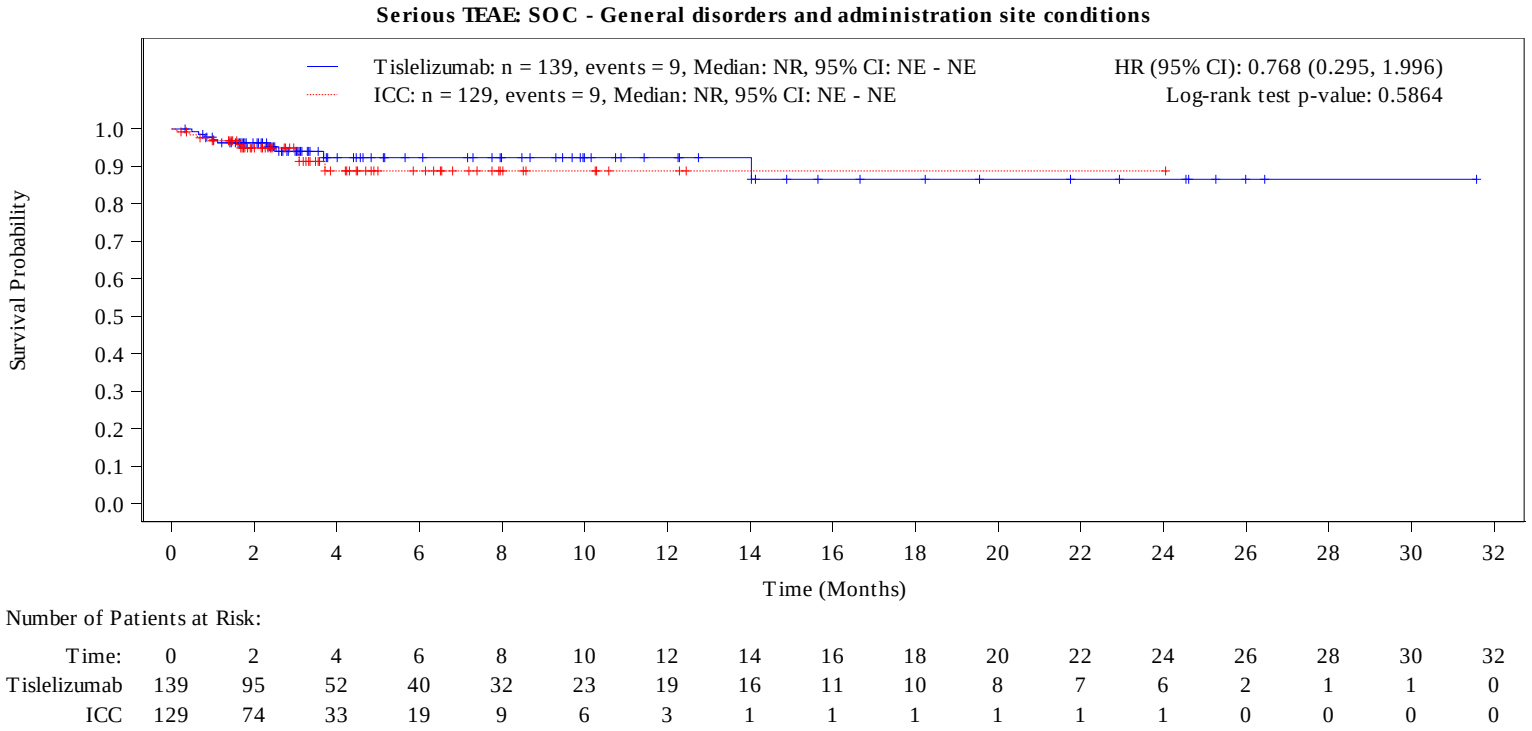
Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-04-b-km-aesocpt-sae-safetys-sa.rtf

Figure 14.3.1.4.b:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-04-b-km-aesocpt-sae-safetys-sa.rtf

Figure 14.3.1.4.b:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

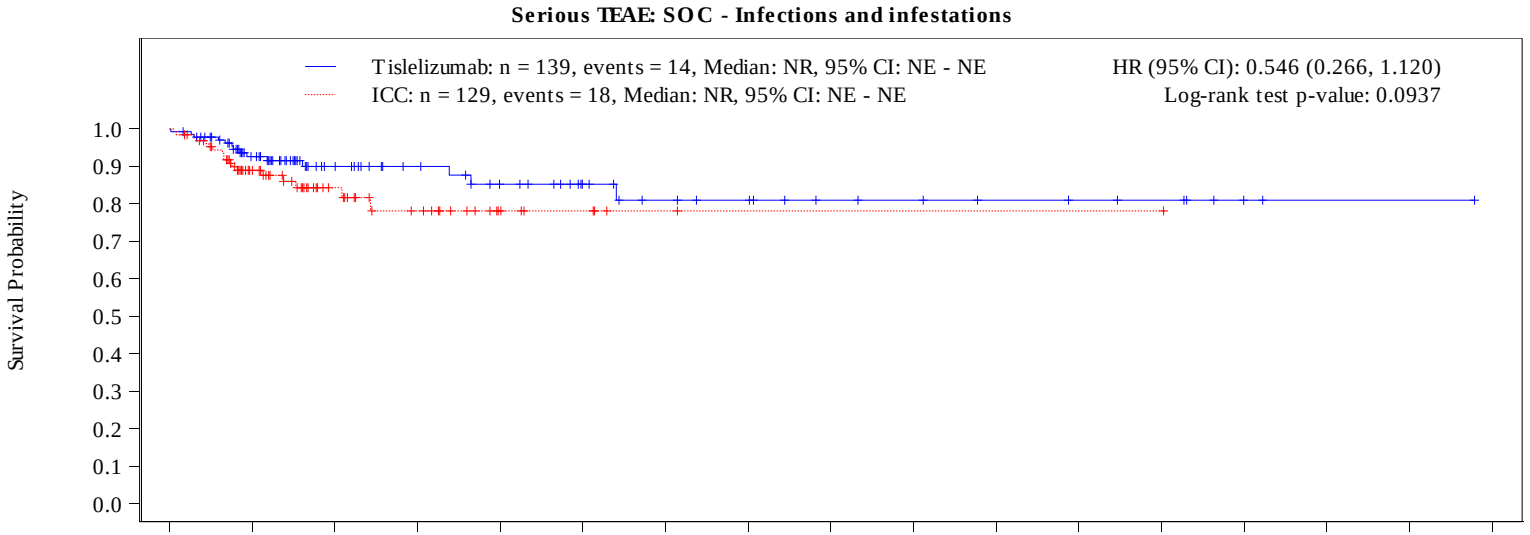


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	95	52	40	32	23	19	16	11	10	8	7	6	2	1	1	0
ICC	129	74	33	19	9	6	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-04-b-km-aesocpt-sae-safetys-sa.rtf

Figure 14.3.1.4.b:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

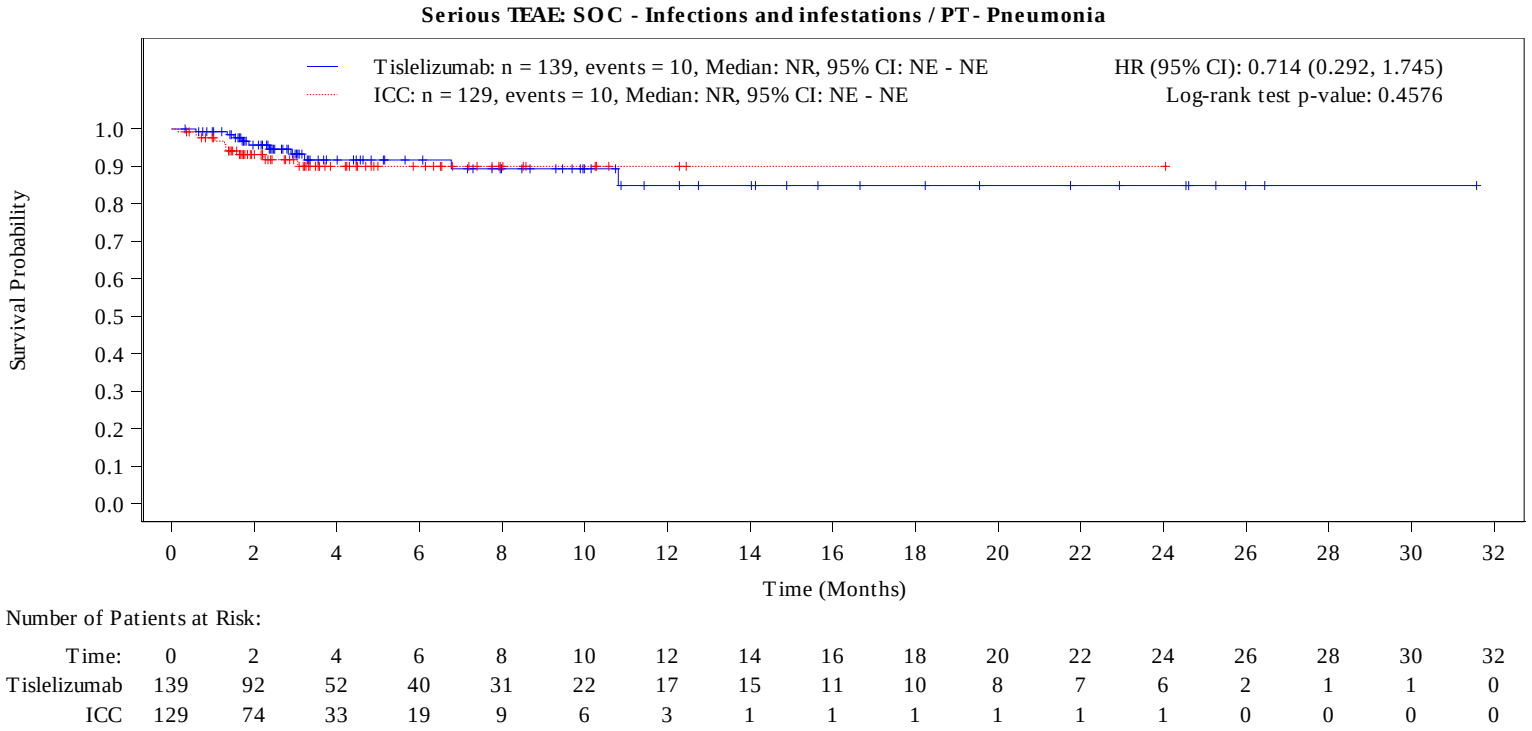


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	89	52	40	31	22	17	15	11	10	8	7	6	2	1	1	0
ICC	129	72	32	18	8	5	2	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-04-b-km-aesocpt-sae-safetys-sa.rtf

Figure 14.3.1.4.b:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

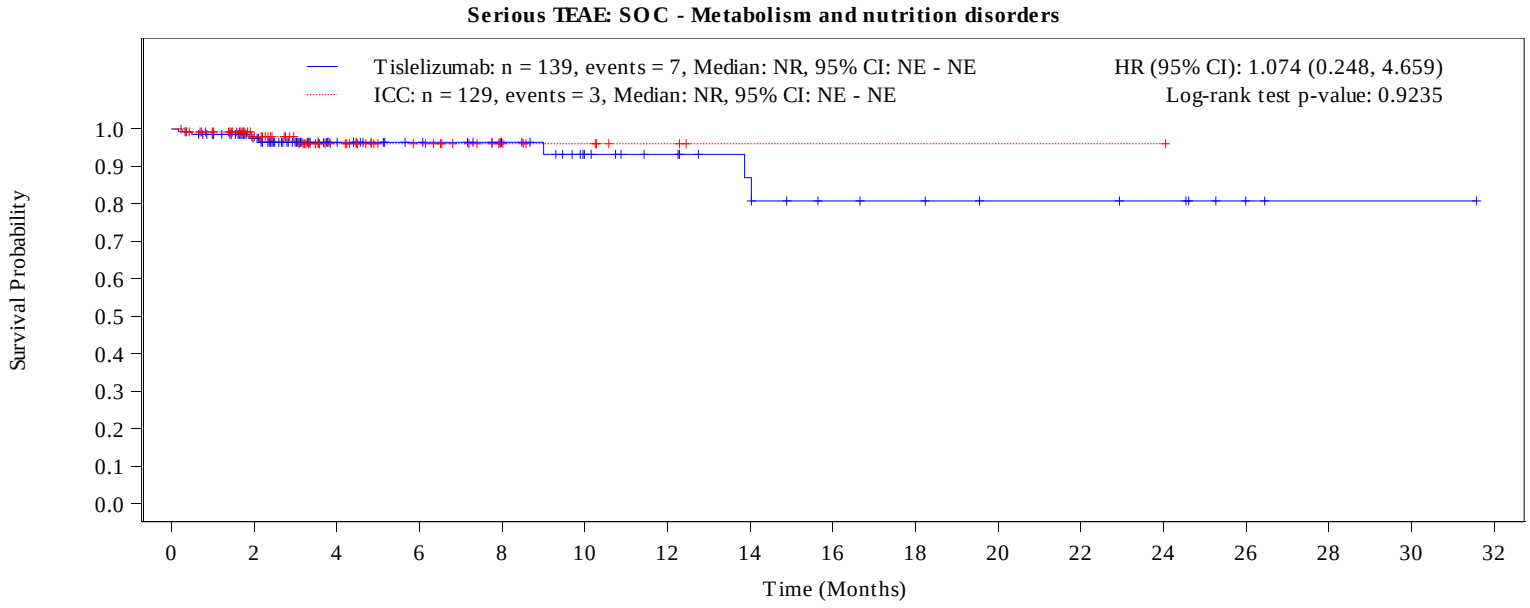


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	92	52	40	31	22	17	15	11	10	8	7	6	2	1	1	0
ICC	129	74	33	19	9	6	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-04-b-km-aesocpt-sae-safetys-sa.rtf

Figure 14.3.1.4.b:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

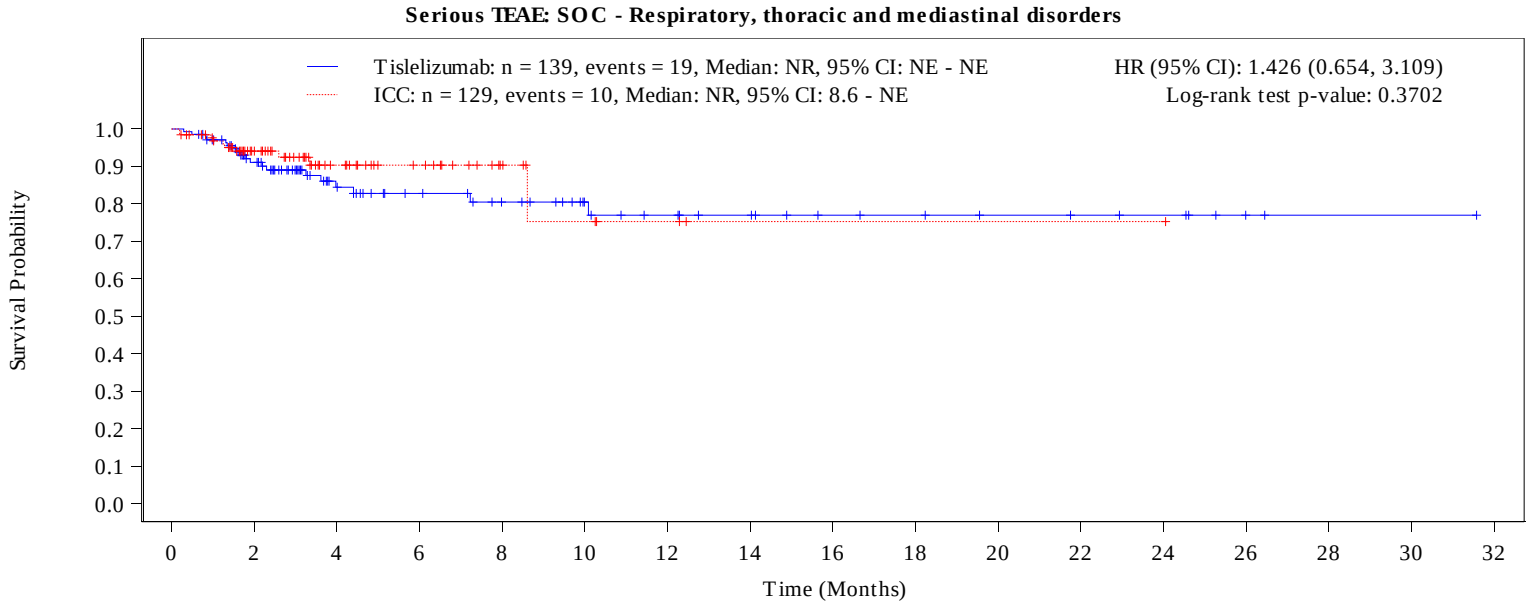


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	93	52	40	32	22	18	14	10	9	7	7	6	2	1	1	0
ICC	129	74	33	19	9	6	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-04-b-km-aesocpt-sae-safetys-sa.rtf

Figure 14.3.1.4.b:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	93	52	39	31	23	19	16	11	10	8	7	6	2	1	1	0
ICC	129	75	32	19	9	5	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 21AUG2024 20:29 f-14-03-01-04-b-km-aesocpt-sae-safetys-sa.rtf

Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	62 (39.5)	9.0 (6.9, 23.6)	149	87 (58.4)	1.0 (0.8, 2.0)	0.455 (0.325, 0.636)	<0.0001
>= 65 Years	98	32 (32.7)	19.4 (8.9, NE)	91	52 (57.1)	1.2 (0.5, 4.7)	0.347 (0.217, 0.553)	<0.0001
Interaction								0.3300
Gender								
Male	216	82 (38.0)	11.0 (7.6, 21.4)	204	122 (59.8)	1.0 (0.8, 2.0)	0.396 (0.296, 0.531)	<0.0001
Female	39	12 (30.8)	NR (4.9, NE)	36	17 (47.2)	NR (0.5, NE)	0.511 (0.242, 1.079)	0.0688
Interaction								0.8481

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	66 (35.3)	19.4 (12.4, NE)	183	105 (57.4)	1.2 (0.9, 2.6)	0.396 (0.287, 0.545)	<0.0001
Non-Smoker	68	28 (41.2)	8.9 (4.9, NE)	57	34 (59.6)	1.0 (0.5, NE)	0.448 (0.266, 0.753)	0.0016
Interaction								0.6378

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	24 (28.9)	NR (21.4, NE)	79	35 (44.3)	4.7 (1.5, NE)	0.534 (0.314, 0.907)	0.0173
Docetaxel	56	21 (37.5)	NR (3.4, NE)	50	37 (74.0)	0.9 (0.3, 1.3)	0.294 (0.168, 0.515)	<0.0001
Irinotecan	116	49 (42.2)	8.9 (4.9, 12.4)	111	67 (60.4)	0.8 (0.5, 2.3)	0.392 (0.265, 0.580)	<0.0001
Interaction								0.3529

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	18 (28.6)	21.4 (7.6, NE)	57	27 (47.4)	2.6 (1.7, NE)	0.389 (0.208, 0.729)	0.0021
1	192	76 (39.6)	9.0 (6.2, 19.4)	183	112 (61.2)	0.9 (0.6, 1.2)	0.407 (0.301, 0.552)	<0.0001
Interaction								0.9049
Region #1								
Asia	201	77 (38.3)	12.4 (7.6, 21.4)	191	116 (60.7)	1.0 (0.7, 1.3)	0.389 (0.287, 0.526)	<0.0001
Europe/North America	54	17 (31.5)	NR (4.9, NE)	49	23 (46.9)	4.7 (1.0, NE)	0.527 (0.280, 0.992)	0.0421
Interaction								0.3960

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	75 (42.6)	8.9 (4.9, 14.7)	168	110 (65.5)	0.8 (0.5, 1.0)	0.389 (0.286, 0.530)	<0.0001
Japan	25	2 (8.0)	NR (21.4, NE)	23	6 (26.1)	NR (2.8, NE)	0.122 (0.015, 1.026)	0.0203
Europe/North America	54	17 (31.5)	NR (4.9, NE)	49	23 (46.9)	4.7 (1.0, NE)	0.527 (0.280, 0.992)	0.0421
Interaction								0.4965

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	203	78 (38.4)	12.4 (7.6, 21.4)	198	118 (59.6)	1.0 (0.8, 1.4)	0.404 (0.300, 0.546)	<0.0001
White	52	16 (30.8)	NR (4.9, NE)	42	21 (50.0)	4.7 (0.6, NE)	0.473 (0.245, 0.910)	0.0209
Interaction								0.6781

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	31 (38.8)	19.4 (6.2, NE)	60	35 (58.3)	1.0 (0.5, 4.1)	0.404 (0.244, 0.670)	0.0002
vCPS < 10%	100	38 (38.0)	9.0 (4.3, NE)	119	77 (64.7)	1.0 (0.7, 1.3)	0.386 (0.259, 0.574)	<0.0001
Missing	75	25 (33.3)	14.7 (6.9, 23.6)	61	27 (44.3)	4.7 (1.0, NE)	0.499 (0.280, 0.889)	0.0146
Interaction								0.5857

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	51 (32.5)	13.8 (8.3, NE)	149	69 (46.3)	2.8 (1.2, NE)	0.515 (0.356, 0.747)	0.0003
>= 65 Years	98	29 (29.6)	19.4 (14.7, NE)	91	38 (41.8)	5.1 (1.3, NE)	0.446 (0.267, 0.745)	0.0014
Interaction								0.7567
Gender								
Male	216	70 (32.4)	19.4 (9.0, NE)	204	94 (46.1)	2.8 (1.4, NE)	0.475 (0.344, 0.656)	<0.0001
Female	39	10 (25.6)	NR (4.9, NE)	36	13 (36.1)	NR (0.6, NE)	0.560 (0.243, 1.291)	0.1628
Interaction								0.9884

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	57 (30.5)	21.4 (14.7, NE)	183	84 (45.9)	2.8 (1.3, NE)	0.450 (0.317, 0.638)	<0.0001
Non-Smoker	68	23 (33.8)	9.0 (4.9, NE)	57	23 (40.4)	NR (1.0, NE)	0.618 (0.341, 1.120)	0.1072
Interaction								0.3302

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	21 (25.3)	NR (21.4, NE)	79	26 (32.9)	NR (4.1, NE)	0.668 (0.372, 1.198)	0.1702
Docetaxel	56	17 (30.4)	NR (8.3, NE)	50	26 (52.0)	2.0 (1.0, NE)	0.353 (0.185, 0.673)	0.0009
Irinotecan	116	42 (36.2)	11.0 (6.2, 19.4)	111	55 (49.5)	2.3 (0.8, NE)	0.445 (0.291, 0.680)	0.0001
Interaction								0.5873

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	13 (20.6)	NR (13.8, NE)	57	18 (31.6)	NR (2.8, NE)	0.420 (0.196, 0.897)	0.0208
1	192	67 (34.9)	14.7 (8.3, NE)	183	89 (48.6)	2.1 (1.0, NE)	0.494 (0.356, 0.687)	<0.0001
Interaction								0.9130
Region #1								
Asia	201	64 (31.8)	19.4 (11.0, NE)	191	91 (47.6)	2.6 (1.2, NE)	0.444 (0.318, 0.621)	<0.0001
Europe/North America	54	16 (29.6)	NR (4.9, NE)	49	16 (32.7)	5.6 (5.1, NE)	0.749 (0.373, 1.506)	0.4134
Interaction								0.1748

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	62 (35.2)	13.8 (8.3, NE)	168	87 (51.8)	1.4 (1.0, 4.1)	0.445 (0.316, 0.626)	<0.0001
Japan	25	2 (8.0)	NR (21.4, NE)	23	4 (17.4)	NR (2.8, NE)	0.194 (0.021, 1.743)	0.1014
Europe/North America	54	16 (29.6)	NR (4.9, NE)	49	16 (32.7)	5.6 (5.1, NE)	0.749 (0.373, 1.506)	0.4134
Interaction								0.3551

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	65 (32.0)	19.4 (11.0, NE)	198	92 (46.5)	2.8 (1.2, NE)	0.468 (0.336, 0.652)	<0.0001
White	52	15 (28.8)	NR (4.9, NE)	42	15 (35.7)	5.6 (2.3, NE)	0.638 (0.310, 1.312)	0.2158
Interaction								0.4143

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	28 (35.0)	19.4 (8.3, NE)	60	29 (48.3)	2.8 (1.0, NE)	0.453 (0.263, 0.780)	0.0032
vCPS < 10%	100	33 (33.0)	NR (4.9, NE)	119	57 (47.9)	2.8 (1.0, NE)	0.526 (0.341, 0.812)	0.0029
Missing	75	19 (25.3)	21.4 (11.0, NE)	61	21 (34.4)	NR (2.1, NE)	0.473 (0.242, 0.923)	0.0237
Interaction								0.9086

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	0 (0.0)	--	149	7 (4.7)	--	--	--
>= 65 Years	98	0 (0.0)	--	91	5 (5.5)	--	--	--
Interaction								--
Gender								
Male	216	0 (0.0)	NR (NE, NE)	204	11 (5.4)	NR (NE, NE)	0.000 (0.000, NE)	0.0003
Female	39	0 (0.0)	NR (NE, NE)	36	1 (2.8)	NR (NE, NE)	0.000 (0.000, NE)	0.2980
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Smoking Status								
Former/Current Smoker	187	0 (0.0)	--	183	9 (4.9)	--	--	--
Non-Smoker	68	0 (0.0)	--	57	3 (5.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	0 (0.0)	--	79	0 (0.0)	--	--	--
Docetaxel	56	0 (0.0)	--	50	8 (16.0)	--	--	--
Irinotecan	116	0 (0.0)	--	111	4 (3.6)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	0 (0.0)	--	57	3 (5.3)	--	--	--
1	192	0 (0.0)	--	183	9 (4.9)	--	--	--
Interaction								--
Region #1								
Asia	201	0 (0.0)	NR (NE, NE)	191	10 (5.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0006
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	2 (4.1)	NR (NE, NE)	0.000 (0.000, NE)	0.1356
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	0 (0.0)	--	168	8 (4.8)	--	--	--
Japan	25	0 (0.0)	--	23	2 (8.7)	--	--	--
Europe/North America	54	0 (0.0)	--	49	2 (4.1)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	203	0 (0.0)	NR (NE, NE)	198	10 (5.1)	NR (NE, NE)	0.000 (0.000, NE)	0.0007
White	52	0 (0.0)	NR (NE, NE)	42	2 (4.8)	NR (NE, NE)	0.000 (0.000, NE)	0.1134
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	0 (0.0)	--	60	4 (6.7)	--	--	--
vCPS < 10%	100	0 (0.0)	--	119	3 (2.5)	--	--	--
Missing	75	0 (0.0)	--	61	5 (8.2)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	7 (4.5)	NR (NE, NE)	149	19 (12.8)	NR (NE, NE)	0.264 (0.108, 0.648)	0.0019
>= 65 Years	98	1 (1.0)	NR (NE, NE)	91	11 (12.1)	NR (NE, NE)	0.068 (0.009, 0.537)	0.0009
Interaction								0.1740
Gender								
Male	216	8 (3.7)	NR (NE, NE)	204	28 (13.7)	NR (NE, NE)	0.205 (0.090, 0.465)	<0.0001
Female	39	0 (0.0)	NR (NE, NE)	36	2 (5.6)	NR (6.3, NE)	0.000 (0.000, NE)	0.0497
Interaction								0.9858

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	5 (2.7)	NR (NE, NE)	183	20 (10.9)	NR (NE, NE)	0.184 (0.066, 0.516)	0.0003
Non-Smoker	68	3 (4.4)	NR (NE, NE)	57	10 (17.5)	NR (6.3, NE)	0.173 (0.045, 0.672)	0.0048
Interaction								0.9616

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	1 (1.2)	NR (NE, NE)	79	2 (2.5)	NR (NE, NE)	0.466 (0.042, 5.137)	0.5228
Docetaxel	56	3 (5.4)	NR (NE, NE)	50	10 (20.0)	NR (6.3, NE)	0.223 (0.061, 0.814)	0.0126
Irinotecan	116	4 (3.4)	NR (NE, NE)	111	18 (16.2)	NR (NE, NE)	0.124 (0.036, 0.429)	0.0001
Interaction								0.7930

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	3 (4.8)	NR (NE, NE)	57	5 (8.8)	NR (NE, NE)	0.350 (0.068, 1.806)	0.1890
1	192	5 (2.6)	NR (NE, NE)	183	25 (13.7)	NR (NE, NE)	0.145 (0.054, 0.389)	<0.0001
Interaction								0.2458
Region #1								
Asia	201	8 (4.0)	NR (NE, NE)	191	29 (15.2)	NR (NE, NE)	0.190 (0.084, 0.432)	<0.0001
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	0.000 (0.000, NE)	0.2888
Interaction								0.9903

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	8 (4.5)	NR (NE, NE)	168	29 (17.3)	NR (NE, NE)	0.190 (0.084, 0.431)	<0.0001
Japan	25	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	0.000 (0.000, NE)	0.2888
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	8 (3.9)	NR (NE, NE)	198	29 (14.6)	NR (NE, NE)	0.196 (0.087, 0.446)	<0.0001
White	52	0 (0.0)	NR (NE, NE)	42	1 (2.4)	NR (NE, NE)	0.000 (0.000, NE)	0.2601
Interaction								0.9902

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	3 (3.8)	NR (NE, NE)	60	9 (15.0)	NR (6.3, NE)	0.136 (0.034, 0.540)	0.0013
vCPS < 10%	100	2 (2.0)	NR (NE, NE)	119	17 (14.3)	NR (NE, NE)	0.130 (0.030, 0.565)	0.0013
Missing	75	3 (4.0)	NR (NE, NE)	61	4 (6.6)	NR (NE, NE)	0.536 (0.119, 2.423)	0.4099
Interaction								0.3639

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	1 (0.6)	NR (NE, NE)	149	14 (9.4)	NR (NE, NE)	0.064 (0.008, 0.490)	0.0004
>= 65 Years	98	1 (1.0)	NR (NE, NE)	91	17 (18.7)	NR (NE, NE)	0.046 (0.006, 0.346)	<0.0001
Interaction								0.8660
Gender								
Male	216	2 (0.9)	NR (NE, NE)	204	28 (13.7)	NR (NE, NE)	0.059 (0.014, 0.248)	<0.0001
Female	39	0 (0.0)	NR (NE, NE)	36	3 (8.3)	NR (NE, NE)	0.000 (0.000, NE)	0.0714
Interaction								0.9889

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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Any TEAE: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	1 (0.5)	NR (NE, NE)	183	20 (10.9)	NR (NE, NE)	0.043 (0.006, 0.324)	<0.0001
Non-Smoker	68	1 (1.5)	NR (NE, NE)	57	11 (19.3)	NR (NE, NE)	0.068 (0.009, 0.528)	0.0006
Interaction								0.7622

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	0 (0.0)	NR (NE, NE)	79	12 (15.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0001
Docetaxel	56	2 (3.6)	NR (NE, NE)	50	9 (18.0)	NR (NE, NE)	0.184 (0.040, 0.852)	0.0142
Irinotecan	116	0 (0.0)	NR (NE, NE)	111	10 (9.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0010
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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ECOG Performance Score								
0	63	2 (3.2)	NR (NE, NE)	57	10 (17.5)	NR (NE, NE)	0.164 (0.036, 0.751)	0.0077
1	192	0 (0.0)	NR (NE, NE)	183	21 (11.5)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9888
Region #1								
Asia	201	2 (1.0)	NR (NE, NE)	191	19 (9.9)	NR (NE, NE)	0.096 (0.022, 0.411)	<0.0001
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	12 (24.5)	NR (4.7, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9891

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	2 (1.1)	NR (NE, NE)	168	19 (11.3)	NR (NE, NE)	0.096 (0.022, 0.410)	<0.0001
Japan	25	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	12 (24.5)	NR (4.7, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	203	2 (1.0)	NR (NE, NE)	198	20 (10.1)	NR (NE, NE)	0.093 (0.022, 0.399)	<0.0001
White	52	0 (0.0)	NR (NE, NE)	42	11 (26.2)	NR (4.7, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9901

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	0 (0.0)	NR (NE, NE)	60	5 (8.3)	NR (NE, NE)	0.000 (0.000, NE)	0.0073
vCPS < 10%	100	1 (1.0)	NR (NE, NE)	119	20 (16.8)	NR (NE, NE)	0.052 (0.007, 0.390)	<0.0001
Missing	75	1 (1.3)	NR (NE, NE)	61	6 (9.8)	NR (NE, NE)	0.118 (0.014, 0.988)	0.0184
Interaction								0.8331

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	26 (16.6)	16.5 (16.1, NE)	149	2 (1.3)	NR (NE, NE)	7.658 (1.805, 32.486)	0.0010
>= 65 Years	98	14 (14.3)	NR (11.6, NE)	91	0 (0.0)	NR (NE, NE)	21717668.717 (0.000, NE)	0.0043
Interaction								0.9863

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Gender								
Male	216	34 (15.7)	NR (16.1, NE)	204	2 (1.0)	NR (NE, NE)	9.696 (2.310, 40.693)	0.0001
Female	39	6 (15.4)	NR (9.0, NE)	36	0 (0.0)	NR (NE, NE)	66553994.403 (0.000, NE)	0.0295
Interaction								0.9867

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	28 (15.0)	NR (16.1, NE)	183	2 (1.1)	NR (NE, NE)	8.807 (2.078, 37.326)	0.0003
Non-Smoker	68	12 (17.6)	NR (8.3, NE)	57	0 (0.0)	NR (NE, NE)	18446825.792 (0.000, NE)	0.0135
Interaction								0.9896

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	18 (21.7)	16.5 (9.0, NE)	79	1 (1.3)	NR (NE, NE)	13.944 (1.844, 105.446)	0.0008
Docetaxel	56	7 (12.5)	18.6 (11.6, NE)	50	0 (0.0)	NR (NE, NE)	54856964.265 (0.000, NE)	0.0399
Irinotecan	116	15 (12.9)	NR (16.1, NE)	111	1 (0.9)	NR (NE, NE)	7.303 (0.949, 56.192)	0.0255
Interaction								0.8952

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	13 (20.6)	16.1 (10.6, NE)	57	0 (0.0)	NR (NE, NE)	19849030.263 (0.000, NE)	0.0138
1	192	27 (14.1)	NR (16.5, NE)	183	2 (1.1)	NR (NE, NE)	9.079 (2.152, 38.309)	0.0003
Interaction								0.9884

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #1								
Asia	201	33 (16.4)	18.6 (11.6, NE)	191	2 (1.0)	NR (NE, NE)	8.562 (2.038, 35.969)	0.0004
Europe/North America	54	7 (13.0)	NR (NE, NE)	49	0 (0.0)	NR (NE, NE)	27493993.855 (0.000, NE)	0.0107
Interaction								0.9897

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Safety Analysis Set

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	26 (14.8)	NR (16.1, NE)	168	2 (1.2)	NR (NE, NE)	7.037 (1.658, 29.867)	0.0020
Japan	25	7 (28.0)	11.6 (4.6, NE)	23	0 (0.0)	NR (NE, NE)	49166268.174 (0.000, NE)	0.0771
Europe/North America	54	7 (13.0)	NR (NE, NE)	49	0 (0.0)	NR (NE, NE)	27493993.855 (0.000, NE)	0.0107
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Safety Analysis Set

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	33 (16.3)	18.6 (11.6, NE)	198	2 (1.0)	NR (NE, NE)	8.935 (2.127, 37.535)	0.0003
White	52	7 (13.5)	NR (NE, NE)	42	0 (0.0)	NR (NE, NE)	24583078.816 (0.000, NE)	0.0165
Interaction								0.9904

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	12 (15.0)	16.1 (11.6, NE)	60	1 (1.7)	NR (NE, NE)	4.151 (0.533, 32.338)	0.1402
vCPS < 10%	100	16 (16.0)	NR (16.5, NE)	119	1 (0.8)	NR (NE, NE)	14.433 (1.904, 109.430)	0.0006
Missing	75	12 (16.0)	NR (10.6, NE)	61	0 (0.0)	NR (NE, NE)	21444275.375 (0.000, NE)	0.0090
Interaction								0.8274

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	20 (12.7)	NR (16.1, NE)	149	1 (0.7)	NR (NE, NE)	10.474 (1.395, 78.615)	0.0043
>= 65 Years	98	10 (10.2)	NR (18.6, NE)	91	0 (0.0)	NR (NE, NE)	21724779.833 (0.000, NE)	0.0123
Interaction								0.9887

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Gender								
Male	216	25 (11.6)	NR (16.5, NE)	204	1 (0.5)	NR (NE, NE)	13.333 (1.792, 99.197)	0.0010
Female	39	5 (12.8)	NR (NE, NE)	36	0 (0.0)	NR (NE, NE)	64142089.228 (0.000, NE)	0.0521
Interaction								0.9892

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	22 (11.8)	NR (16.5, NE)	183	1 (0.5)	NR (NE, NE)	12.548 (1.678, 93.841)	0.0015
Non-Smoker	68	8 (11.8)	NR (10.6, NE)	57	0 (0.0)	NR (NE, NE)	18720464.176 (0.000, NE)	0.0387
Interaction								0.9916

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	13 (15.7)	NR (16.5, NE)	79	0 (0.0)	NR (NE, NE)	25104900.387 (0.000, NE)	0.0020
Docetaxel	56	5 (8.9)	18.6 (NE, NE)	50	0 (0.0)	NR (NE, NE)	57484283.130 (0.000, NE)	0.0674
Irinotecan	116	12 (10.3)	NR (16.1, NE)	111	1 (0.9)	NR (NE, NE)	5.426 (0.687, 42.874)	0.0732
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	9 (14.3)	NR (16.1, NE)	57	0 (0.0)	NR (NE, NE)	18314934.177 (0.000, NE)	0.0555
1	192	21 (10.9)	NR (16.5, NE)	183	1 (0.5)	NR (NE, NE)	13.247 (1.775, 98.850)	0.0010
Interaction								0.9907

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #1								
Asia	201	25 (12.4)	NR (16.5, NE)	191	1 (0.5)	NR (NE, NE)	13.038 (1.754, 96.896)	0.0011
Europe/North America	54	5 (9.3)	NR (NE, NE)	49	0 (0.0)	NR (NE, NE)	23801941.383 (0.000, NE)	0.0484
Interaction								0.9916

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	21 (11.9)	NR (16.5, NE)	168	1 (0.6)	NR (NE, NE)	11.222 (1.499, 84.006)	0.0029
Japan	25	4 (16.0)	NR (4.6, NE)	23	0 (0.0)	NR (NE, NE)	47674440.539 (0.000, NE)	0.1771
Europe/North America	54	5 (9.3)	NR (NE, NE)	49	0 (0.0)	NR (NE, NE)	23801941.383 (0.000, NE)	0.0484
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	25 (12.3)	NR (16.5, NE)	198	1 (0.5)	NR (NE, NE)	13.629 (1.834, 101.278)	0.0008
White	52	5 (9.6)	NR (NE, NE)	42	0 (0.0)	NR (NE, NE)	21614353.258 (0.000, NE)	0.0635
Interaction								0.9922

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	8 (10.0)	NR (16.1, NE)	60	0 (0.0)	NR (NE, NE)	14654601.957 (0.000, NE)	0.1013
vCPS < 10%	100	13 (13.0)	NR (16.5, NE)	119	1 (0.8)	NR (NE, NE)	10.720 (1.390, 82.666)	0.0043
Missing	75	9 (12.0)	NR (10.6, NE)	61	0 (0.0)	NR (NE, NE)	19687134.325 (0.000, NE)	0.0412
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	93 (59.2)	2.0 (1.2, 4.0)	149	104 (69.8)	0.4 (0.2, 0.8)	0.518 (0.389, 0.690)	<0.0001
>= 65 Years	98	56 (57.1)	3.4 (2.2, 6.3)	91	67 (73.6)	0.4 (0.2, 0.7)	0.395 (0.272, 0.574)	<0.0001
Interaction								0.4710
Gender								
Male	216	123 (56.9)	3.3 (1.9, 5.8)	204	143 (70.1)	0.4 (0.3, 0.7)	0.467 (0.364, 0.599)	<0.0001
Female	39	26 (66.7)	1.4 (0.7, 4.2)	36	28 (77.8)	0.2 (0.1, 1.1)	0.466 (0.266, 0.814)	0.0052
Interaction								0.9646

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	112 (59.9)	2.4 (1.4, 4.0)	183	132 (72.1)	0.3 (0.2, 0.7)	0.488 (0.377, 0.632)	<0.0001
Non-Smoker	68	37 (54.4)	5.8 (1.3, 8.6)	57	39 (68.4)	0.5 (0.2, 1.2)	0.408 (0.253, 0.657)	0.0001
Interaction								0.8141

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	53 (63.9)	2.0 (1.2, 3.4)	79	50 (63.3)	1.1 (0.5, 2.3)	0.724 (0.489, 1.073)	0.1031
Docetaxel	56	35 (62.5)	2.9 (0.8, 7.2)	50	29 (58.0)	1.1 (0.3, 6.1)	0.709 (0.427, 1.178)	0.1776
Irinotecan	116	61 (52.6)	5.6 (1.3, 6.6)	111	92 (82.9)	0.2 (0.1, 0.3)	0.257 (0.180, 0.365)	<0.0001
Interaction								<0.0001

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	35 (55.6)	5.9 (2.0, 8.6)	57	38 (66.7)	0.8 (0.3, 1.9)	0.446 (0.274, 0.727)	0.0008
1	192	114 (59.4)	2.2 (1.2, 3.4)	183	133 (72.7)	0.3 (0.2, 0.5)	0.469 (0.363, 0.606)	<0.0001
Interaction								0.7699
Region #1								
Asia	201	108 (53.7)	3.4 (2.0, 5.9)	191	133 (69.6)	0.3 (0.2, 0.6)	0.423 (0.325, 0.549)	<0.0001
Europe/North America	54	41 (75.9)	1.3 (0.5, 2.4)	49	38 (77.6)	0.5 (0.3, 1.2)	0.642 (0.405, 1.017)	0.0525
Interaction								0.0367

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	97 (55.1)	3.4 (1.8, 5.8)	168	118 (70.2)	0.3 (0.2, 0.5)	0.421 (0.319, 0.555)	<0.0001
Japan	25	11 (44.0)	9.8 (1.5, NE)	23	15 (65.2)	1.1 (0.3, NE)	0.422 (0.187, 0.953)	0.0317
Europe/North America	54	41 (75.9)	1.3 (0.5, 2.4)	49	38 (77.6)	0.5 (0.3, 1.2)	0.642 (0.405, 1.017)	0.0525
Interaction								0.1080

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	110 (54.2)	3.4 (2.0, 5.9)	198	138 (69.7)	0.3 (0.2, 0.7)	0.433 (0.334, 0.560)	<0.0001
White	52	39 (75.0)	1.3 (0.5, 2.5)	42	33 (78.6)	0.4 (0.3, 1.2)	0.588 (0.362, 0.957)	0.0272
Interaction								0.1190

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	51 (63.8)	3.0 (1.3, 6.0)	60	48 (80.0)	0.2 (0.1, 0.4)	0.356 (0.233, 0.542)	<0.0001
vCPS < 10%	100	63 (63.0)	1.5 (0.9, 5.8)	119	86 (72.3)	0.4 (0.3, 0.9)	0.527 (0.376, 0.738)	0.0001
Missing	75	35 (46.7)	4.2 (2.5, NE)	61	37 (60.7)	0.5 (0.1, NE)	0.490 (0.306, 0.784)	0.0021
Interaction								0.3281

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Abdominal pain upper

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	7 (4.5)	NR (NE, NE)	149	9 (6.0)	NR (NE, NE)	0.629 (0.232, 1.710)	0.3588
>= 65 Years	98	2 (2.0)	NR (NE, NE)	91	7 (7.7)	NR (6.9, NE)	0.195 (0.039, 0.989)	0.0302
Interaction								0.2575
Gender								
Male	216	9 (4.2)	NR (NE, NE)	204	11 (5.4)	NR (NE, NE)	0.637 (0.260, 1.558)	0.3188
Female	39	0 (0.0)	NR (NE, NE)	36	5 (13.9)	NR (NE, NE)	0.000 (0.000, NE)	0.0141
Interaction								0.9869

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Gastrointestinal disorders / PT - Abdominal pain upper

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Smoking Status								
Former/Current Smoker	187	7 (3.7)	NR (NE, NE)	183	10 (5.5)	NR (NE, NE)	0.590 (0.222, 1.564)	0.2828
Non-Smoker	68	2 (2.9)	NR (NE, NE)	57	6 (10.5)	NR (6.9, NE)	0.202 (0.039, 1.059)	0.0385
Interaction								0.3467

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
Adverse events were classified based on MedDRA v23.0.
System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.
Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.
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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Abdominal pain upper

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	1 (1.2)	NR (NE, NE)	79	7 (8.9)	NR (NE, NE)	0.131 (0.016, 1.067)	0.0245
Docetaxel	56	3 (5.4)	NR (NE, NE)	50	3 (6.0)	NR (6.9, NE)	0.700 (0.138, 3.536)	0.6635
Irinotecan	116	5 (4.3)	NR (NE, NE)	111	6 (5.4)	NR (NE, NE)	0.569 (0.165, 1.956)	0.3653
Interaction								0.3126

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Abdominal pain upper

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	1 (1.6)	NR (NE, NE)	57	8 (14.0)	NR (6.9, NE)	0.089 (0.011, 0.721)	0.0048
1	192	8 (4.2)	NR (NE, NE)	183	8 (4.4)	NR (NE, NE)	0.812 (0.301, 2.191)	0.6803
Interaction								0.0623
Region #1								
Asia	201	7 (3.5)	NR (NE, NE)	191	9 (4.7)	NR (NE, NE)	0.614 (0.225, 1.673)	0.3349
Europe/North America	54	2 (3.7)	NR (NE, NE)	49	7 (14.3)	NR (6.9, NE)	0.220 (0.045, 1.075)	0.0397
Interaction								0.2919

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Abdominal pain upper

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	7 (4.0)	NR (NE, NE)	168	9 (5.4)	NR (NE, NE)	0.614 (0.225, 1.673)	0.3354
Japan	25	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Europe/North America	54	2 (3.7)	NR (NE, NE)	49	7 (14.3)	NR (6.9, NE)	0.220 (0.045, 1.075)	0.0397
Interaction								0.5697

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Abdominal pain upper

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	7 (3.4)	NR (NE, NE)	198	9 (4.5)	NR (NE, NE)	0.636 (0.233, 1.730)	0.3709
White	52	2 (3.8)	NR (NE, NE)	42	7 (16.7)	NR (6.9, NE)	0.197 (0.041, 0.961)	0.0249
Interaction								0.2186

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Abdominal pain upper

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	4 (5.0)	NR (NE, NE)	60	6 (10.0)	NR (NE, NE)	0.356 (0.096, 1.319)	0.1073
vCPS < 10%	100	3 (3.0)	NR (NE, NE)	119	8 (6.7)	NR (NE, NE)	0.418 (0.111, 1.581)	0.1852
Missing	75	2 (2.7)	NR (NE, NE)	61	2 (3.3)	NR (6.9, NE)	0.638 (0.088, 4.622)	0.6532
Interaction								0.8205

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	14 (8.9)	NR (NE, NE)	149	44 (29.5)	NR (NE, NE)	0.237 (0.129, 0.434)	<0.0001
>= 65 Years	98	18 (18.4)	NR (NE, NE)	91	33 (36.3)	NR (3.3, NE)	0.374 (0.209, 0.670)	0.0006
Interaction								0.2418
Gender								
Male	216	24 (11.1)	NR (NE, NE)	204	65 (31.9)	NR (NE, NE)	0.267 (0.166, 0.428)	<0.0001
Female	39	8 (20.5)	NR (7.5, NE)	36	12 (33.3)	NR (1.7, NE)	0.451 (0.180, 1.128)	0.0801
Interaction								0.2019

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	27 (14.4)	NR (NE, NE)	183	63 (34.4)	NR (4.4, NE)	0.308 (0.195, 0.486)	<0.0001
Non-Smoker	68	5 (7.4)	NR (NE, NE)	57	14 (24.6)	NR (NE, NE)	0.268 (0.096, 0.744)	0.0066
Interaction								0.6831

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	13 (15.7)	NR (NE, NE)	79	15 (19.0)	NR (NE, NE)	0.705 (0.334, 1.486)	0.3545
Docetaxel	56	6 (10.7)	NR (NE, NE)	50	8 (16.0)	NR (NE, NE)	0.553 (0.191, 1.607)	0.2696
Irinotecan	116	13 (11.2)	NR (NE, NE)	111	54 (48.6)	4.4 (0.4, NE)	0.140 (0.074, 0.266)	<0.0001
Interaction								0.0020

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	4 (6.3)	NR (NE, NE)	57	16 (28.1)	NR (NE, NE)	0.164 (0.053, 0.501)	0.0003
1	192	28 (14.6)	NR (NE, NE)	183	61 (33.3)	NR (4.4, NE)	0.332 (0.211, 0.521)	<0.0001
Interaction								0.2726
Region #1								
Asia	201	16 (8.0)	NR (NE, NE)	191	56 (29.3)	NR (NE, NE)	0.213 (0.122, 0.372)	<0.0001
Europe/North America	54	16 (29.6)	NR (7.5, NE)	49	21 (42.9)	NR (0.5, NE)	0.486 (0.250, 0.944)	0.0290
Interaction								0.0283

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	14 (8.0)	NR (NE, NE)	168	53 (31.5)	NR (NE, NE)	0.194 (0.107, 0.351)	<0.0001
Japan	25	2 (8.0)	NR (NE, NE)	23	3 (13.0)	NR (2.6, NE)	0.539 (0.089, 3.271)	0.4952
Europe/North America	54	16 (29.6)	NR (7.5, NE)	49	21 (42.9)	NR (0.5, NE)	0.486 (0.250, 0.944)	0.0290
Interaction								0.0552

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	17 (8.4)	NR (NE, NE)	198	56 (28.3)	NR (NE, NE)	0.236 (0.137, 0.407)	<0.0001
White	52	15 (28.8)	NR (7.5, NE)	42	21 (50.0)	1.7 (0.4, NE)	0.373 (0.189, 0.733)	0.0028
Interaction								0.1636

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	12 (15.0)	NR (NE, NE)	60	20 (33.3)	NR (3.3, NE)	0.327 (0.158, 0.677)	0.0015
vCPS < 10%	100	16 (16.0)	NR (NE, NE)	119	42 (35.3)	NR (NE, NE)	0.333 (0.186, 0.597)	<0.0001
Missing	75	4 (5.3)	NR (NE, NE)	61	15 (24.6)	NR (4.4, NE)	0.184 (0.061, 0.557)	0.0008
Interaction								0.5259

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Nausea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	24 (15.3)	NR (NE, NE)	149	47 (31.5)	NR (5.1, NE)	0.394 (0.240, 0.646)	0.0001
>= 65 Years	98	12 (12.2)	NR (NE, NE)	91	25 (27.5)	NR (5.0, NE)	0.325 (0.162, 0.652)	0.0009
Interaction								0.8965
Gender								
Male	216	28 (13.0)	NR (NE, NE)	204	58 (28.4)	NR (5.1, NE)	0.358 (0.227, 0.565)	<0.0001
Female	39	8 (20.5)	NR (4.7, NE)	36	14 (38.9)	NR (1.1, NE)	0.363 (0.148, 0.890)	0.0212
Interaction								0.8162

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Nausea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	29 (15.5)	NR (NE, NE)	183	54 (29.5)	NR (5.0, NE)	0.406 (0.257, 0.641)	<0.0001
Non-Smoker	68	7 (10.3)	NR (NE, NE)	57	18 (31.6)	NR (3.8, NE)	0.261 (0.109, 0.629)	0.0013
Interaction								0.3320

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Nausea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	15 (18.1)	NR (NE, NE)	79	14 (17.7)	NR (NE, NE)	0.924 (0.445, 1.919)	0.8328
Docetaxel	56	7 (12.5)	NR (NE, NE)	50	5 (10.0)	NR (4.2, NE)	1.090 (0.342, 3.469)	0.8841
Irinotecan	116	14 (12.1)	NR (NE, NE)	111	53 (47.7)	2.4 (1.1, 5.1)	0.159 (0.087, 0.292)	<0.0001
Interaction								0.0001

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Nausea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	3 (4.8)	NR (NE, NE)	57	10 (17.5)	NR (NE, NE)	0.233 (0.064, 0.851)	0.0163
1	192	33 (17.2)	NR (NE, NE)	183	62 (33.9)	5.1 (3.0, NE)	0.377 (0.246, 0.579)	<0.0001
Interaction								0.4140
Region #1								
Asia	201	25 (12.4)	NR (NE, NE)	191	57 (29.8)	NR (5.1, NE)	0.321 (0.200, 0.517)	<0.0001
Europe/North America	54	11 (20.4)	NR (NE, NE)	49	15 (30.6)	NR (2.6, NE)	0.544 (0.248, 1.194)	0.1228
Interaction								0.1917

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Nausea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	21 (11.9)	NR (NE, NE)	168	56 (33.3)	NR (3.8, NE)	0.268 (0.162, 0.445)	<0.0001
Japan	25	4 (16.0)	NR (NE, NE)	23	1 (4.3)	NR (NE, NE)	3.318 (0.369, 29.832)	0.2564
Europe/North America	54	11 (20.4)	NR (NE, NE)	49	15 (30.6)	NR (2.6, NE)	0.544 (0.248, 1.194)	0.1228
Interaction								0.0315

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Nausea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	25 (12.3)	NR (NE, NE)	198	59 (29.8)	NR (5.1, NE)	0.321 (0.200, 0.515)	<0.0001
White	52	11 (21.2)	NR (NE, NE)	42	13 (31.0)	5.0 (2.6, NE)	0.547 (0.243, 1.235)	0.1403
Interaction								0.1890

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Nausea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	14 (17.5)	NR (NE, NE)	60	19 (31.7)	NR (3.0, NE)	0.401 (0.198, 0.809)	0.0081
vCPS < 10%	100	13 (13.0)	NR (NE, NE)	119	37 (31.1)	NR (3.8, NE)	0.329 (0.174, 0.621)	0.0003
Missing	75	9 (12.0)	NR (NE, NE)	61	16 (26.2)	NR (5.0, NE)	0.379 (0.167, 0.861)	0.0155
Interaction								0.9401

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Vomiting

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	21 (13.4)	NR (NE, NE)	149	33 (22.1)	NR (NE, NE)	0.466 (0.267, 0.815)	0.0059
>= 65 Years	98	6 (6.1)	NR (NE, NE)	91	15 (16.5)	NR (NE, NE)	0.339 (0.132, 0.875)	0.0187
Interaction								0.4442
Gender								
Male	216	24 (11.1)	NR (NE, NE)	204	38 (18.6)	NR (NE, NE)	0.476 (0.283, 0.803)	0.0042
Female	39	3 (7.7)	NR (NE, NE)	36	10 (27.8)	NR (2.7, NE)	0.239 (0.066, 0.869)	0.0178
Interaction								0.2650

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Vomiting

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	19 (10.2)	NR (NE, NE)	183	34 (18.6)	NR (NE, NE)	0.447 (0.252, 0.792)	0.0045
Non-Smoker	68	8 (11.8)	NR (NE, NE)	57	14 (24.6)	NR (3.0, NE)	0.374 (0.155, 0.900)	0.0222
Interaction								0.8050

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Vomiting

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	8 (9.6)	NR (NE, NE)	79	6 (7.6)	NR (NE, NE)	1.201 (0.416, 3.469)	0.7349
Docetaxel	56	4 (7.1)	NR (NE, NE)	50	5 (10.0)	NR (NE, NE)	0.611 (0.163, 2.282)	0.4576
Irinotecan	116	15 (12.9)	NR (NE, NE)	111	37 (33.3)	NR (3.5, NE)	0.264 (0.141, 0.493)	<0.0001
Interaction								0.0465

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Vomiting

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	3 (4.8)	NR (14.0, NE)	57	4 (7.0)	NR (NE, NE)	0.393 (0.072, 2.165)	0.2668
1	192	24 (12.5)	NR (NE, NE)	183	44 (24.0)	NR (NE, NE)	0.421 (0.255, 0.695)	0.0005
Interaction								0.6614
Region #1								
Asia	201	21 (10.4)	NR (NE, NE)	191	41 (21.5)	NR (NE, NE)	0.380 (0.222, 0.650)	0.0002
Europe/North America	54	6 (11.1)	NR (NE, NE)	49	7 (14.3)	NR (5.7, NE)	0.727 (0.244, 2.165)	0.5640
Interaction								0.3273

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Vomiting

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	20 (11.4)	NR (NE, NE)	168	40 (23.8)	NR (NE, NE)	0.365 (0.211, 0.631)	0.0002
Japan	25	1 (4.0)	NR (NE, NE)	23	1 (4.3)	NR (NE, NE)	0.895 (0.056, 14.318)	0.9378
Europe/North America	54	6 (11.1)	NR (NE, NE)	49	7 (14.3)	NR (5.7, NE)	0.727 (0.244, 2.165)	0.5640
Interaction								0.5287

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Vomiting

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	21 (10.3)	NR (NE, NE)	198	42 (21.2)	NR (NE, NE)	0.383 (0.225, 0.654)	0.0002
White	52	6 (11.5)	NR (NE, NE)	42	6 (14.3)	NR (5.7, NE)	0.753 (0.242, 2.337)	0.6214
Interaction								0.3215

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Vomiting

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	7 (8.8)	NR (NE, NE)	60	12 (20.0)	NR (5.7, NE)	0.298 (0.114, 0.780)	0.0091
vCPS < 10%	100	15 (15.0)	NR (NE, NE)	119	25 (21.0)	NR (NE, NE)	0.616 (0.324, 1.172)	0.1344
Missing	75	5 (6.7)	NR (NE, NE)	61	11 (18.0)	NR (NE, NE)	0.340 (0.118, 0.980)	0.0356
Interaction								0.4364

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	61 (38.9)	10.3 (7.7, NE)	149	89 (59.7)	1.0 (0.7, 2.1)	0.436 (0.311, 0.611)	<0.0001
>= 65 Years	98	56 (57.1)	3.6 (2.1, 7.6)	91	58 (63.7)	1.0 (0.7, 2.3)	0.549 (0.371, 0.811)	0.0020
Interaction								0.1375
Gender								
Male	216	95 (44.0)	7.7 (5.5, 11.0)	204	123 (60.3)	1.0 (0.8, 1.6)	0.466 (0.352, 0.616)	<0.0001
Female	39	22 (56.4)	2.4 (1.0, 8.5)	36	24 (66.7)	1.3 (0.5, 2.6)	0.563 (0.305, 1.039)	0.0588
Interaction								0.3500

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	87 (46.5)	7.6 (2.8, 11.0)	183	118 (64.5)	1.0 (0.7, 1.3)	0.469 (0.352, 0.626)	<0.0001
Non-Smoker	68	30 (44.1)	7.0 (2.8, 14.5)	57	29 (50.9)	1.9 (0.7, NE)	0.520 (0.301, 0.898)	0.0165
Interaction								0.3808

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	46 (55.4)	3.5 (1.9, 9.9)	79	49 (62.0)	1.7 (0.8, 2.6)	0.614 (0.403, 0.936)	0.0211
Docetaxel	56	27 (48.2)	5.5 (2.9, 8.6)	50	28 (56.0)	1.3 (0.8, NE)	0.548 (0.315, 0.951)	0.0281
Irinotecan	116	44 (37.9)	13.8 (6.1, NE)	111	70 (63.1)	0.8 (0.5, 1.5)	0.384 (0.258, 0.571)	<0.0001
Interaction								0.0982

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	35 (55.6)	6.9 (2.7, 8.5)	57	33 (57.9)	2.1 (0.9, 3.0)	0.588 (0.352, 0.981)	0.0378
1	192	82 (42.7)	7.6 (3.5, 12.7)	183	114 (62.3)	0.9 (0.6, 1.6)	0.446 (0.332, 0.599)	<0.0001
Interaction								0.1174
Region #1								
Asia	201	77 (38.3)	9.9 (6.4, 17.5)	191	111 (58.1)	1.1 (0.8, 2.0)	0.408 (0.301, 0.555)	<0.0001
Europe/North America	54	40 (74.1)	1.0 (0.6, 2.5)	49	36 (73.5)	1.0 (0.5, 1.9)	0.757 (0.475, 1.206)	0.2312
Interaction								0.0127

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	64 (36.4)	11.0 (6.4, NE)	168	97 (57.7)	1.0 (0.8, 2.0)	0.404 (0.290, 0.562)	<0.0001
Japan	25	13 (52.0)	6.9 (1.9, NE)	23	14 (60.9)	1.7 (0.4, NE)	0.432 (0.187, 1.000)	0.0431
Europe/North America	54	40 (74.1)	1.0 (0.6, 2.5)	49	36 (73.5)	1.0 (0.5, 1.9)	0.757 (0.475, 1.206)	0.2312
Interaction								0.0341

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	77 (37.9)	9.9 (6.4, 17.5)	198	115 (58.1)	1.1 (0.8, 2.0)	0.404 (0.298, 0.547)	<0.0001
White	52	40 (76.9)	0.8 (0.5, 2.5)	42	32 (76.2)	0.8 (0.5, 1.5)	0.751 (0.465, 1.213)	0.2305
Interaction								0.0193

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	41 (51.3)	6.4 (2.1, 8.5)	60	44 (73.3)	0.7 (0.3, 1.1)	0.382 (0.245, 0.597)	<0.0001
vCPS < 10%	100	47 (47.0)	7.7 (2.7, 11.0)	119	65 (54.6)	1.9 (0.9, 2.7)	0.574 (0.385, 0.855)	0.0053
Missing	75	29 (38.7)	9.9 (2.8, NE)	61	38 (62.3)	0.9 (0.5, 1.7)	0.425 (0.259, 0.698)	0.0004
Interaction								0.2132

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	14 (8.9)	NR (17.5, NE)	149	23 (15.4)	NR (9.0, NE)	0.405 (0.200, 0.819)	0.0093
>= 65 Years	98	13 (13.3)	NR (NE, NE)	91	12 (13.2)	NR (NE, NE)	0.807 (0.361, 1.806)	0.6002
Interaction								0.2483
Gender								
Male	216	24 (11.1)	NR (NE, NE)	204	29 (14.2)	NR (NE, NE)	0.601 (0.343, 1.050)	0.0704
Female	39	3 (7.7)	NR (14.5, NE)	36	6 (16.7)	9.0 (9.0, NE)	0.320 (0.077, 1.331)	0.1004
Interaction								0.5578

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	22 (11.8)	NR (NE, NE)	183	31 (16.9)	NR (9.0, NE)	0.529 (0.302, 0.928)	0.0237
Non-Smoker	68	5 (7.4)	NR (14.5, NE)	57	4 (7.0)	NR (NE, NE)	0.808 (0.209, 3.124)	0.7564
Interaction								0.4754

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	12 (14.5)	NR (NE, NE)	79	7 (8.9)	NR (9.0, NE)	1.493 (0.584, 3.820)	0.3991
Docetaxel	56	6 (10.7)	17.5 (8.6, NE)	50	10 (20.0)	NR (4.1, NE)	0.377 (0.133, 1.067)	0.0564
Irinotecan	116	9 (7.8)	NR (14.5, NE)	111	18 (16.2)	NR (NE, NE)	0.315 (0.131, 0.757)	0.0063
Interaction								0.0952

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	7 (11.1)	NR (14.5, NE)	57	6 (10.5)	NR (NE, NE)	0.638 (0.193, 2.109)	0.4571
1	192	20 (10.4)	NR (NE, NE)	183	29 (15.8)	NR (9.0, NE)	0.514 (0.287, 0.922)	0.0228
Interaction								0.4152
Region #1								
Asia	201	10 (5.0)	NR (NE, NE)	191	24 (12.6)	NR (9.0, NE)	0.283 (0.130, 0.618)	0.0008
Europe/North America	54	17 (31.5)	14.5 (8.6, NE)	49	11 (22.4)	NR (4.1, NE)	1.136 (0.524, 2.464)	0.7461
Interaction								0.0088

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	10 (5.7)	NR (NE, NE)	168	24 (14.3)	NR (9.0, NE)	0.285 (0.131, 0.619)	0.0008
Japan	25	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Europe/North America	54	17 (31.5)	14.5 (8.6, NE)	49	11 (22.4)	NR (4.1, NE)	1.136 (0.524, 2.464)	0.7461
Interaction								0.0339

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	10 (4.9)	NR (NE, NE)	198	24 (12.1)	NR (9.0, NE)	0.292 (0.134, 0.637)	0.0011
White	52	17 (32.7)	14.5 (8.6, NE)	42	11 (26.2)	NR (3.0, NE)	0.985 (0.454, 2.137)	0.9695
Interaction								0.0218

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	9 (11.3)	NR (14.5, NE)	60	10 (16.7)	NR (9.0, NE)	0.478 (0.189, 1.204)	0.1090
vCPS < 10%	100	13 (13.0)	NR (14.5, NE)	119	16 (13.4)	NR (NE, NE)	0.686 (0.316, 1.490)	0.3376
Missing	75	5 (6.7)	NR (NE, NE)	61	9 (14.8)	NR (NE, NE)	0.417 (0.140, 1.244)	0.1048
Interaction								0.4164

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - General disorders and administration site conditions / PT - Malaise

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	7 (4.5)	NR (NE, NE)	149	25 (16.8)	NR (NE, NE)	0.184 (0.075, 0.452)	<0.0001
>= 65 Years	98	9 (9.2)	NR (NE, NE)	91	11 (12.1)	NR (NE, NE)	0.612 (0.248, 1.507)	0.2797
Interaction								0.0844
Gender								
Male	216	12 (5.6)	NR (NE, NE)	204	32 (15.7)	NR (NE, NE)	0.272 (0.136, 0.542)	<0.0001
Female	39	4 (10.3)	NR (7.7, NE)	36	4 (11.1)	NR (NE, NE)	0.632 (0.151, 2.641)	0.5258
Interaction								0.1816

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Safety Analysis Set
Any TEAE: SOC - General disorders and administration site conditions / PT - Malaise

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Smoking Status								
Former/Current Smoker	187	10 (5.3)	NR (NE, NE)	183	26 (14.2)	NR (NE, NE)	0.288 (0.134, 0.618)	0.0007
Non-Smoker	68	6 (8.8)	NR (8.5, NE)	57	10 (17.5)	NR (NE, NE)	0.346 (0.121, 0.994)	0.0400
Interaction								0.6415

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	6 (7.2)	NR (NE, NE)	79	5 (6.3)	NR (NE, NE)	0.794 (0.233, 2.709)	0.7119
Docetaxel	56	5 (8.9)	NR (13.3, NE)	50	7 (14.0)	NR (NE, NE)	0.532 (0.166, 1.705)	0.2784
Irinotecan	116	5 (4.3)	NR (NE, NE)	111	24 (21.6)	NR (NE, NE)	0.156 (0.059, 0.415)	<0.0001
Interaction								0.0370

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - General disorders and administration site conditions / PT - Malaise

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	5 (7.9)	NR (13.3, NE)	57	10 (17.5)	NR (NE, NE)	0.249 (0.075, 0.824)	0.0147
1	192	11 (5.7)	NR (NE, NE)	183	26 (14.2)	NR (NE, NE)	0.341 (0.167, 0.695)	0.0019
Interaction								0.9714
Region #1								
Asia	201	16 (8.0)	NR (NE, NE)	191	35 (18.3)	NR (NE, NE)	0.313 (0.169, 0.578)	<0.0001
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	0.000 (0.000, NE)	0.2888
Interaction								0.9879

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - General disorders and administration site conditions / PT - Malaise

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	11 (6.3)	NR (NE, NE)	168	31 (18.5)	NR (NE, NE)	0.268 (0.132, 0.542)	<0.0001
Japan	25	5 (20.0)	NR (7.7, NE)	23	4 (17.4)	NR (2.6, NE)	0.596 (0.144, 2.472)	0.4708
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	0.000 (0.000, NE)	0.2888
Interaction								0.2655

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - General disorders and administration site conditions / PT - Malaise

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	16 (7.9)	NR (NE, NE)	198	35 (17.7)	NR (NE, NE)	0.322 (0.174, 0.597)	0.0002
White	52	0 (0.0)	NR (NE, NE)	42	1 (2.4)	NR (NE, NE)	0.000 (0.000, NE)	0.2601
Interaction								0.9878

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - General disorders and administration site conditions / PT - Malaise

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	7 (8.8)	NR (NE, NE)	60	11 (18.3)	NR (NE, NE)	0.351 (0.133, 0.925)	0.0269
vCPS < 10%	100	3 (3.0)	NR (13.3, NE)	119	14 (11.8)	NR (NE, NE)	0.156 (0.035, 0.685)	0.0046
Missing	75	6 (8.0)	NR (NE, NE)	61	11 (18.0)	NR (NE, NE)	0.356 (0.130, 0.975)	0.0355
Interaction								0.7745

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	49 (31.2)	15.8 (7.3, NE)	149	42 (28.2)	8.0 (4.9, NE)	0.865 (0.568, 1.317)	0.4964
>= 65 Years	98	26 (26.5)	13.7 (9.5, NE)	91	32 (35.2)	9.2 (2.8, NE)	0.469 (0.267, 0.822)	0.0068
Interaction								0.2507
Gender								
Male	216	65 (30.1)	13.7 (9.5, NE)	204	60 (29.4)	8.0 (5.3, NE)	0.757 (0.527, 1.088)	0.1304
Female	39	10 (25.6)	11.3 (2.7, NE)	36	14 (38.9)	3.0 (2.4, NE)	0.459 (0.195, 1.081)	0.0675
Interaction								0.2523

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	53 (28.3)	13.8 (9.5, NE)	183	59 (32.2)	8.0 (5.3, NE)	0.619 (0.421, 0.910)	0.0137
Non-Smoker	68	22 (32.4)	10.5 (3.2, NE)	57	15 (26.3)	NR (3.1, NE)	0.986 (0.506, 1.920)	0.9664
Interaction								0.2565

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	25 (30.1)	13.8 (5.3, NE)	79	24 (30.4)	8.0 (3.4, NE)	0.809 (0.454, 1.443)	0.4708
Docetaxel	56	18 (32.1)	9.5 (3.2, NE)	50	22 (44.0)	3.1 (1.4, NE)	0.479 (0.251, 0.914)	0.0223
Irinotecan	116	32 (27.6)	15.8 (11.3, NE)	111	28 (25.2)	9.2 (5.8, NE)	0.780 (0.459, 1.325)	0.3560
Interaction								0.6313

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	18 (28.6)	13.8 (11.3, NE)	57	14 (24.6)	8.0 (5.3, NE)	0.744 (0.353, 1.567)	0.4343
1	192	57 (29.7)	13.7 (5.6, NE)	183	60 (32.8)	NR (2.8, NE)	0.676 (0.466, 0.981)	0.0378
Interaction								0.3980
Region #1								
Asia	201	59 (29.4)	13.7 (6.3, NE)	191	54 (28.3)	NR (5.8, NE)	0.725 (0.495, 1.063)	0.0973
Europe/North America	54	16 (29.6)	NR (7.3, NE)	49	20 (40.8)	5.3 (2.5, 9.2)	0.608 (0.308, 1.198)	0.1455
Interaction								0.6723

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Safety Analysis Set

Any TEAE: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	51 (29.0)	13.7 (6.3, NE)	168	46 (27.4)	NR (5.8, NE)	0.736 (0.488, 1.110)	0.1413
Japan	25	8 (32.0)	11.5 (5.6, NE)	23	8 (34.8)	NR (3.0, NE)	0.633 (0.219, 1.834)	0.3952
Europe/North America	54	16 (29.6)	NR (7.3, NE)	49	20 (40.8)	5.3 (2.5, 9.2)	0.608 (0.308, 1.198)	0.1455
Interaction								0.9125

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	60 (29.6)	13.7 (6.3, NE)	198	56 (28.3)	NR (5.8, NE)	0.738 (0.506, 1.076)	0.1127
White	52	15 (28.8)	NR (7.3, NE)	42	18 (42.9)	5.3 (2.5, 9.2)	0.560 (0.277, 1.135)	0.1024
Interaction								0.5055

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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Safety Analysis Set

Any TEAE: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	20 (25.0)	15.8 (9.5, NE)	60	21 (35.0)	8.0 (2.6, NE)	0.414 (0.213, 0.803)	0.0072
vCPS < 10%	100	39 (39.0)	7.3 (3.8, NE)	119	40 (33.6)	5.3 (3.4, NE)	0.955 (0.610, 1.497)	0.8416
Missing	75	16 (21.3)	13.7 (11.5, NE)	61	13 (21.3)	NR (NE, NE)	0.739 (0.346, 1.578)	0.4326
Interaction								0.1054

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	79 (50.3)	2.8 (2.1, 7.6)	149	101 (67.8)	0.5 (0.5, 0.8)	0.474 (0.350, 0.640)	<0.0001
>= 65 Years	98	49 (50.0)	4.4 (2.7, 9.7)	91	65 (71.4)	0.5 (0.4, 1.0)	0.364 (0.246, 0.539)	<0.0001
Interaction								0.4000
Gender								
Male	216	111 (51.4)	3.4 (2.1, 7.6)	204	146 (71.6)	0.5 (0.5, 0.7)	0.419 (0.325, 0.542)	<0.0001
Female	39	17 (43.6)	2.8 (2.1, NE)	36	20 (55.6)	1.0 (0.3, NE)	0.522 (0.271, 1.004)	0.0439
Interaction								0.5274

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	93 (49.7)	3.5 (2.1, 9.7)	183	125 (68.3)	0.7 (0.5, 0.9)	0.429 (0.325, 0.567)	<0.0001
Non-Smoker	68	35 (51.5)	2.8 (1.5, 6.6)	57	41 (71.9)	0.5 (0.3, 0.7)	0.426 (0.268, 0.678)	0.0001
Interaction								0.9471

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	27 (32.5)	NR (7.0, NE)	79	45 (57.0)	1.2 (0.5, 3.5)	0.362 (0.222, 0.591)	<0.0001
Docetaxel	56	31 (55.4)	2.1 (1.2, 7.7)	50	39 (78.0)	0.3 (0.3, 0.7)	0.355 (0.217, 0.583)	<0.0001
Irinotecan	116	70 (60.3)	2.1 (1.0, 2.8)	111	82 (73.9)	0.5 (0.5, 0.7)	0.483 (0.347, 0.673)	<0.0001
Interaction								0.3394

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	27 (42.9)	15.8 (2.2, NE)	57	36 (63.2)	0.5 (0.5, 3.5)	0.402 (0.240, 0.674)	0.0002
1	192	101 (52.6)	2.8 (2.0, 6.2)	183	130 (71.0)	0.5 (0.5, 0.7)	0.441 (0.337, 0.576)	<0.0001
Interaction								0.6089
Region #1								
Asia	201	117 (58.2)	2.1 (1.7, 3.4)	191	148 (77.5)	0.5 (0.4, 0.5)	0.386 (0.299, 0.499)	<0.0001
Europe/North America	54	11 (20.4)	NR (NE, NE)	49	18 (36.7)	3.3 (2.4, NE)	0.436 (0.205, 0.929)	0.0262
Interaction								0.8562

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	106 (60.2)	2.1 (1.4, 2.8)	168	132 (78.6)	0.5 (0.4, 0.5)	0.408 (0.313, 0.534)	<0.0001
Japan	25	11 (44.0)	4.4 (2.8, NE)	23	16 (69.6)	0.5 (0.3, 1.7)	0.217 (0.084, 0.561)	0.0004
Europe/North America	54	11 (20.4)	NR (NE, NE)	49	18 (36.7)	3.3 (2.4, NE)	0.436 (0.205, 0.929)	0.0262
Interaction								0.6337

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	117 (57.6)	2.1 (2.0, 3.4)	198	151 (76.3)	0.5 (0.4, 0.5)	0.398 (0.309, 0.513)	<0.0001
White	52	11 (21.2)	NR (NE, NE)	42	15 (35.7)	3.3 (2.4, NE)	0.470 (0.215, 1.031)	0.0525
Interaction								0.7577

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	39 (48.8)	6.6 (2.2, NE)	60	39 (65.0)	0.7 (0.4, 1.4)	0.399 (0.252, 0.634)	<0.0001
vCPS < 10%	100	52 (52.0)	2.9 (1.5, 9.7)	119	83 (69.7)	0.5 (0.5, 0.9)	0.487 (0.342, 0.694)	<0.0001
Missing	75	37 (49.3)	2.8 (2.1, 13.8)	61	44 (72.1)	0.5 (0.3, 0.9)	0.388 (0.244, 0.615)	<0.0001
Interaction								0.7913

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	29 (18.5)	NR (14.9, NE)	149	5 (3.4)	NR (NE, NE)	4.310 (1.657, 11.215)	0.0011
>= 65 Years	98	8 (8.2)	NR (NE, NE)	91	6 (6.6)	NR (NE, NE)	0.995 (0.338, 2.926)	0.9922
Interaction								0.0325

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Gender								
Male	216	32 (14.8)	NR (NE, NE)	204	11 (5.4)	NR (NE, NE)	2.220 (1.110, 4.443)	0.0205
Female	39	5 (12.8)	NR (4.9, NE)	36	0 (0.0)	NR (NE, NE)	54752211.366 (0.000, NE)	0.0768
Interaction								0.9830

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	27 (14.4)	NR (NE, NE)	183	9 (4.9)	NR (NE, NE)	2.356 (1.100, 5.049)	0.0230
Non-Smoker	68	10 (14.7)	NR (11.0, NE)	57	2 (3.5)	NR (NE, NE)	3.386 (0.732, 15.656)	0.0976
Interaction								0.6076

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ICC Options								
Paclitaxel	83	8 (9.6)	NR (NE, NE)	79	2 (2.5)	NR (NE, NE)	3.494 (0.740, 16.499)	0.0914
Docetaxel	56	5 (8.9)	NR (NE, NE)	50	1 (2.0)	NR (NE, NE)	3.683 (0.426, 31.829)	0.2040
Irinotecan	116	24 (20.7)	NR (11.0, NE)	111	8 (7.2)	NR (NE, NE)	1.969 (0.867, 4.468)	0.0989
Interaction								0.8019

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	10 (15.9)	NR (14.9, NE)	57	0 (0.0)	NR (NE, NE)	22644564.356 (0.000, NE)	0.0102
1	192	27 (14.1)	NR (NE, NE)	183	11 (6.0)	NR (NE, NE)	1.900 (0.936, 3.860)	0.0705
Interaction								0.9853

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #1								
Asia	201	34 (16.9)	NR (NE, NE)	191	10 (5.2)	NR (NE, NE)	2.539 (1.245, 5.178)	0.0079
Europe/North America	54	3 (5.6)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	2.322 (0.240, 22.447)	0.4539
Interaction								0.9467

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	32 (18.2)	NR (14.9, NE)	168	10 (6.0)	NR (NE, NE)	2.395 (1.168, 4.913)	0.0138
Japan	25	2 (8.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	64906194.937 (0.000, NE)	0.2144
Europe/North America	54	3 (5.6)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	2.322 (0.240, 22.447)	0.4539
Interaction								0.9997

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	203	34 (16.7)	NR (NE, NE)	198	10 (5.1)	NR (NE, NE)	2.622 (1.286, 5.349)	0.0058
White	52	3 (5.8)	NR (NE, NE)	42	1 (2.4)	NR (NE, NE)	2.083 (0.216, 20.125)	0.5169
Interaction								0.8463

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	16 (20.0)	NR (14.9, NE)	60	5 (8.3)	NR (NE, NE)	1.714 (0.620, 4.735)	0.2921
vCPS < 10%	100	11 (11.0)	NR (NE, NE)	119	3 (2.5)	NR (NE, NE)	3.561 (0.981, 12.926)	0.0397
Missing	75	10 (13.3)	NR (NE, NE)	61	3 (4.9)	NR (NE, NE)	2.429 (0.666, 8.861)	0.1642
Interaction								0.6926

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Investigations / PT - Blood alkaline phosphatase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	14 (8.9)	NR (NE, NE)	149	3 (2.0)	NR (NE, NE)	3.748 (1.071, 13.118)	0.0265
>= 65 Years	98	3 (3.1)	NR (NE, NE)	91	2 (2.2)	NR (NE, NE)	1.271 (0.211, 7.656)	0.7930
Interaction								0.3146

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Blood alkaline phosphatase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Gender								
Male	216	16 (7.4)	NR (NE, NE)	204	5 (2.5)	NR (NE, NE)	2.669 (0.974, 7.314)	0.0468
Female	39	1 (2.6)	NR (NE, NE)	36	0 (0.0)	NR (NE, NE)	15114368.536 (0.000, NE)	0.5351
Interaction								0.9894

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Investigations / PT - Blood alkaline phosphatase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	16 (8.6)	NR (NE, NE)	183	4 (2.2)	NR (NE, NE)	3.315 (1.103, 9.966)	0.0235
Non-Smoker	68	1 (1.5)	NR (NE, NE)	57	1 (1.8)	NR (NE, NE)	0.868 (0.054, 13.879)	0.9200
Interaction								0.3255

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Blood alkaline phosphatase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	4 (4.8)	NR (NE, NE)	79	2 (2.5)	NR (NE, NE)	1.656 (0.301, 9.117)	0.5581
Docetaxel	56	4 (7.1)	NR (NE, NE)	50	0 (0.0)	NR (NE, NE)	23406417.934 (0.000, NE)	0.0807
Irinotecan	116	9 (7.8)	NR (NE, NE)	111	3 (2.7)	NR (NE, NE)	2.545 (0.683, 9.479)	0.1485
Interaction								0.9776

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Blood alkaline phosphatase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	4 (6.3)	NR (NE, NE)	57	0 (0.0)	NR (NE, NE)	20169752.646 (0.000, NE)	0.1181
1	192	13 (6.8)	NR (NE, NE)	183	5 (2.7)	NR (NE, NE)	2.271 (0.807, 6.388)	0.1093
Interaction								0.9902

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Blood alkaline phosphatase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #1								
Asia	201	16 (8.0)	NR (NE, NE)	191	4 (2.1)	NR (NE, NE)	3.313 (1.103, 9.955)	0.0235
Europe/North America	54	1 (1.9)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	0.735 (0.045, 11.895)	0.8279
Interaction								0.3733

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Blood alkaline phosphatase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	14 (8.0)	NR (NE, NE)	168	4 (2.4)	NR (NE, NE)	2.999 (0.983, 9.147)	0.0422
Japan	25	2 (8.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	59628177.664 (0.000, NE)	0.2639
Europe/North America	54	1 (1.9)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	0.735 (0.045, 11.895)	0.8279
Interaction								0.7242

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Blood alkaline phosphatase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	16 (7.9)	NR (NE, NE)	198	5 (2.5)	NR (NE, NE)	2.748 (1.002, 7.535)	0.0403
White	52	1 (1.9)	NR (NE, NE)	42	0 (0.0)	NR (NE, NE)	50251318.483 (0.000, NE)	0.4561
Interaction								0.9926

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Blood alkaline phosphatase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	4 (5.0)	NR (NE, NE)	60	1 (1.7)	NR (NE, NE)	2.523 (0.276, 23.072)	0.3966
vCPS < 10%	100	9 (9.0)	NR (NE, NE)	119	3 (2.5)	NR (NE, NE)	3.073 (0.827, 11.420)	0.0775
Missing	75	4 (5.3)	NR (NE, NE)	61	1 (1.6)	NR (NE, NE)	3.078 (0.344, 27.567)	0.2890
Interaction								0.9789

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Investigations / PT - Blood creatine phosphokinase MB increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	6 (3.8)	--	149	1 (0.7)	--	--	--
>= 65 Years	98	5 (5.1)	--	91	0 (0.0)	--	--	--
Interaction								--
Gender								
Male	216	11 (5.1)	NR (NE, NE)	204	1 (0.5)	NR (NE, NE)	7.964 (1.019, 62.270)	0.0193
Female	39	0 (0.0)	NR (NE, NE)	36	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9995

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Investigations / PT - Blood creatine phosphokinase MB increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Smoking Status								
Former/Current Smoker	187	6 (3.2)	--	183	1 (0.5)	--	--	--
Non-Smoker	68	5 (7.4)	--	57	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Investigations / PT - Blood creatine phosphokinase MB increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ICC Options								
Paclitaxel	83	2 (2.4)	--	79	0 (0.0)	--	--	--
Docetaxel	56	1 (1.8)	--	50	0 (0.0)	--	--	--
Irinotecan	116	8 (6.9)	--	111	1 (0.9)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Blood creatine phosphokinase MB increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	3 (4.8)	--	57	0 (0.0)	--	--	--
1	192	8 (4.2)	--	183	1 (0.5)	--	--	--
Interaction								--
Region #1								
Asia	201	11 (5.5)	NR (NE, NE)	191	1 (0.5)	NR (NE, NE)	7.811 (0.997, 61.192)	0.0211
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9994

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

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Safety Analysis Set
Any TEAE: SOC - Investigations / PT - Blood creatine phosphokinase MB increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	10 (5.7)	NR (NE, NE)	168	1 (0.6)	NR (NE, NE)	7.309 (0.924, 57.782)	0.0279
Japan	25	1 (4.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	50648531.709 (0.000, NE)	0.4533
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

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	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	11 (5.4)	NR (NE, NE)	198	1 (0.5)	NR (NE, NE)	8.078 (1.031, 63.260)	0.0184
White	52	0 (0.0)	NR (NE, NE)	42	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9994

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Any TEAE: SOC - Investigations / PT - Blood creatine phosphokinase MB increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	1 (1.3)	--	60	0 (0.0)	--	--	--
vCPS < 10%	100	4 (4.0)	--	119	1 (0.8)	--	--	--
Missing	75	6 (8.0)	--	61	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Blood creatine phosphokinase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	7 (4.5)	--	149	0 (0.0)	--	--	--
>= 65 Years	98	3 (3.1)	--	91	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Blood creatine phosphokinase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Gender								
Male	216	10 (4.6)	NR (NE, NE)	204	0 (0.0)	NR (NE, NE)	25050718.902 (0.000, NE)	0.0066
Female	39	0 (0.0)	NR (NE, NE)	36	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9979

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

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Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Blood creatine phosphokinase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Smoking Status								
Former/Current Smoker	187	7 (3.7)	--	183	0 (0.0)	--	--	--
Non-Smoker	68	3 (4.4)	--	57	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ICC Options								
Paclitaxel	83	2 (2.4)	--	79	0 (0.0)	--	--	--
Docetaxel	56	1 (1.8)	--	50	0 (0.0)	--	--	--
Irinotecan	116	7 (6.0)	--	111	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

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Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Blood creatine phosphokinase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	3 (4.8)	--	57	0 (0.0)	--	--	--
1	192	7 (3.6)	--	183	0 (0.0)	--	--	--
Interaction								--
Region #1								
Asia	201	9 (4.5)	--	191	0 (0.0)	--	--	--
Europe/North America	54	1 (1.9)	--	49	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Investigations / PT - Blood creatine phosphokinase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	8 (4.5)	--	168	0 (0.0)	--	--	--
Japan	25	1 (4.0)	--	23	0 (0.0)	--	--	--
Europe/North America	54	1 (1.9)	--	49	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	203	9 (4.4)	--	198	0 (0.0)	--	--	--
White	52	1 (1.9)	--	42	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

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	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Baseline PD-L1 Status								
vCPS >= 10%	80	3 (3.8)	--	60	0 (0.0)	--	--	--
vCPS < 10%	100	4 (4.0)	--	119	0 (0.0)	--	--	--
Missing	75	3 (4.0)	--	61	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	8 (5.1)	NR (18.6, NE)	149	10 (6.7)	NR (NE, NE)	0.579 (0.219, 1.528)	0.2627
>= 65 Years	98	4 (4.1)	NR (NE, NE)	91	12 (13.2)	NR (NE, NE)	0.273 (0.088, 0.851)	0.0164
Interaction								0.2327
Gender								
Male	216	9 (4.2)	NR (NE, NE)	204	19 (9.3)	NR (NE, NE)	0.349 (0.152, 0.801)	0.0092
Female	39	3 (7.7)	NR (NE, NE)	36	3 (8.3)	NR (NE, NE)	0.824 (0.165, 4.110)	0.8133
Interaction								0.3510

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	9 (4.8)	NR (NE, NE)	183	15 (8.2)	NR (NE, NE)	0.523 (0.228, 1.200)	0.1185
Non-Smoker	68	3 (4.4)	NR (18.6, NE)	57	7 (12.3)	NR (NE, NE)	0.271 (0.069, 1.070)	0.0469
Interaction								0.5898

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	1 (1.2)	NR (NE, NE)	79	4 (5.1)	NR (NE, NE)	0.232 (0.026, 2.074)	0.1520
Docetaxel	56	2 (3.6)	NR (NE, NE)	50	6 (12.0)	NR (NE, NE)	0.262 (0.053, 1.305)	0.0777
Irinotecan	116	9 (7.8)	NR (18.6, NE)	111	12 (10.8)	NR (NE, NE)	0.496 (0.199, 1.234)	0.1236
Interaction								0.5255

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	2 (3.2)	NR (NE, NE)	57	6 (10.5)	NR (NE, NE)	0.241 (0.048, 1.210)	0.0613
1	192	10 (5.2)	NR (NE, NE)	183	16 (8.7)	NR (NE, NE)	0.494 (0.221, 1.107)	0.0801
Interaction								0.4386
Region #1								
Asia	201	10 (5.0)	NR (NE, NE)	191	18 (9.4)	NR (NE, NE)	0.411 (0.186, 0.909)	0.0233
Europe/North America	54	2 (3.7)	NR (NE, NE)	49	4 (8.2)	NR (NE, NE)	0.428 (0.078, 2.337)	0.3104
Interaction								0.9364

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	10 (5.7)	NR (NE, NE)	168	16 (9.5)	NR (NE, NE)	0.458 (0.204, 1.030)	0.0530
Japan	25	0 (0.0)	NR (NE, NE)	23	2 (8.7)	NR (NE, NE)	0.000 (0.000, NE)	0.1361
Europe/North America	54	2 (3.7)	NR (NE, NE)	49	4 (8.2)	NR (NE, NE)	0.428 (0.078, 2.337)	0.3104
Interaction								0.9775

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	203	10 (4.9)	NR (NE, NE)	198	19 (9.6)	NR (NE, NE)	0.402 (0.183, 0.883)	0.0189
White	52	2 (3.8)	NR (NE, NE)	42	3 (7.1)	NR (NE, NE)	0.510 (0.085, 3.055)	0.4497
Interaction								0.9045

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	2 (2.5)	NR (NE, NE)	60	4 (6.7)	NR (NE, NE)	0.342 (0.062, 1.869)	0.1936
vCPS < 10%	100	6 (6.0)	NR (NE, NE)	119	14 (11.8)	NR (NE, NE)	0.444 (0.170, 1.159)	0.0872
Missing	75	4 (5.3)	NR (18.6, NE)	61	4 (6.6)	NR (NE, NE)	0.489 (0.107, 2.224)	0.3451
Interaction								0.7668

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	5 (3.2)	NR (NE, NE)	149	57 (38.3)	NR (2.4, NE)	0.063 (0.025, 0.157)	<0.0001
>= 65 Years	98	1 (1.0)	NR (NE, NE)	91	37 (40.7)	NR (2.1, NE)	0.019 (0.003, 0.142)	<0.0001
Interaction								0.2874
Gender								
Male	216	4 (1.9)	NR (NE, NE)	204	83 (40.7)	NR (2.4, NE)	0.033 (0.012, 0.092)	<0.0001
Female	39	2 (5.1)	NR (NE, NE)	36	11 (30.6)	NR (NE, NE)	0.147 (0.033, 0.666)	0.0036
Interaction								0.1265

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	3 (1.6)	NR (NE, NE)	183	71 (38.8)	NR (2.8, NE)	0.030 (0.009, 0.096)	<0.0001
Non-Smoker	68	3 (4.4)	NR (NE, NE)	57	23 (40.4)	NR (1.2, NE)	0.091 (0.027, 0.304)	<0.0001
Interaction								0.2274

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	1 (1.2)	NR (NE, NE)	79	30 (38.0)	NR (2.4, NE)	0.025 (0.003, 0.182)	<0.0001
Docetaxel	56	0 (0.0)	NR (NE, NE)	50	25 (50.0)	2.8 (0.3, NE)	0.000 (0.000, NE)	<0.0001
Irinotecan	116	5 (4.3)	NR (NE, NE)	111	39 (35.1)	NR (2.1, NE)	0.098 (0.038, 0.249)	<0.0001
Interaction								0.4746

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	2 (3.2)	NR (NE, NE)	57	22 (38.6)	NR (1.3, NE)	0.063 (0.015, 0.268)	<0.0001
1	192	4 (2.1)	NR (NE, NE)	183	72 (39.3)	NR (2.8, NE)	0.040 (0.015, 0.110)	<0.0001
Interaction								0.6084
Region #1								
Asia	201	5 (2.5)	NR (NE, NE)	191	89 (46.6)	2.8 (1.2, NE)	0.038 (0.015, 0.094)	<0.0001
Europe/North America	54	1 (1.9)	NR (NE, NE)	49	5 (10.2)	NR (NE, NE)	0.159 (0.019, 1.364)	0.0543
Interaction								0.2087

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	5 (2.8)	NR (NE, NE)	168	76 (45.2)	2.8 (1.2, NE)	0.045 (0.018, 0.112)	<0.0001
Japan	25	0 (0.0)	NR (NE, NE)	23	13 (56.5)	0.8 (0.5, NE)	0.000 (0.000, NE)	<0.0001
Europe/North America	54	1 (1.9)	NR (NE, NE)	49	5 (10.2)	NR (NE, NE)	0.159 (0.019, 1.364)	0.0543
Interaction								0.5434

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	203	5 (2.5)	NR (NE, NE)	198	90 (45.5)	3.0 (1.2, NE)	0.039 (0.016, 0.097)	<0.0001
White	52	1 (1.9)	NR (NE, NE)	42	4 (9.5)	NR (NE, NE)	0.173 (0.019, 1.554)	0.0756
Interaction								0.1949

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	2 (2.5)	NR (NE, NE)	60	27 (45.0)	2.8 (1.0, NE)	0.036 (0.008, 0.152)	<0.0001
vCPS < 10%	100	2 (2.0)	NR (NE, NE)	119	43 (36.1)	NR (NE, NE)	0.043 (0.010, 0.180)	<0.0001
Missing	75	2 (2.7)	NR (NE, NE)	61	24 (39.3)	NR (1.0, NE)	0.057 (0.013, 0.242)	<0.0001
Interaction								0.9672

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	6 (3.8)	NR (NE, NE)	149	63 (42.3)	NR (0.9, NE)	0.066 (0.028, 0.153)	<0.0001
>= 65 Years	98	3 (3.1)	NR (NE, NE)	91	35 (38.5)	NR (1.5, NE)	0.064 (0.020, 0.210)	<0.0001
Interaction								0.8870
Gender								
Male	216	7 (3.2)	NR (NE, NE)	204	85 (41.7)	NR (NE, NE)	0.058 (0.027, 0.126)	<0.0001
Female	39	2 (5.1)	NR (NE, NE)	36	13 (36.1)	NR (0.5, NE)	0.120 (0.027, 0.532)	0.0007
Interaction								0.4631

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	5 (2.7)	NR (NE, NE)	183	69 (37.7)	NR (NE, NE)	0.054 (0.022, 0.134)	<0.0001
Non-Smoker	68	4 (5.9)	NR (NE, NE)	57	29 (50.9)	1.2 (0.5, NE)	0.086 (0.030, 0.246)	<0.0001
Interaction								0.5484

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	0 (0.0)	NR (NE, NE)	79	21 (26.6)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Docetaxel	56	4 (7.1)	NR (NE, NE)	50	27 (54.0)	0.8 (0.3, NE)	0.091 (0.031, 0.262)	<0.0001
Irinotecan	116	5 (4.3)	NR (NE, NE)	111	50 (45.0)	NR (0.9, NE)	0.068 (0.027, 0.171)	<0.0001
Interaction								0.9718

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	3 (4.8)	NR (NE, NE)	57	25 (43.9)	NR (0.8, NE)	0.079 (0.024, 0.265)	<0.0001
1	192	6 (3.1)	NR (NE, NE)	183	73 (39.9)	NR (NE, NE)	0.061 (0.026, 0.140)	<0.0001
Interaction								0.6383
Region #1								
Asia	201	9 (4.5)	NR (NE, NE)	191	96 (50.3)	1.2 (0.7, NE)	0.061 (0.031, 0.122)	<0.0001
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	2 (4.1)	NR (NE, NE)	0.000 (0.000, NE)	0.1344
Interaction								0.9818

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Region #2								
Asia (excluding Japan)	176	8 (4.5)	NR (NE, NE)	168	84 (50.0)	1.2 (0.7, NE)	0.061 (0.029, 0.127)	<0.0001
Japan	25	1 (4.0)	NR (NE, NE)	23	12 (52.2)	0.8 (0.5, NE)	0.060 (0.008, 0.464)	0.0002
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	2 (4.1)	NR (NE, NE)	0.000 (0.000, NE)	0.1344
Interaction								0.9891

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	9 (4.4)	NR (NE, NE)	198	97 (49.0)	NR (0.7, NE)	0.063 (0.032, 0.126)	<0.0001
White	52	0 (0.0)	NR (NE, NE)	42	1 (2.4)	NR (NE, NE)	0.000 (0.000, NE)	0.2611
Interaction								0.9828

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	5 (6.3)	NR (NE, NE)	60	21 (35.0)	NR (1.5, NE)	0.131 (0.049, 0.349)	<0.0001
vCPS < 10%	100	3 (3.0)	NR (NE, NE)	119	47 (39.5)	NR (NE, NE)	0.057 (0.018, 0.185)	<0.0001
Missing	75	1 (1.3)	NR (NE, NE)	61	30 (49.2)	NR (0.5, NE)	0.021 (0.003, 0.157)	<0.0001
Interaction								0.1995

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	75 (47.8)	4.9 (2.1, 13.8)	149	87 (58.4)	1.2 (0.7, 2.2)	0.577 (0.420, 0.791)	0.0005
>= 65 Years	98	41 (41.8)	8.6 (3.4, NE)	91	54 (59.3)	1.5 (0.7, 5.7)	0.454 (0.299, 0.690)	0.0001
Interaction								0.4826
Gender								
Male	216	98 (45.4)	8.3 (3.4, 13.8)	204	121 (59.3)	1.2 (0.7, 2.2)	0.516 (0.393, 0.678)	<0.0001
Female	39	18 (46.2)	2.8 (1.5, NE)	36	20 (55.6)	1.2 (0.5, NE)	0.650 (0.341, 1.237)	0.1800
Interaction								0.7253

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	87 (46.5)	5.5 (2.9, 13.8)	183	110 (60.1)	1.2 (0.7, 2.2)	0.526 (0.395, 0.702)	<0.0001
Non-Smoker	68	29 (42.6)	8.6 (2.3, NE)	57	31 (54.4)	1.2 (0.5, 5.7)	0.554 (0.331, 0.929)	0.0218
Interaction								0.9356

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	28 (33.7)	NR (8.3, NE)	79	36 (45.6)	4.8 (2.3, NE)	0.607 (0.366, 1.007)	0.0491
Docetaxel	56	31 (55.4)	3.7 (1.4, 9.0)	50	31 (62.0)	1.2 (0.5, 3.7)	0.549 (0.326, 0.926)	0.0198
Irinotecan	116	57 (49.1)	3.3 (2.1, 14.0)	111	74 (66.7)	0.7 (0.5, 1.1)	0.416 (0.291, 0.595)	<0.0001
Interaction								0.3333

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	20 (31.7)	14.0 (8.6, NE)	57	32 (56.1)	3.7 (0.7, 6.6)	0.351 (0.196, 0.631)	0.0002
1	192	96 (50.0)	3.4 (2.1, 7.7)	183	109 (59.6)	1.2 (0.7, 2.0)	0.584 (0.441, 0.772)	0.0001
Interaction								0.1531
Region #1								
Asia	201	95 (47.3)	5.5 (2.8, 13.8)	191	120 (62.8)	0.9 (0.6, 1.3)	0.478 (0.363, 0.631)	<0.0001
Europe/North America	54	21 (38.9)	9.0 (4.2, NE)	49	21 (42.9)	4.2 (2.8, 6.6)	0.736 (0.397, 1.365)	0.3252
Interaction								0.1182

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	89 (50.6)	3.4 (2.1, 8.3)	168	109 (64.9)	0.7 (0.5, 1.2)	0.495 (0.371, 0.659)	<0.0001
Japan	25	6 (24.0)	NR (10.2, NE)	23	11 (47.8)	NR (0.7, NE)	0.258 (0.082, 0.817)	0.0122
Europe/North America	54	21 (38.9)	9.0 (4.2, NE)	49	21 (42.9)	4.2 (2.8, 6.6)	0.736 (0.397, 1.365)	0.3252
Interaction								0.2184

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	96 (47.3)	5.5 (2.8, 13.8)	198	121 (61.1)	1.0 (0.7, 1.4)	0.506 (0.384, 0.666)	<0.0001
White	52	20 (38.5)	9.0 (4.2, NE)	42	20 (47.6)	3.7 (1.9, 6.6)	0.634 (0.337, 1.193)	0.1506
Interaction								0.3693

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	30 (37.5)	14.0 (4.1, NE)	60	37 (61.7)	1.1 (0.5, 2.3)	0.341 (0.205, 0.567)	<0.0001
vCPS < 10%	100	50 (50.0)	4.9 (2.1, 9.0)	119	66 (55.5)	1.9 (0.8, 4.2)	0.700 (0.483, 1.014)	0.0558
Missing	75	36 (48.0)	4.2 (2.3, 13.8)	61	38 (62.3)	1.2 (0.5, 3.5)	0.537 (0.338, 0.854)	0.0069
Interaction								0.0667

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	30 (19.1)	NR (14.0, NE)	149	52 (34.9)	6.6 (3.7, NE)	0.391 (0.246, 0.620)	<0.0001
>= 65 Years	98	10 (10.2)	NR (NE, NE)	91	32 (35.2)	5.7 (3.4, NE)	0.206 (0.100, 0.424)	<0.0001
Interaction								0.1522
Gender								
Male	216	34 (15.7)	NR (NE, NE)	204	74 (36.3)	5.7 (3.7, NE)	0.304 (0.200, 0.461)	<0.0001
Female	39	6 (15.4)	NR (NE, NE)	36	10 (27.8)	NR (2.8, NE)	0.422 (0.150, 1.193)	0.0932
Interaction								0.5539

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	35 (18.7)	NR (NE, NE)	183	71 (38.8)	5.7 (3.5, NE)	0.335 (0.221, 0.508)	<0.0001
Non-Smoker	68	5 (7.4)	NR (NE, NE)	57	13 (22.8)	NR (3.4, NE)	0.240 (0.085, 0.683)	0.0037
Interaction								0.5660

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	15 (18.1)	NR (NE, NE)	79	23 (29.1)	6.6 (5.7, NE)	0.511 (0.265, 0.985)	0.0406
Docetaxel	56	12 (21.4)	NR (9.0, NE)	50	16 (32.0)	NR (3.2, NE)	0.478 (0.221, 1.033)	0.0534
Irinotecan	116	13 (11.2)	NR (NE, NE)	111	45 (40.5)	3.4 (2.0, NE)	0.168 (0.088, 0.322)	<0.0001
Interaction								0.0213

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	9 (14.3)	NR (14.0, NE)	57	21 (36.8)	6.6 (3.7, NE)	0.247 (0.108, 0.565)	0.0003
1	192	31 (16.1)	NR (NE, NE)	183	63 (34.4)	5.7 (3.4, NE)	0.343 (0.222, 0.531)	<0.0001
Interaction								0.6293
Region #1								
Asia	201	29 (14.4)	NR (NE, NE)	191	65 (34.0)	NR (3.5, NE)	0.306 (0.196, 0.479)	<0.0001
Europe/North America	54	11 (20.4)	NR (9.0, NE)	49	19 (38.8)	5.7 (2.8, NE)	0.375 (0.175, 0.802)	0.0084
Interaction								0.4021

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	28 (15.9)	NR (NE, NE)	168	60 (35.7)	NR (3.4, NE)	0.320 (0.202, 0.505)	<0.0001
Japan	25	1 (4.0)	NR (NE, NE)	23	5 (21.7)	NR (NE, NE)	0.179 (0.021, 1.537)	0.0740
Europe/North America	54	11 (20.4)	NR (9.0, NE)	49	19 (38.8)	5.7 (2.8, NE)	0.375 (0.175, 0.802)	0.0084
Interaction								0.5292

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Safety Analysis Set
Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	29 (14.3)	NR (NE, NE)	198	66 (33.3)	NR (5.7, NE)	0.310 (0.199, 0.485)	<0.0001
White	52	11 (21.2)	NR (9.0, NE)	42	18 (42.9)	4.2 (2.6, NE)	0.348 (0.162, 0.749)	0.0047
Interaction								0.5759

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	12 (15.0)	NR (NE, NE)	60	23 (38.3)	5.7 (2.9, NE)	0.253 (0.123, 0.521)	<0.0001
vCPS < 10%	100	21 (21.0)	NR (9.0, NE)	119	40 (33.6)	5.7 (3.7, NE)	0.466 (0.273, 0.795)	0.0040
Missing	75	7 (9.3)	NR (NE, NE)	61	21 (34.4)	NR (3.5, NE)	0.214 (0.091, 0.507)	0.0001
Interaction								0.1301

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Metabolism and nutrition disorders / PT - Hyponatraemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	22 (14.0)	NR (14.5, NE)	149	19 (12.8)	NR (NE, NE)	0.810 (0.429, 1.529)	0.5128
>= 65 Years	98	10 (10.2)	NR (NE, NE)	91	14 (15.4)	NR (6.9, NE)	0.460 (0.193, 1.095)	0.0717
Interaction								0.2572
Gender								
Male	216	28 (13.0)	NR (17.2, NE)	204	26 (12.7)	NR (NE, NE)	0.714 (0.408, 1.248)	0.2328
Female	39	4 (10.3)	NR (NE, NE)	36	7 (19.4)	NR (NE, NE)	0.492 (0.144, 1.685)	0.2448
Interaction								0.3150

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Metabolism and nutrition disorders / PT - Hyponatraemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	24 (12.8)	NR (NE, NE)	183	21 (11.5)	NR (NE, NE)	0.823 (0.449, 1.509)	0.5270
Non-Smoker	68	8 (11.8)	NR (17.2, NE)	57	12 (21.1)	NR (4.8, NE)	0.384 (0.147, 1.002)	0.0418
Interaction								0.2051

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Metabolism and nutrition disorders / PT - Hyponatraemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	3 (3.6)	NR (NE, NE)	79	3 (3.8)	NR (NE, NE)	0.860 (0.172, 4.291)	0.8540
Docetaxel	56	9 (16.1)	NR (9.0, NE)	50	5 (10.0)	NR (NE, NE)	1.040 (0.327, 3.301)	0.9472
Irinotecan	116	20 (17.2)	NR (14.5, NE)	111	25 (22.5)	NR (3.9, NE)	0.491 (0.262, 0.922)	0.0229
Interaction								0.3924

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders / PT - Hyponatraemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	5 (7.9)	NR (14.5, NE)	57	5 (8.8)	NR (NE, NE)	0.524 (0.136, 2.012)	0.3389
1	192	27 (14.1)	NR (17.2, NE)	183	28 (15.3)	NR (6.9, NE)	0.687 (0.397, 1.187)	0.1737
Interaction								0.9793
Region #1								
Asia	201	30 (14.9)	NR (17.2, NE)	191	32 (16.8)	NR (NE, NE)	0.614 (0.364, 1.036)	0.0640
Europe/North America	54	2 (3.7)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	1.552 (0.139, 17.293)	0.7178
Interaction								0.4707

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders / PT - Hyponatraemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	28 (15.9)	NR (14.5, NE)	168	30 (17.9)	NR (6.9, NE)	0.616 (0.359, 1.058)	0.0748
Japan	25	2 (8.0)	NR (10.6, NE)	23	2 (8.7)	NR (NE, NE)	0.589 (0.073, 4.782)	0.6172
Europe/North America	54	2 (3.7)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	1.552 (0.139, 17.293)	0.7178
Interaction								0.7723

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Metabolism and nutrition disorders / PT - Hyponatraemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	31 (15.3)	NR (17.2, NE)	198	32 (16.2)	NR (NE, NE)	0.663 (0.395, 1.112)	0.1151
White	52	1 (1.9)	NR (NE, NE)	42	1 (2.4)	NR (4.8, NE)	0.644 (0.040, 10.446)	0.7552
Interaction								0.9908

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders / PT - Hyponatraemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	7 (8.8)	NR (14.5, NE)	60	7 (11.7)	NR (NE, NE)	0.474 (0.155, 1.446)	0.1787
vCPS < 10%	100	15 (15.0)	NR (NE, NE)	119	17 (14.3)	NR (NE, NE)	0.883 (0.438, 1.780)	0.7268
Missing	75	10 (13.3)	NR (13.8, NE)	61	9 (14.8)	NR (6.9, NE)	0.634 (0.244, 1.653)	0.3456
Interaction								0.7165

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Musculoskeletal and connective tissue disorders / PT - Myalgia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	5 (3.2)	NR (NE, NE)	149	7 (4.7)	NR (NE, NE)	0.663 (0.210, 2.090)	0.4794
>= 65 Years	98	2 (2.0)	NR (NE, NE)	91	7 (7.7)	NR (NE, NE)	0.150 (0.027, 0.835)	0.0162
Interaction								0.3080
Gender								
Male	216	7 (3.2)	NR (NE, NE)	204	12 (5.9)	NR (NE, NE)	0.428 (0.159, 1.151)	0.0830
Female	39	0 (0.0)	NR (NE, NE)	36	2 (5.6)	NR (NE, NE)	0.000 (0.000, NE)	0.1382
Interaction								0.9918

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Musculoskeletal and connective tissue disorders / PT - Myalgia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	7 (3.7)	NR (NE, NE)	183	14 (7.7)	NR (NE, NE)	0.377 (0.144, 0.990)	0.0393
Non-Smoker	68	0 (0.0)	NR (NE, NE)	57	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9998

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Musculoskeletal and connective tissue disorders / PT - Myalgia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	4 (4.8)	NR (NE, NE)	79	11 (13.9)	NR (NE, NE)	0.302 (0.095, 0.959)	0.0309
Docetaxel	56	0 (0.0)	NR (NE, NE)	50	3 (6.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0631
Irinotecan	116	3 (2.6)	NR (NE, NE)	111	0 (0.0)	NR (NE, NE)	28387187.655 (0.000, NE)	0.1661
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Musculoskeletal and connective tissue disorders / PT - Myalgia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	1 (1.6)	NR (NE, NE)	57	2 (3.5)	NR (NE, NE)	0.444 (0.040, 4.901)	0.4962
1	192	6 (3.1)	NR (NE, NE)	183	12 (6.6)	NR (NE, NE)	0.367 (0.131, 1.028)	0.0474
Interaction								0.9142

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Musculoskeletal and connective tissue disorders / PT - Myalgia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #1								
Asia	201	5 (2.5)	NR (NE, NE)	191	14 (7.3)	NR (NE, NE)	0.300 (0.107, 0.845)	0.0157
Europe/North America	54	2 (3.7)	NR (13.2, NE)	49	0 (0.0)	NR (NE, NE)	26442990.638 (0.000, NE)	0.3458
Interaction								0.9911

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Musculoskeletal and connective tissue disorders / PT - Myalgia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	5 (2.8)	NR (NE, NE)	168	11 (6.5)	NR (NE, NE)	0.383 (0.131, 1.119)	0.0683
Japan	25	0 (0.0)	NR (NE, NE)	23	3 (13.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0648
Europe/North America	54	2 (3.7)	NR (13.2, NE)	49	0 (0.0)	NR (NE, NE)	26442990.638 (0.000, NE)	0.3458
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Musculoskeletal and connective tissue disorders / PT - Myalgia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	5 (2.5)	NR (NE, NE)	198	14 (7.1)	NR (NE, NE)	0.310 (0.110, 0.871)	0.0189
White	52	2 (3.8)	NR (13.2, NE)	42	0 (0.0)	NR (NE, NE)	23828168.300 (0.000, NE)	0.3746
Interaction								0.9871

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Musculoskeletal and connective tissue disorders / PT - Myalgia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	4 (5.0)	--	60	4 (6.7)	--	--	--
vCPS < 10%	100	2 (2.0)	--	119	6 (5.0)	--	--	--
Missing	75	1 (1.3)	--	61	4 (6.6)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Neoplasms benign, malignant and unspecified (incl cysts and polyps)

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	11 (7.0)	NR (NE, NE)	149	5 (3.4)	NR (NE, NE)	1.684 (0.580, 4.885)	0.3324
>= 65 Years	98	12 (12.2)	NR (NE, NE)	91	3 (3.3)	NR (NE, NE)	3.564 (1.004, 12.649)	0.0357
Interaction								0.4282
Gender								
Male	216	18 (8.3)	NR (NE, NE)	204	6 (2.9)	NR (NE, NE)	2.334 (0.920, 5.918)	0.0661
Female	39	5 (12.8)	NR (NE, NE)	36	2 (5.6)	NR (NE, NE)	2.421 (0.470, 12.481)	0.2750
Interaction								0.9515

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Neoplasms benign, malignant and unspecified (incl cysts and polyps)

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	16 (8.6)	NR (NE, NE)	183	5 (2.7)	NR (NE, NE)	2.611 (0.950, 7.177)	0.0535
Non-Smoker	68	7 (10.3)	NR (NE, NE)	57	3 (5.3)	NR (NE, NE)	1.886 (0.487, 7.306)	0.3504
Interaction								0.6597

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Safety Analysis Set
Any TEAE: SOC - Neoplasms benign, malignant and unspecified (incl cysts and polyps)

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	9 (10.8)	NR (NE, NE)	79	3 (3.8)	NR (NE, NE)	2.890 (0.782, 10.685)	0.0953
Docetaxel	56	5 (8.9)	NR (NE, NE)	50	1 (2.0)	NR (NE, NE)	4.017 (0.468, 34.460)	0.1700
Irinotecan	116	9 (7.8)	NR (NE, NE)	111	4 (3.6)	NR (NE, NE)	1.501 (0.451, 4.997)	0.5054
Interaction								0.7549

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Neoplasms benign, malignant and unspecified (incl cysts and polyps)

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	4 (6.3)	NR (NE, NE)	57	2 (3.5)	NR (NE, NE)	1.801 (0.330, 9.832)	0.4909
1	192	19 (9.9)	NR (NE, NE)	183	6 (3.3)	NR (NE, NE)	2.523 (1.001, 6.362)	0.0423
Interaction								0.6368
Region #1								
Asia	201	14 (7.0)	NR (NE, NE)	191	6 (3.1)	NR (NE, NE)	1.737 (0.660, 4.570)	0.2574
Europe/North America	54	9 (16.7)	NR (NE, NE)	49	2 (4.1)	NR (NE, NE)	4.225 (0.913, 19.556)	0.0448
Interaction								0.3925

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Safety Analysis Set

Any TEAE: SOC - Neoplasms benign, malignant and unspecified (incl cysts and polyps)

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	10 (5.7)	NR (NE, NE)	168	5 (3.0)	NR (NE, NE)	1.450 (0.488, 4.303)	0.5012
Japan	25	4 (16.0)	NR (NE, NE)	23	1 (4.3)	NR (4.3, NE)	3.227 (0.354, 29.446)	0.2731
Europe/North America	54	9 (16.7)	NR (NE, NE)	49	2 (4.1)	NR (NE, NE)	4.225 (0.913, 19.556)	0.0448
Interaction								0.5737

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Neoplasms benign, malignant and unspecified (incl cysts and polyps)

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	203	14 (6.9)	NR (NE, NE)	198	6 (3.0)	NR (NE, NE)	1.797 (0.683, 4.727)	0.2284
White	52	9 (17.3)	NR (NE, NE)	42	2 (4.8)	NR (NE, NE)	3.737 (0.807, 17.296)	0.0701
Interaction								0.4915

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Neoplasms benign, malignant and unspecified (incl cysts and polyps)

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	9 (11.3)	NR (NE, NE)	60	1 (1.7)	NR (NE, NE)	6.120 (0.774, 48.373)	0.0499
vCPS < 10%	100	7 (7.0)	NR (NE, NE)	119	4 (3.4)	NR (NE, NE)	1.759 (0.512, 6.044)	0.3639
Missing	75	7 (9.3)	NR (NE, NE)	61	3 (4.9)	NR (NE, NE)	1.485 (0.369, 5.977)	0.5755
Interaction								0.6053

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	19 (12.1)	NR (17.8, NE)	149	35 (23.5)	9.7 (9.7, NE)	0.360 (0.199, 0.649)	0.0004
>= 65 Years	98	14 (14.3)	NR (20.6, NE)	91	28 (30.8)	7.4 (5.3, NE)	0.291 (0.149, 0.567)	0.0001
Interaction								0.7522
Gender								
Male	216	23 (10.6)	NR (20.6, NE)	204	50 (24.5)	9.7 (7.4, NE)	0.261 (0.153, 0.446)	<0.0001
Female	39	10 (25.6)	NR (3.5, NE)	36	13 (36.1)	NR (2.2, NE)	0.557 (0.241, 1.290)	0.1648
Interaction								0.1666

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	23 (12.3)	NR (22.6, NE)	183	47 (25.7)	7.4 (5.3, NE)	0.313 (0.184, 0.531)	<0.0001
Non-Smoker	68	10 (14.7)	17.8 (8.3, NE)	57	16 (28.1)	NR (2.2, NE)	0.353 (0.157, 0.796)	0.0089
Interaction								0.6580

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	13 (15.7)	NR (NE, NE)	79	36 (45.6)	2.8 (1.4, NE)	0.230 (0.120, 0.438)	<0.0001
Docetaxel	56	9 (16.1)	20.6 (17.8, NE)	50	7 (14.0)	NR (NE, NE)	0.932 (0.344, 2.526)	0.8898
Irinotecan	116	11 (9.5)	NR (22.6, NE)	111	20 (18.0)	7.4 (5.3, NE)	0.293 (0.130, 0.662)	0.0019
Interaction								0.0395

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	4 (6.3)	NR (20.6, NE)	57	21 (36.8)	7.4 (2.8, NE)	0.079 (0.023, 0.273)	<0.0001
1	192	29 (15.1)	NR (17.8, NE)	183	42 (23.0)	9.7 (5.3, NE)	0.460 (0.282, 0.750)	0.0014
Interaction								0.0086
Region #1								
Asia	201	18 (9.0)	NR (22.6, NE)	191	44 (23.0)	9.7 (5.3, NE)	0.246 (0.138, 0.437)	<0.0001
Europe/North America	54	15 (27.8)	NR (6.2, NE)	49	19 (38.8)	7.4 (1.4, NE)	0.496 (0.244, 1.005)	0.0468
Interaction								0.0733

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	17 (9.7)	NR (20.6, NE)	168	35 (20.8)	9.7 (5.3, NE)	0.305 (0.167, 0.558)	<0.0001
Japan	25	1 (4.0)	NR (NE, NE)	23	9 (39.1)	2.8 (1.0, NE)	0.060 (0.007, 0.486)	0.0005
Europe/North America	54	15 (27.8)	NR (6.2, NE)	49	19 (38.8)	7.4 (1.4, NE)	0.496 (0.244, 1.005)	0.0468
Interaction								0.0618

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	18 (8.9)	NR (22.6, NE)	198	45 (22.7)	9.7 (5.3, NE)	0.248 (0.140, 0.440)	<0.0001
White	52	15 (28.8)	NR (6.2, NE)	42	18 (42.9)	7.4 (1.0, NE)	0.452 (0.221, 0.922)	0.0249
Interaction								0.1263

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	9 (11.3)	NR (NE, NE)	60	12 (20.0)	9.7 (9.7, NE)	0.373 (0.151, 0.921)	0.0265
vCPS < 10%	100	17 (17.0)	17.8 (8.3, NE)	119	29 (24.4)	NR (7.4, NE)	0.501 (0.270, 0.930)	0.0255
Missing	75	7 (9.3)	NR (20.6, NE)	61	22 (36.1)	5.3 (2.8, NE)	0.124 (0.046, 0.332)	<0.0001
Interaction								0.0519

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders / PT - Dizziness

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	4 (2.5)	NR (NE, NE)	149	13 (8.7)	NR (NE, NE)	0.244 (0.079, 0.755)	0.0082
>= 65 Years	98	7 (7.1)	NR (NE, NE)	91	6 (6.6)	NR (NE, NE)	0.827 (0.270, 2.533)	0.7382
Interaction								0.1020
Gender								
Male	216	7 (3.2)	NR (NE, NE)	204	14 (6.9)	NR (NE, NE)	0.387 (0.154, 0.974)	0.0367
Female	39	4 (10.3)	NR (8.3, NE)	36	5 (13.9)	NR (NE, NE)	0.583 (0.153, 2.213)	0.4226
Interaction								0.5156

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders / PT - Dizziness

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	6 (3.2)	NR (NE, NE)	183	13 (7.1)	NR (NE, NE)	0.371 (0.139, 0.988)	0.0391
Non-Smoker	68	5 (7.4)	NR (NE, NE)	57	6 (10.5)	NR (NE, NE)	0.507 (0.150, 1.719)	0.2670
Interaction								0.5462

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders / PT - Dizziness

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	6 (7.2)	NR (NE, NE)	79	5 (6.3)	NR (NE, NE)	0.946 (0.284, 3.150)	0.9281
Docetaxel	56	2 (3.6)	NR (NE, NE)	50	2 (4.0)	NR (NE, NE)	0.669 (0.093, 4.800)	0.6872
Irinotecan	116	3 (2.6)	NR (NE, NE)	111	12 (10.8)	NR (NE, NE)	0.167 (0.046, 0.616)	0.0027
Interaction								0.1396

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders / PT - Dizziness

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	2 (3.2)	NR (NE, NE)	57	5 (8.8)	NR (NE, NE)	0.267 (0.050, 1.414)	0.0975
1	192	9 (4.7)	NR (NE, NE)	183	14 (7.7)	NR (NE, NE)	0.489 (0.208, 1.149)	0.0941
Interaction								0.5661
Region #1								
Asia	201	4 (2.0)	NR (NE, NE)	191	16 (8.4)	NR (NE, NE)	0.196 (0.064, 0.597)	0.0015
Europe/North America	54	7 (13.0)	NR (8.3, NE)	49	3 (6.1)	NR (NE, NE)	1.753 (0.449, 6.848)	0.4131
Interaction								0.0088

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders / PT - Dizziness

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	4 (2.3)	NR (NE, NE)	168	15 (8.9)	NR (NE, NE)	0.216 (0.071, 0.662)	0.0033
Japan	25	0 (0.0)	NR (NE, NE)	23	1 (4.3)	NR (2.4, NE)	0.000 (0.000, NE)	0.1573
Europe/North America	54	7 (13.0)	NR (8.3, NE)	49	3 (6.1)	NR (NE, NE)	1.753 (0.449, 6.848)	0.4131
Interaction								0.0408

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders / PT - Dizziness

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	4 (2.0)	NR (NE, NE)	198	16 (8.1)	NR (NE, NE)	0.202 (0.066, 0.615)	0.0019
White	52	7 (13.5)	NR (8.3, NE)	42	3 (7.1)	NR (NE, NE)	1.552 (0.398, 6.053)	0.5236
Interaction								0.0146

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders / PT - Dizziness

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	6 (7.5)	NR (NE, NE)	60	2 (3.3)	NR (NE, NE)	1.850 (0.368, 9.292)	0.4483
vCPS < 10%	100	4 (4.0)	NR (NE, NE)	119	12 (10.1)	NR (NE, NE)	0.303 (0.096, 0.954)	0.0312
Missing	75	1 (1.3)	NR (NE, NE)	61	5 (8.2)	NR (NE, NE)	0.132 (0.015, 1.150)	0.0321
Interaction								0.1148

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders / PT - Peripheral sensory neuropathy

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	1 (0.6)	NR (NE, NE)	149	10 (6.7)	NR (9.7, NE)	0.068 (0.008, 0.548)	0.0012
>= 65 Years	98	1 (1.0)	NR (NE, NE)	91	13 (14.3)	NR (NE, NE)	0.058 (0.008, 0.445)	0.0002
Interaction								0.8462
Gender								
Male	216	0 (0.0)	NR (NE, NE)	204	19 (9.3)	NR (9.7, NE)	0.000 (0.000, NE)	<0.0001
Female	39	2 (5.1)	NR (NE, NE)	36	4 (11.1)	NR (NE, NE)	0.389 (0.071, 2.149)	0.2622
Interaction								0.9885

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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Safety Analysis Set
Any TEAE: SOC - Nervous system disorders / PT - Peripheral sensory neuropathy

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	2 (1.1)	NR (NE, NE)	183	19 (10.4)	NR (9.7, NE)	0.070 (0.016, 0.306)	<0.0001
Non-Smoker	68	0 (0.0)	NR (NE, NE)	57	4 (7.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0262
Interaction								0.9913

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Safety Analysis Set
Any TEAE: SOC - Nervous system disorders / PT - Peripheral sensory neuropathy

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	1 (1.2)	NR (NE, NE)	79	19 (24.1)	9.7 (9.7, NE)	0.035 (0.005, 0.266)	<0.0001
Docetaxel	56	0 (0.0)	NR (NE, NE)	50	3 (6.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0608
Irinotecan	116	1 (0.9)	NR (NE, NE)	111	1 (0.9)	NR (NE, NE)	0.950 (0.059, 15.190)	0.9711
Interaction								0.2390

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	0 (0.0)	NR (NE, NE)	57	8 (14.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0014
1	192	2 (1.0)	NR (NE, NE)	183	15 (8.2)	NR (9.7, NE)	0.081 (0.018, 0.370)	<0.0001
Interaction								0.9908
Region #1								
Asia	201	0 (0.0)	NR (NE, NE)	191	14 (7.3)	NR (9.7, NE)	0.000 (0.000, NE)	<0.0001
Europe/North America	54	2 (3.7)	NR (NE, NE)	49	9 (18.4)	NR (NE, NE)	0.176 (0.038, 0.815)	0.0122
Interaction								0.9889

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-aesocpt-sub.sas 21AUG2024 22:54 t-14-03-01-02-02-02-01-s-aesocpt-sub-safety-sa.rtf

Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders / PT - Peripheral sensory neuropathy

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	0 (0.0)	NR (NE, NE)	168	7 (4.2)	NR (9.7, NE)	0.000 (0.000, NE)	0.0003
Japan	25	0 (0.0)	NR (NE, NE)	23	7 (30.4)	NR (1.0, NE)	0.000 (0.000, NE)	0.0015
Europe/North America	54	2 (3.7)	NR (NE, NE)	49	9 (18.4)	NR (NE, NE)	0.176 (0.038, 0.815)	0.0122
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Nervous system disorders / PT - Peripheral sensory neuropathy

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	0 (0.0)	NR (NE, NE)	198	15 (7.6)	NR (9.7, NE)	0.000 (0.000, NE)	<0.0001
White	52	2 (3.8)	NR (NE, NE)	42	8 (19.0)	NR (NE, NE)	0.175 (0.037, 0.827)	0.0130
Interaction								0.9889

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders / PT - Peripheral sensory neuropathy

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	2 (2.5)	NR (NE, NE)	60	3 (5.0)	NR (9.7, NE)	0.325 (0.051, 2.081)	0.2150
vCPS < 10%	100	0 (0.0)	NR (NE, NE)	119	11 (9.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0010
Missing	75	0 (0.0)	NR (NE, NE)	61	9 (14.8)	NR (3.5, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Skin and subcutaneous tissue disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	35 (22.3)	NR (NE, NE)	149	38 (25.5)	NR (NE, NE)	0.760 (0.478, 1.209)	0.2437
>= 65 Years	98	25 (25.5)	30.5 (10.3, NE)	91	29 (31.9)	5.3 (5.1, NE)	0.564 (0.323, 0.986)	0.0413
Interaction								0.7440
Gender								
Male	216	48 (22.2)	30.5 (NE, NE)	204	49 (24.0)	NR (5.3, NE)	0.739 (0.492, 1.110)	0.1420
Female	39	12 (30.8)	NR (2.6, NE)	36	18 (50.0)	1.9 (0.9, NE)	0.421 (0.199, 0.888)	0.0192
Interaction								0.2755

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Skin and subcutaneous tissue disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	44 (23.5)	30.5 (10.7, NE)	183	53 (29.0)	NR (5.3, NE)	0.629 (0.417, 0.949)	0.0255
Non-Smoker	68	16 (23.5)	NR (5.1, NE)	57	14 (24.6)	NR (3.0, NE)	0.789 (0.383, 1.625)	0.5180
Interaction								0.4920

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Skin and subcutaneous tissue disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	23 (27.7)	NR (NE, NE)	79	37 (46.8)	3.0 (1.3, NE)	0.517 (0.307, 0.873)	0.0116
Docetaxel	56	14 (25.0)	10.3 (7.0, NE)	50	12 (24.0)	NR (NE, NE)	0.783 (0.358, 1.712)	0.5374
Irinotecan	116	23 (19.8)	30.5 (NE, NE)	111	18 (16.2)	NR (5.3, NE)	0.898 (0.474, 1.702)	0.7405
Interaction								0.2820

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Skin and subcutaneous tissue disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	18 (28.6)	NR (7.0, NE)	57	21 (36.8)	NR (3.0, NE)	0.598 (0.317, 1.131)	0.1091
1	192	42 (21.9)	30.5 (NE, NE)	183	46 (25.1)	NR (5.1, NE)	0.700 (0.456, 1.073)	0.0988
Interaction								0.7415
Region #1								
Asia	201	46 (22.9)	30.5 (10.7, NE)	191	49 (25.7)	NR (NE, NE)	0.680 (0.450, 1.027)	0.0646
Europe/North America	54	14 (25.9)	NR (NE, NE)	49	18 (36.7)	5.3 (2.4, NE)	0.647 (0.321, 1.303)	0.2182
Interaction								0.8244

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Skin and subcutaneous tissue disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	40 (22.7)	30.5 (10.7, NE)	168	36 (21.4)	NR (NE, NE)	0.837 (0.528, 1.325)	0.4457
Japan	25	6 (24.0)	NR (10.3, NE)	23	13 (56.5)	0.7 (0.5, NE)	0.222 (0.078, 0.629)	0.0020
Europe/North America	54	14 (25.9)	NR (NE, NE)	49	18 (36.7)	5.3 (2.4, NE)	0.647 (0.321, 1.303)	0.2182
Interaction								0.0742

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Skin and subcutaneous tissue disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	46 (22.7)	30.5 (10.7, NE)	198	53 (26.8)	NR (5.1, NE)	0.639 (0.426, 0.959)	0.0288
White	52	14 (26.9)	NR (NE, NE)	42	14 (33.3)	NR (2.4, NE)	0.755 (0.359, 1.586)	0.4560
Interaction								0.8107

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Skin and subcutaneous tissue disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	16 (20.0)	NR (10.7, NE)	60	17 (28.3)	NR (5.1, NE)	0.487 (0.243, 0.976)	0.0380
vCPS < 10%	100	32 (32.0)	NR (5.1, NE)	119	33 (27.7)	NR (5.3, NE)	1.091 (0.669, 1.781)	0.7260
Missing	75	12 (16.0)	30.5 (9.6, NE)	61	17 (27.9)	NR (NE, NE)	0.374 (0.170, 0.822)	0.0107
Interaction								0.0581

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Skin and subcutaneous tissue disorders / PT - Alopecia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	0 (0.0)	NR (NE, NE)	149	24 (16.1)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
>= 65 Years	98	0 (0.0)	NR (NE, NE)	91	18 (19.8)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9999
Gender								
Male	216	0 (0.0)	NR (NE, NE)	204	29 (14.2)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Female	39	0 (0.0)	NR (NE, NE)	36	13 (36.1)	NR (1.9, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9997

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Skin and subcutaneous tissue disorders / PT - Alopecia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	0 (0.0)	NR (NE, NE)	183	34 (18.6)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Non-Smoker	68	0 (0.0)	NR (NE, NE)	57	8 (14.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0009
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Skin and subcutaneous tissue disorders / PT - Alopecia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	0 (0.0)	NR (NE, NE)	79	24 (30.4)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Docetaxel	56	0 (0.0)	NR (NE, NE)	50	10 (20.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0002
Irinotecan	116	0 (0.0)	NR (NE, NE)	111	8 (7.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0027
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Skin and subcutaneous tissue disorders / PT - Alopecia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	0 (0.0)	NR (NE, NE)	57	16 (28.1)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
1	192	0 (0.0)	NR (NE, NE)	183	26 (14.2)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9998
Region #1								
Asia	201	0 (0.0)	NR (NE, NE)	191	31 (16.2)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	11 (22.4)	NR (NE, NE)	0.000 (0.000, NE)	0.0002
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Skin and subcutaneous tissue disorders / PT - Alopecia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	0 (0.0)	NR (NE, NE)	168	20 (11.9)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Japan	25	0 (0.0)	NR (NE, NE)	23	11 (47.8)	NR (0.7, NE)	0.000 (0.000, NE)	<0.0001
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	11 (22.4)	NR (NE, NE)	0.000 (0.000, NE)	0.0002
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Skin and subcutaneous tissue disorders / PT - Alopecia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	0 (0.0)	NR (NE, NE)	198	33 (16.7)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
White	52	0 (0.0)	NR (NE, NE)	42	9 (21.4)	NR (NE, NE)	0.000 (0.000, NE)	0.0003
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Skin and subcutaneous tissue disorders / PT - Alopecia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	0 (0.0)	NR (NE, NE)	60	10 (16.7)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
vCPS < 10%	100	0 (0.0)	NR (NE, NE)	119	23 (19.3)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Missing	75	0 (0.0)	NR (NE, NE)	61	9 (14.8)	NR (NE, NE)	0.000 (0.000, NE)	0.0003
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	27 (35.1)	NR (4.3, NE)	70	40 (57.1)	1.4 (0.9, 5.6)	0.473 (0.289, 0.774)	0.0020
>= 65 Years	62	18 (29.0)	NR (21.4, NE)	59	32 (54.2)	1.5 (0.9, NE)	0.368 (0.201, 0.674)	0.0006
Interaction								0.6273
Gender								
Male	118	41 (34.7)	21.4 (8.9, NE)	106	62 (58.5)	1.4 (1.0, 4.1)	0.431 (0.288, 0.645)	<0.0001
Female	21	4 (19.0)	NR (NE, NE)	23	10 (43.5)	NR (0.5, NE)	0.377 (0.118, 1.203)	0.0797
Interaction								0.6354

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	34 (32.7)	21.4 (8.9, NE)	101	55 (54.5)	2.0 (1.0, 5.6)	0.440 (0.284, 0.680)	0.0001
Non-Smoker	35	11 (31.4)	NR (2.1, NE)	28	17 (60.7)	1.2 (0.5, NE)	0.395 (0.183, 0.853)	0.0129
Interaction								0.7237
ICC Options								
Paclitaxel	83	24 (28.9)	NR (21.4, NE)	79	35 (44.3)	4.7 (1.5, NE)	0.534 (0.314, 0.907)	0.0173
Docetaxel	56	21 (37.5)	NR (3.4, NE)	50	37 (74.0)	0.9 (0.3, 1.3)	0.294 (0.168, 0.515)	<0.0001
Interaction								0.1463

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	8 (18.6)	NR (21.4, NE)	37	17 (45.9)	5.6 (1.7, NE)	0.296 (0.122, 0.718)	0.0037
1	96	37 (38.5)	NR (3.4, NE)	92	55 (59.8)	1.0 (0.5, 4.1)	0.456 (0.298, 0.697)	0.0002
Interaction								0.4889
Region #1								
Asia	103	34 (33.0)	NR (21.4, NE)	99	54 (54.5)	1.4 (1.0, NE)	0.446 (0.288, 0.692)	0.0002
Europe/North America	36	11 (30.6)	NR (8.9, NE)	30	18 (60.0)	1.5 (0.5, 5.6)	0.386 (0.180, 0.828)	0.0102
Interaction								0.8971

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	32 (41.0)	NR (2.1, NE)	76	48 (63.2)	1.0 (0.5, 2.0)	0.478 (0.303, 0.752)	0.0008
Japan	25	2 (8.0)	NR (21.4, NE)	23	6 (26.1)	NR (2.8, NE)	0.122 (0.015, 1.026)	0.0203
Europe/North America	36	11 (30.6)	NR (8.9, NE)	30	18 (60.0)	1.5 (0.5, 5.6)	0.386 (0.180, 0.828)	0.0102
Interaction								0.7324

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	35 (33.3)	NR (21.4, NE)	106	56 (52.8)	1.7 (1.0, NE)	0.476 (0.309, 0.732)	0.0004
White	34	10 (29.4)	NR (8.9, NE)	23	16 (69.6)	1.0 (0.5, 5.6)	0.304 (0.137, 0.677)	0.0017
Interaction								0.4371

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	14 (31.1)	NR (3.4, NE)	34	20 (58.8)	1.1 (0.5, NE)	0.375 (0.187, 0.749)	0.0036
vCPS < 10%	53	18 (34.0)	NR (4.3, NE)	54	35 (64.8)	1.0 (0.5, 2.2)	0.362 (0.203, 0.647)	0.0003
Missing	41	13 (31.7)	21.4 (6.9, NE)	41	17 (41.5)	4.7 (1.4, NE)	0.612 (0.290, 1.291)	0.1814
Interaction								0.4226

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	22 (28.6)	NR (8.3, NE)	70	31 (44.3)	5.6 (1.4, NE)	0.531 (0.306, 0.920)	0.0211
>= 65 Years	62	16 (25.8)	NR (21.4, NE)	59	21 (35.6)	5.1 (4.1, NE)	0.518 (0.262, 1.025)	0.0529
Interaction								0.9494
Gender								
Male	118	34 (28.8)	NR (21.4, NE)	106	45 (42.5)	5.1 (2.0, NE)	0.516 (0.327, 0.814)	0.0036
Female	21	4 (19.0)	NR (NE, NE)	23	7 (30.4)	NR (0.5, NE)	0.555 (0.162, 1.897)	0.3323
Interaction								0.8628

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	30 (28.8)	NR (21.4, NE)	101	44 (43.6)	5.1 (1.4, NE)	0.493 (0.307, 0.795)	0.0028
Non-Smoker	35	8 (22.9)	NR (4.3, NE)	28	8 (28.6)	NR (2.1, NE)	0.727 (0.272, 1.943)	0.5216
Interaction								0.6063
ICC Options								
Paclitaxel	83	21 (25.3)	NR (21.4, NE)	79	26 (32.9)	NR (4.1, NE)	0.668 (0.372, 1.198)	0.1702
Docetaxel	56	17 (30.4)	NR (8.3, NE)	50	26 (52.0)	2.0 (1.0, NE)	0.353 (0.185, 0.673)	0.0009
Interaction								0.2529

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	5 (11.6)	NR (21.4, NE)	37	8 (21.6)	NR (5.6, NE)	0.388 (0.116, 1.296)	0.1096
1	96	33 (34.4)	NR (8.3, NE)	92	44 (47.8)	4.1 (1.1, NE)	0.530 (0.334, 0.840)	0.0056
Interaction								0.8283
Region #1								
Asia	103	27 (26.2)	NR (21.4, NE)	99	40 (40.4)	NR (2.0, NE)	0.487 (0.295, 0.803)	0.0037
Europe/North America	36	11 (30.6)	NR (8.9, NE)	30	12 (40.0)	5.6 (1.0, NE)	0.645 (0.281, 1.479)	0.2922
Interaction								0.4809

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	25 (32.1)	NR (8.3, NE)	76	36 (47.4)	2.0 (1.1, NE)	0.514 (0.306, 0.862)	0.0097
Japan	25	2 (8.0)	NR (21.4, NE)	23	4 (17.4)	NR (2.8, NE)	0.194 (0.021, 1.743)	0.1014
Europe/North America	36	11 (30.6)	NR (8.9, NE)	30	12 (40.0)	5.6 (1.0, NE)	0.645 (0.281, 1.479)	0.2922
Interaction								0.7207

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	28 (26.7)	NR (21.4, NE)	106	41 (38.7)	NR (2.1, NE)	0.533 (0.326, 0.871)	0.0101
White	34	10 (29.4)	NR (8.9, NE)	23	11 (47.8)	5.1 (0.5, NE)	0.485 (0.204, 1.155)	0.0914
Interaction								0.9725

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	14 (31.1)	NR (8.3, NE)	34	17 (50.0)	4.1 (0.8, NE)	0.457 (0.223, 0.937)	0.0278
vCPS < 10%	53	16 (30.2)	NR (8.9, NE)	54	23 (42.6)	5.6 (1.1, NE)	0.560 (0.292, 1.071)	0.0743
Missing	41	8 (19.5)	21.4 (21.4, NE)	41	12 (29.3)	NR (5.1, NE)	0.521 (0.205, 1.327)	0.1579
Interaction								0.8811

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	3 (3.9)	NR (NE, NE)	70	7 (10.0)	NR (NE, NE)	0.361 (0.093, 1.396)	0.1227
>= 65 Years	62	1 (1.6)	NR (NE, NE)	59	5 (8.5)	NR (6.3, NE)	0.145 (0.016, 1.282)	0.0465
Interaction								0.5525
Gender								
Male	118	4 (3.4)	NR (NE, NE)	106	11 (10.4)	NR (NE, NE)	0.301 (0.096, 0.946)	0.0289
Female	21	0 (0.0)	NR (NE, NE)	23	1 (4.3)	NR (6.3, NE)	0.000 (0.000, NE)	0.1573
Interaction								0.9940

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	2 (1.9)	--	101	7 (6.9)	--	--	--
Non-Smoker	35	2 (5.7)	--	28	5 (17.9)	--	--	--
Interaction								--
ICC Options								
Paclitaxel	83	1 (1.2)	NR (NE, NE)	79	2 (2.5)	NR (NE, NE)	0.466 (0.042, 5.137)	0.5228
Docetaxel	56	3 (5.4)	NR (NE, NE)	50	10 (20.0)	NR (6.3, NE)	0.223 (0.061, 0.814)	0.0126
Interaction								0.6435

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	2 (4.7)	NR (NE, NE)	37	4 (10.8)	NR (NE, NE)	0.413 (0.076, 2.258)	0.2912
1	96	2 (2.1)	NR (NE, NE)	92	8 (8.7)	NR (NE, NE)	0.202 (0.042, 0.960)	0.0261
Interaction								0.6072
Region #1								
Asia	103	4 (3.9)	NR (NE, NE)	99	11 (11.1)	NR (NE, NE)	0.308 (0.098, 0.970)	0.0329
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	1 (3.3)	NR (NE, NE)	0.000 (0.000, NE)	0.2733
Interaction								0.9923

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Any TEAE: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	4 (5.1)	NR (NE, NE)	76	11 (14.5)	NR (NE, NE)	0.312 (0.099, 0.982)	0.0347
Japan	25	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	1 (3.3)	NR (NE, NE)	0.000 (0.000, NE)	0.2733
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	4 (3.8)	NR (NE, NE)	106	11 (10.4)	NR (NE, NE)	0.326 (0.103, 1.028)	0.0438
White	34	0 (0.0)	NR (NE, NE)	23	1 (4.3)	NR (NE, NE)	0.000 (0.000, NE)	0.2240
Interaction								0.9921

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Baseline PD-L1 Status								
vCPS >= 10%	45	1 (2.2)	--	34	5 (14.7)	--	--	--
vCPS < 10%	53	1 (1.9)	--	54	6 (11.1)	--	--	--
Missing	41	2 (4.9)	--	41	1 (2.4)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	77	1 (1.3)	NR (NE, NE)	70	8 (11.4)	NR (NE, NE)	0.107 (0.013, 0.852)	0.0098
>= 65 Years	62	1 (1.6)	NR (NE, NE)	59	13 (22.0)	NR (4.7, NE)	0.060 (0.008, 0.465)	0.0003
Interaction								0.7412
Gender								
Male	118	2 (1.7)	NR (NE, NE)	106	18 (17.0)	NR (NE, NE)	0.087 (0.020, 0.375)	<0.0001
Female	21	0 (0.0)	NR (NE, NE)	23	3 (13.0)	NR (NE, NE)	0.000 (0.000, NE)	0.1022
Interaction								0.9901

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Any TEAE: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	1 (1.0)	NR (NE, NE)	101	13 (12.9)	NR (NE, NE)	0.065 (0.009, 0.502)	0.0005
Non-Smoker	35	1 (2.9)	NR (NE, NE)	28	8 (28.6)	NR (2.2, NE)	0.090 (0.011, 0.717)	0.0041
Interaction								0.8583
ICC Options								
Paclitaxel	83	0 (0.0)	NR (NE, NE)	79	12 (15.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0001
Docetaxel	56	2 (3.6)	NR (NE, NE)	50	9 (18.0)	NR (NE, NE)	0.184 (0.040, 0.852)	0.0142
Interaction								0.9911

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Any TEAE: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	43	2 (4.7)	NR (NE, NE)	37	7 (18.9)	NR (NE, NE)	0.232 (0.048, 1.115)	0.0453
1	96	0 (0.0)	NR (NE, NE)	92	14 (15.2)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9903
Region #1								
Asia	103	2 (1.9)	NR (NE, NE)	99	9 (9.1)	NR (NE, NE)	0.204 (0.044, 0.946)	0.0239
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	12 (40.0)	4.7 (1.5, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9910

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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Any TEAE: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	2 (2.6)	NR (NE, NE)	76	9 (11.8)	NR (NE, NE)	0.205 (0.044, 0.947)	0.0238
Japan	25	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	12 (40.0)	4.7 (1.5, NE)	0.000 (0.000, NE)	<0.0001
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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Race								
Asian and other	105	2 (1.9)	NR (NE, NE)	106	10 (9.4)	NR (NE, NE)	0.193 (0.042, 0.880)	0.0173
White	34	0 (0.0)	NR (NE, NE)	23	11 (47.8)	4.7 (1.0, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9886

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Any TEAE: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	0 (0.0)	NR (NE, NE)	34	3 (8.8)	NR (NE, NE)	0.000 (0.000, NE)	0.0436
vCPS < 10%	53	1 (1.9)	NR (NE, NE)	54	14 (25.9)	NR (NE, NE)	0.060 (0.008, 0.460)	0.0002
Missing	41	1 (2.4)	NR (NE, NE)	41	4 (9.8)	NR (4.7, NE)	0.226 (0.025, 2.038)	0.1457
Interaction								0.6493

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	14 (18.2)	16.5 (9.0, NE)	70	1 (1.4)	NR (NE, NE)	10.081 (1.317, 77.160)	0.0057
>= 65 Years	62	11 (17.7)	18.6 (10.6, NE)	59	0 (0.0)	NR (NE, NE)	24037176.663 (0.000, NE)	0.0081
Interaction								0.9926

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Gender								
Male	118	21 (17.8)	18.6 (11.6, NE)	106	1 (0.9)	NR (NE, NE)	13.067 (1.739, 98.165)	0.0012
Female	21	4 (19.0)	9.0 (2.3, NE)	23	0 (0.0)	NR (NE, NE)	101665480.453 (0.000, NE)	0.0290
Interaction								0.9923

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	16 (15.4)	NR (16.5, NE)	101	1 (1.0)	NR (NE, NE)	11.529 (1.509, 88.089)	0.0028
Non-Smoker	35	9 (25.7)	9.0 (4.2, NE)	28	0 (0.0)	NR (NE, NE)	58638083.119 (0.000, NE)	0.0175
Interaction								0.9922

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	18 (21.7)	16.5 (9.0, NE)	79	1 (1.3)	NR (NE, NE)	13.944 (1.844, 105.446)	0.0008
Docetaxel	56	7 (12.5)	18.6 (11.6, NE)	50	0 (0.0)	NR (NE, NE)	54856964.265 (0.000, NE)	0.0399
Interaction								0.9908

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	11 (25.6)	11.6 (8.3, NE)	37	0 (0.0)	NR (NE, NE)	20986149.621 (0.000, NE)	0.0166
1	96	14 (14.6)	NR (16.5, NE)	92	1 (1.1)	NR (NE, NE)	11.413 (1.496, 87.049)	0.0029
Interaction								0.9902

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #1								
Asia	103	20 (19.4)	16.5 (10.6, NE)	99	1 (1.0)	NR (NE, NE)	12.205 (1.624, 91.730)	0.0019
Europe/North America	36	5 (13.9)	NR (NE, NE)	30	0 (0.0)	NR (NE, NE)	27971823.757 (0.000, NE)	0.0296
Interaction								0.9918

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	13 (16.7)	18.6 (16.5, NE)	76	1 (1.3)	NR (NE, NE)	9.219 (1.196, 71.068)	0.0094
Japan	25	7 (28.0)	11.6 (4.6, NE)	23	0 (0.0)	NR (NE, NE)	49166268.174 (0.000, NE)	0.0771
Europe/North America	36	5 (13.9)	NR (NE, NE)	30	0 (0.0)	NR (NE, NE)	27971823.757 (0.000, NE)	0.0296
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	20 (19.0)	16.5 (10.6, NE)	106	1 (0.9)	NR (NE, NE)	12.976 (1.726, 97.567)	0.0013
White	34	5 (14.7)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	23616334.021 (0.000, NE)	0.0482
Interaction								0.9927

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	6 (13.3)	NR (9.0, NE)	34	1 (2.9)	NR (NE, NE)	2.930 (0.348, 24.669)	0.3003
vCPS < 10%	53	10 (18.9)	NR (16.5, NE)	54	0 (0.0)	NR (NE, NE)	28203570.659 (0.000, NE)	0.0032
Missing	41	9 (22.0)	18.6 (4.6, NE)	41	0 (0.0)	NR (NE, NE)	76459732.458 (0.000, NE)	0.0102
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	77	11 (14.3)	NR (4.9, NE)	70	0 (0.0)	NR (NE, NE)	22765671.292 (0.000, NE)	0.0061
>= 65 Years	62	7 (11.3)	NR (18.6, NE)	59	0 (0.0)	NR (NE, NE)	24550528.718 (0.000, NE)	0.0265
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Gender								
Male	118	15 (12.7)	NR (16.5, NE)	106	0 (0.0)	NR (NE, NE)	22555386.209 (0.000, NE)	0.0024
Female	21	3 (14.3)	NR (2.3, NE)	23	0 (0.0)	NR (NE, NE)	92609463.771 (0.000, NE)	0.0744
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	13 (12.5)	NR (16.5, NE)	101	0 (0.0)	NR (NE, NE)	23958115.109 (0.000, NE)	0.0032
Non-Smoker	35	5 (14.3)	NR (4.2, NE)	28	0 (0.0)	NR (NE, NE)	57917086.185 (0.000, NE)	0.0728
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	13 (15.7)	NR (16.5, NE)	79	0 (0.0)	NR (NE, NE)	25104900.387 (0.000, NE)	0.0020
Docetaxel	56	5 (8.9)	18.6 (NE, NE)	50	0 (0.0)	NR (NE, NE)	57484283.130 (0.000, NE)	0.0674
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	43	8 (18.6)	18.6 (10.6, NE)	37	0 (0.0)	NR (NE, NE)	21206999.553 (0.000, NE)	0.0376
1	96	10 (10.4)	NR (16.5, NE)	92	0 (0.0)	NR (NE, NE)	23910491.194 (0.000, NE)	0.0057
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Region #1								
Asia	103	14 (13.6)	NR (16.5, NE)	99	0 (0.0)	NR (NE, NE)	21617628.785 (0.000, NE)	0.0030
Europe/North America	36	4 (11.1)	NR (4.9, NE)	30	0 (0.0)	NR (NE, NE)	68856680.057 (0.000, NE)	0.0661
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Region #2								
Asia (excluding Japan)	78	10 (12.8)	NR (16.5, NE)	76	0 (0.0)	NR (NE, NE)	22973526.585 (0.000, NE)	0.0083
Japan	25	4 (16.0)	NR (4.6, NE)	23	0 (0.0)	NR (NE, NE)	47674440.539 (0.000, NE)	0.1771
Europe/North America	36	4 (11.1)	NR (4.9, NE)	30	0 (0.0)	NR (NE, NE)	68856680.057 (0.000, NE)	0.0661
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
Adverse events were classified based on MedDRA v23.0.
System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.
Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	105	14 (13.3)	NR (16.5, NE)	106	0 (0.0)	NR (NE, NE)	22788639.858 (0.000, NE)	0.0022
White	34	4 (11.8)	NR (4.9, NE)	23	0 (0.0)	NR (NE, NE)	59592827.419 (0.000, NE)	0.0928
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Baseline PD-L1 Status								
vCPS >= 10%	45	3 (6.7)	--	34	0 (0.0)	--	--	--
vCPS < 10%	53	8 (15.1)	--	54	0 (0.0)	--	--	--
Missing	41	7 (17.1)	--	41	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Gastrointestinal disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	47 (61.0)	2.0 (0.9, 5.9)	70	40 (57.1)	1.2 (0.7, 2.6)	0.807 (0.527, 1.237)	0.3199
>= 65 Years	62	41 (66.1)	2.4 (1.4, 3.4)	59	39 (66.1)	1.1 (0.4, 2.1)	0.627 (0.398, 0.988)	0.0407
Interaction								0.6505
Gender								
Male	118	75 (63.6)	2.4 (1.4, 3.4)	106	62 (58.5)	1.2 (0.7, 2.6)	0.770 (0.546, 1.086)	0.1316
Female	21	13 (61.9)	2.1 (0.3, 6.2)	23	17 (73.9)	1.0 (0.1, 2.1)	0.512 (0.242, 1.081)	0.0709
Interaction								0.3205

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Gastrointestinal disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	70 (67.3)	2.0 (1.2, 3.1)	101	61 (60.4)	1.1 (0.4, 2.3)	0.783 (0.552, 1.111)	0.1643
Non-Smoker	35	18 (51.4)	2.9 (0.8, NE)	28	18 (64.3)	1.2 (0.5, 5.1)	0.538 (0.273, 1.061)	0.0684
Interaction								0.4118
ICC Options								
Paclitaxel	83	53 (63.9)	2.0 (1.2, 3.4)	79	50 (63.3)	1.1 (0.5, 2.3)	0.724 (0.489, 1.073)	0.1031
Docetaxel	56	35 (62.5)	2.9 (0.8, 7.2)	50	29 (58.0)	1.1 (0.3, 6.1)	0.709 (0.427, 1.178)	0.1776
Interaction								0.9221

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Gastrointestinal disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	23 (53.5)	5.9 (2.0, 9.8)	37	24 (64.9)	1.3 (0.4, 5.1)	0.486 (0.267, 0.883)	0.0148
1	96	65 (67.7)	1.4 (0.8, 2.9)	92	55 (59.8)	1.1 (0.5, 2.3)	0.847 (0.588, 1.220)	0.3661
Interaction								0.1498
Region #1								
Asia	103	61 (59.2)	3.0 (1.8, 4.1)	99	56 (56.6)	1.1 (0.5, 2.3)	0.687 (0.474, 0.995)	0.0441
Europe/North America	36	27 (75.0)	1.2 (0.3, 2.5)	30	23 (76.7)	1.1 (0.4, 2.3)	0.778 (0.439, 1.380)	0.3812
Interaction								0.5802

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Gastrointestinal disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	50 (64.1)	2.2 (1.2, 3.4)	76	41 (53.9)	1.2 (0.4, NE)	0.802 (0.526, 1.221)	0.2983
Japan	25	11 (44.0)	9.8 (1.5, NE)	23	15 (65.2)	1.1 (0.3, NE)	0.422 (0.187, 0.953)	0.0317
Europe/North America	36	27 (75.0)	1.2 (0.3, 2.5)	30	23 (76.7)	1.1 (0.4, 2.3)	0.778 (0.439, 1.380)	0.3812
Interaction								0.2206

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Gastrointestinal disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	63 (60.0)	2.9 (1.8, 3.7)	106	61 (57.5)	1.1 (0.6, 2.3)	0.698 (0.487, 1.001)	0.0478
White	34	25 (73.5)	1.2 (0.3, 2.5)	23	18 (78.3)	1.2 (0.2, 2.3)	0.706 (0.378, 1.321)	0.2631
Interaction								0.8590

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Gastrointestinal disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	34 (75.6)	1.9 (0.6, 3.3)	34	25 (73.5)	0.4 (0.2, 1.9)	0.591 (0.346, 1.009)	0.0486
vCPS < 10%	53	37 (69.8)	1.5 (0.8, 3.7)	54	32 (59.3)	1.5 (0.7, 2.6)	0.882 (0.541, 1.439)	0.6130
Missing	41	17 (41.5)	4.1 (2.5, NE)	41	22 (53.7)	1.0 (0.3, NE)	0.562 (0.297, 1.063)	0.0698
Interaction								0.2513

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Gastrointestinal disorders / PT - Abdominal pain upper

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	2 (2.6)	--	70	4 (5.7)	--	--	--
>= 65 Years	62	2 (3.2)	--	59	6 (10.2)	--	--	--
Interaction								--
Gender								
Male	118	4 (3.4)	NR (NE, NE)	106	6 (5.7)	NR (NE, NE)	0.512 (0.142, 1.838)	0.2955
Female	21	0 (0.0)	NR (NE, NE)	23	4 (17.4)	NR (NE, NE)	0.000 (0.000, NE)	0.0478
Interaction								0.9926

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Gastrointestinal disorders / PT - Abdominal pain upper

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Smoking Status								
Former/Current Smoker	104	2 (1.9)	--	101	5 (5.0)	--	--	--
Non-Smoker	35	2 (5.7)	--	28	5 (17.9)	--	--	--
Interaction								--
ICC Options								
Paclitaxel	83	1 (1.2)	--	79	7 (8.9)	--	--	--
Docetaxel	56	3 (5.4)	--	50	3 (6.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Gastrointestinal disorders / PT - Abdominal pain upper

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	43	0 (0.0)	--	37	5 (13.5)	--	--	--
1	96	4 (4.2)	--	92	5 (5.4)	--	--	--
Interaction								--
Region #1								
Asia	103	3 (2.9)	--	99	6 (6.1)	--	--	--
Europe/North America	36	1 (2.8)	--	30	4 (13.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Gastrointestinal disorders / PT - Abdominal pain upper

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Region #2								
Asia (excluding Japan)	78	3 (3.8)	--	76	6 (7.9)	--	--	--
Japan	25	0 (0.0)	--	23	0 (0.0)	--	--	--
Europe/North America	36	1 (2.8)	--	30	4 (13.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Gastrointestinal disorders / PT - Abdominal pain upper

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	3 (2.9)	--	106	6 (5.7)	--	--	--
White	34	1 (2.9)	--	23	4 (17.4)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Gastrointestinal disorders / PT - Abdominal pain upper

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Baseline PD-L1 Status								
vCPS >= 10%	45	2 (4.4)	--	34	5 (14.7)	--	--	--
vCPS < 10%	53	1 (1.9)	--	54	3 (5.6)	--	--	--
Missing	41	1 (2.4)	--	41	2 (4.9)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - General disorders and administration site conditions

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	34 (44.2)	8.5 (2.5, NE)	70	39 (55.7)	1.7 (1.0, 3.0)	0.536 (0.333, 0.865)	0.0089
>= 65 Years	62	39 (62.9)	3.5 (1.3, 7.6)	59	38 (64.4)	1.0 (0.5, 2.6)	0.626 (0.391, 1.003)	0.0465
Interaction								0.4646
Gender								
Male	118	62 (52.5)	6.9 (2.7, 8.6)	106	61 (57.5)	1.3 (0.9, 2.6)	0.587 (0.406, 0.849)	0.0039
Female	21	11 (52.4)	2.2 (0.3, NE)	23	16 (69.6)	1.8 (0.3, 2.7)	0.595 (0.269, 1.317)	0.1908
Interaction								0.9457

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - General disorders and administration site conditions

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	56 (53.8)	3.6 (2.2, 8.6)	101	62 (61.4)	1.3 (0.9, 2.3)	0.571 (0.392, 0.831)	0.0028
Non-Smoker	35	17 (48.6)	7.7 (2.1, NE)	28	15 (53.6)	1.9 (0.4, NE)	0.594 (0.283, 1.247)	0.1611
Interaction								0.7813
ICC Options								
Paclitaxel	83	46 (55.4)	3.5 (1.9, 9.9)	79	49 (62.0)	1.7 (0.8, 2.6)	0.614 (0.403, 0.936)	0.0211
Docetaxel	56	27 (48.2)	5.5 (2.9, 8.6)	50	28 (56.0)	1.3 (0.8, NE)	0.548 (0.315, 0.951)	0.0281
Interaction								0.8261

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - General disorders and administration site conditions

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	22 (51.2)	7.7 (2.7, 9.9)	37	20 (54.1)	2.6 (1.0, NE)	0.589 (0.308, 1.126)	0.1037
1	96	51 (53.1)	3.5 (2.0, 10.3)	92	57 (62.0)	1.2 (0.6, 1.9)	0.562 (0.379, 0.833)	0.0033
Interaction								0.6043
Region #1								
Asia	103	47 (45.6)	7.7 (3.6, 11.0)	99	55 (55.6)	1.6 (0.9, 3.0)	0.525 (0.348, 0.791)	0.0016
Europe/North America	36	26 (72.2)	2.2 (0.7, 3.5)	30	22 (73.3)	1.0 (0.4, 2.7)	0.670 (0.372, 1.209)	0.1753
Interaction								0.3422

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - General disorders and administration site conditions

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	34 (43.6)	7.7 (3.4, 12.7)	76	41 (53.9)	1.6 (0.9, NE)	0.545 (0.338, 0.878)	0.0107
Japan	25	13 (52.0)	6.9 (1.9, NE)	23	14 (60.9)	1.7 (0.4, NE)	0.432 (0.187, 1.000)	0.0431
Europe/North America	36	26 (72.2)	2.2 (0.7, 3.5)	30	22 (73.3)	1.0 (0.4, 2.7)	0.670 (0.372, 1.209)	0.1753
Interaction								0.6259

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - General disorders and administration site conditions

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	47 (44.8)	7.7 (3.6, 11.0)	106	59 (55.7)	1.7 (0.9, 2.7)	0.511 (0.341, 0.766)	0.0009
White	34	26 (76.5)	1.7 (0.5, 2.8)	23	18 (78.3)	0.9 (0.2, 1.9)	0.655 (0.352, 1.217)	0.1715
Interaction								0.4257

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - General disorders and administration site conditions

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	29 (64.4)	2.9 (1.2, 7.0)	34	23 (67.6)	1.0 (0.2, 2.5)	0.590 (0.337, 1.032)	0.0590
vCPS < 10%	53	30 (56.6)	7.7 (1.2, 11.0)	54	30 (55.6)	2.1 (0.9, 3.0)	0.669 (0.390, 1.147)	0.1380
Missing	41	14 (34.1)	9.9 (2.5, NE)	41	24 (58.5)	1.1 (0.8, NE)	0.413 (0.208, 0.818)	0.0084
Interaction								0.3768

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Infections and infestations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	27 (35.1)	10.5 (3.8, NE)	70	23 (32.9)	8.0 (3.4, NE)	0.871 (0.495, 1.533)	0.6307
>= 65 Years	62	16 (25.8)	11.5 (5.6, NE)	59	23 (39.0)	3.1 (2.6, NE)	0.446 (0.225, 0.883)	0.0173
Interaction								0.2131
Gender								
Male	118	39 (33.1)	10.5 (5.3, NE)	106	38 (35.8)	8.0 (3.1, NE)	0.708 (0.447, 1.122)	0.1390
Female	21	4 (19.0)	NR (2.1, NE)	23	8 (34.8)	3.1 (2.4, NE)	0.468 (0.135, 1.618)	0.2195
Interaction								0.3507

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Infections and infestations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	32 (30.8)	11.5 (5.6, NE)	101	38 (37.6)	8.0 (2.8, NE)	0.609 (0.374, 0.990)	0.0428
Non-Smoker	35	11 (31.4)	10.5 (2.8, NE)	28	8 (28.6)	4.9 (3.1, NE)	0.952 (0.375, 2.415)	0.9176
Interaction								0.3903
ICC Options								
Paclitaxel	83	25 (30.1)	13.8 (5.3, NE)	79	24 (30.4)	8.0 (3.4, NE)	0.809 (0.454, 1.443)	0.4708
Docetaxel	56	18 (32.1)	9.5 (3.2, NE)	50	22 (44.0)	3.1 (1.4, NE)	0.479 (0.251, 0.914)	0.0223
Interaction								0.3368

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Infections and infestations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	10 (23.3)	13.8 (7.3, NE)	37	10 (27.0)	8.0 (4.9, NE)	0.574 (0.223, 1.473)	0.2417
1	96	33 (34.4)	5.6 (3.8, NE)	92	36 (39.1)	3.1 (2.4, NE)	0.675 (0.416, 1.094)	0.1074
Interaction								0.8864
Region #1								
Asia	103	33 (32.0)	10.5 (5.3, NE)	99	35 (35.4)	NR (2.8, NE)	0.639 (0.390, 1.046)	0.0719
Europe/North America	36	10 (27.8)	NR (7.3, NE)	30	11 (36.7)	5.3 (2.8, NE)	0.741 (0.312, 1.763)	0.4965
Interaction								0.8433

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Infections and infestations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	25 (32.1)	9.5 (4.9, NE)	76	27 (35.5)	NR (2.4, NE)	0.635 (0.364, 1.107)	0.1057
Japan	25	8 (32.0)	11.5 (5.6, NE)	23	8 (34.8)	NR (3.0, NE)	0.633 (0.219, 1.834)	0.3952
Europe/North America	36	10 (27.8)	NR (7.3, NE)	30	11 (36.7)	5.3 (2.8, NE)	0.741 (0.312, 1.763)	0.4965
Interaction								0.9487

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Infections and infestations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	34 (32.4)	10.5 (5.3, NE)	106	37 (34.9)	NR (2.8, NE)	0.668 (0.412, 1.083)	0.0984
White	34	9 (26.5)	NR (7.3, NE)	23	9 (39.1)	5.3 (2.8, NE)	0.689 (0.272, 1.748)	0.4303
Interaction								0.9570

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Infections and infestations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	11 (24.4)	13.8 (5.3, NE)	34	15 (44.1)	2.8 (2.2, NE)	0.298 (0.127, 0.699)	0.0033
vCPS < 10%	53	23 (43.4)	5.6 (2.8, NE)	54	21 (38.9)	4.9 (3.0, NE)	0.923 (0.505, 1.688)	0.7950
Missing	41	9 (22.0)	11.5 (3.2, NE)	41	10 (24.4)	NR (NE, NE)	0.731 (0.288, 1.854)	0.5057
Interaction								0.1533

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	30 (39.0)	NR (2.2, NE)	70	47 (67.1)	0.5 (0.4, 1.2)	0.363 (0.227, 0.580)	<0.0001
>= 65 Years	62	28 (45.2)	7.7 (2.8, 15.8)	59	37 (62.7)	1.0 (0.3, 3.0)	0.383 (0.227, 0.646)	0.0002
Interaction								0.6443
Gender								
Male	118	51 (43.2)	7.7 (2.9, NE)	106	73 (68.9)	0.5 (0.4, 1.2)	0.361 (0.249, 0.523)	<0.0001
Female	21	7 (33.3)	NR (2.1, NE)	23	11 (47.8)	NR (0.3, NE)	0.493 (0.190, 1.279)	0.1329
Interaction								0.6121

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	45 (43.3)	7.6 (2.8, NE)	101	66 (65.3)	0.7 (0.5, 1.4)	0.384 (0.259, 0.569)	<0.0001
Non-Smoker	35	13 (37.1)	9.2 (2.1, NE)	28	18 (64.3)	0.5 (0.3, NE)	0.356 (0.170, 0.745)	0.0032
Interaction								0.8108
ICC Options								
Paclitaxel	83	27 (32.5)	NR (7.0, NE)	79	45 (57.0)	1.2 (0.5, 3.5)	0.362 (0.222, 0.591)	<0.0001
Docetaxel	56	31 (55.4)	2.1 (1.2, 7.7)	50	39 (78.0)	0.3 (0.3, 0.7)	0.355 (0.217, 0.583)	<0.0001
Interaction								0.9321

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	13 (30.2)	15.8 (9.2, NE)	37	22 (59.5)	0.7 (0.3, NE)	0.307 (0.149, 0.630)	0.0005
1	96	45 (46.9)	4.4 (2.1, 9.7)	92	62 (67.4)	0.5 (0.4, 1.2)	0.409 (0.275, 0.608)	<0.0001
Interaction								0.3792
Region #1								
Asia	103	52 (50.5)	3.5 (2.1, 9.2)	99	74 (74.7)	0.5 (0.3, 0.5)	0.339 (0.233, 0.492)	<0.0001
Europe/North America	36	6 (16.7)	NR (NE, NE)	30	10 (33.3)	NR (3.0, NE)	0.421 (0.153, 1.163)	0.0833
Interaction								0.8084

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	41 (52.6)	2.8 (2.0, 7.7)	76	58 (76.3)	0.4 (0.3, 0.7)	0.368 (0.243, 0.559)	<0.0001
Japan	25	11 (44.0)	4.4 (2.8, NE)	23	16 (69.6)	0.5 (0.3, 1.7)	0.217 (0.084, 0.561)	0.0004
Europe/North America	36	6 (16.7)	NR (NE, NE)	30	10 (33.3)	NR (3.0, NE)	0.421 (0.153, 1.163)	0.0833
Interaction								0.8711

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	52 (49.5)	3.5 (2.1, 9.2)	106	77 (72.6)	0.5 (0.3, 0.7)	0.354 (0.244, 0.512)	<0.0001
White	34	6 (17.6)	NR (NE, NE)	23	7 (30.4)	NR (3.0, NE)	0.513 (0.172, 1.531)	0.2187
Interaction								0.6203

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	18 (40.0)	7.6 (3.1, NE)	34	22 (64.7)	0.6 (0.3, 1.5)	0.370 (0.196, 0.699)	0.0012
vCPS < 10%	53	22 (41.5)	9.7 (2.1, NE)	54	34 (63.0)	0.6 (0.3, 3.3)	0.412 (0.237, 0.716)	0.0009
Missing	41	18 (43.9)	9.2 (2.1, NE)	41	28 (68.3)	0.5 (0.3, 1.7)	0.359 (0.190, 0.677)	0.0007
Interaction								0.9608

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	8 (10.4)	--	70	1 (1.4)	--	--	--
>= 65 Years	62	5 (8.1)	--	59	2 (3.4)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Gender								
Male	118	10 (8.5)	NR (NE, NE)	106	3 (2.8)	NR (NE, NE)	2.729 (0.748, 9.961)	0.1118
Female	21	3 (14.3)	NR (2.8, NE)	23	0 (0.0)	NR (NE, NE)	74428493.556 (0.000, NE)	0.1010
Interaction								0.9933

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	10 (9.6)	NR (NE, NE)	101	2 (2.0)	NR (NE, NE)	4.164 (0.907, 19.126)	0.0460
Non-Smoker	35	3 (8.6)	NR (NE, NE)	28	1 (3.6)	NR (NE, NE)	2.217 (0.230, 21.341)	0.4794
Interaction								0.6601
ICC Options								
Paclitaxel	83	8 (9.6)	NR (NE, NE)	79	2 (2.5)	NR (NE, NE)	3.494 (0.740, 16.499)	0.0914
Docetaxel	56	5 (8.9)	NR (NE, NE)	50	1 (2.0)	NR (NE, NE)	3.683 (0.426, 31.829)	0.2040
Interaction								0.9176

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	4 (9.3)	NR (NE, NE)	37	0 (0.0)	NR (NE, NE)	22891617.579 (0.000, NE)	0.0846
1	96	9 (9.4)	NR (NE, NE)	92	3 (3.3)	NR (NE, NE)	2.596 (0.699, 9.646)	0.1380
Interaction								0.9910

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Region #1								
Asia	103	10 (9.7)	NR (NE, NE)	99	3 (3.0)	NR (NE, NE)	2.833 (0.776, 10.342)	0.0981
Europe/North America	36	3 (8.3)	NR (NE, NE)	30	0 (0.0)	NR (NE, NE)	62814472.592 (0.000, NE)	0.1317
Interaction								0.9920

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	8 (10.3)	NR (NE, NE)	76	3 (3.9)	NR (NE, NE)	2.307 (0.609, 8.743)	0.2031
Japan	25	2 (8.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	64906194.937 (0.000, NE)	0.2144
Europe/North America	36	3 (8.3)	NR (NE, NE)	30	0 (0.0)	NR (NE, NE)	62814472.592 (0.000, NE)	0.1317
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	10 (9.5)	NR (NE, NE)	106	3 (2.8)	NR (NE, NE)	2.987 (0.818, 10.906)	0.0809
White	34	3 (8.8)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	55484688.828 (0.000, NE)	0.1646
Interaction								0.9928

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	5 (11.1)	--	34	1 (2.9)	--	--	--
vCPS < 10%	53	3 (5.7)	--	54	1 (1.9)	--	--	--
Missing	41	5 (12.2)	--	41	1 (2.4)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	2 (2.6)	--	70	3 (4.3)	--	--	--
>= 65 Years	62	1 (1.6)	--	59	7 (11.9)	--	--	--
Interaction								--
Gender								
Male	118	2 (1.7)	NR (NE, NE)	106	9 (8.5)	NR (NE, NE)	0.186 (0.040, 0.860)	0.0153
Female	21	1 (4.8)	NR (NE, NE)	23	1 (4.3)	NR (NE, NE)	1.047 (0.065, 16.744)	0.9743
Interaction								0.2665

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Smoking Status								
Former/Current Smoker	104	3 (2.9)	NR (NE, NE)	101	9 (8.9)	NR (NE, NE)	0.302 (0.082, 1.118)	0.0558
Non-Smoker	35	0 (0.0)	NR (NE, NE)	28	1 (3.6)	NR (NE, NE)	0.000 (0.000, NE)	0.2618
Interaction								0.9930
ICC Options								
Paclitaxel	83	1 (1.2)	--	79	4 (5.1)	--	--	--
Docetaxel	56	2 (3.6)	--	50	6 (12.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

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Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	43	1 (2.3)	--	37	3 (8.1)	--	--	--
1	96	2 (2.1)	--	92	7 (7.6)	--	--	--
Interaction								--
Region #1								
Asia	103	2 (1.9)	--	99	6 (6.1)	--	--	--
Europe/North America	36	1 (2.8)	--	30	4 (13.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Region #2								
Asia (excluding Japan)	78	2 (2.6)	--	76	4 (5.3)	--	--	--
Japan	25	0 (0.0)	--	23	2 (8.7)	--	--	--
Europe/North America	36	1 (2.8)	--	30	4 (13.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	2 (1.9)	--	106	7 (6.6)	--	--	--
White	34	1 (2.9)	--	23	3 (13.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	1 (2.2)	--	34	2 (5.9)	--	--	--
vCPS < 10%	53	2 (3.8)	--	54	6 (11.1)	--	--	--
Missing	41	0 (0.0)	--	41	2 (4.9)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	77	1 (1.3)	NR (NE, NE)	70	34 (48.6)	2.4 (0.5, NE)	0.019 (0.003, 0.138)	<0.0001
>= 65 Years	62	0 (0.0)	NR (NE, NE)	59	21 (35.6)	NR (2.8, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9857
Gender								
Male	118	0 (0.0)	NR (NE, NE)	106	48 (45.3)	3.0 (1.0, NE)	0.000 (0.000, NE)	<0.0001
Female	21	1 (4.8)	NR (NE, NE)	23	7 (30.4)	NR (0.5, NE)	0.137 (0.017, 1.114)	0.0288
Interaction								0.9846

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Smoking Status								
Former/Current Smoker	104	1 (1.0)	NR (NE, NE)	101	44 (43.6)	3.0 (1.2, NE)	0.016 (0.002, 0.116)	<0.0001
Non-Smoker	35	0 (0.0)	NR (NE, NE)	28	11 (39.3)	NR (0.5, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9888
ICC Options								
Paclitaxel	83	1 (1.2)	NR (NE, NE)	79	30 (38.0)	NR (2.4, NE)	0.025 (0.003, 0.182)	<0.0001
Docetaxel	56	0 (0.0)	NR (NE, NE)	50	25 (50.0)	2.8 (0.3, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9860

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	1 (2.3)	NR (NE, NE)	37	18 (48.6)	2.4 (0.5, NE)	0.036 (0.005, 0.273)	<0.0001
1	96	0 (0.0)	NR (NE, NE)	92	37 (40.2)	NR (1.4, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9873
Region #1								
Asia	103	0 (0.0)	NR (NE, NE)	99	52 (52.5)	1.2 (0.5, NE)	0.000 (0.000, NE)	<0.0001
Europe/North America	36	1 (2.8)	NR (NE, NE)	30	3 (10.0)	NR (NE, NE)	0.270 (0.028, 2.598)	0.2223
Interaction								0.9869

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Region #2								
Asia (excluding Japan)	78	0 (0.0)	NR (NE, NE)	76	39 (51.3)	1.4 (0.5, NE)	0.000 (0.000, NE)	<0.0001
Japan	25	0 (0.0)	NR (NE, NE)	23	13 (56.5)	0.8 (0.5, NE)	0.000 (0.000, NE)	<0.0001
Europe/North America	36	1 (2.8)	NR (NE, NE)	30	3 (10.0)	NR (NE, NE)	0.270 (0.028, 2.598)	0.2223
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	0 (0.0)	NR (NE, NE)	106	53 (50.0)	2.4 (0.7, NE)	0.000 (0.000, NE)	<0.0001
White	34	1 (2.9)	NR (NE, NE)	23	2 (8.7)	NR (NE, NE)	0.337 (0.031, 3.712)	0.3476
Interaction								0.9859

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	0 (0.0)	NR (NE, NE)	34	16 (47.1)	3.0 (0.7, NE)	0.000 (0.000, NE)	<0.0001
vCPS < 10%	53	1 (1.9)	NR (NE, NE)	54	19 (35.2)	NR (2.4, NE)	0.042 (0.006, 0.318)	<0.0001
Missing	41	0 (0.0)	NR (NE, NE)	41	20 (48.8)	1.2 (0.5, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	77	1 (1.3)	NR (NE, NE)	70	32 (45.7)	NR (0.5, NE)	0.022 (0.003, 0.160)	<0.0001
>= 65 Years	62	3 (4.8)	NR (NE, NE)	59	16 (27.1)	NR (NE, NE)	0.154 (0.045, 0.530)	0.0006
Interaction								0.1101
Gender								
Male	118	2 (1.7)	NR (NE, NE)	106	42 (39.6)	NR (NE, NE)	0.034 (0.008, 0.140)	<0.0001
Female	21	2 (9.5)	NR (NE, NE)	23	6 (26.1)	NR (NE, NE)	0.336 (0.068, 1.666)	0.1554
Interaction								0.0406

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	2 (1.9)	NR (NE, NE)	101	37 (36.6)	NR (NE, NE)	0.042 (0.010, 0.175)	<0.0001
Non-Smoker	35	2 (5.7)	NR (NE, NE)	28	11 (39.3)	NR (0.5, NE)	0.121 (0.027, 0.548)	0.0009
Interaction								0.3418
ICC Options								
Paclitaxel	83	0 (0.0)	NR (NE, NE)	79	21 (26.6)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Docetaxel	56	4 (7.1)	NR (NE, NE)	50	27 (54.0)	0.8 (0.3, NE)	0.091 (0.031, 0.262)	<0.0001
Interaction								0.9852

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	2 (4.7)	NR (NE, NE)	37	14 (37.8)	NR (0.8, NE)	0.097 (0.022, 0.430)	0.0001
1	96	2 (2.1)	NR (NE, NE)	92	34 (37.0)	NR (NE, NE)	0.046 (0.011, 0.193)	<0.0001
Interaction								0.4331
Region #1								
Asia	103	4 (3.9)	NR (NE, NE)	99	47 (47.5)	NR (0.5, NE)	0.060 (0.022, 0.168)	<0.0001
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	1 (3.3)	NR (NE, NE)	0.000 (0.000, NE)	0.2733
Interaction								0.9910

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	3 (3.8)	NR (NE, NE)	76	35 (46.1)	NR (0.5, NE)	0.061 (0.018, 0.199)	<0.0001
Japan	25	1 (4.0)	NR (NE, NE)	23	12 (52.2)	0.8 (0.5, NE)	0.060 (0.008, 0.464)	0.0002
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	1 (3.3)	NR (NE, NE)	0.000 (0.000, NE)	0.2733
Interaction								0.9996

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	4 (3.8)	NR (NE, NE)	106	48 (45.3)	NR (0.5, NE)	0.063 (0.023, 0.175)	<0.0001
White	34	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9986

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Baseline PD-L1 Status								
vCPS >= 10%	45	2 (4.4)	NR (NE, NE)	34	10 (29.4)	NR (NE, NE)	0.131 (0.029, 0.601)	0.0019
vCPS < 10%	53	2 (3.8)	NR (NE, NE)	54	18 (33.3)	NR (NE, NE)	0.084 (0.019, 0.370)	<0.0001
Missing	41	0 (0.0)	NR (NE, NE)	41	20 (48.8)	NR (0.3, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9476

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	36 (46.8)	4.9 (2.0, NE)	70	38 (54.3)	1.9 (1.0, 6.6)	0.681 (0.428, 1.085)	0.0987
>= 65 Years	62	23 (37.1)	9.0 (4.1, NE)	59	29 (49.2)	3.5 (1.2, NE)	0.519 (0.292, 0.924)	0.0224
Interaction								0.6192
Gender								
Male	118	52 (44.1)	8.6 (3.6, 13.8)	106	56 (52.8)	2.6 (1.3, 5.7)	0.629 (0.427, 0.927)	0.0169
Female	21	7 (33.3)	NR (1.0, NE)	23	11 (47.8)	2.8 (0.3, NE)	0.608 (0.235, 1.572)	0.2931
Interaction								0.6045

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	48 (46.2)	8.3 (2.3, NE)	101	53 (52.5)	2.6 (1.2, 6.6)	0.705 (0.473, 1.050)	0.0799
Non-Smoker	35	11 (31.4)	9.0 (3.6, NE)	28	14 (50.0)	4.8 (0.5, NE)	0.375 (0.160, 0.879)	0.0179
Interaction								0.3138
ICC Options								
Paclitaxel	83	28 (33.7)	NR (8.3, NE)	79	36 (45.6)	4.8 (2.3, NE)	0.607 (0.366, 1.007)	0.0491
Docetaxel	56	31 (55.4)	3.7 (1.4, 9.0)	50	31 (62.0)	1.2 (0.5, 3.7)	0.549 (0.326, 0.926)	0.0198
Interaction								0.9514

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	11 (25.6)	NR (8.6, NE)	37	20 (54.1)	4.8 (0.7, 6.6)	0.272 (0.124, 0.599)	0.0005
1	96	48 (50.0)	3.6 (2.0, 9.0)	92	47 (51.1)	2.3 (1.2, NE)	0.808 (0.537, 1.216)	0.2981
Interaction								0.0342
Region #1								
Asia	103	44 (42.7)	9.0 (3.4, NE)	99	55 (55.6)	1.4 (0.7, 5.7)	0.551 (0.367, 0.826)	0.0030
Europe/North America	36	15 (41.7)	8.6 (1.4, NE)	30	12 (40.0)	4.8 (2.8, NE)	0.880 (0.399, 1.945)	0.7504
Interaction								0.1278

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	38 (48.7)	3.7 (2.0, NE)	76	44 (57.9)	1.2 (0.6, 3.5)	0.634 (0.409, 0.984)	0.0376
Japan	25	6 (24.0)	NR (10.2, NE)	23	11 (47.8)	NR (0.7, NE)	0.258 (0.082, 0.817)	0.0122
Europe/North America	36	15 (41.7)	8.6 (1.4, NE)	30	12 (40.0)	4.8 (2.8, NE)	0.880 (0.399, 1.945)	0.7504
Interaction								0.1748

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	45 (42.9)	9.0 (3.4, NE)	106	56 (52.8)	1.7 (1.2, 5.7)	0.599 (0.401, 0.896)	0.0104
White	34	14 (41.2)	8.6 (1.4, NE)	23	11 (47.8)	4.8 (2.6, NE)	0.707 (0.310, 1.613)	0.4018
Interaction								0.4423

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	16 (35.6)	13.8 (4.1, NE)	34	22 (64.7)	1.0 (0.3, NE)	0.312 (0.157, 0.619)	0.0003
vCPS < 10%	53	29 (54.7)	3.7 (1.4, 9.0)	54	22 (40.7)	4.8 (2.6, NE)	1.189 (0.676, 2.090)	0.5439
Missing	41	14 (34.1)	NR (2.3, NE)	41	23 (56.1)	1.4 (0.6, NE)	0.499 (0.256, 0.972)	0.0349
Interaction								0.0034

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	77	20 (26.0)	NR (9.0, NE)	70	19 (27.1)	NR (3.7, NE)	0.788 (0.418, 1.485)	0.4575
>= 65 Years	62	7 (11.3)	NR (NE, NE)	59	20 (33.9)	5.7 (3.5, NE)	0.245 (0.101, 0.597)	0.0008
Interaction								0.0394
Gender								
Male	118	25 (21.2)	NR (NE, NE)	106	33 (31.1)	6.6 (5.7, NE)	0.532 (0.314, 0.903)	0.0170
Female	21	2 (9.5)	NR (NE, NE)	23	6 (26.1)	NR (2.8, NE)	0.350 (0.071, 1.735)	0.1785
Interaction								0.4675

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	25 (24.0)	NR (9.0, NE)	101	35 (34.7)	6.6 (3.5, NE)	0.538 (0.319, 0.908)	0.0178
Non-Smoker	35	2 (5.7)	NR (NE, NE)	28	4 (14.3)	NR (5.7, NE)	0.338 (0.062, 1.855)	0.1903
Interaction								0.6135
ICC Options								
Paclitaxel	83	15 (18.1)	NR (NE, NE)	79	23 (29.1)	6.6 (5.7, NE)	0.511 (0.265, 0.985)	0.0406
Docetaxel	56	12 (21.4)	NR (9.0, NE)	50	16 (32.0)	NR (3.2, NE)	0.478 (0.221, 1.033)	0.0534
Interaction								0.9700

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	6 (14.0)	NR (NE, NE)	37	12 (32.4)	6.6 (3.7, NE)	0.293 (0.106, 0.808)	0.0121
1	96	21 (21.9)	NR (9.0, NE)	92	27 (29.3)	NR (3.5, NE)	0.627 (0.353, 1.115)	0.1066
Interaction								0.2691
Region #1								
Asia	103	18 (17.5)	NR (NE, NE)	99	28 (28.3)	NR (5.7, NE)	0.499 (0.274, 0.907)	0.0196
Europe/North America	36	9 (25.0)	NR (4.9, NE)	30	11 (36.7)	5.7 (2.8, NE)	0.520 (0.207, 1.304)	0.1547
Interaction								0.6407

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	17 (21.8)	NR (9.0, NE)	76	23 (30.3)	NR (5.7, NE)	0.595 (0.316, 1.118)	0.1010
Japan	25	1 (4.0)	NR (NE, NE)	23	5 (21.7)	NR (NE, NE)	0.179 (0.021, 1.537)	0.0740
Europe/North America	36	9 (25.0)	NR (4.9, NE)	30	11 (36.7)	5.7 (2.8, NE)	0.520 (0.207, 1.304)	0.1547
Interaction								0.3955

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

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Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	18 (17.1)	NR (NE, NE)	106	29 (27.4)	NR (5.7, NE)	0.507 (0.280, 0.918)	0.0219
White	34	9 (26.5)	NR (4.9, NE)	23	10 (43.5)	6.6 (2.6, NE)	0.470 (0.184, 1.200)	0.1046
Interaction								0.8805

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

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Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	7 (15.6)	NR (NE, NE)	34	13 (38.2)	6.6 (0.7, NE)	0.299 (0.118, 0.758)	0.0068
vCPS < 10%	53	18 (34.0)	9.0 (3.9, NE)	54	14 (25.9)	NR (3.7, NE)	1.101 (0.540, 2.244)	0.7895
Missing	41	2 (4.9)	NR (NE, NE)	41	12 (29.3)	NR (3.5, NE)	0.144 (0.032, 0.645)	0.0032
Interaction								0.0060

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Musculoskeletal and connective tissue disorders / PT - Myalgia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	3 (3.9)	NR (NE, NE)	70	7 (10.0)	NR (NE, NE)	0.374 (0.097, 1.448)	0.1370
>= 65 Years	62	1 (1.6)	NR (NE, NE)	59	7 (11.9)	NR (NE, NE)	0.111 (0.013, 0.915)	0.0141
Interaction								0.3906
Gender								
Male	118	4 (3.4)	NR (NE, NE)	106	12 (11.3)	NR (NE, NE)	0.268 (0.086, 0.835)	0.0146
Female	21	0 (0.0)	NR (NE, NE)	23	2 (8.7)	NR (NE, NE)	0.000 (0.000, NE)	0.1718
Interaction								0.9932

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Musculoskeletal and connective tissue disorders / PT - Myalgia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	4 (3.8)	NR (NE, NE)	101	14 (13.9)	NR (NE, NE)	0.243 (0.079, 0.745)	0.0072
Non-Smoker	35	0 (0.0)	NR (NE, NE)	28	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9995
ICC Options								
Paclitaxel	83	4 (4.8)	NR (NE, NE)	79	11 (13.9)	NR (NE, NE)	0.302 (0.095, 0.959)	0.0309
Docetaxel	56	0 (0.0)	NR (NE, NE)	50	3 (6.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0631
Interaction								0.9899

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

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Adverse events were classified based on MedDRA v23.0.

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Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	0 (0.0)	NR (NE, NE)	37	2 (5.4)	NR (NE, NE)	0.000 (0.000, NE)	0.1248
1	96	4 (4.2)	NR (NE, NE)	92	12 (13.0)	NR (NE, NE)	0.282 (0.090, 0.881)	0.0198
Interaction								0.9909
Region #1								
Asia	103	4 (3.9)	NR (NE, NE)	99	14 (14.1)	NR (NE, NE)	0.241 (0.079, 0.737)	0.0066
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9995

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

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Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	4 (5.1)	NR (NE, NE)	76	11 (14.5)	NR (NE, NE)	0.313 (0.099, 0.989)	0.0357
Japan	25	0 (0.0)	NR (NE, NE)	23	3 (13.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0648
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

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	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	105	4 (3.8)	NR (NE, NE)	106	14 (13.2)	NR (NE, NE)	0.255 (0.083, 0.780)	0.0096
White	34	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9995

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

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	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	2 (4.4)	--	34	4 (11.8)	--	--	--
vCPS < 10%	53	2 (3.8)	--	54	6 (11.1)	--	--	--
Missing	41	0 (0.0)	--	41	4 (9.8)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Neoplasms benign, malignant and unspecified (incl cysts and polyps)

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	5 (6.5)	NR (NE, NE)	70	2 (2.9)	NR (NE, NE)	2.263 (0.439, 11.663)	0.3157
>= 65 Years	62	9 (14.5)	NR (NE, NE)	59	2 (3.4)	NR (NE, NE)	4.233 (0.914, 19.613)	0.0446
Interaction								0.5608
Gender								
Male	118	11 (9.3)	NR (NE, NE)	106	2 (1.9)	NR (NE, NE)	4.722 (1.046, 21.315)	0.0259
Female	21	3 (14.3)	NR (NE, NE)	23	2 (8.7)	NR (NE, NE)	1.795 (0.300, 10.757)	0.5158
Interaction								0.3976

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Neoplasms benign, malignant and unspecified (incl cysts and polyps)

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	11 (10.6)	NR (NE, NE)	101	3 (3.0)	NR (NE, NE)	3.407 (0.949, 12.229)	0.0455
Non-Smoker	35	3 (8.6)	NR (NE, NE)	28	1 (3.6)	NR (NE, NE)	2.447 (0.254, 23.540)	0.4231
Interaction								0.7977
ICC Options								
Paclitaxel	83	9 (10.8)	NR (NE, NE)	79	3 (3.8)	NR (NE, NE)	2.890 (0.782, 10.685)	0.0953
Docetaxel	56	5 (8.9)	NR (NE, NE)	50	1 (2.0)	NR (NE, NE)	4.017 (0.468, 34.460)	0.1700
Interaction								0.7889

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Neoplasms benign, malignant and unspecified (incl cysts and polyps)

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	3 (7.0)	NR (NE, NE)	37	1 (2.7)	NR (NE, NE)	2.716 (0.282, 26.118)	0.3674
1	96	11 (11.5)	NR (NE, NE)	92	3 (3.3)	NR (NE, NE)	3.405 (0.949, 12.216)	0.0453
Interaction								0.8306
Region #1								
Asia	103	8 (7.8)	NR (NE, NE)	99	2 (2.0)	NR (NE, NE)	3.577 (0.758, 16.878)	0.0854
Europe/North America	36	6 (16.7)	NR (NE, NE)	30	2 (6.7)	NR (NE, NE)	2.816 (0.568, 13.971)	0.1856
Interaction								0.8181

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Neoplasms benign, malignant and unspecified (incl cysts and polyps)

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	4 (5.1)	--	76	1 (1.3)	--	--	--
Japan	25	4 (16.0)	--	23	1 (4.3)	--	--	--
Europe/North America	36	6 (16.7)	--	30	2 (6.7)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Any TEAE: SOC - Neoplasms benign, malignant and unspecified (incl cysts and polyps)

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	8 (7.6)	NR (NE, NE)	106	2 (1.9)	NR (NE, NE)	3.771 (0.799, 17.795)	0.0716
White	34	6 (17.6)	NR (NE, NE)	23	2 (8.7)	NR (NE, NE)	2.302 (0.464, 11.423)	0.2939
Interaction								0.6518

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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Any TEAE: SOC - Neoplasms benign, malignant and unspecified (incl cysts and polyps)

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	6 (13.3)	--	34	1 (2.9)	--	--	--
vCPS < 10%	53	4 (7.5)	--	54	1 (1.9)	--	--	--
Missing	41	4 (9.8)	--	41	2 (4.9)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Nervous system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	13 (16.9)	NR (17.8, NE)	70	23 (32.9)	9.7 (3.5, NE)	0.375 (0.186, 0.758)	0.0044
>= 65 Years	62	9 (14.5)	NR (20.6, NE)	59	20 (33.9)	NR (2.4, NE)	0.290 (0.129, 0.649)	0.0014
Interaction								0.6125
Gender								
Male	118	17 (14.4)	NR (17.8, NE)	106	32 (30.2)	9.7 (3.5, NE)	0.305 (0.163, 0.569)	<0.0001
Female	21	5 (23.8)	NR (3.5, NE)	23	11 (47.8)	2.4 (0.8, NE)	0.400 (0.138, 1.160)	0.0787
Interaction								0.7930

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Any TEAE: SOC - Nervous system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	15 (14.4)	NR (20.6, NE)	101	32 (31.7)	9.7 (3.5, NE)	0.315 (0.167, 0.596)	0.0002
Non-Smoker	35	7 (20.0)	17.8 (6.2, NE)	28	11 (39.3)	NR (0.9, NE)	0.362 (0.139, 0.940)	0.0293
Interaction								0.8152
ICC Options								
Paclitaxel	83	13 (15.7)	NR (NE, NE)	79	36 (45.6)	2.8 (1.4, NE)	0.230 (0.120, 0.438)	<0.0001
Docetaxel	56	9 (16.1)	20.6 (17.8, NE)	50	7 (14.0)	NR (NE, NE)	0.932 (0.344, 2.526)	0.8898
Interaction								0.0160

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	3 (7.0)	NR (20.6, NE)	37	16 (43.2)	NR (1.0, NE)	0.077 (0.018, 0.338)	<0.0001
1	96	19 (19.8)	NR (17.8, NE)	92	27 (29.3)	9.7 (3.5, NE)	0.503 (0.277, 0.914)	0.0211
Interaction								0.0113
Region #1								
Asia	103	13 (12.6)	NR (17.8, NE)	99	28 (28.3)	9.7 (3.5, NE)	0.300 (0.153, 0.591)	0.0002
Europe/North America	36	9 (25.0)	NR (3.5, NE)	30	15 (50.0)	2.4 (0.5, NE)	0.337 (0.142, 0.798)	0.0093
Interaction								0.7801

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Any TEAE: SOC - Nervous system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	12 (15.4)	20.6 (17.8, NE)	76	19 (25.0)	9.7 (9.7, NE)	0.446 (0.214, 0.930)	0.0270
Japan	25	1 (4.0)	NR (NE, NE)	23	9 (39.1)	2.8 (1.0, NE)	0.060 (0.007, 0.486)	0.0005
Europe/North America	36	9 (25.0)	NR (3.5, NE)	30	15 (50.0)	2.4 (0.5, NE)	0.337 (0.142, 0.798)	0.0093
Interaction								0.1445

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Nervous system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	13 (12.4)	NR (17.8, NE)	106	29 (27.4)	9.7 (3.5, NE)	0.308 (0.157, 0.605)	0.0003
White	34	9 (26.5)	NR (3.5, NE)	23	14 (60.9)	0.7 (0.4, NE)	0.263 (0.110, 0.632)	0.0013
Interaction								0.7899

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Nervous system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	8 (17.8)	NR (NE, NE)	34	9 (26.5)	9.7 (2.7, NE)	0.463 (0.174, 1.233)	0.1145
vCPS < 10%	53	11 (20.8)	17.8 (17.8, NE)	54	17 (31.5)	NR (2.4, NE)	0.489 (0.223, 1.069)	0.0665
Missing	41	3 (7.3)	20.6 (20.6, NE)	41	17 (41.5)	3.5 (1.0, NE)	0.083 (0.019, 0.364)	<0.0001
Interaction								0.1031

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Nervous system disorders / PT - Peripheral sensory neuropathy

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	0 (0.0)	NR (NE, NE)	70	10 (14.3)	NR (9.7, NE)	0.000 (0.000, NE)	0.0002
>= 65 Years	62	1 (1.6)	NR (NE, NE)	59	12 (20.3)	NR (NE, NE)	0.067 (0.009, 0.518)	0.0006
Interaction								0.9924
Gender								
Male	118	0 (0.0)	NR (NE, NE)	106	18 (17.0)	NR (9.7, NE)	0.000 (0.000, NE)	<0.0001
Female	21	1 (4.8)	NR (2.5, NE)	23	4 (17.4)	NR (2.4, NE)	0.234 (0.026, 2.109)	0.1589
Interaction								0.9894

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Nervous system disorders / PT - Peripheral sensory neuropathy

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	1 (1.0)	NR (NE, NE)	101	18 (17.8)	9.7 (9.7, NE)	0.036 (0.005, 0.277)	<0.0001
Non-Smoker	35	0 (0.0)	NR (NE, NE)	28	4 (14.3)	NR (NE, NE)	0.000 (0.000, NE)	0.0199
Interaction								0.9923
ICC Options								
Paclitaxel	83	1 (1.2)	NR (NE, NE)	79	19 (24.1)	9.7 (9.7, NE)	0.035 (0.005, 0.266)	<0.0001
Docetaxel	56	0 (0.0)	NR (NE, NE)	50	3 (6.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0608
Interaction								0.9927

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Nervous system disorders / PT - Peripheral sensory neuropathy

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	0 (0.0)	NR (NE, NE)	37	8 (21.6)	NR (NE, NE)	0.000 (0.000, NE)	0.0010
1	96	1 (1.0)	NR (NE, NE)	92	14 (15.2)	9.7 (9.7, NE)	0.044 (0.006, 0.346)	<0.0001
Interaction								0.9906
Region #1								
Asia	103	0 (0.0)	NR (NE, NE)	99	14 (14.1)	NR (9.7, NE)	0.000 (0.000, NE)	<0.0001
Europe/North America	36	1 (2.8)	NR (NE, NE)	30	8 (26.7)	NR (NE, NE)	0.088 (0.011, 0.709)	0.0040
Interaction								0.9922

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Nervous system disorders / PT - Peripheral sensory neuropathy

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	0 (0.0)	--	76	7 (9.2)	--	--	--
Japan	25	0 (0.0)	--	23	7 (30.4)	--	--	--
Europe/North America	36	1 (2.8)	--	30	8 (26.7)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Nervous system disorders / PT - Peripheral sensory neuropathy

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	0 (0.0)	NR (NE, NE)	106	15 (14.2)	NR (9.7, NE)	0.000 (0.000, NE)	<0.0001
White	34	1 (2.9)	NR (NE, NE)	23	7 (30.4)	NR (2.4, NE)	0.081 (0.010, 0.657)	0.0026
Interaction								0.9893

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Nervous system disorders / PT - Peripheral sensory neuropathy

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	1 (2.2)	NR (NE, NE)	34	3 (8.8)	NR (9.7, NE)	0.177 (0.018, 1.758)	0.0986
vCPS < 10%	53	0 (0.0)	NR (NE, NE)	54	10 (18.5)	NR (NE, NE)	0.000 (0.000, NE)	0.0006
Missing	41	0 (0.0)	NR (NE, NE)	41	9 (22.0)	NR (3.5, NE)	0.000 (0.000, NE)	0.0004
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Skin and subcutaneous tissue disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	20 (26.0)	NR (7.0, NE)	70	26 (37.1)	NR (1.4, NE)	0.616 (0.343, 1.106)	0.0996
>= 65 Years	62	17 (27.4)	NR (9.6, NE)	59	23 (39.0)	5.1 (1.9, NE)	0.555 (0.293, 1.054)	0.0673
Interaction								0.9742
Gender								
Male	118	33 (28.0)	NR (9.6, NE)	106	34 (32.1)	NR (5.1, NE)	0.746 (0.460, 1.210)	0.2320
Female	21	4 (19.0)	NR (2.2, NE)	23	15 (65.2)	1.4 (0.7, 1.9)	0.196 (0.064, 0.596)	0.0014
Interaction								0.0381

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Skin and subcutaneous tissue disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	27 (26.0)	NR (9.6, NE)	101	38 (37.6)	NR (2.4, NE)	0.556 (0.337, 0.917)	0.0193
Non-Smoker	35	10 (28.6)	NR (2.1, NE)	28	11 (39.3)	NR (1.9, NE)	0.679 (0.288, 1.600)	0.3700
Interaction								0.7075
ICC Options								
Paclitaxel	83	23 (27.7)	NR (NE, NE)	79	37 (46.8)	3.0 (1.3, NE)	0.517 (0.307, 0.873)	0.0116
Docetaxel	56	14 (25.0)	10.3 (7.0, NE)	50	12 (24.0)	NR (NE, NE)	0.783 (0.358, 1.712)	0.5374
Interaction								0.2720

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Skin and subcutaneous tissue disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	13 (30.2)	NR (7.0, NE)	37	17 (45.9)	NR (0.7, NE)	0.492 (0.237, 1.021)	0.0509
1	96	24 (25.0)	NR (9.6, NE)	92	32 (34.8)	NR (1.9, NE)	0.622 (0.365, 1.061)	0.0776
Interaction								0.6060
Region #1								
Asia	103	29 (28.2)	NR (9.6, NE)	99	37 (37.4)	NR (1.9, NE)	0.605 (0.370, 0.989)	0.0420
Europe/North America	36	8 (22.2)	NR (NE, NE)	30	12 (40.0)	NR (1.4, NE)	0.523 (0.214, 1.281)	0.1487
Interaction								0.7619

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Skin and subcutaneous tissue disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	23 (29.5)	NR (7.0, NE)	76	24 (31.6)	NR (5.1, NE)	0.822 (0.462, 1.461)	0.5014
Japan	25	6 (24.0)	NR (10.3, NE)	23	13 (56.5)	0.7 (0.5, NE)	0.222 (0.078, 0.629)	0.0020
Europe/North America	36	8 (22.2)	NR (NE, NE)	30	12 (40.0)	NR (1.4, NE)	0.523 (0.214, 1.281)	0.1487
Interaction								0.0949

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Skin and subcutaneous tissue disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	29 (27.6)	NR (9.6, NE)	106	41 (38.7)	5.1 (1.9, NE)	0.569 (0.351, 0.920)	0.0194
White	34	8 (23.5)	NR (NE, NE)	23	8 (34.8)	NR (1.4, NE)	0.660 (0.248, 1.761)	0.4036
Interaction								0.8285

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Skin and subcutaneous tissue disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	10 (22.2)	NR (10.3, NE)	34	14 (41.2)	5.1 (1.6, NE)	0.423 (0.187, 0.957)	0.0323
vCPS < 10%	53	22 (41.5)	7.0 (2.1, NE)	54	20 (37.0)	NR (1.4, NE)	1.076 (0.584, 1.980)	0.8143
Missing	41	5 (12.2)	NR (9.6, NE)	41	15 (36.6)	NR (1.9, NE)	0.218 (0.072, 0.658)	0.0029
Interaction								0.0396

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Skin and subcutaneous tissue disorders / PT - Alopecia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	0 (0.0)	NR (NE, NE)	70	18 (25.7)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
>= 65 Years	62	0 (0.0)	NR (NE, NE)	59	16 (27.1)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								1.0000
Gender								
Male	118	0 (0.0)	NR (NE, NE)	106	22 (20.8)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Female	21	0 (0.0)	NR (NE, NE)	23	12 (52.2)	1.9 (0.9, NE)	0.000 (0.000, NE)	0.0002
Interaction								0.9997

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Skin and subcutaneous tissue disorders / PT - Alopecia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	0 (0.0)	NR (NE, NE)	101	27 (26.7)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Non-Smoker	35	0 (0.0)	NR (NE, NE)	28	7 (25.0)	NR (1.9, NE)	0.000 (0.000, NE)	0.0011
Interaction								0.9999
ICC Options								
Paclitaxel	83	0 (0.0)	NR (NE, NE)	79	24 (30.4)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Docetaxel	56	0 (0.0)	NR (NE, NE)	50	10 (20.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0002
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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Any TEAE: SOC - Skin and subcutaneous tissue disorders / PT - Alopecia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	0 (0.0)	NR (NE, NE)	37	13 (35.1)	NR (1.0, NE)	0.000 (0.000, NE)	<0.0001
1	96	0 (0.0)	NR (NE, NE)	92	21 (22.8)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9998
Region #1								
Asia	103	0 (0.0)	NR (NE, NE)	99	25 (25.3)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	9 (30.0)	NR (2.4, NE)	0.000 (0.000, NE)	0.0005
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

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Any TEAE: SOC - Skin and subcutaneous tissue disorders / PT - Alopecia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	0 (0.0)	NR (NE, NE)	76	14 (18.4)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Japan	25	0 (0.0)	NR (NE, NE)	23	11 (47.8)	NR (0.7, NE)	0.000 (0.000, NE)	<0.0001
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	9 (30.0)	NR (2.4, NE)	0.000 (0.000, NE)	0.0005
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	0 (0.0)	NR (NE, NE)	106	27 (25.5)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
White	34	0 (0.0)	NR (NE, NE)	23	7 (30.4)	NR (2.4, NE)	0.000 (0.000, NE)	0.0007
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

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Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	0 (0.0)	NR (NE, NE)	34	10 (29.4)	NR (1.9, NE)	0.000 (0.000, NE)	<0.0001
vCPS < 10%	53	0 (0.0)	NR (NE, NE)	54	16 (29.6)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Missing	41	0 (0.0)	NR (NE, NE)	41	8 (19.5)	NR (NE, NE)	0.000 (0.000, NE)	0.0024
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	14 (8.9)	NR (NE, NE)	149	34 (22.8)	NR (NE, NE)	0.275 (0.144, 0.524)	<0.0001
>= 65 Years	98	4 (4.1)	NR (NE, NE)	91	22 (24.2)	9.2 (NE, NE)	0.121 (0.039, 0.374)	<0.0001
Interaction								0.1661
Gender								
Male	216	17 (7.9)	NR (NE, NE)	204	49 (24.0)	NR (9.2, NE)	0.235 (0.133, 0.416)	<0.0001
Female	39	1 (2.6)	NR (NE, NE)	36	7 (19.4)	NR (NE, NE)	0.120 (0.015, 0.978)	0.0173
Interaction								0.4290

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	15 (8.0)	NR (NE, NE)	183	41 (22.4)	NR (9.2, NE)	0.257 (0.139, 0.475)	<0.0001
Non-Smoker	68	3 (4.4)	NR (NE, NE)	57	15 (26.3)	NR (NE, NE)	0.128 (0.036, 0.448)	0.0002
Interaction								0.2707

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	4 (4.8)	NR (NE, NE)	79	12 (15.2)	NR (NE, NE)	0.281 (0.091, 0.872)	0.0188
Docetaxel	56	9 (16.1)	NR (7.6, NE)	50	19 (38.0)	NR (1.3, NE)	0.301 (0.134, 0.676)	0.0018
Irinotecan	116	5 (4.3)	NR (17.5, NE)	111	25 (22.5)	NR (9.2, NE)	0.113 (0.039, 0.329)	<0.0001
Interaction								0.5205

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	2 (3.2)	NR (17.5, NE)	57	11 (19.3)	NR (9.2, NE)	0.059 (0.008, 0.464)	0.0003
1	192	16 (8.3)	NR (NE, NE)	183	45 (24.6)	NR (NE, NE)	0.268 (0.151, 0.476)	<0.0001
Interaction								0.3658
Region #1								
Asia	201	15 (7.5)	NR (NE, NE)	191	44 (23.0)	NR (NE, NE)	0.233 (0.127, 0.429)	<0.0001
Europe/North America	54	3 (5.6)	NR (NE, NE)	49	12 (24.5)	NR (9.2, NE)	0.180 (0.050, 0.645)	0.0032
Interaction								0.7390

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	14 (8.0)	NR (NE, NE)	168	39 (23.2)	NR (NE, NE)	0.246 (0.130, 0.465)	<0.0001
Japan	25	1 (4.0)	NR (NE, NE)	23	5 (21.7)	NR (2.8, NE)	0.146 (0.017, 1.262)	0.0427
Europe/North America	54	3 (5.6)	NR (NE, NE)	49	12 (24.5)	NR (9.2, NE)	0.180 (0.050, 0.645)	0.0032
Interaction								0.8069

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	15 (7.4)	NR (NE, NE)	198	45 (22.7)	NR (NE, NE)	0.236 (0.129, 0.433)	<0.0001
White	52	3 (5.8)	NR (NE, NE)	42	11 (26.2)	NR (9.2, NE)	0.173 (0.048, 0.628)	0.0026
Interaction								0.6798

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	7 (8.8)	NR (17.5, NE)	60	16 (26.7)	NR (NE, NE)	0.205 (0.079, 0.530)	0.0003
vCPS < 10%	100	9 (9.0)	NR (NE, NE)	119	32 (26.9)	NR (9.2, NE)	0.252 (0.119, 0.533)	0.0001
Missing	75	2 (2.7)	NR (NE, NE)	61	8 (13.1)	NR (NE, NE)	0.181 (0.038, 0.857)	0.0155
Interaction								0.8399

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	12 (7.6)	NR (NE, NE)	149	17 (11.4)	NR (NE, NE)	0.494 (0.230, 1.062)	0.0651
>= 65 Years	98	3 (3.1)	NR (NE, NE)	91	9 (9.9)	9.2 (9.2, NE)	0.218 (0.055, 0.871)	0.0193
Interaction								0.3096
Gender								
Male	216	14 (6.5)	NR (NE, NE)	204	22 (10.8)	NR (9.2, NE)	0.439 (0.219, 0.880)	0.0171
Female	39	1 (2.6)	NR (NE, NE)	36	4 (11.1)	NR (NE, NE)	0.219 (0.024, 1.958)	0.1354
Interaction								0.4534

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	12 (6.4)	NR (NE, NE)	183	19 (10.4)	NR (9.2, NE)	0.451 (0.212, 0.957)	0.0333
Non-Smoker	68	3 (4.4)	NR (NE, NE)	57	7 (12.3)	NR (NE, NE)	0.290 (0.074, 1.137)	0.0593
Interaction								0.5333

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ICC Options								
Paclitaxel	83	4 (4.8)	NR (NE, NE)	79	6 (7.6)	NR (NE, NE)	0.582 (0.164, 2.065)	0.3961
Docetaxel	56	6 (10.7)	NR (NE, NE)	50	4 (8.0)	NR (NE, NE)	1.130 (0.317, 4.034)	0.8505
Irinotecan	116	5 (4.3)	NR (17.5, NE)	111	16 (14.4)	NR (9.2, NE)	0.170 (0.055, 0.523)	0.0005
Interaction								0.1253

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	1 (1.6)	NR (17.5, NE)	57	3 (5.3)	NR (9.2, NE)	0.000 (0.000, NE)	0.0169
1	192	14 (7.3)	NR (NE, NE)	183	23 (12.6)	NR (NE, NE)	0.473 (0.242, 0.924)	0.0249
Interaction								0.5918
Region #1								
Asia	201	12 (6.0)	NR (NE, NE)	191	20 (10.5)	NR (NE, NE)	0.434 (0.208, 0.906)	0.0222
Europe/North America	54	3 (5.6)	NR (NE, NE)	49	6 (12.2)	NR (9.2, NE)	0.364 (0.089, 1.489)	0.1436
Interaction								0.9057

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	11 (6.3)	NR (NE, NE)	168	17 (10.1)	NR (NE, NE)	0.472 (0.217, 1.030)	0.0538
Japan	25	1 (4.0)	NR (NE, NE)	23	3 (13.0)	NR (2.8, NE)	0.253 (0.026, 2.451)	0.2007
Europe/North America	54	3 (5.6)	NR (NE, NE)	49	6 (12.2)	NR (9.2, NE)	0.364 (0.089, 1.489)	0.1436
Interaction								0.8215

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	12 (5.9)	NR (NE, NE)	198	21 (10.6)	NR (NE, NE)	0.428 (0.207, 0.887)	0.0189
White	52	3 (5.8)	NR (NE, NE)	42	5 (11.9)	NR (9.2, NE)	0.387 (0.091, 1.655)	0.1851
Interaction								0.9816

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	6 (7.5)	NR (17.5, NE)	60	5 (8.3)	NR (NE, NE)	0.610 (0.182, 2.044)	0.4180
vCPS < 10%	100	7 (7.0)	NR (NE, NE)	119	18 (15.1)	NR (9.2, NE)	0.372 (0.154, 0.900)	0.0225
Missing	75	2 (2.7)	NR (NE, NE)	61	3 (4.9)	NR (NE, NE)	0.478 (0.079, 2.892)	0.4111
Interaction								0.7469

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	0 (0.0)	--	149	6 (4.0)	--	--	--
>= 65 Years	98	0 (0.0)	--	91	5 (5.5)	--	--	--
Interaction								--
Gender								
Male	216	0 (0.0)	NR (NE, NE)	204	10 (4.9)	NR (NE, NE)	0.000 (0.000, NE)	0.0006
Female	39	0 (0.0)	NR (NE, NE)	36	1 (2.8)	NR (NE, NE)	0.000 (0.000, NE)	0.2980
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	0 (0.0)	--	183	8 (4.4)	--	--	--
Non-Smoker	68	0 (0.0)	--	57	3 (5.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	0 (0.0)	--	79	0 (0.0)	--	--	--
Docetaxel	56	0 (0.0)	--	50	8 (16.0)	--	--	--
Irinotecan	116	0 (0.0)	--	111	3 (2.7)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	0 (0.0)	--	57	2 (3.5)	--	--	--
1	192	0 (0.0)	--	183	9 (4.9)	--	--	--
Interaction								--
Region #1								
Asia	201	0 (0.0)	--	191	9 (4.7)	--	--	--
Europe/North America	54	0 (0.0)	--	49	2 (4.1)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	0 (0.0)	--	168	7 (4.2)	--	--	--
Japan	25	0 (0.0)	--	23	2 (8.7)	--	--	--
Europe/North America	54	0 (0.0)	--	49	2 (4.1)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	203	0 (0.0)	--	198	9 (4.5)	--	--	--
White	52	0 (0.0)	--	42	2 (4.8)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

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Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	0 (0.0)	--	60	4 (6.7)	--	--	--
vCPS < 10%	100	0 (0.0)	--	119	3 (2.5)	--	--	--
Missing	75	0 (0.0)	--	61	4 (6.6)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	0 (0.0)	NR (NE, NE)	149	11 (7.4)	NR (NE, NE)	0.000 (0.000, NE)	0.0005
>= 65 Years	98	0 (0.0)	NR (NE, NE)	91	6 (6.6)	NR (NE, NE)	0.000 (0.000, NE)	0.0095
Interaction								1.0000
Gender								
Male	216	0 (0.0)	NR (NE, NE)	204	16 (7.8)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Female	39	0 (0.0)	NR (NE, NE)	36	1 (2.8)	NR (NE, NE)	0.000 (0.000, NE)	0.3042
Interaction								0.9998

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	0 (0.0)	NR (NE, NE)	183	11 (6.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0006
Non-Smoker	68	0 (0.0)	NR (NE, NE)	57	6 (10.5)	NR (NE, NE)	0.000 (0.000, NE)	0.0066
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	0 (0.0)	--	79	1 (1.3)	--	--	--
Docetaxel	56	0 (0.0)	--	50	7 (14.0)	--	--	--
Irinotecan	116	0 (0.0)	--	111	9 (8.1)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	0 (0.0)	NR (NE, NE)	57	4 (7.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0330
1	192	0 (0.0)	NR (NE, NE)	183	13 (7.1)	NR (NE, NE)	0.000 (0.000, NE)	0.0002
Interaction								1.0000
Region #1								
Asia	201	0 (0.0)	NR (NE, NE)	191	16 (8.4)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	0.000 (0.000, NE)	0.2888
Interaction								0.9997

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	0 (0.0)	NR (NE, NE)	168	16 (9.5)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Japan	25	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	0.000 (0.000, NE)	0.2888
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	203	0 (0.0)	NR (NE, NE)	198	16 (8.1)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
White	52	0 (0.0)	NR (NE, NE)	42	1 (2.4)	NR (NE, NE)	0.000 (0.000, NE)	0.2601
Interaction								0.9997

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	0 (0.0)	NR (NE, NE)	60	6 (10.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0033
vCPS < 10%	100	0 (0.0)	NR (NE, NE)	119	10 (8.4)	NR (NE, NE)	0.000 (0.000, NE)	0.0030
Missing	75	0 (0.0)	NR (NE, NE)	61	1 (1.6)	NR (NE, NE)	0.000 (0.000, NE)	0.2668
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	1 (0.6)	--	149	8 (5.4)	--	--	--
>= 65 Years	98	0 (0.0)	--	91	8 (8.8)	--	--	--
Interaction								--
Gender								
Male	216	1 (0.5)	NR (NE, NE)	204	14 (6.9)	NR (NE, NE)	0.056 (0.007, 0.436)	0.0002
Female	39	0 (0.0)	NR (NE, NE)	36	2 (5.6)	NR (NE, NE)	0.000 (0.000, NE)	0.1435
Interaction								0.9917

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	1 (0.5)	NR (NE, NE)	183	11 (6.0)	NR (NE, NE)	0.071 (0.009, 0.563)	0.0013
Non-Smoker	68	0 (0.0)	NR (NE, NE)	57	5 (8.8)	NR (NE, NE)	0.000 (0.000, NE)	0.0130
Interaction								0.9927

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ICC Options								
Paclitaxel	83	0 (0.0)	--	79	5 (6.3)	--	--	--
Docetaxel	56	1 (1.8)	--	50	7 (14.0)	--	--	--
Irinotecan	116	0 (0.0)	--	111	4 (3.6)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

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Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	1 (1.6)	NR (NE, NE)	57	4 (7.0)	NR (NE, NE)	0.180 (0.020, 1.653)	0.0894
1	192	0 (0.0)	NR (NE, NE)	183	12 (6.6)	NR (NE, NE)	0.000 (0.000, NE)	0.0003
Interaction								0.9915
Region #1								
Asia	201	1 (0.5)	NR (NE, NE)	191	11 (5.8)	NR (NE, NE)	0.068 (0.009, 0.546)	0.0011
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	5 (10.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0152
Interaction								0.9903

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	1 (0.6)	NR (NE, NE)	168	11 (6.5)	NR (NE, NE)	0.068 (0.008, 0.543)	0.0011
Japan	25	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	5 (10.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0152
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	203	1 (0.5)	NR (NE, NE)	198	11 (5.6)	NR (NE, NE)	0.070 (0.009, 0.559)	0.0013
White	52	0 (0.0)	NR (NE, NE)	42	5 (11.9)	NR (NE, NE)	0.000 (0.000, NE)	0.0096
Interaction								0.9913

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Baseline PD-L1 Status								
vCPS >= 10%	80	0 (0.0)	NR (NE, NE)	60	3 (5.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0416
vCPS < 10%	100	1 (1.0)	NR (NE, NE)	119	10 (8.4)	NR (NE, NE)	0.094 (0.012, 0.756)	0.0065
Missing	75	0 (0.0)	NR (NE, NE)	61	3 (4.9)	NR (NE, NE)	0.000 (0.000, NE)	0.0530
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	25 (15.9)	NR (20.9, NE)	149	28 (18.8)	NR (8.9, NE)	0.604 (0.348, 1.049)	0.0705
>= 65 Years	98	13 (13.3)	NR (NE, NE)	91	17 (18.7)	NR (6.1, NE)	0.569 (0.273, 1.186)	0.1268
Interaction								0.7073
Gender								
Male	216	35 (16.2)	NR (NE, NE)	204	38 (18.6)	NR (8.9, NE)	0.646 (0.404, 1.033)	0.0659
Female	39	3 (7.7)	NR (NE, NE)	36	7 (19.4)	NR (NE, NE)	0.346 (0.089, 1.342)	0.1077
Interaction								0.2971

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	28 (15.0)	NR (NE, NE)	183	34 (18.6)	NR (8.9, NE)	0.616 (0.371, 1.024)	0.0589
Non-Smoker	68	10 (14.7)	NR (20.9, NE)	57	11 (19.3)	NR (NE, NE)	0.580 (0.243, 1.384)	0.2142
Interaction								0.9523

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	10 (12.0)	NR (NE, NE)	79	9 (11.4)	NR (8.9, NE)	0.909 (0.367, 2.254)	0.8372
Docetaxel	56	8 (14.3)	NR (9.7, NE)	50	5 (10.0)	NR (6.1, NE)	1.075 (0.344, 3.359)	0.9010
Irinotecan	116	20 (17.2)	NR (20.9, NE)	111	31 (27.9)	NR (NE, NE)	0.411 (0.229, 0.738)	0.0021
Interaction								0.1421

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	5 (7.9)	NR (NE, NE)	57	9 (15.8)	NR (8.9, NE)	0.381 (0.126, 1.154)	0.0764
1	192	33 (17.2)	NR (20.9, NE)	183	36 (19.7)	NR (NE, NE)	0.655 (0.405, 1.059)	0.0816
Interaction								0.3663
Region #1								
Asia	201	28 (13.9)	NR (NE, NE)	191	31 (16.2)	NR (NE, NE)	0.644 (0.382, 1.085)	0.0954
Europe/North America	54	10 (18.5)	NR (NE, NE)	49	14 (28.6)	8.9 (6.1, NE)	0.525 (0.232, 1.190)	0.1164
Interaction								0.7262

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	26 (14.8)	NR (20.9, NE)	168	28 (16.7)	NR (NE, NE)	0.659 (0.382, 1.136)	0.1306
Japan	25	2 (8.0)	NR (NE, NE)	23	3 (13.0)	NR (2.4, NE)	0.525 (0.087, 3.174)	0.4757
Europe/North America	54	10 (18.5)	NR (NE, NE)	49	14 (28.6)	8.9 (6.1, NE)	0.525 (0.232, 1.190)	0.1164
Interaction								0.8634

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	29 (14.3)	NR (NE, NE)	198	32 (16.2)	NR (NE, NE)	0.669 (0.401, 1.117)	0.1214
White	52	9 (17.3)	NR (NE, NE)	42	13 (31.0)	8.9 (6.1, NE)	0.440 (0.187, 1.037)	0.0536
Interaction								0.4430

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	12 (15.0)	NR (NE, NE)	60	16 (26.7)	NR (8.9, NE)	0.331 (0.154, 0.714)	0.0032
vCPS < 10%	100	17 (17.0)	NR (NE, NE)	119	24 (20.2)	NR (6.1, NE)	0.716 (0.383, 1.338)	0.2924
Missing	75	9 (12.0)	NR (20.9, NE)	61	5 (8.2)	NR (NE, NE)	1.159 (0.377, 3.563)	0.7969
Interaction								0.1978

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	2 (1.3)	--	149	7 (4.7)	--	--	--
>= 65 Years	98	1 (1.0)	--	91	8 (8.8)	--	--	--
Interaction								--
Gender								
Male	216	3 (1.4)	NR (NE, NE)	204	13 (6.4)	NR (NE, NE)	0.192 (0.054, 0.675)	0.0041
Female	39	0 (0.0)	NR (NE, NE)	36	2 (5.6)	NR (NE, NE)	0.000 (0.000, NE)	0.1408
Interaction								0.9900

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	3 (1.6)	NR (NE, NE)	183	11 (6.0)	NR (NE, NE)	0.232 (0.065, 0.835)	0.0148
Non-Smoker	68	0 (0.0)	NR (NE, NE)	57	4 (7.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0283
Interaction								0.9912

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	1 (1.2)	NR (NE, NE)	79	2 (2.5)	NR (NE, NE)	0.464 (0.042, 5.115)	0.5202
Docetaxel	56	0 (0.0)	NR (NE, NE)	50	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Irinotecan	116	2 (1.7)	NR (NE, NE)	111	13 (11.7)	NR (NE, NE)	0.123 (0.028, 0.549)	0.0011
Interaction								0.6492

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	0 (0.0)	NR (NE, NE)	57	2 (3.5)	NR (NE, NE)	0.000 (0.000, NE)	0.1351
1	192	3 (1.6)	NR (NE, NE)	183	13 (7.1)	NR (NE, NE)	0.192 (0.055, 0.677)	0.0042
Interaction								0.9921
Region #1								
Asia	201	3 (1.5)	NR (NE, NE)	191	11 (5.8)	NR (NE, NE)	0.224 (0.062, 0.807)	0.0123
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	4 (8.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0310
Interaction								0.9920

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	3 (1.7)	NR (NE, NE)	168	11 (6.5)	NR (NE, NE)	0.222 (0.062, 0.801)	0.0118
Japan	25	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	4 (8.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0310
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	203	3 (1.5)	NR (NE, NE)	198	11 (5.6)	NR (NE, NE)	0.232 (0.064, 0.834)	0.0148
White	52	0 (0.0)	NR (NE, NE)	42	4 (9.5)	NR (NE, NE)	0.000 (0.000, NE)	0.0215
Interaction								0.9923

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	1 (1.3)	NR (NE, NE)	60	5 (8.3)	NR (NE, NE)	0.117 (0.014, 1.012)	0.0199
vCPS < 10%	100	2 (2.0)	NR (NE, NE)	119	10 (8.4)	NR (NE, NE)	0.218 (0.048, 0.996)	0.0307
Missing	75	0 (0.0)	NR (NE, NE)	61	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9228

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	9 (5.7)	NR (NE, NE)	149	13 (8.7)	NR (NE, NE)	0.457 (0.188, 1.115)	0.0779
>= 65 Years	98	6 (6.1)	NR (NE, NE)	91	12 (13.2)	NR (NE, NE)	0.313 (0.112, 0.872)	0.0198
Interaction								0.6358
Gender								
Male	216	13 (6.0)	NR (NE, NE)	204	19 (9.3)	NR (NE, NE)	0.423 (0.200, 0.897)	0.0209
Female	39	2 (5.1)	NR (NE, NE)	36	6 (16.7)	NR (2.6, NE)	0.238 (0.047, 1.198)	0.0596
Interaction								0.4681

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	8 (4.3)	NR (NE, NE)	183	17 (9.3)	NR (NE, NE)	0.281 (0.110, 0.716)	0.0046
Non-Smoker	68	7 (10.3)	NR (NE, NE)	57	8 (14.0)	NR (3.7, NE)	0.522 (0.185, 1.470)	0.2112
Interaction								0.4382

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	7 (8.4)	NR (NE, NE)	79	6 (7.6)	NR (NE, NE)	0.837 (0.268, 2.607)	0.7580
Docetaxel	56	4 (7.1)	NR (13.3, NE)	50	5 (10.0)	NR (3.7, NE)	0.539 (0.141, 2.060)	0.3594
Irinotecan	116	4 (3.4)	NR (NE, NE)	111	14 (12.6)	NR (NE, NE)	0.193 (0.062, 0.603)	0.0018
Interaction								0.1015

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	2 (3.2)	NR (NE, NE)	57	4 (7.0)	NR (5.7, NE)	0.156 (0.017, 1.416)	0.0594
1	192	13 (6.8)	NR (NE, NE)	183	21 (11.5)	NR (NE, NE)	0.425 (0.209, 0.865)	0.0152
Interaction								0.8005
Region #1								
Asia	201	10 (5.0)	NR (NE, NE)	191	14 (7.3)	NR (NE, NE)	0.441 (0.186, 1.044)	0.0564
Europe/North America	54	5 (9.3)	NR (NE, NE)	49	11 (22.4)	NR (5.6, NE)	0.350 (0.121, 1.010)	0.0422
Interaction								0.6307

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	8 (4.5)	NR (NE, NE)	168	14 (8.3)	NR (NE, NE)	0.347 (0.137, 0.882)	0.0207
Japan	25	2 (8.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	58857345.823 (0.000, NE)	0.2435
Europe/North America	54	5 (9.3)	NR (NE, NE)	49	11 (22.4)	NR (5.6, NE)	0.350 (0.121, 1.010)	0.0422
Interaction								0.9878

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	10 (4.9)	NR (NE, NE)	198	16 (8.1)	NR (NE, NE)	0.384 (0.165, 0.891)	0.0213
White	52	5 (9.6)	NR (NE, NE)	42	9 (21.4)	NR (5.6, NE)	0.388 (0.130, 1.161)	0.0787
Interaction								0.8227

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	5 (6.3)	NR (NE, NE)	60	8 (13.3)	NR (NE, NE)	0.318 (0.101, 0.998)	0.0393
vCPS < 10%	100	4 (4.0)	NR (13.3, NE)	119	16 (13.4)	NR (5.7, NE)	0.118 (0.027, 0.517)	0.0007
Missing	75	6 (8.0)	NR (NE, NE)	61	1 (1.6)	NR (NE, NE)	4.314 (0.517, 35.993)	0.1409
Interaction								0.0642

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	15 (9.6)	NR (NE, NE)	149	16 (10.7)	NR (NE, NE)	0.680 (0.330, 1.403)	0.2940
>= 65 Years	98	5 (5.1)	NR (NE, NE)	91	15 (16.5)	9.2 (9.2, NE)	0.161 (0.052, 0.496)	0.0005
Interaction								0.0948
Gender								
Male	216	19 (8.8)	NR (NE, NE)	204	27 (13.2)	NR (9.2, NE)	0.459 (0.247, 0.853)	0.0118
Female	39	1 (2.6)	NR (7.3, NE)	36	4 (11.1)	NR (NE, NE)	0.166 (0.018, 1.533)	0.0748
Interaction								0.4103

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	16 (8.6)	NR (NE, NE)	183	26 (14.2)	NR (9.2, NE)	0.400 (0.205, 0.781)	0.0055
Non-Smoker	68	4 (5.9)	NR (NE, NE)	57	5 (8.8)	NR (4.9, NE)	0.497 (0.130, 1.896)	0.2972
Interaction								0.7938

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	9 (10.8)	NR (NE, NE)	79	10 (12.7)	NR (NE, NE)	0.694 (0.276, 1.744)	0.4344
Docetaxel	56	3 (5.4)	NR (NE, NE)	50	7 (14.0)	NR (NE, NE)	0.313 (0.081, 1.215)	0.0762
Irinotecan	116	8 (6.9)	NR (15.8, NE)	111	14 (12.6)	NR (9.2, NE)	0.296 (0.110, 0.795)	0.0109
Interaction								0.5561

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	3 (4.8)	NR (15.8, NE)	57	6 (10.5)	NR (9.2, NE)	0.204 (0.040, 1.043)	0.0367
1	192	17 (8.9)	NR (NE, NE)	183	25 (13.7)	NR (NE, NE)	0.487 (0.258, 0.918)	0.0233
Interaction								0.5979
Region #1								
Asia	201	14 (7.0)	NR (NE, NE)	191	20 (10.5)	NR (NE, NE)	0.468 (0.228, 0.959)	0.0340
Europe/North America	54	6 (11.1)	NR (NE, NE)	49	11 (22.4)	9.2 (4.9, NE)	0.402 (0.147, 1.099)	0.0665
Interaction								0.8635

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	14 (8.0)	NR (NE, NE)	168	16 (9.5)	NR (NE, NE)	0.579 (0.273, 1.228)	0.1500
Japan	25	0 (0.0)	NR (NE, NE)	23	4 (17.4)	NR (NE, NE)	0.000 (0.000, NE)	0.0336
Europe/North America	54	6 (11.1)	NR (NE, NE)	49	11 (22.4)	9.2 (4.9, NE)	0.402 (0.147, 1.099)	0.0665
Interaction								0.8611

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	15 (7.4)	NR (NE, NE)	198	21 (10.6)	NR (NE, NE)	0.502 (0.251, 1.005)	0.0475
White	52	5 (9.6)	NR (NE, NE)	42	10 (23.8)	9.2 (4.9, NE)	0.323 (0.109, 0.955)	0.0316
Interaction								0.5495

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	3 (3.8)	NR (15.8, NE)	60	7 (11.7)	NR (NE, NE)	0.210 (0.052, 0.845)	0.0168
vCPS < 10%	100	15 (15.0)	NR (NE, NE)	119	18 (15.1)	NR (9.2, NE)	0.780 (0.387, 1.569)	0.4846
Missing	75	2 (2.7)	NR (13.7, NE)	61	6 (9.8)	NR (NE, NE)	0.119 (0.014, 0.991)	0.0187
Interaction								0.1098

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations / PT - Pneumonia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	10 (6.4)	NR (NE, NE)	149	6 (4.0)	NR (NE, NE)	1.144 (0.404, 3.235)	0.8003
>= 65 Years	98	2 (2.0)	NR (NE, NE)	91	11 (12.1)	NR (NE, NE)	0.094 (0.018, 0.485)	0.0008
Interaction								0.0173
Gender								
Male	216	12 (5.6)	NR (NE, NE)	204	15 (7.4)	NR (NE, NE)	0.520 (0.235, 1.151)	0.1012
Female	39	0 (0.0)	NR (NE, NE)	36	2 (5.6)	NR (NE, NE)	0.000 (0.000, NE)	0.1082
Interaction								0.9904

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

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Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations / PT - Pneumonia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	8 (4.3)	NR (NE, NE)	183	14 (7.7)	NR (NE, NE)	0.357 (0.140, 0.912)	0.0249
Non-Smoker	68	4 (5.9)	NR (NE, NE)	57	3 (5.3)	NR (NE, NE)	0.876 (0.191, 4.015)	0.8645
Interaction								0.3692

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations / PT - Pneumonia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	4 (4.8)	NR (NE, NE)	79	6 (7.6)	NR (NE, NE)	0.496 (0.133, 1.848)	0.2874
Docetaxel	56	3 (5.4)	NR (NE, NE)	50	5 (10.0)	NR (NE, NE)	0.435 (0.104, 1.829)	0.2427
Irinotecan	116	5 (4.3)	NR (15.8, NE)	111	6 (5.4)	NR (NE, NE)	0.434 (0.117, 1.606)	0.2004
Interaction								0.9803

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations / PT - Pneumonia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	1 (1.6)	NR (15.8, NE)	57	2 (3.5)	NR (NE, NE)	0.000 (0.000, NE)	0.1342
1	192	11 (5.7)	NR (NE, NE)	183	15 (8.2)	NR (NE, NE)	0.510 (0.230, 1.132)	0.0920
Interaction								0.7271
Region #1								
Asia	201	11 (5.5)	NR (NE, NE)	191	13 (6.8)	NR (NE, NE)	0.564 (0.244, 1.299)	0.1730
Europe/North America	54	1 (1.9)	NR (NE, NE)	49	4 (8.2)	NR (NE, NE)	0.186 (0.021, 1.669)	0.0922
Interaction								0.3573

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations / PT - Pneumonia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	11 (6.3)	NR (NE, NE)	168	10 (6.0)	NR (NE, NE)	0.718 (0.295, 1.745)	0.4626
Japan	25	0 (0.0)	NR (NE, NE)	23	3 (13.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0704
Europe/North America	54	1 (1.9)	NR (NE, NE)	49	4 (8.2)	NR (NE, NE)	0.186 (0.021, 1.669)	0.0922
Interaction								0.5248

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations / PT - Pneumonia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	11 (5.4)	NR (NE, NE)	198	14 (7.1)	NR (NE, NE)	0.540 (0.237, 1.227)	0.1357
White	52	1 (1.9)	NR (NE, NE)	42	3 (7.1)	NR (NE, NE)	0.217 (0.023, 2.095)	0.1467
Interaction								0.4640

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations / PT - Pneumonia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	3 (3.8)	NR (15.8, NE)	60	3 (5.0)	NR (NE, NE)	0.457 (0.086, 2.417)	0.3463
vCPS < 10%	100	8 (8.0)	NR (NE, NE)	119	10 (8.4)	NR (NE, NE)	0.717 (0.278, 1.852)	0.4902
Missing	75	1 (1.3)	NR (NE, NE)	61	4 (6.6)	NR (NE, NE)	0.176 (0.019, 1.591)	0.0817
Interaction								0.4066

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	17 (10.8)	NR (NE, NE)	149	50 (33.6)	NR (4.1, NE)	0.219 (0.123, 0.388)	<0.0001
>= 65 Years	98	8 (8.2)	NR (NE, NE)	91	40 (44.0)	NR (1.2, NE)	0.118 (0.053, 0.264)	<0.0001
Interaction								0.1854
Gender								
Male	216	22 (10.2)	NR (NE, NE)	204	82 (40.2)	NR (2.1, NE)	0.162 (0.099, 0.267)	<0.0001
Female	39	3 (7.7)	NR (NE, NE)	36	8 (22.2)	NR (NE, NE)	0.277 (0.073, 1.055)	0.0442
Interaction								0.5203

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

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Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	17 (9.1)	NR (NE, NE)	183	68 (37.2)	NR (4.1, NE)	0.153 (0.087, 0.269)	<0.0001
Non-Smoker	68	8 (11.8)	NR (NE, NE)	57	22 (38.6)	NR (1.0, NE)	0.237 (0.105, 0.535)	0.0002
Interaction								0.5944

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	6 (7.2)	NR (NE, NE)	79	24 (30.4)	NR (4.1, NE)	0.185 (0.075, 0.456)	<0.0001
Docetaxel	56	6 (10.7)	NR (13.8, NE)	50	27 (54.0)	1.0 (0.3, NE)	0.108 (0.041, 0.285)	<0.0001
Irinotecan	116	13 (11.2)	NR (NE, NE)	111	39 (35.1)	NR (2.1, NE)	0.208 (0.108, 0.403)	<0.0001
Interaction								0.3980

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	4 (6.3)	NR (NE, NE)	57	19 (33.3)	NR (2.4, NE)	0.105 (0.031, 0.362)	<0.0001
1	192	21 (10.9)	NR (NE, NE)	183	71 (38.8)	NR (2.1, NE)	0.193 (0.117, 0.319)	<0.0001
Interaction								0.4637
Region #1								
Asia	201	21 (10.4)	NR (NE, NE)	191	81 (42.4)	4.1 (2.0, NE)	0.149 (0.090, 0.249)	<0.0001
Europe/North America	54	4 (7.4)	NR (NE, NE)	49	9 (18.4)	NR (NE, NE)	0.347 (0.106, 1.132)	0.0654
Interaction								0.2540

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	19 (10.8)	NR (NE, NE)	168	71 (42.3)	4.1 (1.4, NE)	0.155 (0.090, 0.265)	<0.0001
Japan	25	2 (8.0)	NR (NE, NE)	23	10 (43.5)	NR (0.5, NE)	0.125 (0.026, 0.593)	0.0018
Europe/North America	54	4 (7.4)	NR (NE, NE)	49	9 (18.4)	NR (NE, NE)	0.347 (0.106, 1.132)	0.0654
Interaction								0.4436

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	21 (10.3)	NR (NE, NE)	198	84 (42.4)	4.1 (2.0, NE)	0.149 (0.090, 0.247)	<0.0001
White	52	4 (7.7)	NR (NE, NE)	42	6 (14.3)	NR (NE, NE)	0.469 (0.132, 1.671)	0.2304
Interaction								0.1264

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	7 (8.8)	NR (NE, NE)	60	22 (36.7)	4.1 (2.0, NE)	0.138 (0.057, 0.334)	<0.0001
vCPS < 10%	100	8 (8.0)	NR (13.8, NE)	119	48 (40.3)	NR (1.4, NE)	0.134 (0.061, 0.298)	<0.0001
Missing	75	10 (13.3)	NR (13.8, NE)	61	20 (32.8)	NR (NE, NE)	0.283 (0.127, 0.627)	0.0008
Interaction								0.3515

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	5 (3.2)	NR (NE, NE)	149	7 (4.7)	NR (NE, NE)	0.610 (0.193, 1.928)	0.3941
>= 65 Years	98	1 (1.0)	NR (NE, NE)	91	11 (12.1)	NR (NE, NE)	0.074 (0.010, 0.576)	0.0012
Interaction								0.0847
Gender								
Male	216	5 (2.3)	NR (NE, NE)	204	15 (7.4)	NR (NE, NE)	0.278 (0.101, 0.769)	0.0083
Female	39	1 (2.6)	NR (NE, NE)	36	3 (8.3)	NR (NE, NE)	0.247 (0.025, 2.434)	0.1969
Interaction								0.9868

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	5 (2.7)	NR (NE, NE)	183	13 (7.1)	NR (NE, NE)	0.334 (0.119, 0.942)	0.0291
Non-Smoker	68	1 (1.5)	NR (NE, NE)	57	5 (8.8)	NR (NE, NE)	0.145 (0.017, 1.246)	0.0414
Interaction								0.5258

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	0 (0.0)	NR (NE, NE)	79	3 (3.8)	NR (NE, NE)	0.000 (0.000, NE)	0.0734
Docetaxel	56	2 (3.6)	NR (NE, NE)	50	6 (12.0)	NR (NE, NE)	0.264 (0.053, 1.315)	0.0786
Irinotecan	116	4 (3.4)	NR (NE, NE)	111	9 (8.1)	NR (NE, NE)	0.325 (0.097, 1.086)	0.0556
Interaction								0.9435

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	1 (1.6)	NR (NE, NE)	57	6 (10.5)	NR (NE, NE)	0.125 (0.015, 1.051)	0.0237
1	192	5 (2.6)	NR (NE, NE)	183	12 (6.6)	NR (NE, NE)	0.356 (0.125, 1.015)	0.0431
Interaction								0.4178
Region #1								
Asia	201	5 (2.5)	NR (NE, NE)	191	15 (7.9)	NR (NE, NE)	0.267 (0.096, 0.741)	0.0065
Europe/North America	54	1 (1.9)	NR (NE, NE)	49	3 (6.1)	NR (NE, NE)	0.288 (0.030, 2.768)	0.2492
Interaction								0.9891

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	5 (2.8)	NR (NE, NE)	168	13 (7.7)	NR (NE, NE)	0.305 (0.108, 0.861)	0.0177
Japan	25	0 (0.0)	NR (NE, NE)	23	2 (8.7)	NR (NE, NE)	0.000 (0.000, NE)	0.1361
Europe/North America	54	1 (1.9)	NR (NE, NE)	49	3 (6.1)	NR (NE, NE)	0.288 (0.030, 2.768)	0.2492
Interaction								0.9912

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	5 (2.5)	NR (NE, NE)	198	16 (8.1)	NR (NE, NE)	0.259 (0.094, 0.712)	0.0048
White	52	1 (1.9)	NR (NE, NE)	42	2 (4.8)	NR (NE, NE)	0.386 (0.035, 4.257)	0.4180
Interaction								0.8151

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	0 (0.0)	NR (NE, NE)	60	3 (5.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0355
vCPS < 10%	100	4 (4.0)	NR (NE, NE)	119	12 (10.1)	NR (NE, NE)	0.348 (0.112, 1.082)	0.0556
Missing	75	2 (2.7)	NR (NE, NE)	61	3 (4.9)	NR (NE, NE)	0.452 (0.074, 2.774)	0.3797
Interaction								0.9571

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	0 (0.0)	NR (NE, NE)	149	36 (24.2)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
>= 65 Years	98	0 (0.0)	NR (NE, NE)	91	27 (29.7)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9999
Gender								
Male	216	0 (0.0)	NR (NE, NE)	204	57 (27.9)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Female	39	0 (0.0)	NR (NE, NE)	36	6 (16.7)	NR (NE, NE)	0.000 (0.000, NE)	0.0089
Interaction								0.9998

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	0 (0.0)	NR (NE, NE)	183	50 (27.3)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Non-Smoker	68	0 (0.0)	NR (NE, NE)	57	13 (22.8)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	0 (0.0)	NR (NE, NE)	79	19 (24.1)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Docetaxel	56	0 (0.0)	NR (NE, NE)	50	19 (38.0)	NR (1.0, NE)	0.000 (0.000, NE)	<0.0001
Irinotecan	116	0 (0.0)	NR (NE, NE)	111	25 (22.5)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	0 (0.0)	NR (NE, NE)	57	14 (24.6)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
1	192	0 (0.0)	NR (NE, NE)	183	49 (26.8)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9999
Region #1								
Asia	201	0 (0.0)	NR (NE, NE)	191	58 (30.4)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	5 (10.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0137
Interaction								0.9995

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	0 (0.0)	NR (NE, NE)	168	49 (29.2)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Japan	25	0 (0.0)	NR (NE, NE)	23	9 (39.1)	NR (0.5, NE)	0.000 (0.000, NE)	0.0005
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	5 (10.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0137
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	203	0 (0.0)	NR (NE, NE)	198	59 (29.8)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
White	52	0 (0.0)	NR (NE, NE)	42	4 (9.5)	NR (NE, NE)	0.000 (0.000, NE)	0.0187
Interaction								0.9994

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	0 (0.0)	NR (NE, NE)	60	15 (25.0)	NR (4.1, NE)	0.000 (0.000, NE)	<0.0001
vCPS < 10%	100	0 (0.0)	NR (NE, NE)	119	34 (28.6)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Missing	75	0 (0.0)	NR (NE, NE)	61	14 (23.0)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	1 (0.6)	NR (NE, NE)	149	30 (20.1)	NR (NE, NE)	0.027 (0.004, 0.198)	<0.0001
>= 65 Years	98	0 (0.0)	NR (NE, NE)	91	18 (19.8)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9863
Gender								
Male	216	1 (0.5)	NR (NE, NE)	204	42 (20.6)	NR (NE, NE)	0.020 (0.003, 0.144)	<0.0001
Female	39	0 (0.0)	NR (NE, NE)	36	6 (16.7)	NR (NE, NE)	0.000 (0.000, NE)	0.0084
Interaction								0.9876

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	0 (0.0)	NR (NE, NE)	183	34 (18.6)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Non-Smoker	68	1 (1.5)	NR (NE, NE)	57	14 (24.6)	NR (NE, NE)	0.050 (0.006, 0.378)	<0.0001
Interaction								0.9874

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	0 (0.0)	NR (NE, NE)	79	8 (10.1)	NR (NE, NE)	0.000 (0.000, NE)	0.0029
Docetaxel	56	0 (0.0)	NR (NE, NE)	50	20 (40.0)	NR (1.0, NE)	0.000 (0.000, NE)	<0.0001
Irinotecan	116	1 (0.9)	NR (NE, NE)	111	20 (18.0)	NR (NE, NE)	0.040 (0.005, 0.300)	<0.0001
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	0 (0.0)	NR (NE, NE)	57	12 (21.1)	NR (NE, NE)	0.000 (0.000, NE)	0.0001
1	192	1 (0.5)	NR (NE, NE)	183	36 (19.7)	NR (NE, NE)	0.023 (0.003, 0.170)	<0.0001
Interaction								0.9890
Region #1								
Asia	201	1 (0.5)	NR (NE, NE)	191	46 (24.1)	NR (NE, NE)	0.018 (0.002, 0.130)	<0.0001
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	2 (4.1)	NR (NE, NE)	0.000 (0.000, NE)	0.1324
Interaction								0.9884

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	1 (0.6)	NR (NE, NE)	168	37 (22.0)	NR (NE, NE)	0.022 (0.003, 0.164)	<0.0001
Japan	25	0 (0.0)	NR (NE, NE)	23	9 (39.1)	NR (0.5, NE)	0.000 (0.000, NE)	0.0005
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	2 (4.1)	NR (NE, NE)	0.000 (0.000, NE)	0.1324
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	1 (0.5)	NR (NE, NE)	198	47 (23.7)	NR (NE, NE)	0.018 (0.002, 0.131)	<0.0001
White	52	0 (0.0)	NR (NE, NE)	42	1 (2.4)	NR (NE, NE)	0.000 (0.000, NE)	0.2611
Interaction								0.9892

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	1 (1.3)	NR (NE, NE)	60	9 (15.0)	NR (NE, NE)	0.067 (0.008, 0.534)	0.0008
vCPS < 10%	100	0 (0.0)	NR (NE, NE)	119	25 (21.0)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Missing	75	0 (0.0)	NR (NE, NE)	61	14 (23.0)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	15 (9.6)	NR (14.5, NE)	149	15 (10.1)	NR (9.6, NE)	0.600 (0.282, 1.274)	0.1788
>= 65 Years	98	11 (11.2)	NR (NE, NE)	91	16 (17.6)	NR (NE, NE)	0.457 (0.203, 1.028)	0.0522
Interaction								0.3724
Gender								
Male	216	23 (10.6)	NR (NE, NE)	204	23 (11.3)	NR (9.6, NE)	0.602 (0.327, 1.109)	0.1001
Female	39	3 (7.7)	NR (NE, NE)	36	8 (22.2)	NR (3.1, NE)	0.281 (0.073, 1.073)	0.0478
Interaction								0.1644

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	21 (11.2)	NR (NE, NE)	183	20 (10.9)	NR (9.6, NE)	0.666 (0.349, 1.272)	0.2151
Non-Smoker	68	5 (7.4)	NR (NE, NE)	57	11 (19.3)	NR (4.8, NE)	0.258 (0.086, 0.775)	0.0099
Interaction								0.1090

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	8 (9.6)	NR (NE, NE)	79	5 (6.3)	NR (NE, NE)	1.246 (0.395, 3.935)	0.7069
Docetaxel	56	10 (17.9)	10.2 (6.9, NE)	50	8 (16.0)	9.6 (4.9, NE)	0.645 (0.242, 1.724)	0.3783
Irinotecan	116	8 (6.9)	NR (14.5, NE)	111	18 (16.2)	NR (NE, NE)	0.244 (0.096, 0.625)	0.0015
Interaction								0.0597

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	6 (9.5)	NR (13.8, NE)	57	8 (14.0)	NR (9.6, NE)	0.319 (0.094, 1.081)	0.0540
1	192	20 (10.4)	NR (NE, NE)	183	23 (12.6)	NR (NE, NE)	0.608 (0.328, 1.127)	0.1102
Interaction								0.7353
Region #1								
Asia	201	23 (11.4)	NR (NE, NE)	191	24 (12.6)	NR (9.6, NE)	0.564 (0.307, 1.037)	0.0618
Europe/North America	54	3 (5.6)	NR (NE, NE)	49	7 (14.3)	NR (NE, NE)	0.352 (0.091, 1.366)	0.1145
Interaction								0.3807

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	17 (9.7)	NR (NE, NE)	168	22 (13.1)	NR (9.6, NE)	0.465 (0.237, 0.912)	0.0227
Japan	25	6 (24.0)	13.8 (4.1, NE)	23	2 (8.7)	NR (NE, NE)	1.558 (0.290, 8.369)	0.6023
Europe/North America	54	3 (5.6)	NR (NE, NE)	49	7 (14.3)	NR (NE, NE)	0.352 (0.091, 1.366)	0.1145
Interaction								0.2324

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	23 (11.3)	NR (NE, NE)	198	24 (12.1)	NR (9.6, NE)	0.582 (0.317, 1.071)	0.0784
White	52	3 (5.8)	NR (NE, NE)	42	7 (16.7)	NR (4.8, NE)	0.311 (0.080, 1.207)	0.0744
Interaction								0.2776

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	7 (8.8)	NR (14.5, NE)	60	9 (15.0)	NR (4.9, NE)	0.274 (0.089, 0.843)	0.0165
vCPS < 10%	100	10 (10.0)	NR (NE, NE)	119	15 (12.6)	NR (NE, NE)	0.600 (0.267, 1.349)	0.2114
Missing	75	9 (12.0)	NR (13.8, NE)	61	7 (11.5)	9.6 (NE, NE)	0.777 (0.276, 2.194)	0.6332
Interaction								0.4852

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	2 (1.3)	--	149	6 (4.0)	--	--	--
>= 65 Years	98	0 (0.0)	--	91	4 (4.4)	--	--	--
Interaction								--
Gender								
Male	216	2 (0.9)	NR (NE, NE)	204	9 (4.4)	NR (NE, NE)	0.089 (0.011, 0.704)	0.0039
Female	39	0 (0.0)	NR (NE, NE)	36	1 (2.8)	NR (NE, NE)	0.000 (0.000, NE)	0.2980
Interaction								0.9947

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	2 (1.1)	NR (NE, NE)	183	9 (4.9)	NR (NE, NE)	0.097 (0.012, 0.767)	0.0061
Non-Smoker	68	0 (0.0)	NR (NE, NE)	57	1 (1.8)	NR (NE, NE)	0.000 (0.000, NE)	0.1649
Interaction								0.9935

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	1 (1.2)	--	79	2 (2.5)	--	--	--
Docetaxel	56	1 (1.8)	--	50	2 (4.0)	--	--	--
Irinotecan	116	0 (0.0)	--	111	6 (5.4)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	1 (1.6)	NR (14.0, NE)	57	1 (1.8)	NR (NE, NE)	0.000 (0.000, NE)	0.2963
1	192	1 (0.5)	NR (NE, NE)	183	9 (4.9)	NR (NE, NE)	0.088 (0.011, 0.699)	0.0038
Interaction								0.2557
Region #1								
Asia	201	1 (0.5)	--	191	6 (3.1)	--	--	--
Europe/North America	54	1 (1.9)	--	49	4 (8.2)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	1 (0.6)	--	168	5 (3.0)	--	--	--
Japan	25	0 (0.0)	--	23	1 (4.3)	--	--	--
Europe/North America	54	1 (1.9)	--	49	4 (8.2)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	203	1 (0.5)	--	198	6 (3.0)	--	--	--
White	52	1 (1.9)	--	42	4 (9.5)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	1 (1.3)	--	60	4 (6.7)	--	--	--
vCPS < 10%	100	1 (1.0)	--	119	3 (2.5)	--	--	--
Missing	75	0 (0.0)	--	61	3 (4.9)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	10 (13.0)	NR (NE, NE)	70	18 (25.7)	NR (NE, NE)	0.398 (0.183, 0.866)	0.0157
>= 65 Years	62	3 (4.8)	NR (NE, NE)	59	13 (22.0)	NR (NE, NE)	0.195 (0.056, 0.686)	0.0044
Interaction								0.2682
Gender								
Male	118	12 (10.2)	NR (NE, NE)	106	26 (24.5)	NR (NE, NE)	0.335 (0.169, 0.667)	0.0010
Female	21	1 (4.8)	NR (NE, NE)	23	5 (21.7)	NR (NE, NE)	0.209 (0.024, 1.791)	0.1115
Interaction								0.5830

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Smoking Status								
Former/Current Smoker	104	10 (9.6)	NR (NE, NE)	101	25 (24.8)	NR (NE, NE)	0.322 (0.154, 0.673)	0.0014
Non-Smoker	35	3 (8.6)	NR (4.3, NE)	28	6 (21.4)	NR (NE, NE)	0.303 (0.074, 1.232)	0.0774
Interaction								0.9711
ICC Options								
Paclitaxel	83	4 (4.8)	NR (NE, NE)	79	12 (15.2)	NR (NE, NE)	0.281 (0.091, 0.872)	0.0188
Docetaxel	56	9 (16.1)	NR (7.6, NE)	50	19 (38.0)	NR (1.3, NE)	0.301 (0.134, 0.676)	0.0018
Interaction								0.9112

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	43	1 (2.3)	NR (NE, NE)	37	8 (21.6)	NR (NE, NE)	0.085 (0.010, 0.686)	0.0033
1	96	12 (12.5)	NR (NE, NE)	92	23 (25.0)	NR (NE, NE)	0.413 (0.205, 0.832)	0.0104
Interaction								0.1722
Region #1								
Asia	103	11 (10.7)	NR (NE, NE)	99	23 (23.2)	NR (NE, NE)	0.369 (0.179, 0.762)	0.0048
Europe/North America	36	2 (5.6)	NR (NE, NE)	30	8 (26.7)	NR (NE, NE)	0.183 (0.039, 0.862)	0.0156
Interaction								0.3978

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	10 (12.8)	NR (NE, NE)	76	18 (23.7)	NR (NE, NE)	0.439 (0.201, 0.957)	0.0323
Japan	25	1 (4.0)	NR (NE, NE)	23	5 (21.7)	NR (2.8, NE)	0.146 (0.017, 1.262)	0.0427
Europe/North America	36	2 (5.6)	NR (NE, NE)	30	8 (26.7)	NR (NE, NE)	0.183 (0.039, 0.862)	0.0156
Interaction								0.4333

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	11 (10.5)	NR (NE, NE)	106	24 (22.6)	NR (NE, NE)	0.376 (0.183, 0.771)	0.0053
White	34	2 (5.9)	NR (NE, NE)	23	7 (30.4)	NR (1.0, NE)	0.167 (0.035, 0.806)	0.0110
Interaction								0.3312

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Baseline PD-L1 Status								
vCPS >= 10%	45	4 (8.9)	NR (NE, NE)	34	8 (23.5)	NR (NE, NE)	0.310 (0.093, 1.032)	0.0429
vCPS < 10%	53	7 (13.2)	NR (NE, NE)	54	17 (31.5)	NR (NE, NE)	0.302 (0.123, 0.742)	0.0056
Missing	41	2 (4.9)	NR (NE, NE)	41	6 (14.6)	NR (NE, NE)	0.307 (0.062, 1.527)	0.1262
Interaction								0.9874

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	0 (0.0)	--	70	4 (5.7)	--	--	--
>= 65 Years	62	0 (0.0)	--	59	4 (6.8)	--	--	--
Interaction								--
Gender								
Male	118	0 (0.0)	--	106	7 (6.6)	--	--	--
Female	21	0 (0.0)	--	23	1 (4.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

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Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	0 (0.0)	--	101	7 (6.9)	--	--	--
Non-Smoker	35	0 (0.0)	--	28	1 (3.6)	--	--	--
Interaction								--
ICC Options								
Paclitaxel	83	0 (0.0)	--	79	0 (0.0)	--	--	--
Docetaxel	56	0 (0.0)	--	50	8 (16.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	0 (0.0)	--	37	2 (5.4)	--	--	--
1	96	0 (0.0)	--	92	6 (6.5)	--	--	--
Interaction								--
Region #1								
Asia	103	0 (0.0)	--	99	7 (7.1)	--	--	--
Europe/North America	36	0 (0.0)	--	30	1 (3.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Region #2								
Asia (excluding Japan)	78	0 (0.0)	--	76	5 (6.6)	--	--	--
Japan	25	0 (0.0)	--	23	2 (8.7)	--	--	--
Europe/North America	36	0 (0.0)	--	30	1 (3.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	105	0 (0.0)	--	106	7 (6.6)	--	--	--
White	34	0 (0.0)	--	23	1 (4.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	0 (0.0)	--	34	2 (5.9)	--	--	--
vCPS < 10%	53	0 (0.0)	--	54	2 (3.7)	--	--	--
Missing	41	0 (0.0)	--	41	4 (9.8)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	0 (0.0)	--	70	5 (7.1)	--	--	--
>= 65 Years	62	0 (0.0)	--	59	3 (5.1)	--	--	--
Interaction								--
Gender								
Male	118	0 (0.0)	--	106	8 (7.5)	--	--	--
Female	21	0 (0.0)	--	23	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	0 (0.0)	--	101	6 (5.9)	--	--	--
Non-Smoker	35	0 (0.0)	--	28	2 (7.1)	--	--	--
Interaction								--
ICC Options								
Paclitaxel	83	0 (0.0)	--	79	1 (1.3)	--	--	--
Docetaxel	56	0 (0.0)	--	50	7 (14.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	43	0 (0.0)	--	37	4 (10.8)	--	--	--
1	96	0 (0.0)	--	92	4 (4.3)	--	--	--
Interaction								--
Region #1								
Asia	103	0 (0.0)	--	99	7 (7.1)	--	--	--
Europe/North America	36	0 (0.0)	--	30	1 (3.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	0 (0.0)	--	76	7 (9.2)	--	--	--
Japan	25	0 (0.0)	--	23	0 (0.0)	--	--	--
Europe/North America	36	0 (0.0)	--	30	1 (3.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	0 (0.0)	--	106	7 (6.6)	--	--	--
White	34	0 (0.0)	--	23	1 (4.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	0 (0.0)	--	34	2 (5.9)	--	--	--
vCPS < 10%	53	0 (0.0)	--	54	5 (9.3)	--	--	--
Missing	41	0 (0.0)	--	41	1 (2.4)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	1 (1.3)	--	70	5 (7.1)	--	--	--
>= 65 Years	62	0 (0.0)	--	59	7 (11.9)	--	--	--
Interaction								--
Gender								
Male	118	1 (0.8)	NR (NE, NE)	106	10 (9.4)	NR (NE, NE)	0.074 (0.009, 0.589)	0.0015
Female	21	0 (0.0)	NR (NE, NE)	23	2 (8.7)	NR (NE, NE)	0.000 (0.000, NE)	0.1820
Interaction								0.9924

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Smoking Status								
Former/Current Smoker	104	1 (1.0)	NR (NE, NE)	101	9 (8.9)	NR (NE, NE)	0.086 (0.011, 0.695)	0.0041
Non-Smoker	35	0 (0.0)	NR (NE, NE)	28	3 (10.7)	NR (NE, NE)	0.000 (0.000, NE)	0.0492
Interaction								0.9936
ICC Options								
Paclitaxel	83	0 (0.0)	--	79	5 (6.3)	--	--	--
Docetaxel	56	1 (1.8)	--	50	7 (14.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	43	1 (2.3)	--	37	3 (8.1)	--	--	--
1	96	0 (0.0)	--	92	9 (9.8)	--	--	--
Interaction								--
Region #1								
Asia	103	1 (1.0)	--	99	7 (7.1)	--	--	--
Europe/North America	36	0 (0.0)	--	30	5 (16.7)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	1 (1.3)	--	76	7 (9.2)	--	--	--
Japan	25	0 (0.0)	--	23	0 (0.0)	--	--	--
Europe/North America	36	0 (0.0)	--	30	5 (16.7)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	1 (1.0)	--	106	7 (6.6)	--	--	--
White	34	0 (0.0)	--	23	5 (21.7)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	0 (0.0)	--	34	2 (5.9)	--	--	--
vCPS < 10%	53	1 (1.9)	--	54	8 (14.8)	--	--	--
Missing	41	0 (0.0)	--	41	2 (4.9)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	7 (9.1)	NR (13.8, NE)	70	28 (40.0)	4.1 (1.4, NE)	0.140 (0.058, 0.343)	<0.0001
>= 65 Years	62	5 (8.1)	NR (NE, NE)	59	23 (39.0)	NR (1.1, NE)	0.157 (0.059, 0.415)	<0.0001
Interaction								0.9064
Gender								
Male	118	11 (9.3)	NR (NE, NE)	106	47 (44.3)	4.1 (1.2, NE)	0.135 (0.068, 0.269)	<0.0001
Female	21	1 (4.8)	NR (3.1, NE)	23	4 (17.4)	NR (NE, NE)	0.246 (0.027, 2.203)	0.1721
Interaction								0.6964

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	11 (10.6)	NR (NE, NE)	101	42 (41.6)	NR (1.4, NE)	0.164 (0.082, 0.330)	<0.0001
Non-Smoker	35	1 (2.9)	NR (NE, NE)	28	9 (32.1)	NR (0.5, NE)	0.080 (0.010, 0.632)	0.0018
Interaction								0.3594
ICC Options								
Paclitaxel	83	6 (7.2)	NR (NE, NE)	79	24 (30.4)	NR (4.1, NE)	0.185 (0.075, 0.456)	<0.0001
Docetaxel	56	6 (10.7)	NR (13.8, NE)	50	27 (54.0)	1.0 (0.3, NE)	0.108 (0.041, 0.285)	<0.0001
Interaction								0.4747

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	4 (9.3)	NR (13.8, NE)	37	14 (37.8)	NR (1.1, NE)	0.137 (0.039, 0.484)	0.0003
1	96	8 (8.3)	NR (NE, NE)	92	37 (40.2)	NR (1.2, NE)	0.154 (0.071, 0.331)	<0.0001
Interaction								0.8519
Region #1								
Asia	103	10 (9.7)	NR (NE, NE)	99	45 (45.5)	4.1 (1.1, NE)	0.129 (0.062, 0.266)	<0.0001
Europe/North America	36	2 (5.6)	NR (NE, NE)	30	6 (20.0)	NR (NE, NE)	0.243 (0.049, 1.209)	0.0596
Interaction								0.5153

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	8 (10.3)	NR (NE, NE)	76	35 (46.1)	4.1 (1.1, NE)	0.133 (0.059, 0.303)	<0.0001
Japan	25	2 (8.0)	NR (NE, NE)	23	10 (43.5)	NR (0.5, NE)	0.125 (0.026, 0.593)	0.0018
Europe/North America	36	2 (5.6)	NR (NE, NE)	30	6 (20.0)	NR (NE, NE)	0.243 (0.049, 1.209)	0.0596
Interaction								0.7778

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	10 (9.5)	NR (NE, NE)	106	48 (45.3)	4.1 (1.1, NE)	0.128 (0.062, 0.263)	<0.0001
White	34	2 (5.9)	NR (NE, NE)	23	3 (13.0)	NR (NE, NE)	0.408 (0.068, 2.453)	0.3061
Interaction								0.2549

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	3 (6.7)	NR (NE, NE)	34	10 (29.4)	NR (4.1, NE)	0.163 (0.044, 0.604)	0.0021
vCPS < 10%	53	4 (7.5)	NR (13.8, NE)	54	26 (48.1)	2.4 (0.5, NE)	0.081 (0.024, 0.268)	<0.0001
Missing	41	5 (12.2)	NR (NE, NE)	41	15 (36.6)	NR (1.2, NE)	0.267 (0.097, 0.736)	0.0053
Interaction								0.4298

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	2 (2.6)	--	70	3 (4.3)	--	--	--
>= 65 Years	62	0 (0.0)	--	59	6 (10.2)	--	--	--
Interaction								--
Gender								
Male	118	2 (1.7)	NR (NE, NE)	106	8 (7.5)	NR (NE, NE)	0.210 (0.044, 0.989)	0.0285
Female	21	0 (0.0)	NR (NE, NE)	23	1 (4.3)	NR (NE, NE)	0.000 (0.000, NE)	0.3393
Interaction								0.9926

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	2 (1.9)	NR (NE, NE)	101	8 (7.9)	NR (NE, NE)	0.229 (0.049, 1.079)	0.0403
Non-Smoker	35	0 (0.0)	NR (NE, NE)	28	1 (3.6)	NR (NE, NE)	0.000 (0.000, NE)	0.2618
Interaction								0.9938
ICC Options								
Paclitaxel	83	0 (0.0)	--	79	3 (3.8)	--	--	--
Docetaxel	56	2 (3.6)	--	50	6 (12.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	1 (2.3)	--	37	3 (8.1)	--	--	--
1	96	1 (1.0)	--	92	6 (6.5)	--	--	--
Interaction								--
Region #1								
Asia	103	2 (1.9)	--	99	6 (6.1)	--	--	--
Europe/North America	36	0 (0.0)	--	30	3 (10.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	2 (2.6)	--	76	4 (5.3)	--	--	--
Japan	25	0 (0.0)	--	23	2 (8.7)	--	--	--
Europe/North America	36	0 (0.0)	--	30	3 (10.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	2 (1.9)	--	106	7 (6.6)	--	--	--
White	34	0 (0.0)	--	23	2 (8.7)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	0 (0.0)	--	34	1 (2.9)	--	--	--
vCPS < 10%	53	2 (3.8)	--	54	6 (11.1)	--	--	--
Missing	41	0 (0.0)	--	41	2 (4.9)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	0 (0.0)	NR (NE, NE)	70	23 (32.9)	NR (2.4, NE)	0.000 (0.000, NE)	<0.0001
>= 65 Years	62	0 (0.0)	NR (NE, NE)	59	15 (25.4)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9999
Gender								
Male	118	0 (0.0)	NR (NE, NE)	106	35 (33.0)	NR (4.1, NE)	0.000 (0.000, NE)	<0.0001
Female	21	0 (0.0)	NR (NE, NE)	23	3 (13.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0931
Interaction								0.9997

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	0 (0.0)	NR (NE, NE)	101	32 (31.7)	NR (4.1, NE)	0.000 (0.000, NE)	<0.0001
Non-Smoker	35	0 (0.0)	NR (NE, NE)	28	6 (21.4)	NR (NE, NE)	0.000 (0.000, NE)	0.0040
Interaction								0.9998
ICC Options								
Paclitaxel	83	0 (0.0)	NR (NE, NE)	79	19 (24.1)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Docetaxel	56	0 (0.0)	NR (NE, NE)	50	19 (38.0)	NR (1.0, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9998

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	43	0 (0.0)	NR (NE, NE)	37	12 (32.4)	NR (2.4, NE)	0.000 (0.000, NE)	<0.0001
1	96	0 (0.0)	NR (NE, NE)	92	26 (28.3)	NR (4.1, NE)	0.000 (0.000, NE)	<0.0001
Interaction								1.0000
Region #1								
Asia	103	0 (0.0)	NR (NE, NE)	99	35 (35.4)	NR (4.1, NE)	0.000 (0.000, NE)	<0.0001
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	3 (10.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0537
Interaction								0.9995

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Region #2								
Asia (excluding Japan)	78	0 (0.0)	NR (NE, NE)	76	26 (34.2)	NR (2.4, NE)	0.000 (0.000, NE)	<0.0001
Japan	25	0 (0.0)	NR (NE, NE)	23	9 (39.1)	NR (0.5, NE)	0.000 (0.000, NE)	0.0005
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	3 (10.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0537
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	105	0 (0.0)	NR (NE, NE)	106	36 (34.0)	NR (4.1, NE)	0.000 (0.000, NE)	<0.0001
White	34	0 (0.0)	NR (NE, NE)	23	2 (8.7)	NR (NE, NE)	0.000 (0.000, NE)	0.0827
Interaction								0.9995

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.
System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.
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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	0 (0.0)	NR (NE, NE)	34	9 (26.5)	NR (4.1, NE)	0.000 (0.000, NE)	0.0001
vCPS < 10%	53	0 (0.0)	NR (NE, NE)	54	17 (31.5)	NR (2.4, NE)	0.000 (0.000, NE)	<0.0001
Missing	41	0 (0.0)	NR (NE, NE)	41	12 (29.3)	NR (NE, NE)	0.000 (0.000, NE)	0.0002
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	0 (0.0)	NR (NE, NE)	70	17 (24.3)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
>= 65 Years	62	0 (0.0)	NR (NE, NE)	59	11 (18.6)	NR (NE, NE)	0.000 (0.000, NE)	0.0004
Interaction								0.9999
Gender								
Male	118	0 (0.0)	NR (NE, NE)	106	25 (23.6)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Female	21	0 (0.0)	NR (NE, NE)	23	3 (13.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0904
Interaction								0.9998

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	0 (0.0)	NR (NE, NE)	101	22 (21.8)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Non-Smoker	35	0 (0.0)	NR (NE, NE)	28	6 (21.4)	NR (NE, NE)	0.000 (0.000, NE)	0.0038
Interaction								1.0000
ICC Options								
Paclitaxel	83	0 (0.0)	NR (NE, NE)	79	8 (10.1)	NR (NE, NE)	0.000 (0.000, NE)	0.0029
Docetaxel	56	0 (0.0)	NR (NE, NE)	50	20 (40.0)	NR (1.0, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9994

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	0 (0.0)	NR (NE, NE)	37	10 (27.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0003
1	96	0 (0.0)	NR (NE, NE)	92	18 (19.6)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9999
Region #1								
Asia	103	0 (0.0)	NR (NE, NE)	99	27 (27.3)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	1 (3.3)	NR (NE, NE)	0.000 (0.000, NE)	0.2733
Interaction								0.9994

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Region #2								
Asia (excluding Japan)	78	0 (0.0)	NR (NE, NE)	76	18 (23.7)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Japan	25	0 (0.0)	NR (NE, NE)	23	9 (39.1)	NR (0.5, NE)	0.000 (0.000, NE)	0.0005
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	1 (3.3)	NR (NE, NE)	0.000 (0.000, NE)	0.2733
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	105	0 (0.0)	NR (NE, NE)	106	28 (26.4)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
White	34	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9965

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.
System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.
Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.
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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	0 (0.0)	NR (NE, NE)	34	4 (11.8)	NR (NE, NE)	0.000 (0.000, NE)	0.0191
vCPS < 10%	53	0 (0.0)	NR (NE, NE)	54	13 (24.1)	NR (NE, NE)	0.000 (0.000, NE)	0.0001
Missing	41	0 (0.0)	NR (NE, NE)	41	11 (26.8)	NR (NE, NE)	0.000 (0.000, NE)	0.0004
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Vascular disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	6 (7.8)	--	70	0 (0.0)	--	--	--
>= 65 Years	62	2 (3.2)	--	59	0 (0.0)	--	--	--
Interaction								--
Gender								
Male	118	7 (5.9)	--	106	0 (0.0)	--	--	--
Female	21	1 (4.8)	--	23	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Vascular disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	7 (6.7)	--	101	0 (0.0)	--	--	--
Non-Smoker	35	1 (2.9)	--	28	0 (0.0)	--	--	--
Interaction								--
ICC Options								
Paclitaxel	83	5 (6.0)	--	79	0 (0.0)	--	--	--
Docetaxel	56	3 (5.4)	--	50	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Vascular disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	4 (9.3)	--	37	0 (0.0)	--	--	--
1	96	4 (4.2)	--	92	0 (0.0)	--	--	--
Interaction								--
Region #1								
Asia	103	5 (4.9)	--	99	0 (0.0)	--	--	--
Europe/North America	36	3 (8.3)	--	30	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Vascular disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	5 (6.4)	--	76	0 (0.0)	--	--	--
Japan	25	0 (0.0)	--	23	0 (0.0)	--	--	--
Europe/North America	36	3 (8.3)	--	30	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Vascular disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	5 (4.8)	--	106	0 (0.0)	--	--	--
White	34	3 (8.8)	--	23	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Vascular disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	4 (8.9)	--	34	0 (0.0)	--	--	--
vCPS < 10%	53	4 (7.5)	--	54	0 (0.0)	--	--	--
Missing	41	0 (0.0)	--	41	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	1 (0.6)	NR (NE, NE)	149	11 (7.4)	NR (NE, NE)	0.083 (0.011, 0.642)	0.0023
>= 65 Years	98	0 (0.0)	NR (NE, NE)	91	8 (8.8)	NR (NE, NE)	0.000 (0.000, NE)	0.0028
Interaction								0.9903
Gender								
Male	216	1 (0.5)	NR (NE, NE)	204	17 (8.3)	NR (NE, NE)	0.053 (0.007, 0.400)	<0.0001
Female	39	0 (0.0)	NR (NE, NE)	36	2 (5.6)	NR (NE, NE)	0.000 (0.000, NE)	0.1408
Interaction								0.9914

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	1 (0.5)	NR (NE, NE)	183	13 (7.1)	NR (NE, NE)	0.072 (0.009, 0.554)	0.0009
Non-Smoker	68	0 (0.0)	NR (NE, NE)	57	6 (10.5)	NR (NE, NE)	0.000 (0.000, NE)	0.0064
Interaction								0.9922

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	0 (0.0)	NR (NE, NE)	79	1 (1.3)	NR (NE, NE)	0.000 (0.000, NE)	0.3049
Docetaxel	56	1 (1.8)	NR (NE, NE)	50	9 (18.0)	NR (NE, NE)	0.093 (0.012, 0.732)	0.0043
Irinotecan	116	0 (0.0)	NR (NE, NE)	111	9 (8.1)	NR (NE, NE)	0.000 (0.000, NE)	0.0017
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	0 (0.0)	NR (NE, NE)	57	2 (3.5)	NR (NE, NE)	0.000 (0.000, NE)	0.1353
1	192	1 (0.5)	NR (NE, NE)	183	17 (9.3)	NR (NE, NE)	0.054 (0.007, 0.403)	<0.0001
Interaction								0.9933
Region #1								
Asia	201	1 (0.5)	NR (NE, NE)	191	18 (9.4)	NR (NE, NE)	0.051 (0.007, 0.380)	<0.0001
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	0.000 (0.000, NE)	0.2888
Interaction								0.9912

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	1 (0.6)	NR (NE, NE)	168	16 (9.5)	NR (NE, NE)	0.057 (0.008, 0.432)	0.0001
Japan	25	0 (0.0)	NR (NE, NE)	23	2 (8.7)	NR (NE, NE)	0.000 (0.000, NE)	0.1354
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	0.000 (0.000, NE)	0.2888
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	1 (0.5)	NR (NE, NE)	198	18 (9.1)	NR (NE, NE)	0.052 (0.007, 0.391)	<0.0001
White	52	0 (0.0)	NR (NE, NE)	42	1 (2.4)	NR (NE, NE)	0.000 (0.000, NE)	0.2601
Interaction								0.9911

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	0 (0.0)	--	60	5 (8.3)	--	--	--
vCPS < 10%	100	0 (0.0)	--	119	9 (7.6)	--	--	--
Missing	75	1 (1.3)	--	61	5 (8.2)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	18 (11.5)	NR (15.8, NE)	149	15 (10.1)	NR (NE, NE)	0.826 (0.409, 1.670)	0.5940
>= 65 Years	98	7 (7.1)	NR (NE, NE)	91	16 (17.6)	9.2 (9.2, NE)	0.226 (0.086, 0.599)	0.0014
Interaction								0.0675
Gender								
Male	216	24 (11.1)	NR (NE, NE)	204	27 (13.2)	NR (9.2, NE)	0.567 (0.318, 1.011)	0.0514
Female	39	1 (2.6)	NR (7.3, NE)	36	4 (11.1)	NR (NE, NE)	0.166 (0.018, 1.533)	0.0748
Interaction								0.2918

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	19 (10.2)	NR (NE, NE)	183	26 (14.2)	NR (9.2, NE)	0.464 (0.247, 0.872)	0.0146
Non-Smoker	68	6 (8.8)	NR (NE, NE)	57	5 (8.8)	NR (4.9, NE)	0.742 (0.220, 2.496)	0.6281
Interaction								0.5222

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	7 (8.4)	NR (NE, NE)	79	11 (13.9)	NR (NE, NE)	0.460 (0.171, 1.236)	0.1151
Docetaxel	56	7 (12.5)	NR (NE, NE)	50	7 (14.0)	NR (NE, NE)	0.700 (0.245, 2.004)	0.5040
Irinotecan	116	11 (9.5)	NR (13.8, NE)	111	13 (11.7)	NR (9.2, NE)	0.453 (0.187, 1.098)	0.0733
Interaction								0.8219

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Safety Analysis Set

Serious TEAE: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	4 (6.3)	NR (15.8, NE)	57	5 (8.8)	NR (9.2, NE)	0.343 (0.080, 1.473)	0.1332
1	192	21 (10.9)	NR (NE, NE)	183	26 (14.2)	NR (NE, NE)	0.552 (0.304, 1.001)	0.0474
Interaction								0.9703
Region #1								
Asia	201	21 (10.4)	NR (NE, NE)	191	20 (10.5)	NR (NE, NE)	0.679 (0.359, 1.285)	0.2311
Europe/North America	54	4 (7.4)	NR (NE, NE)	49	11 (22.4)	9.2 (4.9, NE)	0.259 (0.081, 0.826)	0.0143
Interaction								0.1615

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Safety Analysis Set

Serious TEAE: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	20 (11.4)	NR (15.8, NE)	168	16 (9.5)	NR (NE, NE)	0.810 (0.409, 1.604)	0.5450
Japan	25	1 (4.0)	NR (6.8, NE)	23	4 (17.4)	NR (NE, NE)	0.148 (0.015, 1.457)	0.0666
Europe/North America	54	4 (7.4)	NR (NE, NE)	49	11 (22.4)	9.2 (4.9, NE)	0.259 (0.081, 0.826)	0.0143
Interaction								0.1178

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Safety Analysis Set

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	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	22 (10.8)	NR (NE, NE)	198	21 (10.6)	NR (NE, NE)	0.710 (0.381, 1.323)	0.2781
White	52	3 (5.8)	NR (NE, NE)	42	10 (23.8)	9.2 (4.9, NE)	0.187 (0.051, 0.690)	0.0050
Interaction								0.0774

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	5 (6.3)	NR (15.8, NE)	60	8 (13.3)	NR (NE, NE)	0.306 (0.096, 0.974)	0.0351
vCPS < 10%	100	15 (15.0)	NR (10.8, NE)	119	16 (13.4)	NR (9.2, NE)	0.824 (0.401, 1.695)	0.5988
Missing	75	5 (6.7)	NR (13.8, NE)	61	7 (11.5)	NR (NE, NE)	0.392 (0.114, 1.349)	0.1240
Interaction								0.2159

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

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Age								
< 65 Years	157	1 (0.6)	--	149	7 (4.7)	--	--	--
>= 65 Years	98	0 (0.0)	--	91	6 (6.6)	--	--	--
Interaction								--
Gender								
Male	216	1 (0.5)	NR (NE, NE)	204	12 (5.9)	NR (NE, NE)	0.076 (0.010, 0.583)	0.0012
Female	39	0 (0.0)	NR (NE, NE)	36	1 (2.8)	NR (NE, NE)	0.000 (0.000, NE)	0.3042
Interaction								0.9928

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

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Smoking Status								
Former/Current Smoker	187	1 (0.5)	--	183	8 (4.4)	--	--	--
Non-Smoker	68	0 (0.0)	--	57	5 (8.8)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

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ICC Options								
Paclitaxel	83	1 (1.2)	--	79	0 (0.0)	--	--	--
Docetaxel	56	0 (0.0)	--	50	4 (8.0)	--	--	--
Irinotecan	116	0 (0.0)	--	111	9 (8.1)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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ECOG Performance Score								
0	63	1 (1.6)	NR (NE, NE)	57	3 (5.3)	NR (NE, NE)	0.296 (0.031, 2.847)	0.2626
1	192	0 (0.0)	NR (NE, NE)	183	10 (5.5)	NR (NE, NE)	0.000 (0.000, NE)	0.0010
Interaction								0.9920
Region #1								
Asia	201	1 (0.5)	NR (NE, NE)	191	13 (6.8)	NR (NE, NE)	0.071 (0.009, 0.540)	0.0007
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9993

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

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Region #2								
Asia (excluding Japan)	176	1 (0.6)	NR (NE, NE)	168	13 (7.7)	NR (NE, NE)	0.071 (0.009, 0.540)	0.0007
Japan	25	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	1 (0.5)	NR (NE, NE)	198	13 (6.6)	NR (NE, NE)	0.073 (0.010, 0.555)	0.0009
White	52	0 (0.0)	NR (NE, NE)	42	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9993

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	0 (0.0)	--	60	3 (5.0)	--	--	--
vCPS < 10%	100	0 (0.0)	--	119	6 (5.0)	--	--	--
Missing	75	1 (1.3)	--	61	4 (6.6)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	0 (0.0)	--	149	6 (4.0)	--	--	--
>= 65 Years	98	0 (0.0)	--	91	4 (4.4)	--	--	--
Interaction								--
Gender								
Male	216	0 (0.0)	--	204	9 (4.4)	--	--	--
Female	39	0 (0.0)	--	36	1 (2.8)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	0 (0.0)	--	183	7 (3.8)	--	--	--
Non-Smoker	68	0 (0.0)	--	57	3 (5.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	0 (0.0)	--	79	0 (0.0)	--	--	--
Docetaxel	56	0 (0.0)	--	50	4 (8.0)	--	--	--
Irinotecan	116	0 (0.0)	--	111	6 (5.4)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	0 (0.0)	--	57	2 (3.5)	--	--	--
1	192	0 (0.0)	--	183	8 (4.4)	--	--	--
Interaction								--
Region #1								
Asia	201	0 (0.0)	NR (NE, NE)	191	10 (5.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0010
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9979

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

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Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	0 (0.0)	NR (NE, NE)	168	10 (6.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0010
Japan	25	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	0 (0.0)	NR (NE, NE)	198	10 (5.1)	NR (NE, NE)	0.000 (0.000, NE)	0.0012
White	52	0 (0.0)	NR (NE, NE)	42	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9979

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

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Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	0 (0.0)	--	60	2 (3.3)	--	--	--
vCPS < 10%	100	0 (0.0)	--	119	6 (5.0)	--	--	--
Missing	75	0 (0.0)	--	61	2 (3.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.4.1.1.b.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	1 (1.3)	--	70	6 (8.6)	--	--	--
>= 65 Years	62	0 (0.0)	--	59	4 (6.8)	--	--	--
Interaction								--
Gender								
Male	118	1 (0.8)	NR (NE, NE)	106	9 (8.5)	NR (NE, NE)	0.096 (0.012, 0.761)	0.0056
Female	21	0 (0.0)	NR (NE, NE)	23	1 (4.3)	NR (NE, NE)	0.000 (0.000, NE)	0.3393
Interaction								0.9934

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.b.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	1 (1.0)	NR (NE, NE)	101	9 (8.9)	NR (NE, NE)	0.104 (0.013, 0.824)	0.0083
Non-Smoker	35	0 (0.0)	NR (NE, NE)	28	1 (3.6)	NR (NE, NE)	0.000 (0.000, NE)	0.2636
Interaction								0.9945
ICC Options								
Paclitaxel	83	0 (0.0)	NR (NE, NE)	79	1 (1.3)	NR (NE, NE)	0.000 (0.000, NE)	0.3049
Docetaxel	56	1 (1.8)	NR (NE, NE)	50	9 (18.0)	NR (NE, NE)	0.093 (0.012, 0.732)	0.0043
Interaction								0.9952

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-aesocpt-sub.sas 21AUG2024 22:54 t-14-03-01-02-04-01-01-b-s-aesocpt-sub-sae-safetys-sa.rtf

Table 14.3.1.2.4.1.1.b.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	0 (0.0)	NR (NE, NE)	37	1 (2.7)	NR (NE, NE)	0.000 (0.000, NE)	0.2810
1	96	1 (1.0)	NR (NE, NE)	92	9 (9.8)	NR (NE, NE)	0.103 (0.013, 0.810)	0.0076
Interaction								0.9943
Region #1								
Asia	103	1 (1.0)	NR (NE, NE)	99	9 (9.1)	NR (NE, NE)	0.103 (0.013, 0.815)	0.0078
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	1 (3.3)	NR (NE, NE)	0.000 (0.000, NE)	0.2733
Interaction								0.9945

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-aesocpt-sub.sas 21AUG2024 22:54 t-14-03-01-02-04-01-01-b-s-aesocpt-sub-sae-safetys-sa.rtf

Table 14.3.1.2.4.1.1.b.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	1 (1.3)	--	76	7 (9.2)	--	--	--
Japan	25	0 (0.0)	--	23	2 (8.7)	--	--	--
Europe/North America	36	0 (0.0)	--	30	1 (3.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-aesocpt-sub.sas 21AUG2024 22:54 t-14-03-01-02-04-01-01-b-s-aesocpt-sub-sae-safetys-sa.rtf

Table 14.3.1.2.4.1.1.b.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	1 (1.0)	NR (NE, NE)	106	9 (8.5)	NR (NE, NE)	0.109 (0.014, 0.858)	0.0099
White	34	0 (0.0)	NR (NE, NE)	23	1 (4.3)	NR (NE, NE)	0.000 (0.000, NE)	0.2240
Interaction								0.9944

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-aesocpt-sub.sas 21AUG2024 22:54 t-14-03-01-02-04-01-01-b-s-aesocpt-sub-sae-safetys-sa.rtf

Table 14.3.1.2.4.1.1.b.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	0 (0.0)	--	34	2 (5.9)	--	--	--
vCPS < 10%	53	0 (0.0)	--	54	4 (7.4)	--	--	--
Missing	41	1 (2.4)	--	41	4 (9.8)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v23.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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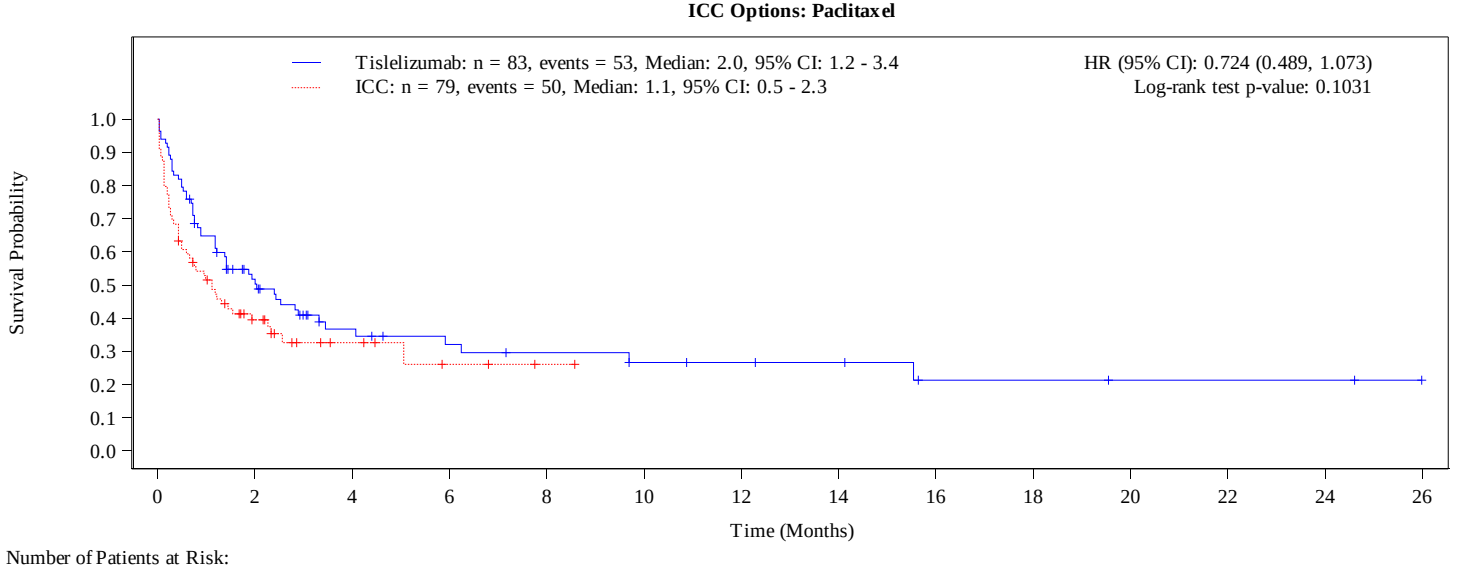
Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders

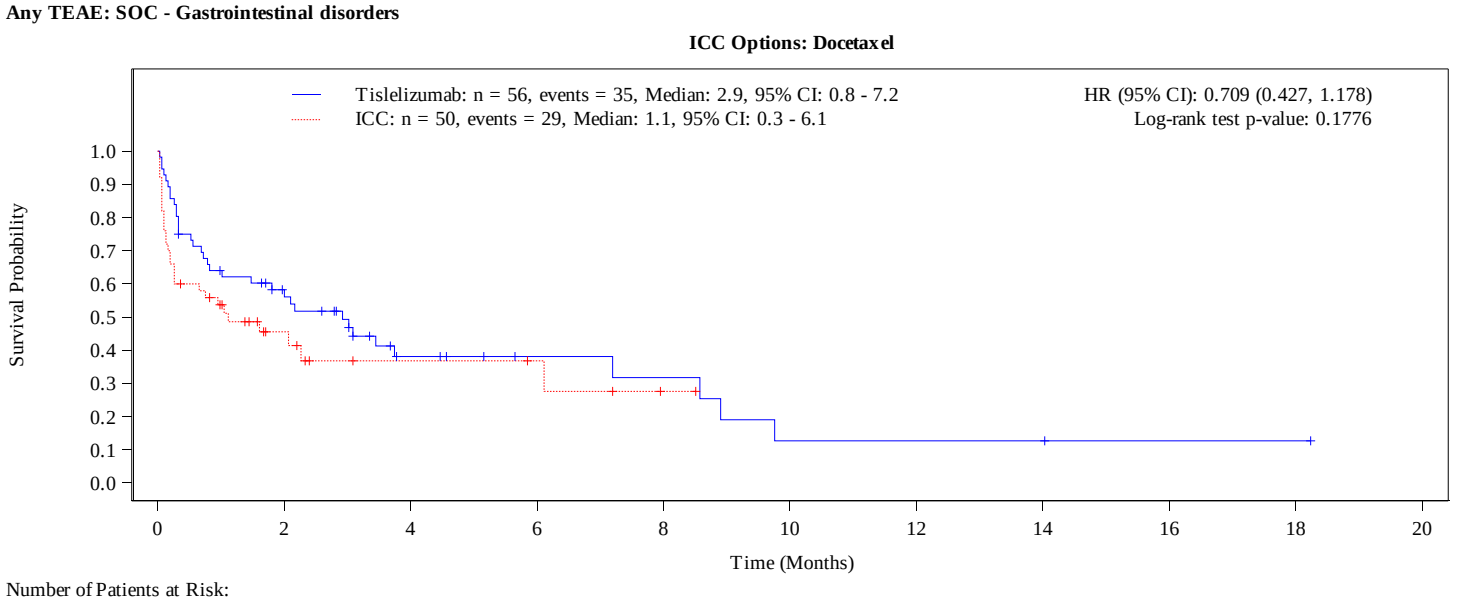


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	83	35	17	13	10	8	7	6	3	3	2	2	2	0
ICC	79	21	8	3	1	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-s-km-socpt-sub-safety-sa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



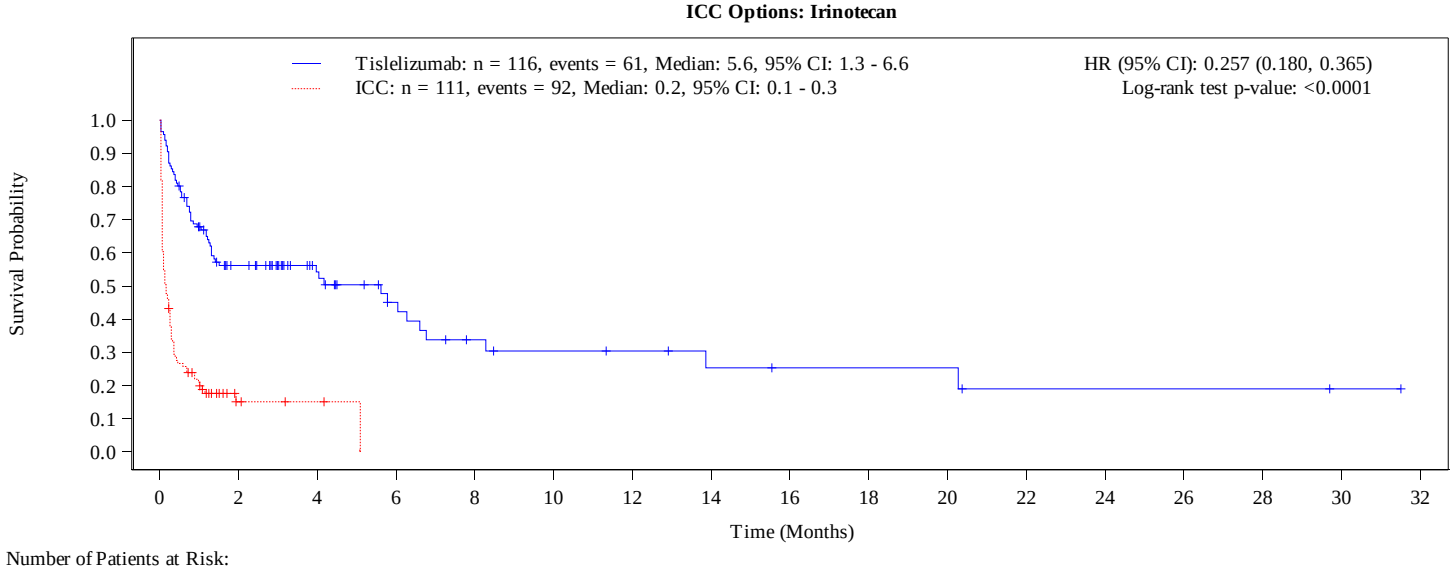
Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20
Tislelizumab	56	27	11	6	5	2	2	2	1	1	0
ICC	50	11	5	4	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-s-km-socpt-sub-safety-sa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders



Number of Patients at Risk:

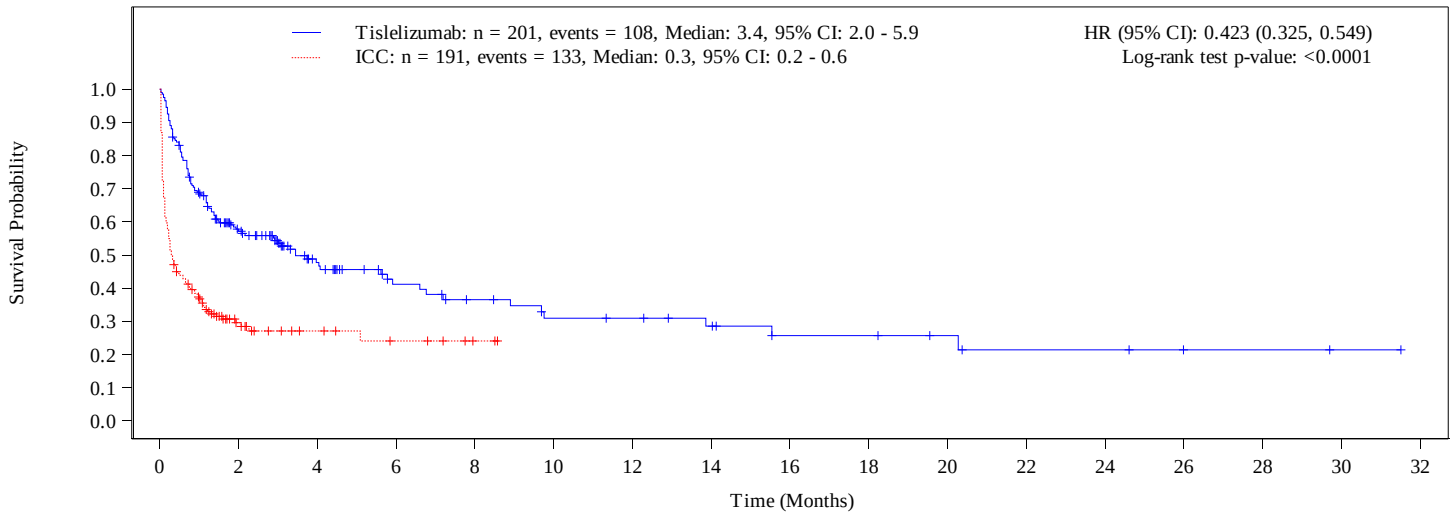
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	116	50	28	16	10	8	7	5	4	4	4	2	2	2	2	1	0
ICC	111	4	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-s-km-socpt-sub-safety-sa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders

Region #1: Asia



Number of Patients at Risk:

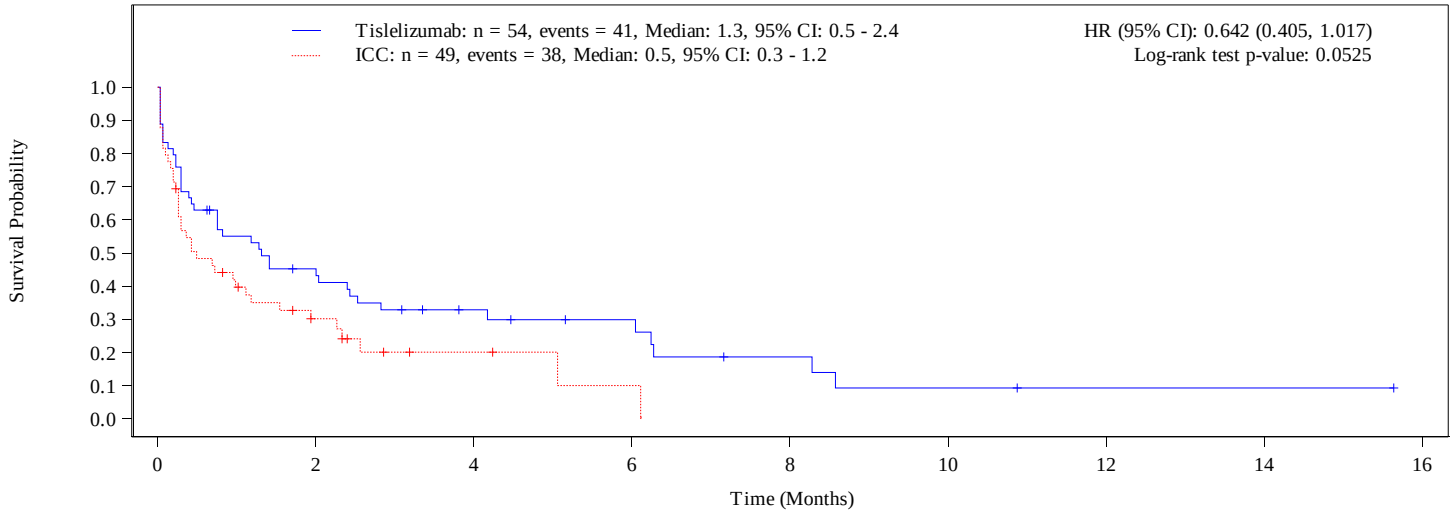
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	201	90	45	27	21	16	15	12	8	8	6	4	4	2	2	1	0
ICC	191	26	12	6	2	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-s-km-socpt-sub-safety-sa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders

Region #1: Europe/North America



Number of Patients at Risk:

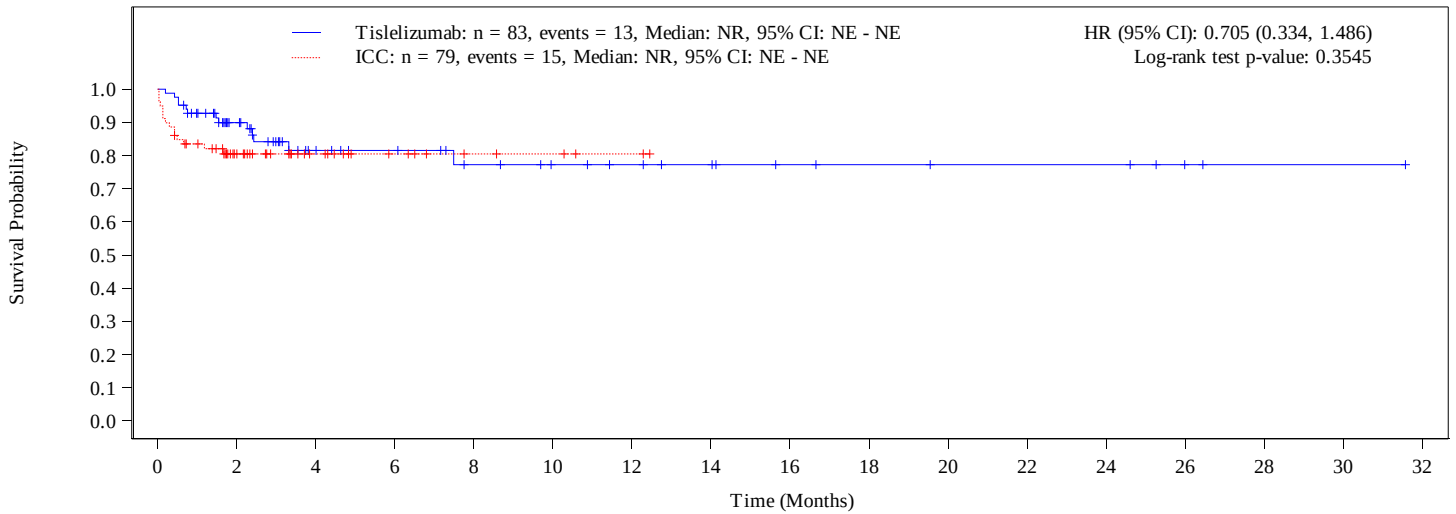
Time:	0	2	4	6	8	10	12	14	16
Tislelizumab	54	22	11	8	4	2	1	1	0
ICC	49	10	3	1	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-s-km-socpt-sub-safety-sa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Diarrhoea

ICC Options: Paclitaxel

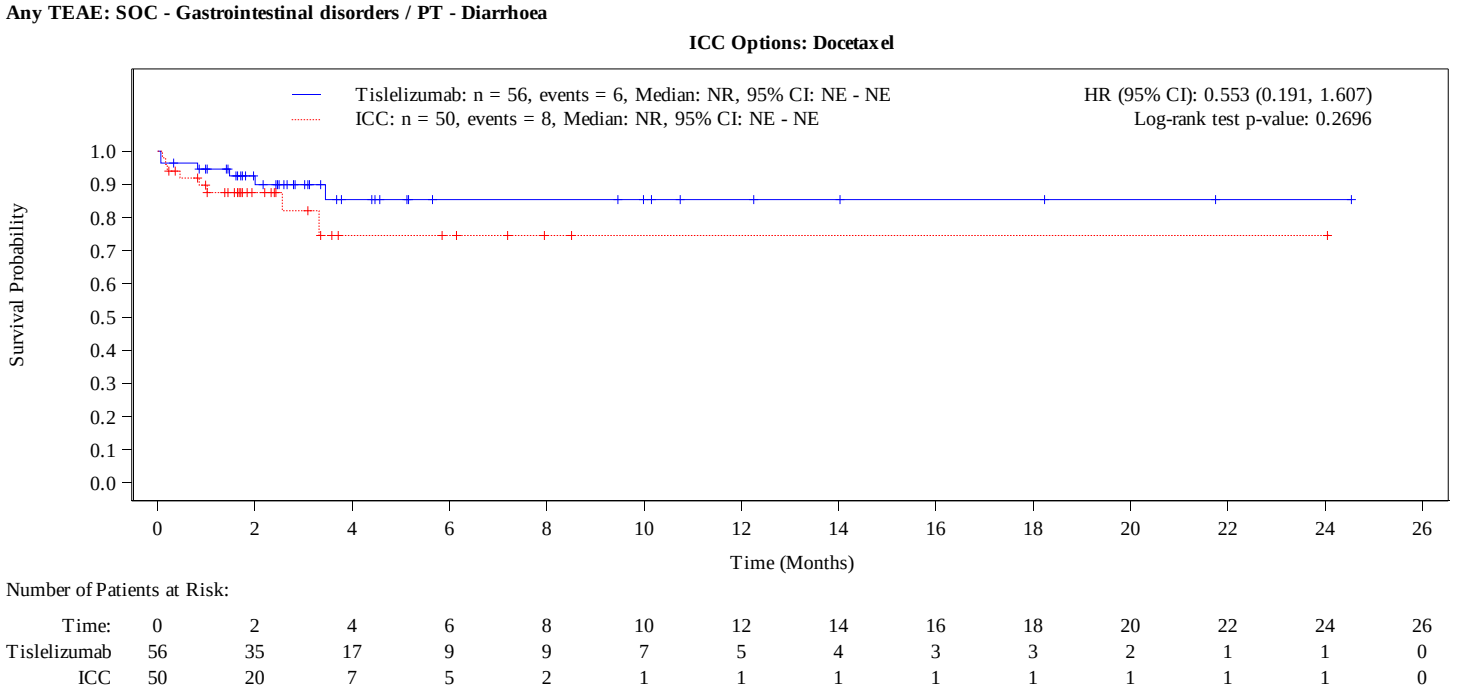


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	83	51	27	23	17	14	12	10	7	6	5	5	5	2	1	1	0
ICC	79	40	17	9	5	4	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-s-km-socpt-sub-safety-sa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

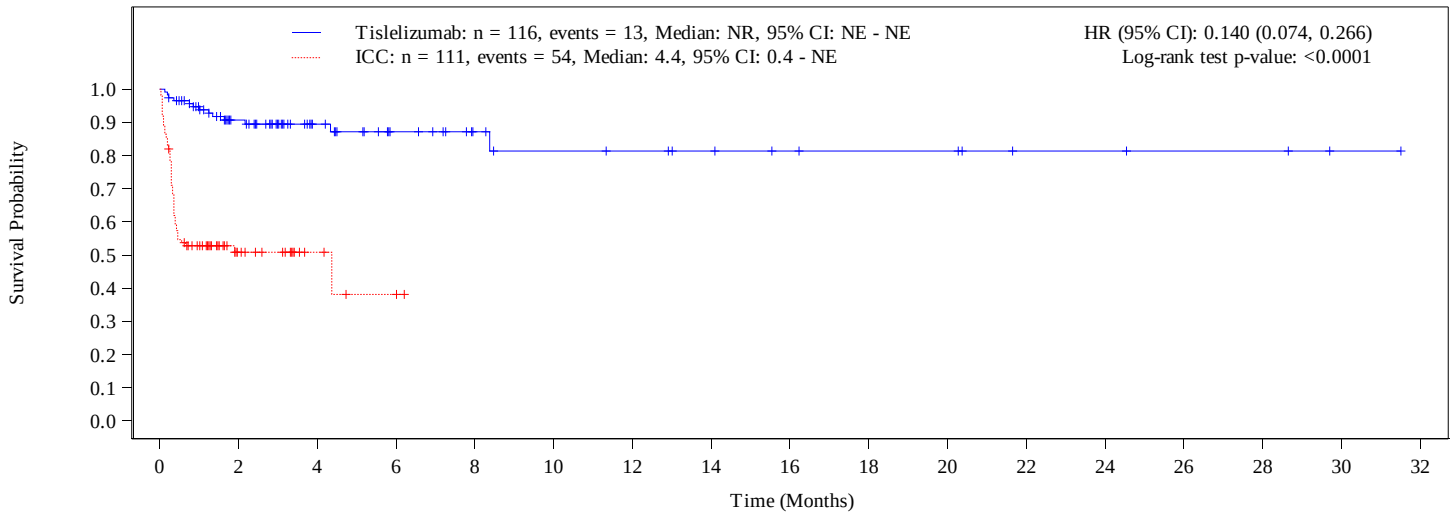


Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-s-km-socpt-sub-safety-sa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Diarrhoea

ICC Options: Irinotecan



Number of Patients at Risk:

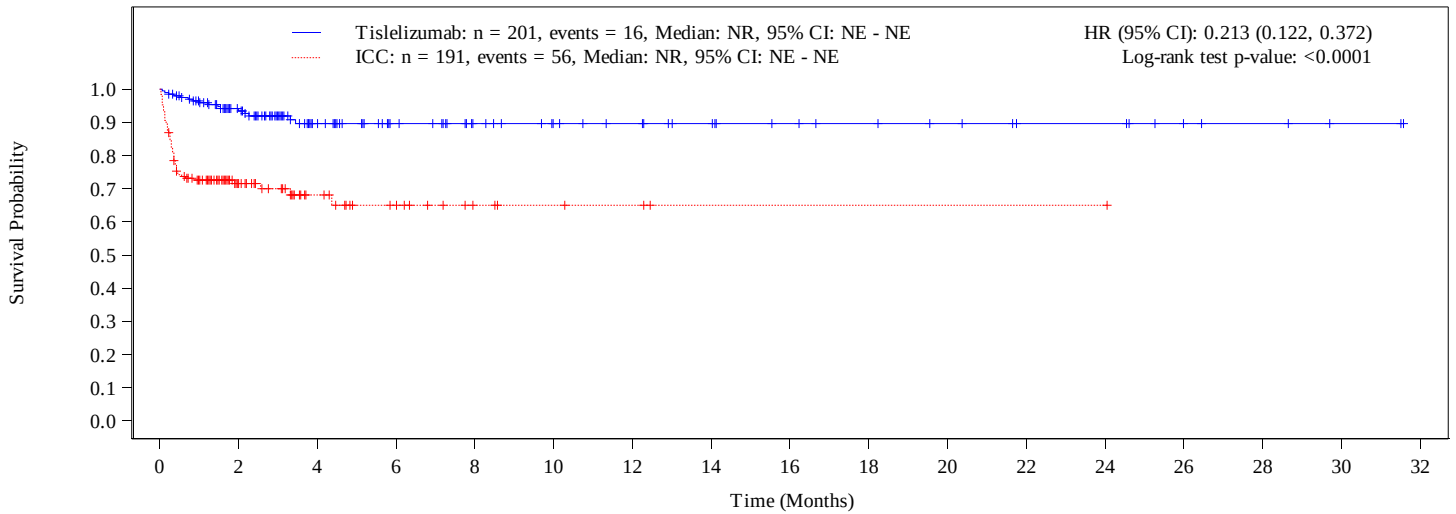
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	116	73	40	24	16	13	12	10	8	7	7	4	4	3	3	1	0
ICC	111	20	5	2	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-s-km-socpt-sub-safety-sa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Diarrhoea

Region #1: Asia



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	201	128	68	46	35	29	26	22	17	15	13	10	10	5	4	2	0
ICC	191	61	24	13	6	4	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
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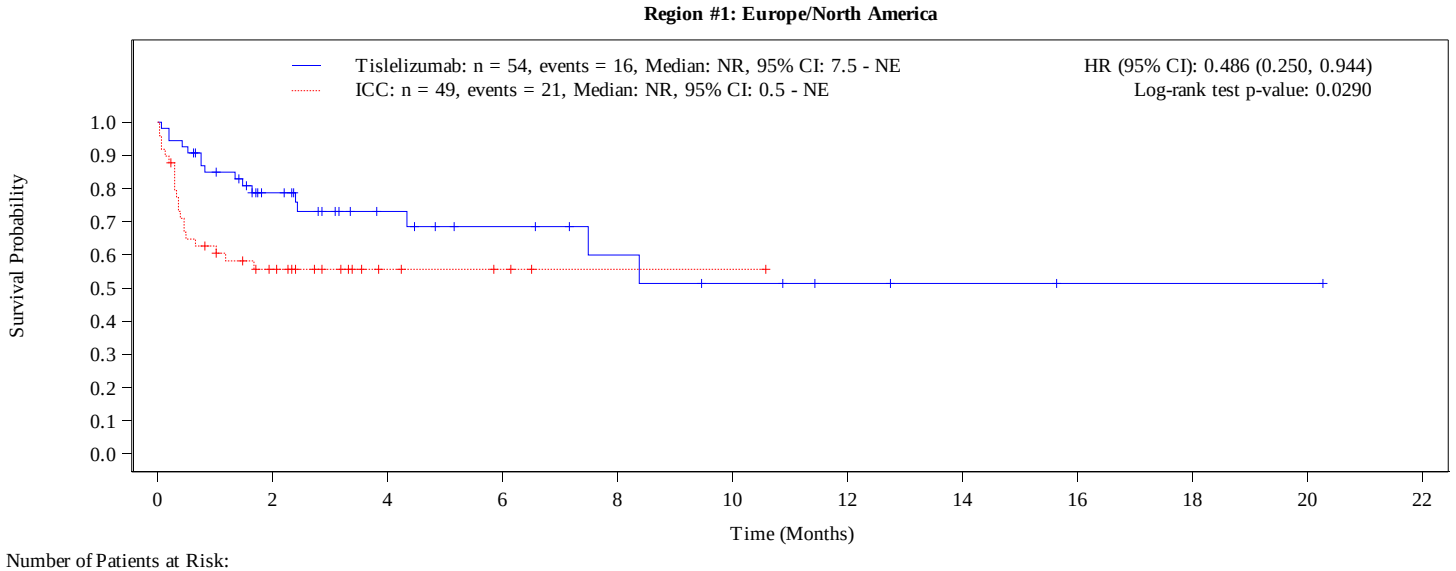
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-s-km-socpt-sub-safety-sa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Diarrhoea

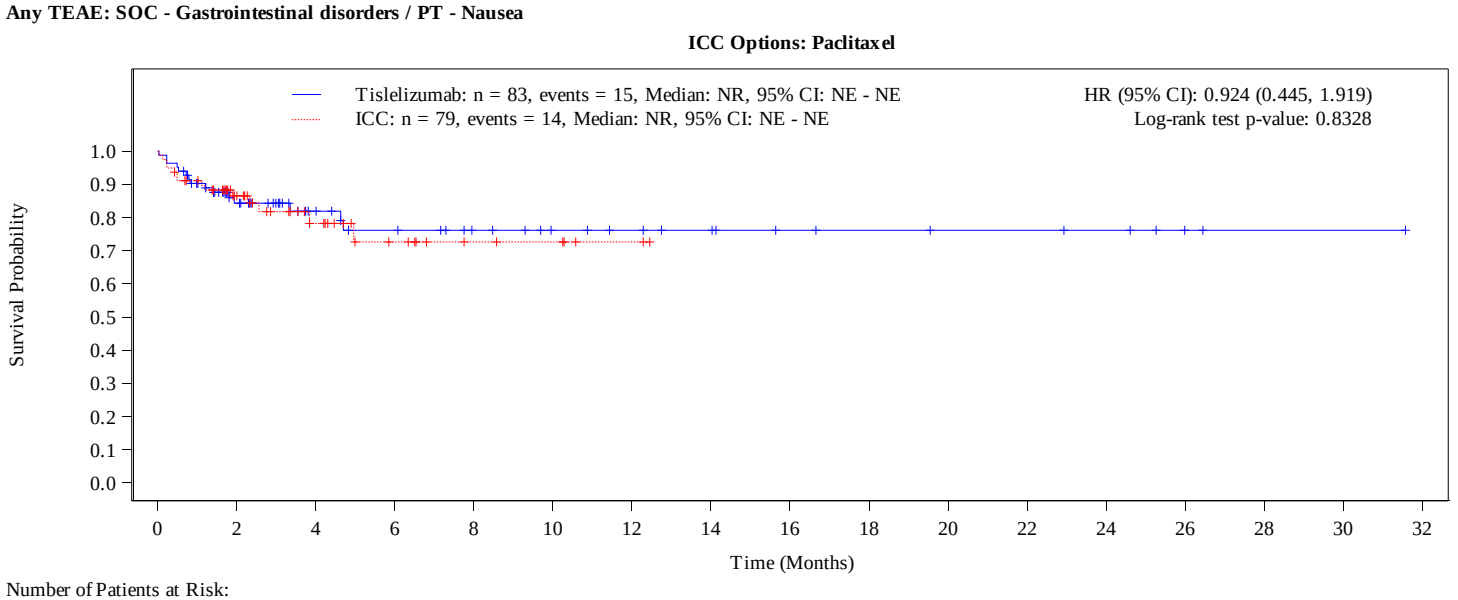


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	54	31	16	10	7	5	3	2	1	1	1	0
ICC	49	19	5	3	1	1	0	0	0	0	0	0

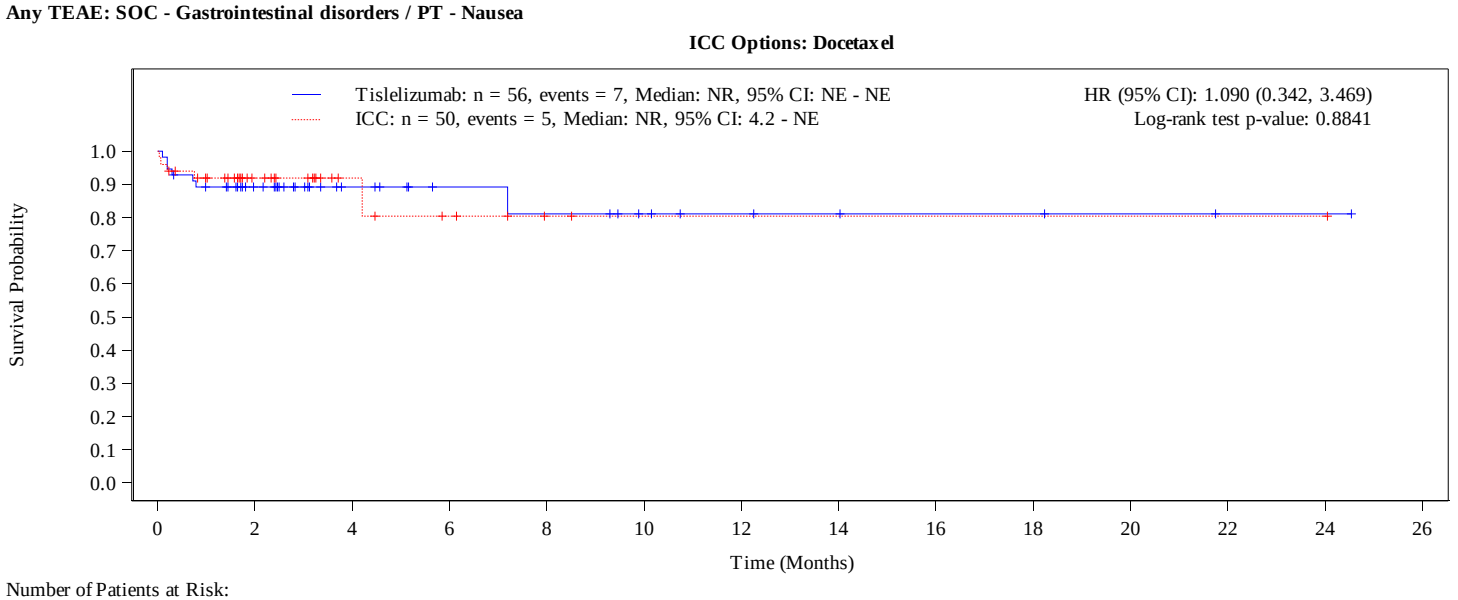
Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-s-km-socpt-sub-safety-sa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-s-km-socpt-sub-safety-sa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



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Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
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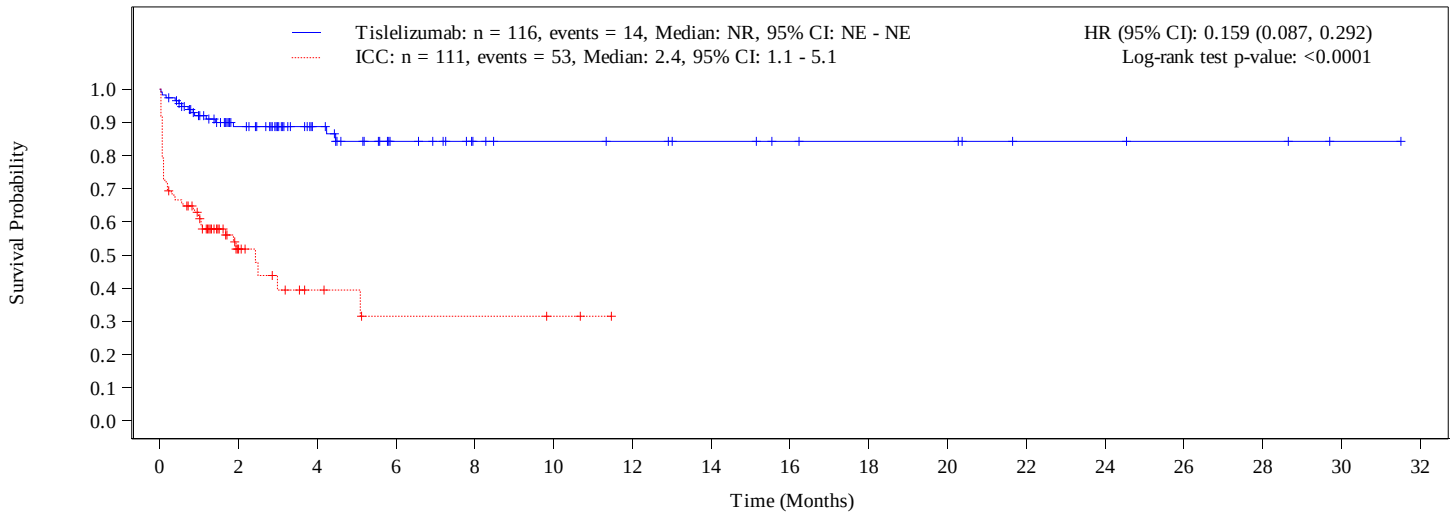
Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Nausea

ICC Options: Irinotecan



Number of Patients at Risk:

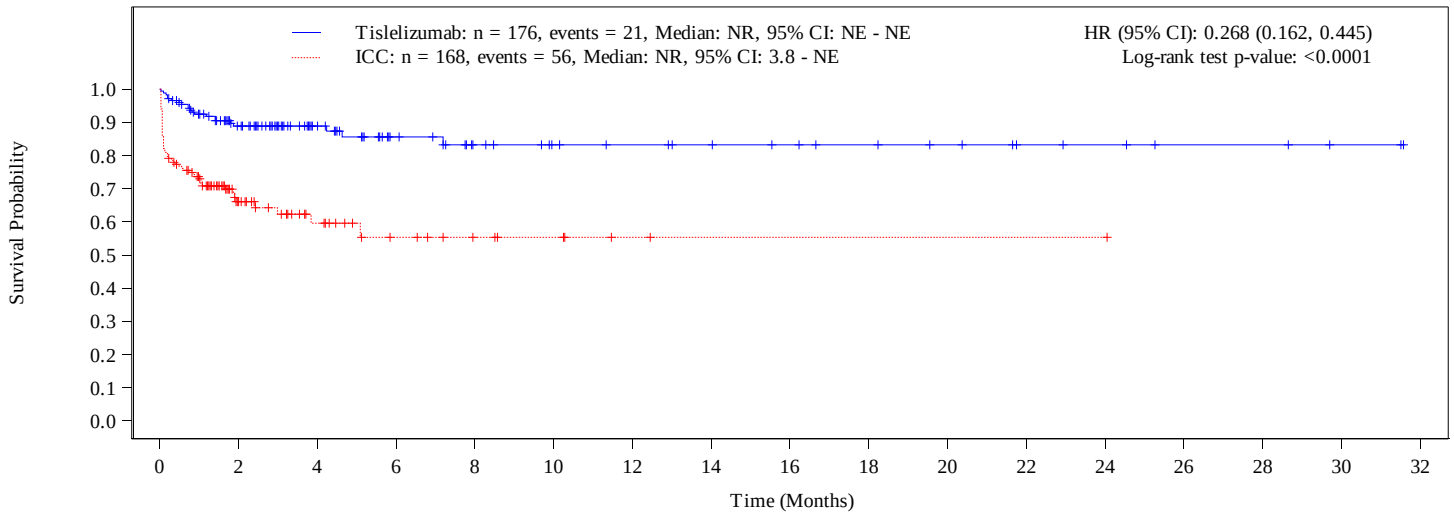
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	116	72	42	24	16	14	12	10	8	7	7	4	4	3	3	1	0
ICC	111	18	6	3	3	2	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-s-km-socpt-sub-safety-sa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Nausea

Region #2: Asia (excluding Japan)



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	176	108	60	38	28	22	20	18	15	13	11	8	7	4	4	2	0
ICC	168	47	22	11	7	5	2	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
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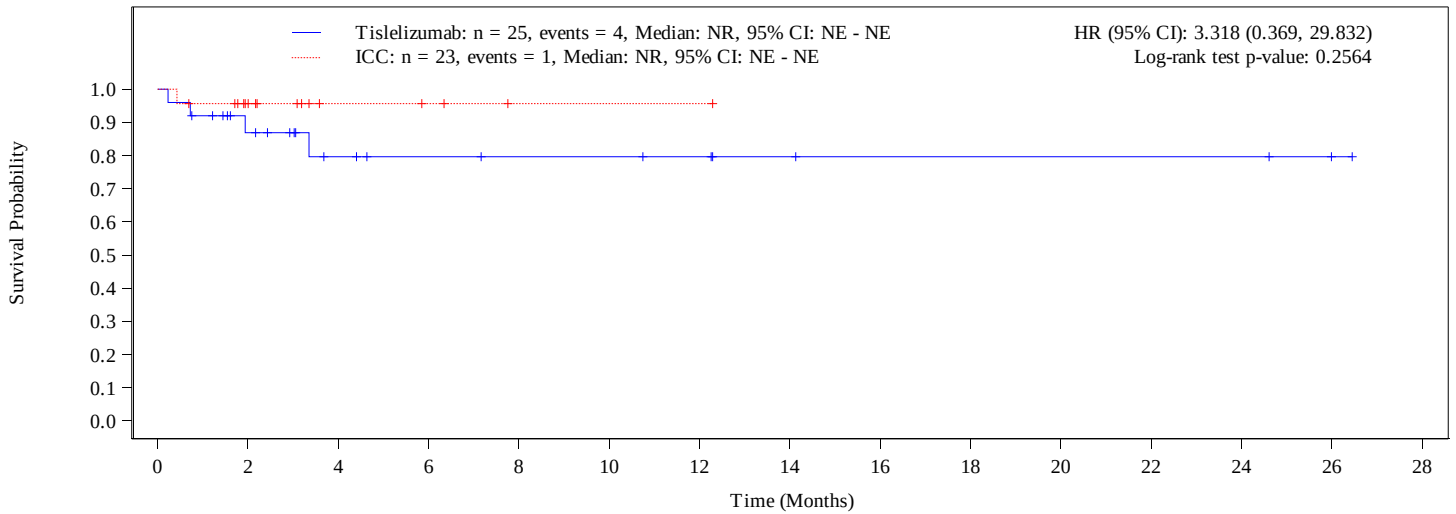
Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Nausea

Region #2: Japan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28
Tislelizumab	25	17	10	8	7	7	6	4	3	3	3	3	3	1	0
ICC	23	12	4	3	1	1	1	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
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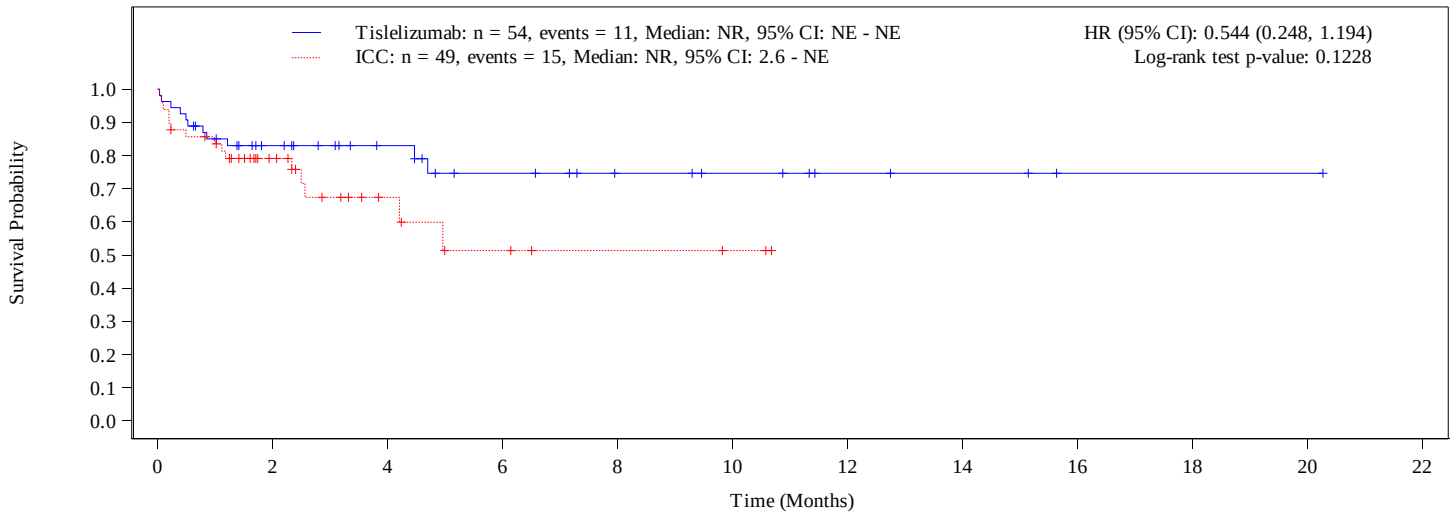
Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Nausea

Region #2: Europe/North America



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	54	34	21	14	10	7	4	3	1	1	1	0
ICC	49	26	9	5	3	2	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
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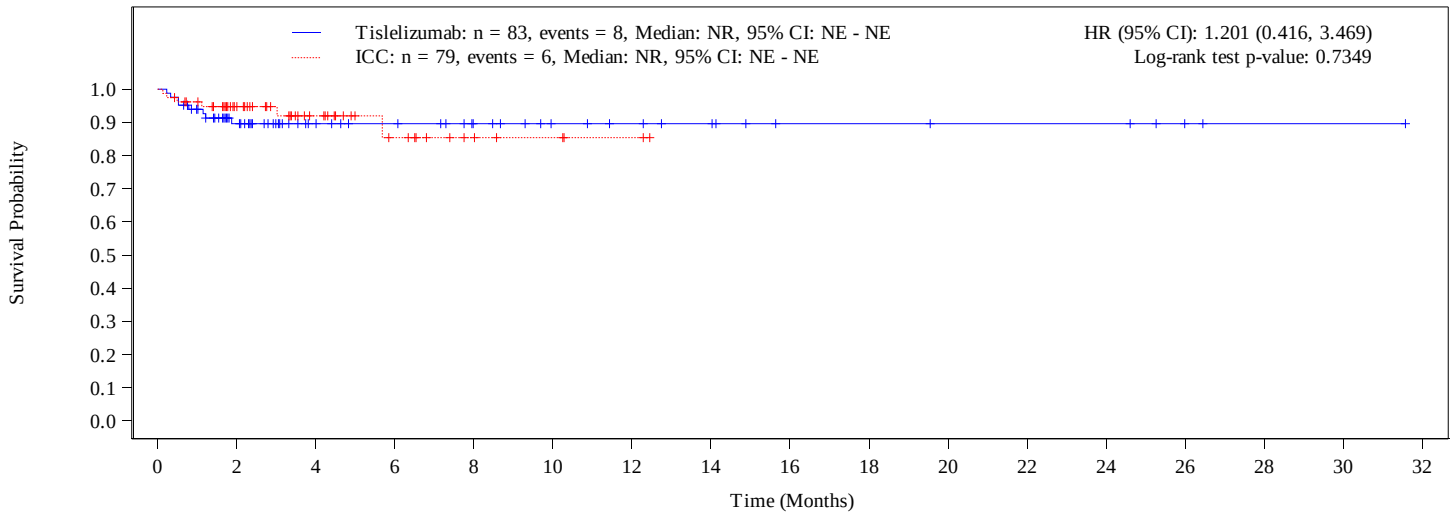
Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Vomiting

ICC Options: Paclitaxel



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	83	53	30	26	19	14	12	10	6	6	5	5	5	2	1	1	0
ICC	79	51	23	12	6	4	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
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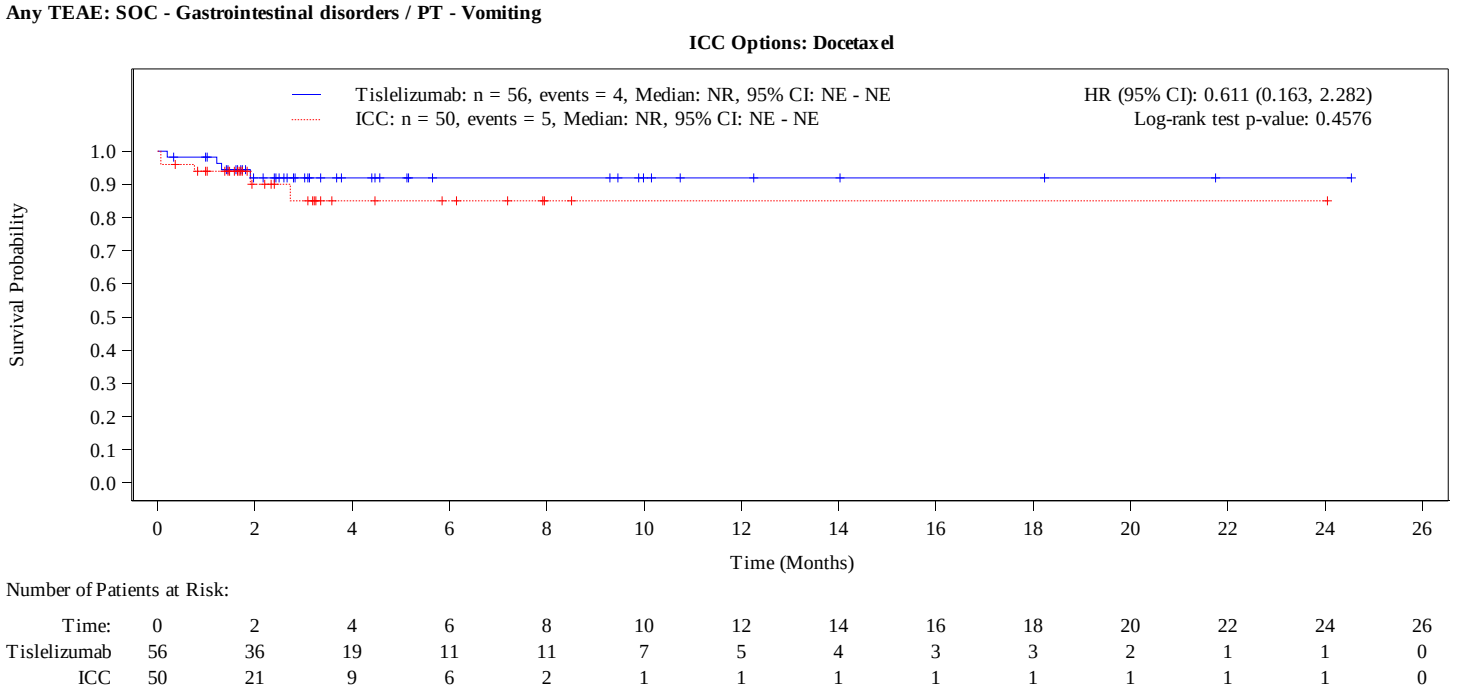
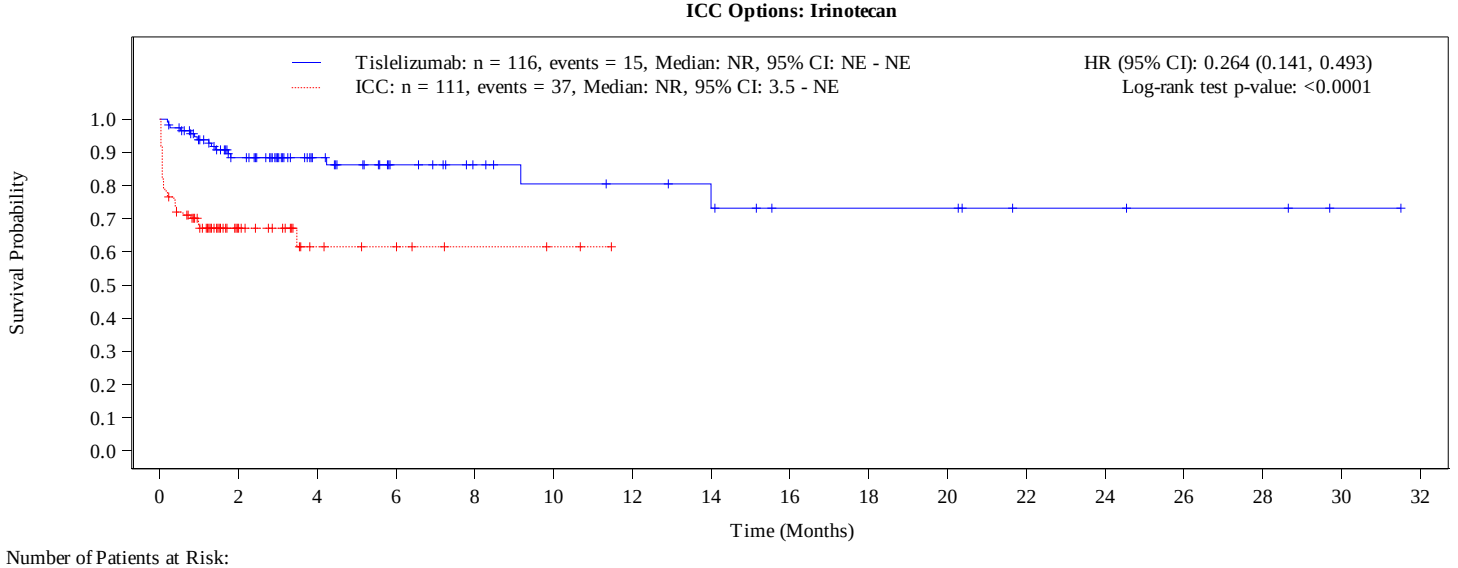
Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-s-km-socpt-sub-safety-sa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Vomiting



Number of Patients at Risk:

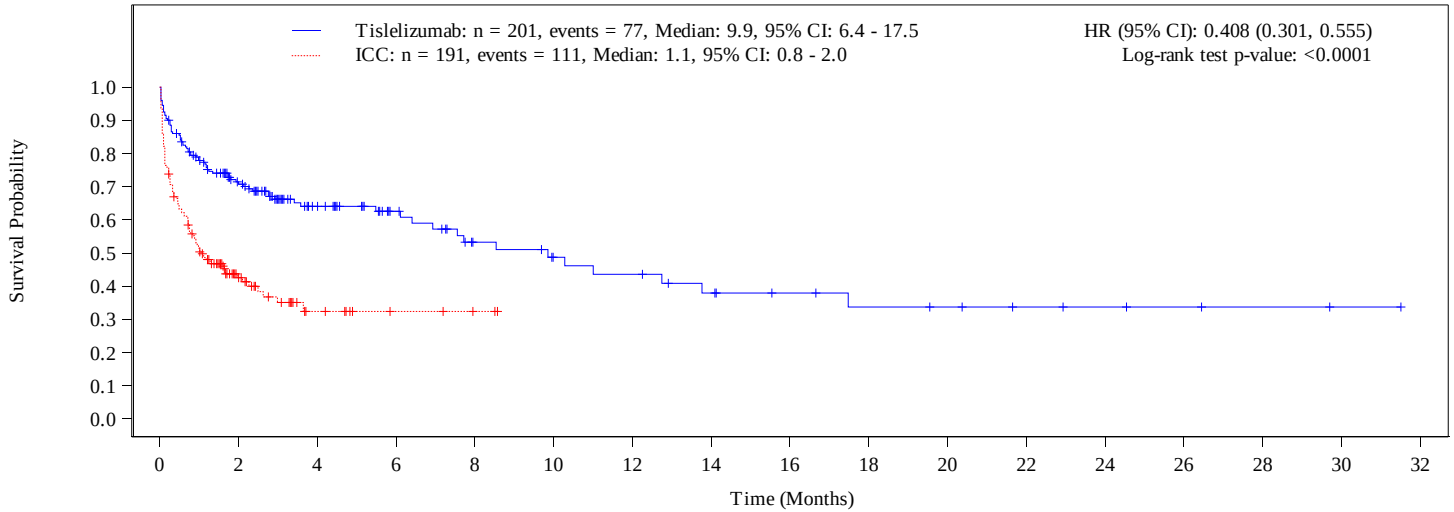
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	116	73	42	24	17	14	12	10	7	7	7	4	4	3	3	1	0
ICC	111	25	8	6	3	2	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-s-km-socpt-sub-safety-sa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions

Region #1: Asia

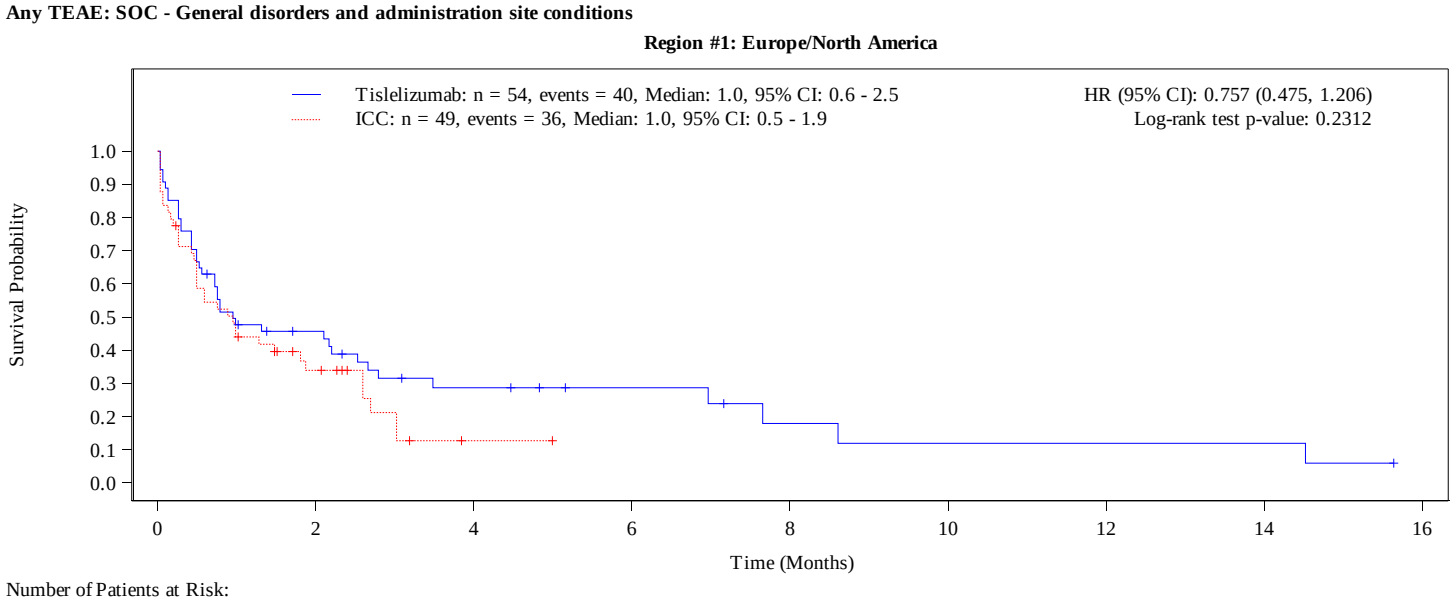


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	201	103	55	36	24	19	17	13	10	8	7	5	4	3	2	1	0
ICC	191	37	10	4	2	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-s-km-socpt-sub-safety-sa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
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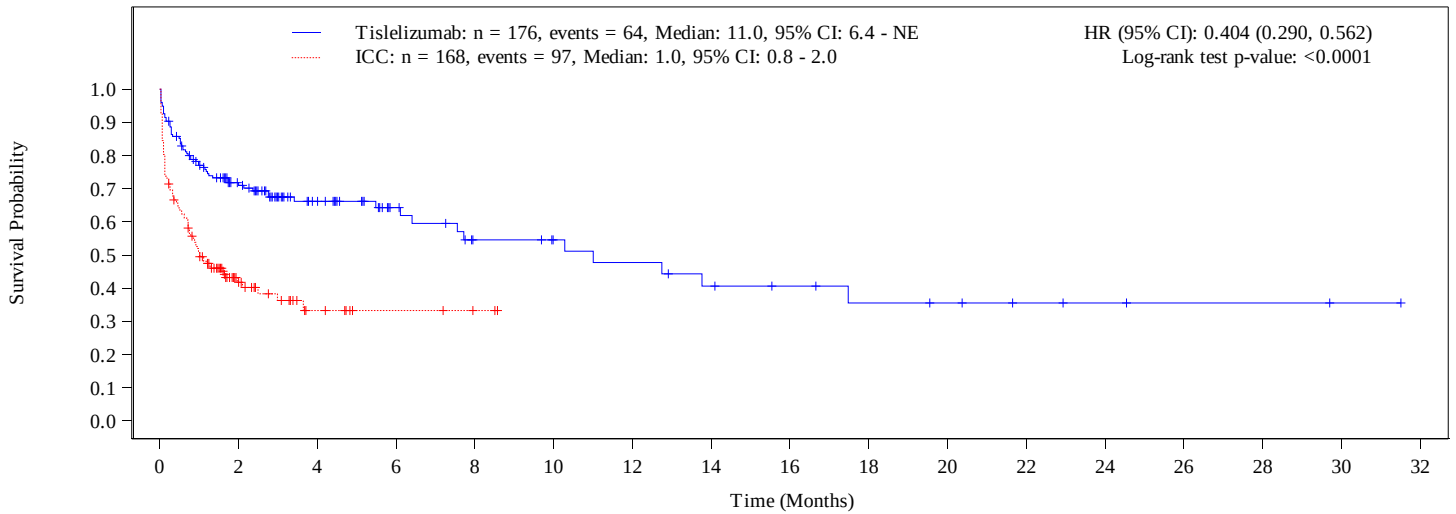
Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions

Region #2: Asia (excluding Japan)



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	176	88	47	28	19	16	14	11	9	7	6	4	3	2	2	1	0
ICC	168	29	9	4	2	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
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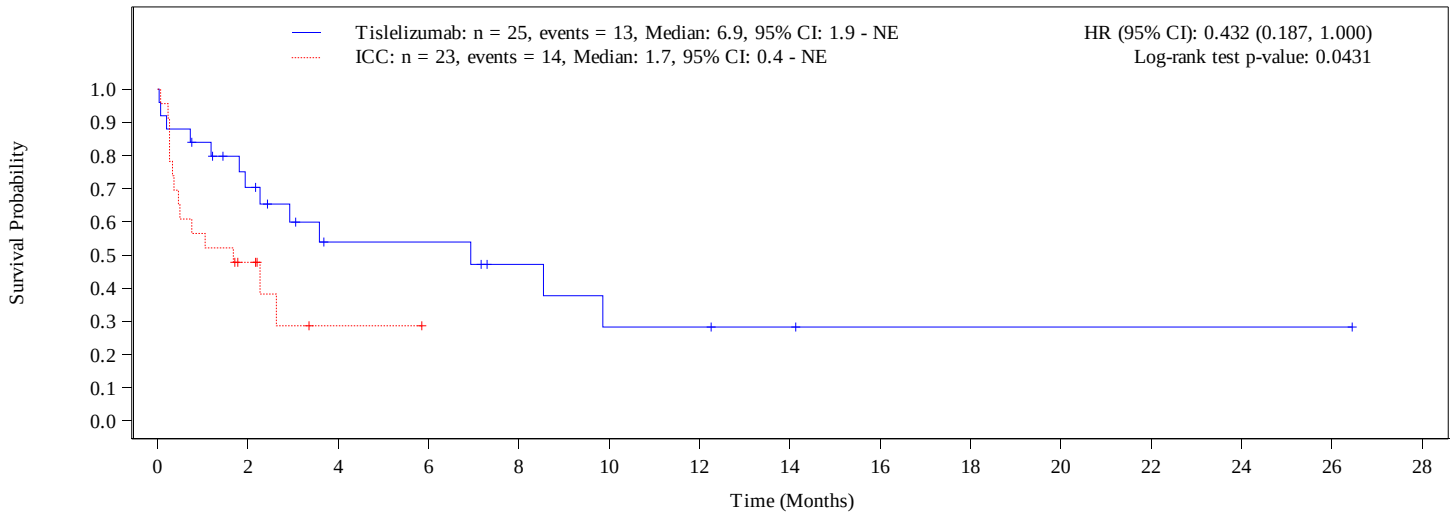
Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions

Region #2: Japan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28
Tislelizumab	25	15	8	8	5	3	3	2	1	1	1	1	1	1	0
ICC	23	8	1	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
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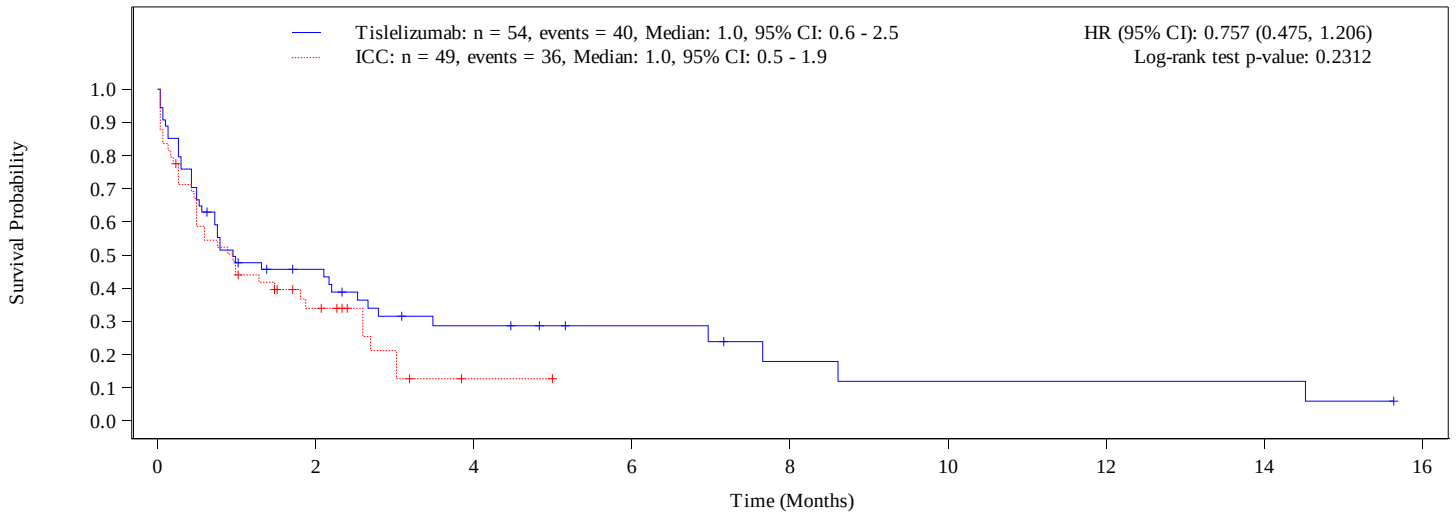
Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions

Region #2: Europe/North America



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16
Tislelizumab	54	20	10	6	3	2	2	2	0
ICC	49	12	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
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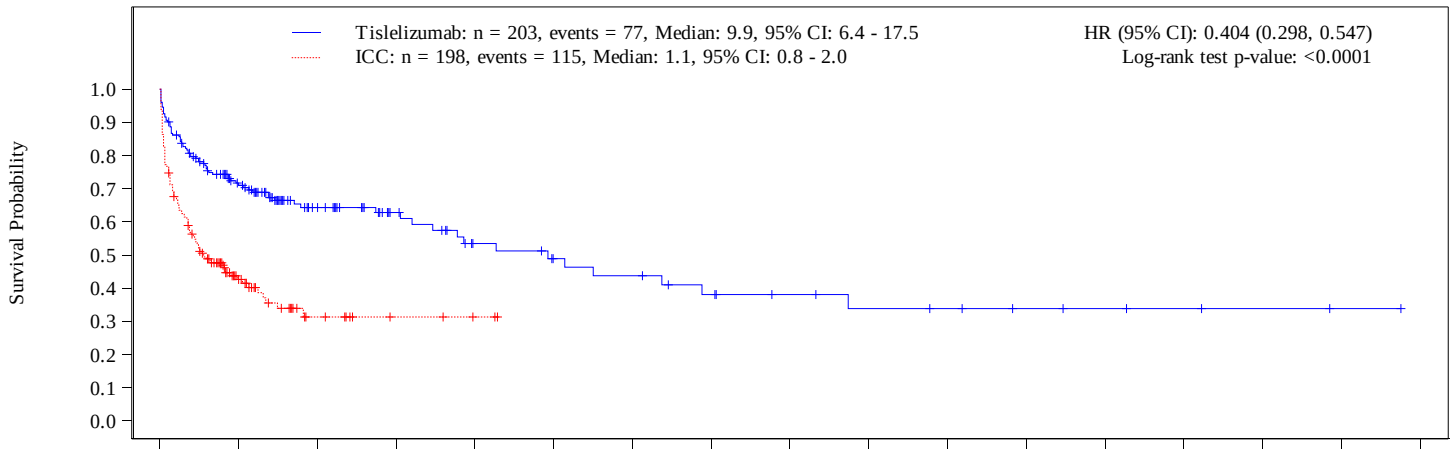
Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions

Race: Asian and other

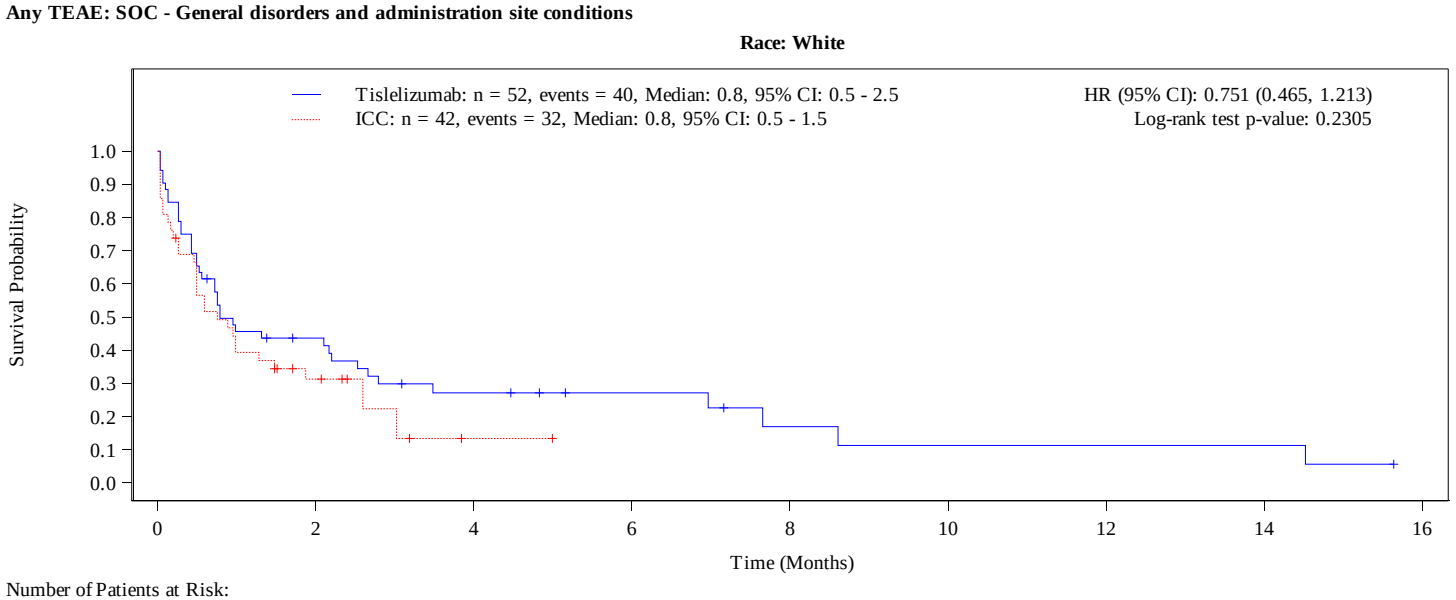


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	203	104	55	36	24	19	17	13	10	8	7	5	4	3	2	1	0
ICC	198	39	10	4	2	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-s-km-socpt-sub-safety-sa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

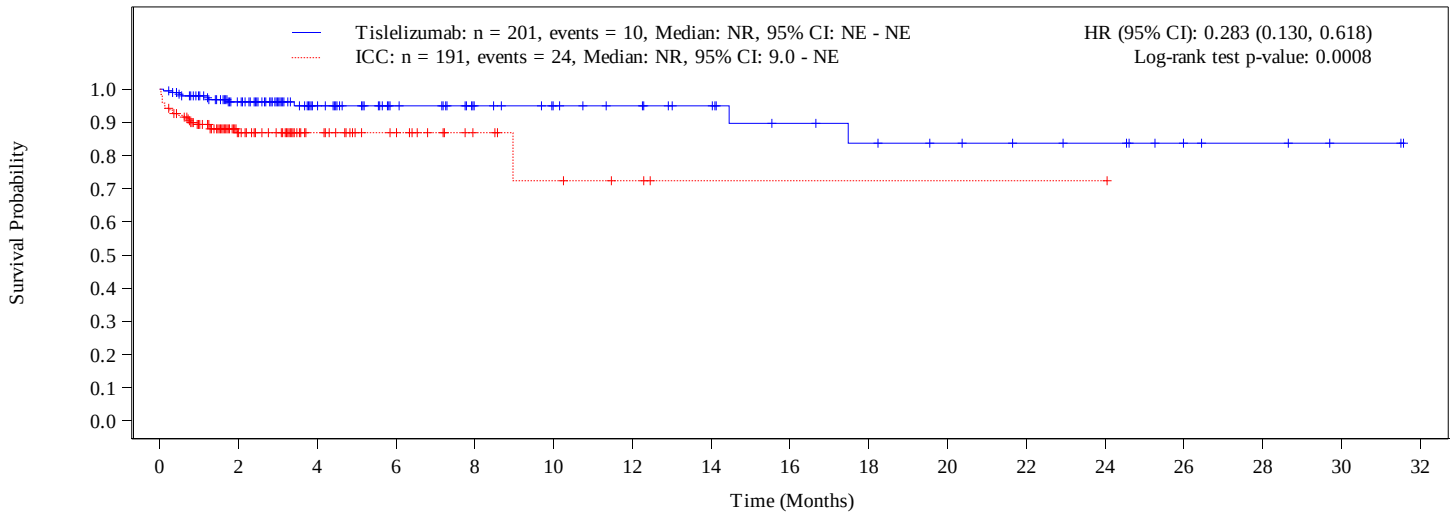


Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-s-km-socpt-sub-safety-sa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

Region #1: Asia



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	201	131	71	46	35	29	26	22	16	14	12	10	9	5	4	2	0
ICC	191	74	31	17	8	5	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
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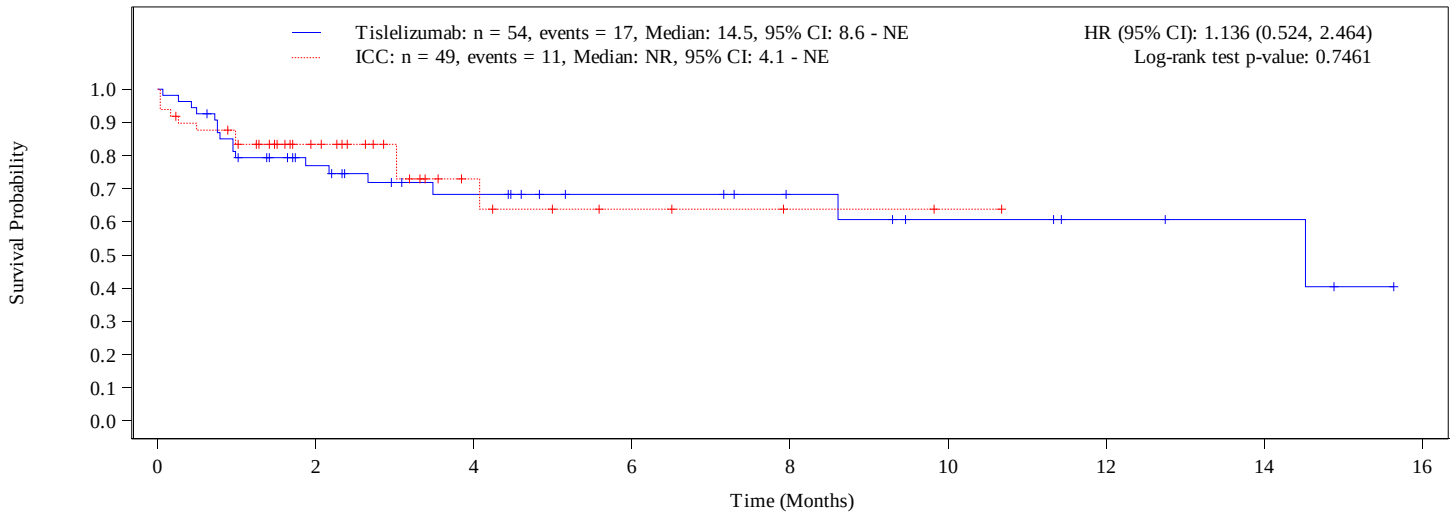
Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

Region #1: Europe/North America



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16
Tislelizumab	54	32	19	12	9	6	4	3	0
ICC	49	27	8	4	2	1	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
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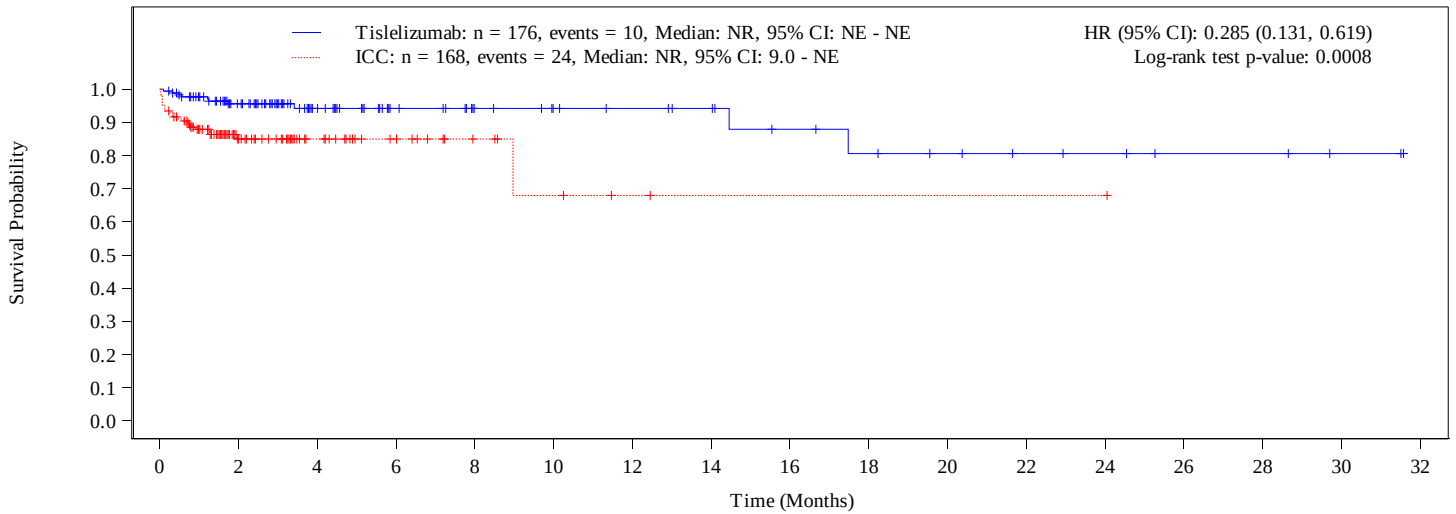
Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

Region #2: Asia (excluding Japan)

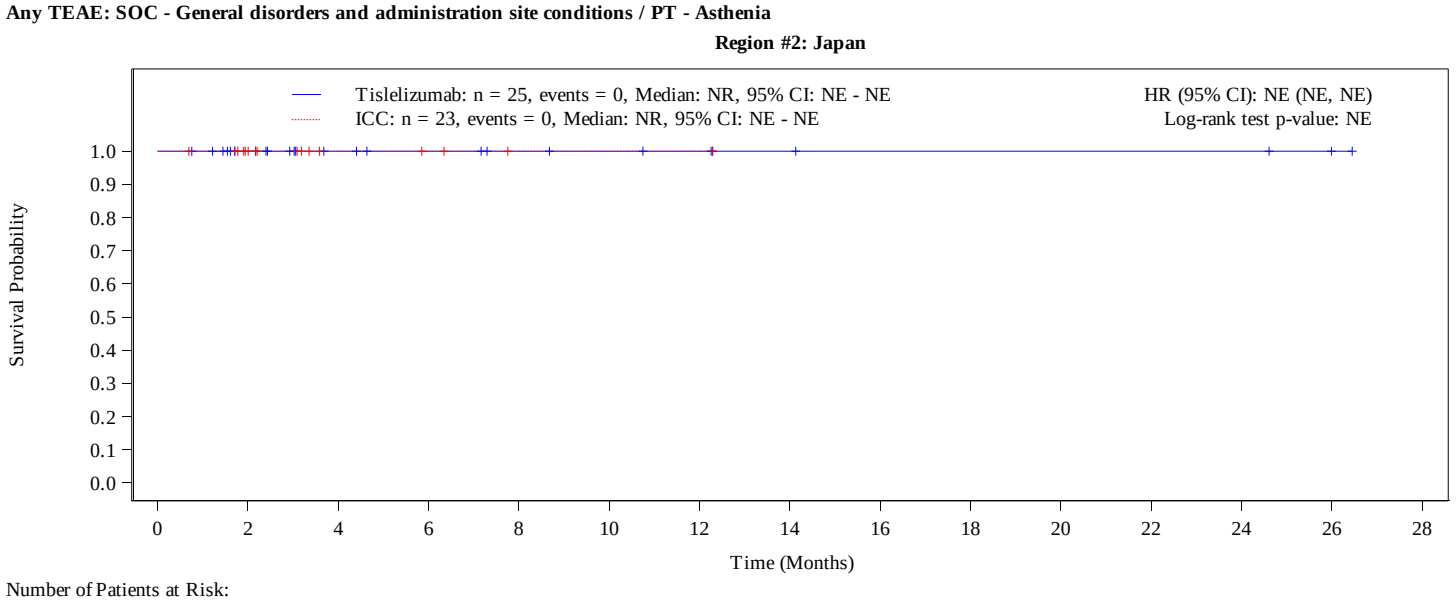


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	176	112	59	36	27	22	20	18	13	11	9	7	6	4	4	2	0
ICC	168	61	27	14	7	4	2	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-s-km-socpt-sub-safety-sa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



Number of Patients at Risk:

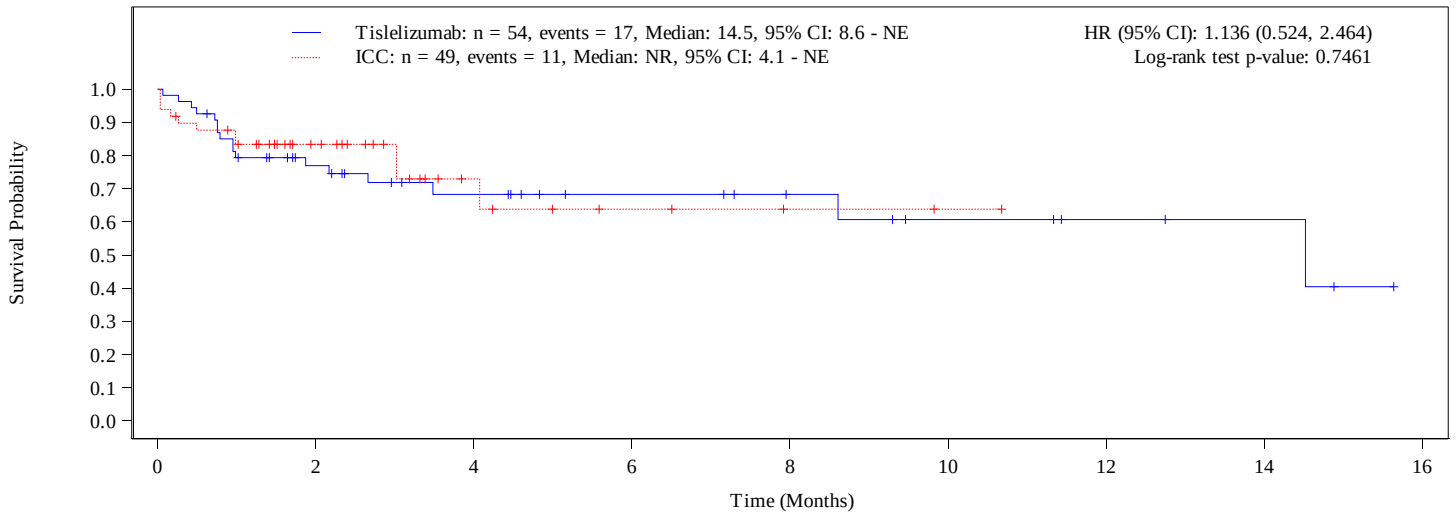
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28
Tislelizumab	25	19	12	10	8	7	6	4	3	3	3	3	3	1	0
ICC	23	13	4	3	1	1	1	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-s-km-socpt-sub-safety-sa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

Region #2: Europe/North America



Number of Patients at Risk:

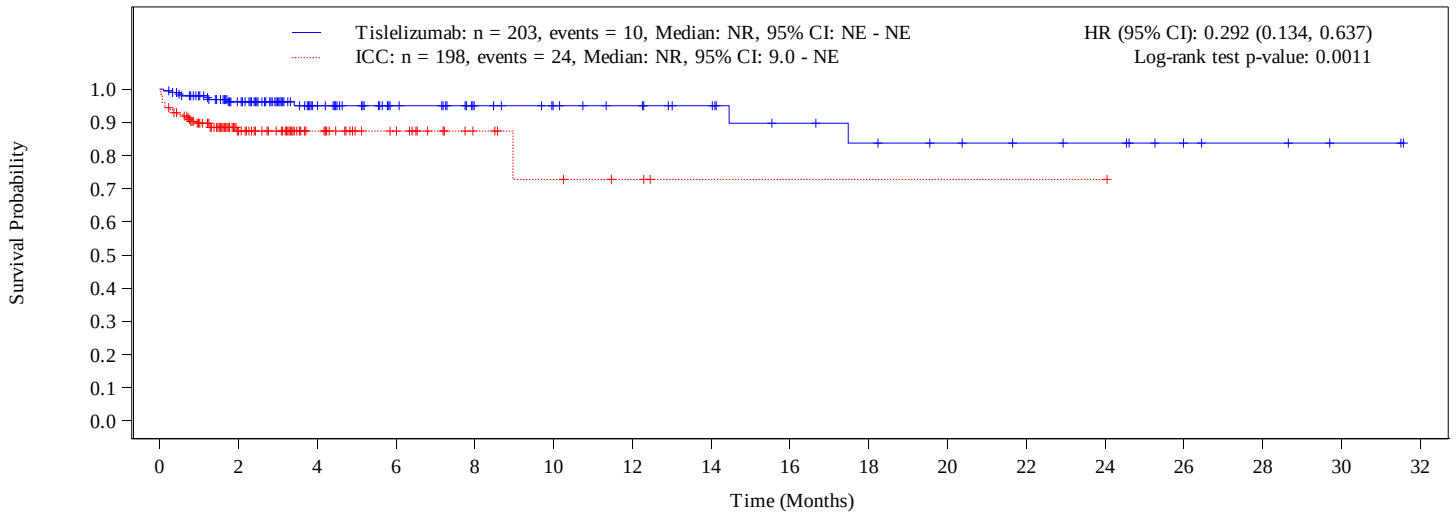
Time:	0	2	4	6	8	10	12	14	16
Tislelizumab	54	32	19	12	9	6	4	3	0
ICC	49	27	8	4	2	1	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-s-km-socpt-sub-safety-sa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

Race: Asian and other

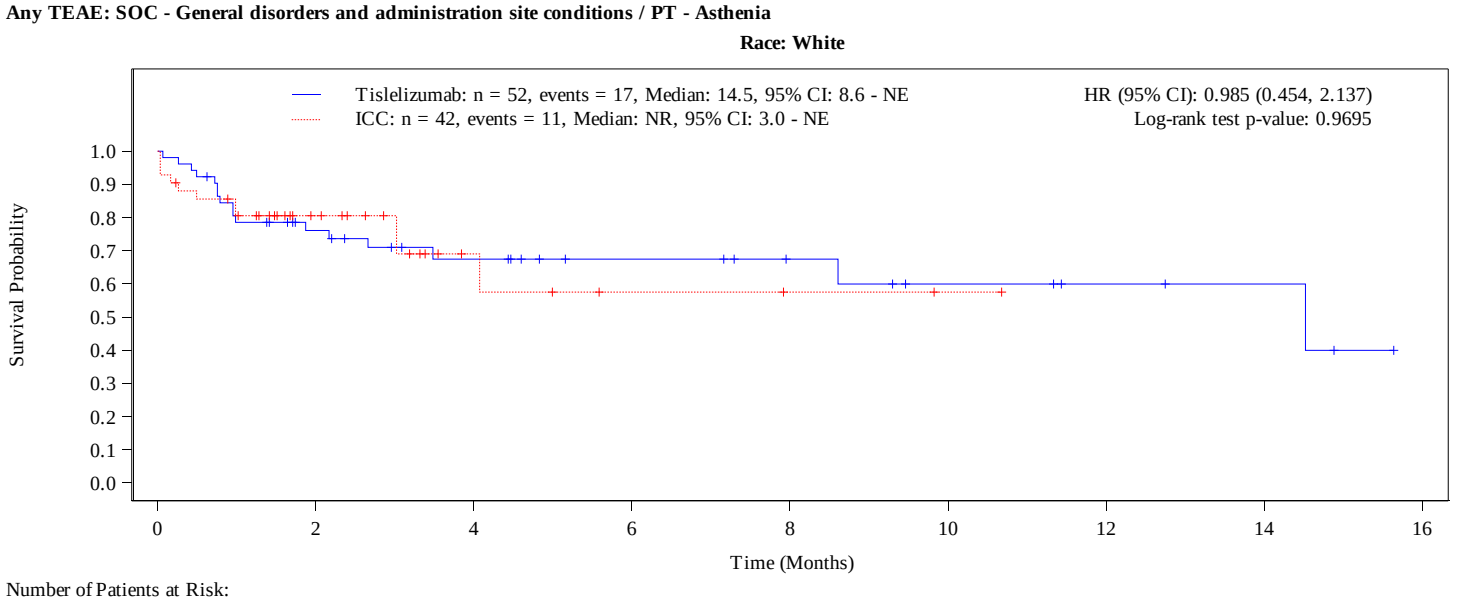


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	203	132	71	46	35	29	26	22	16	14	12	10	9	5	4	2	0
ICC	198	79	33	18	8	5	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-s-km-socpt-sub-safety-sa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

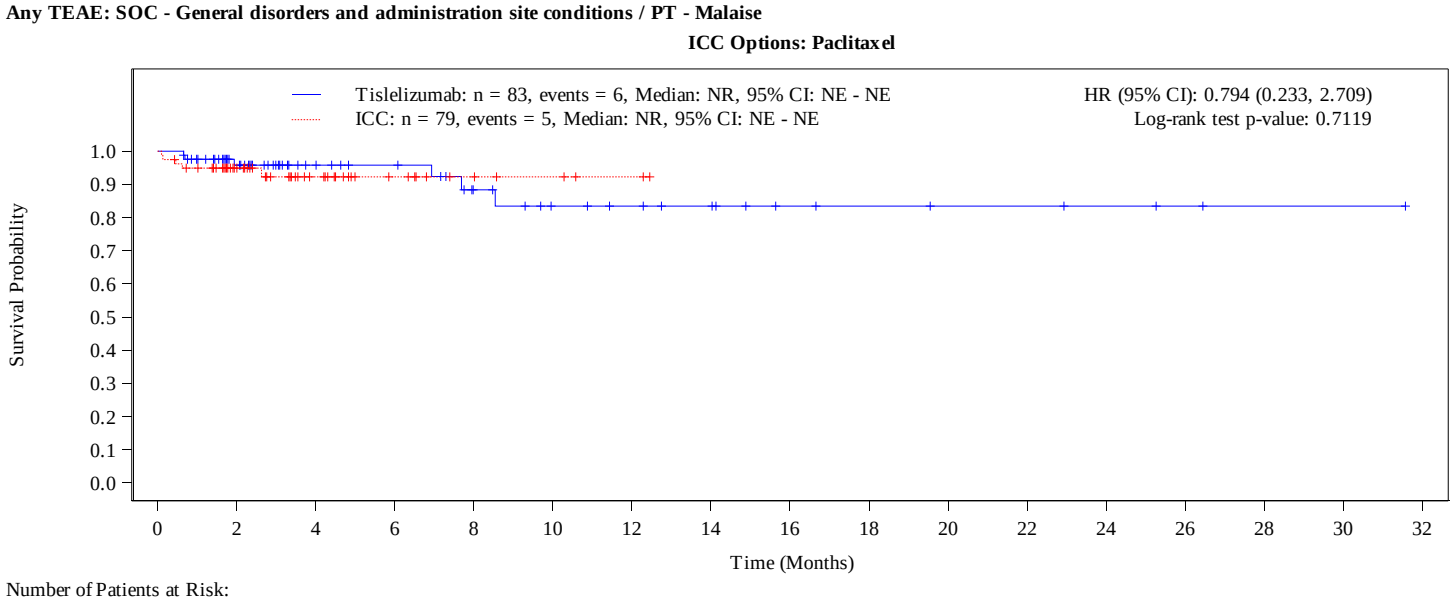


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16
Tislelizumab	52	31	19	12	9	6	4	3	0
ICC	42	22	6	3	2	1	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-s-km-socpt-sub-safety-sa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

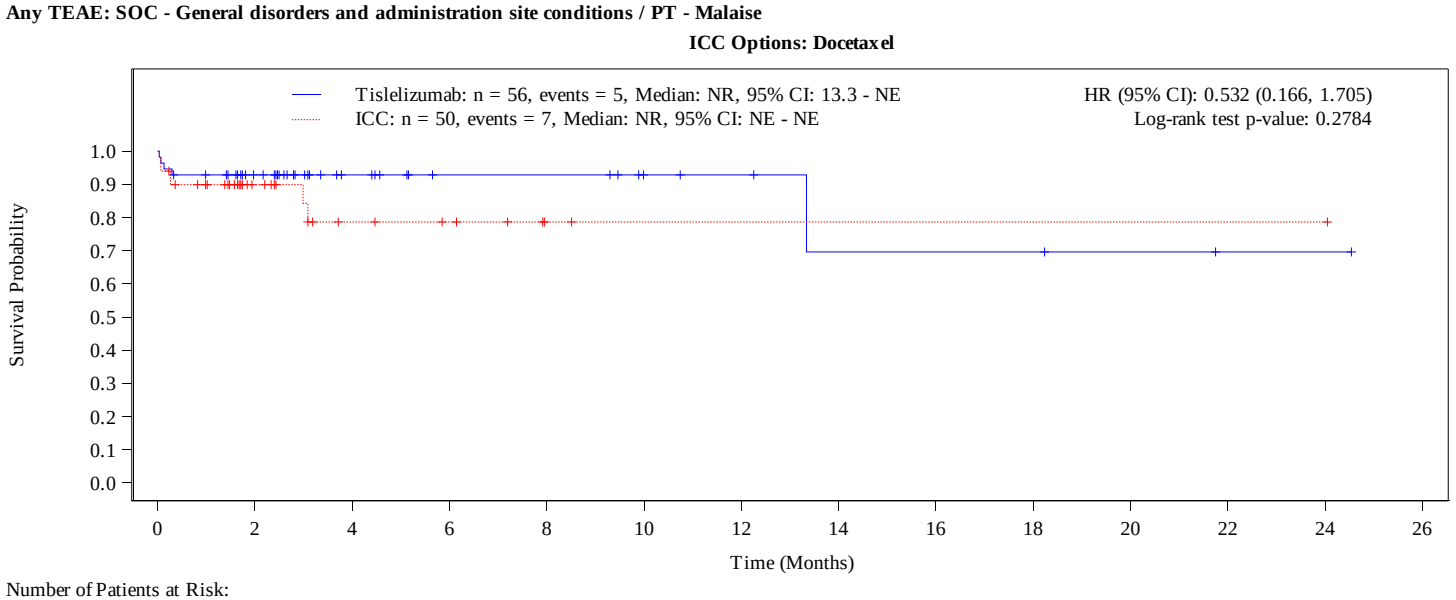


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	83	54	33	29	19	14	12	10	6	5	4	4	3	2	1	1	0
ICC	79	50	22	11	6	4	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-s-km-socpt-sub-safety-sa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



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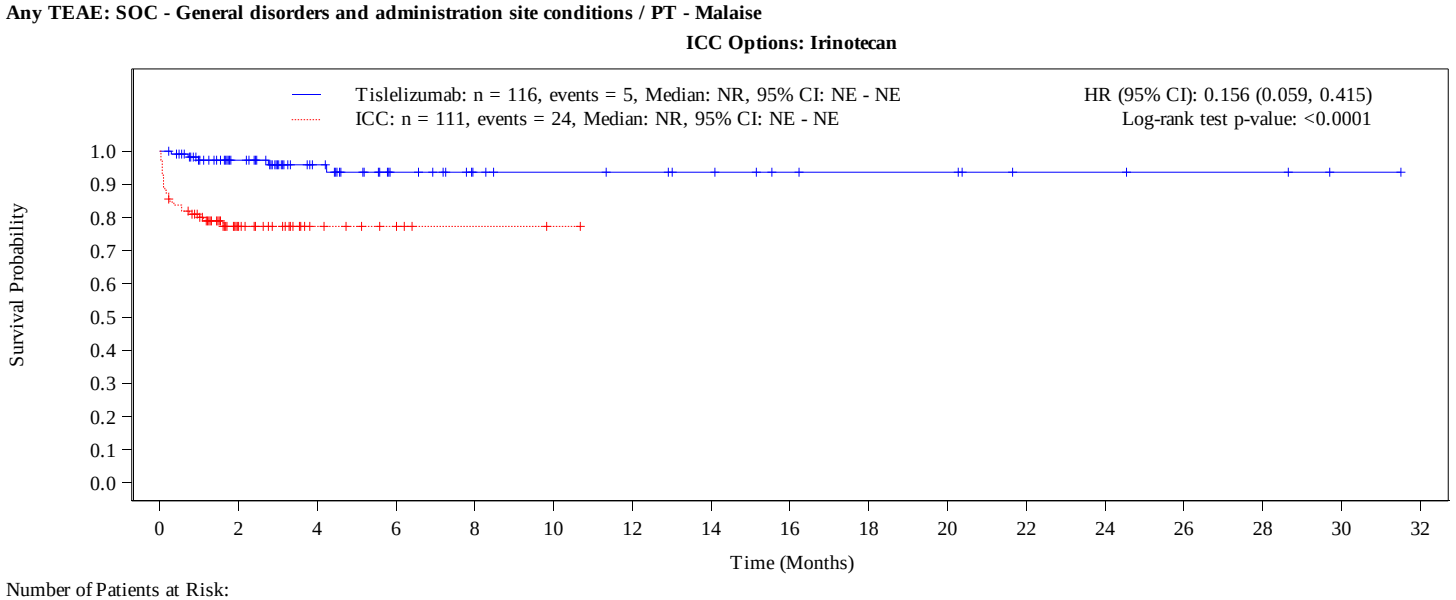
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-s-km-socpt-sub-safety-sa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

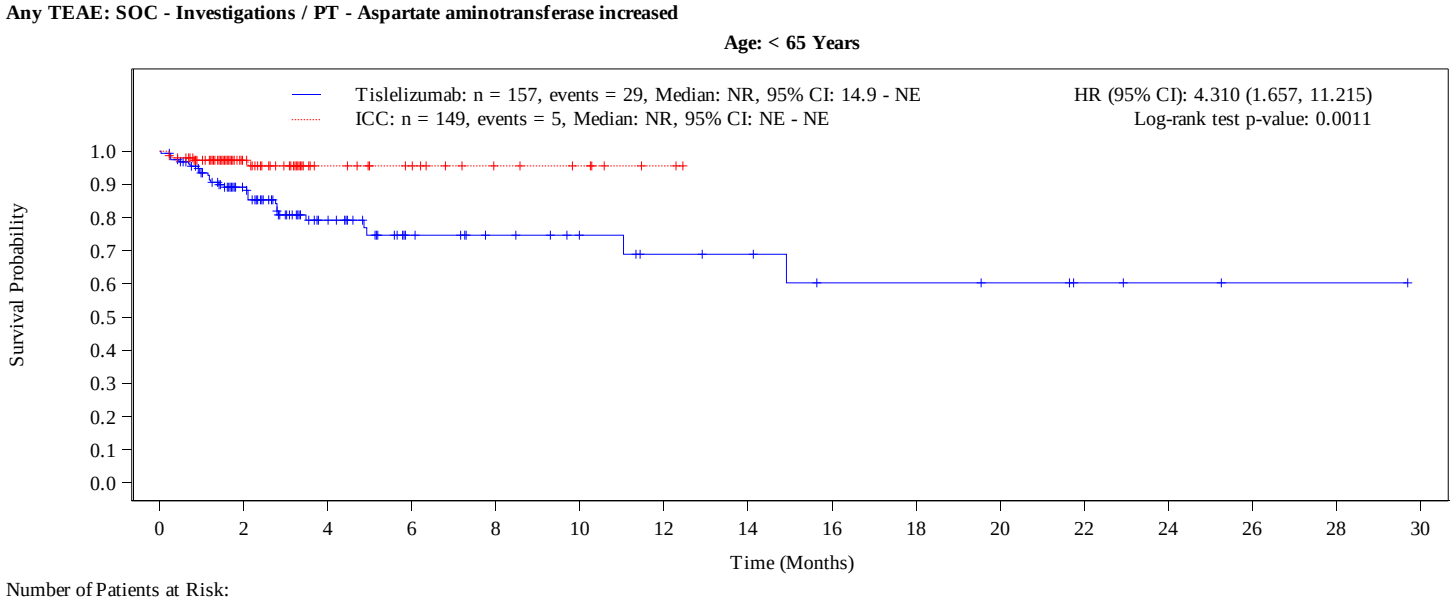


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	116	77	44	24	16	14	13	11	8	7	7	4	4	3	3	1	0
ICC	111	28	9	5	2	1	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-s-km-socpt-sub-safety-sa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
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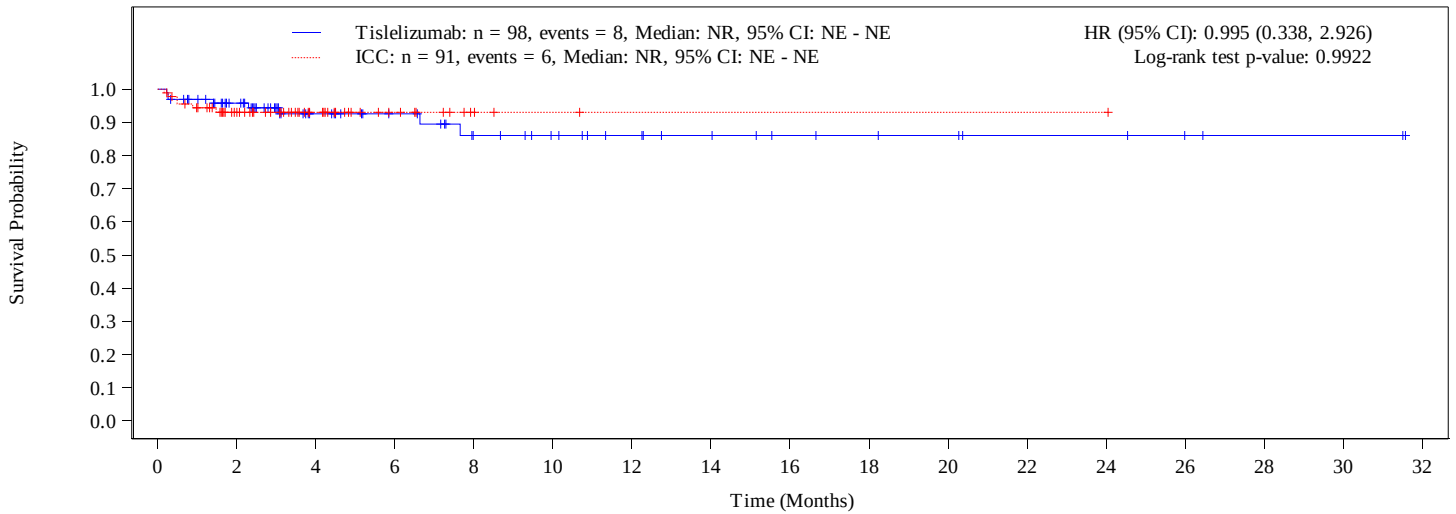
Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

Age: >= 65 Years



Number of Patients at Risk:

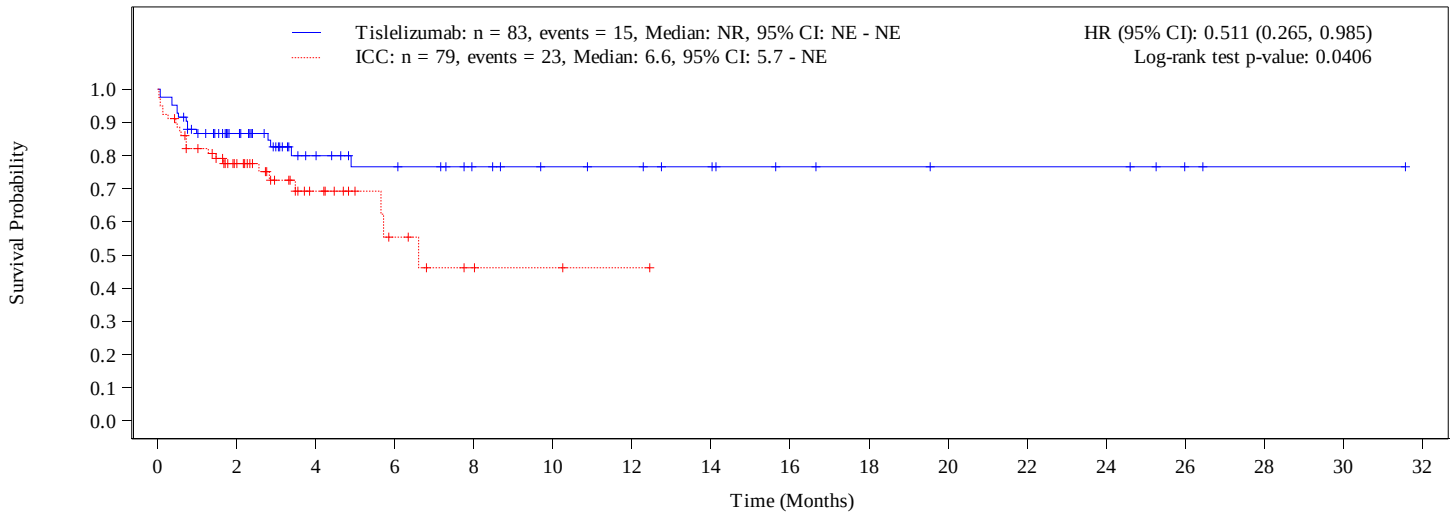
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	98	71	39	31	23	19	15	12	9	8	7	5	5	3	2	2	0
ICC	91	54	24	11	4	2	1	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-s-km-socpt-sub-safety-sa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

ICC Options: Paclitaxel

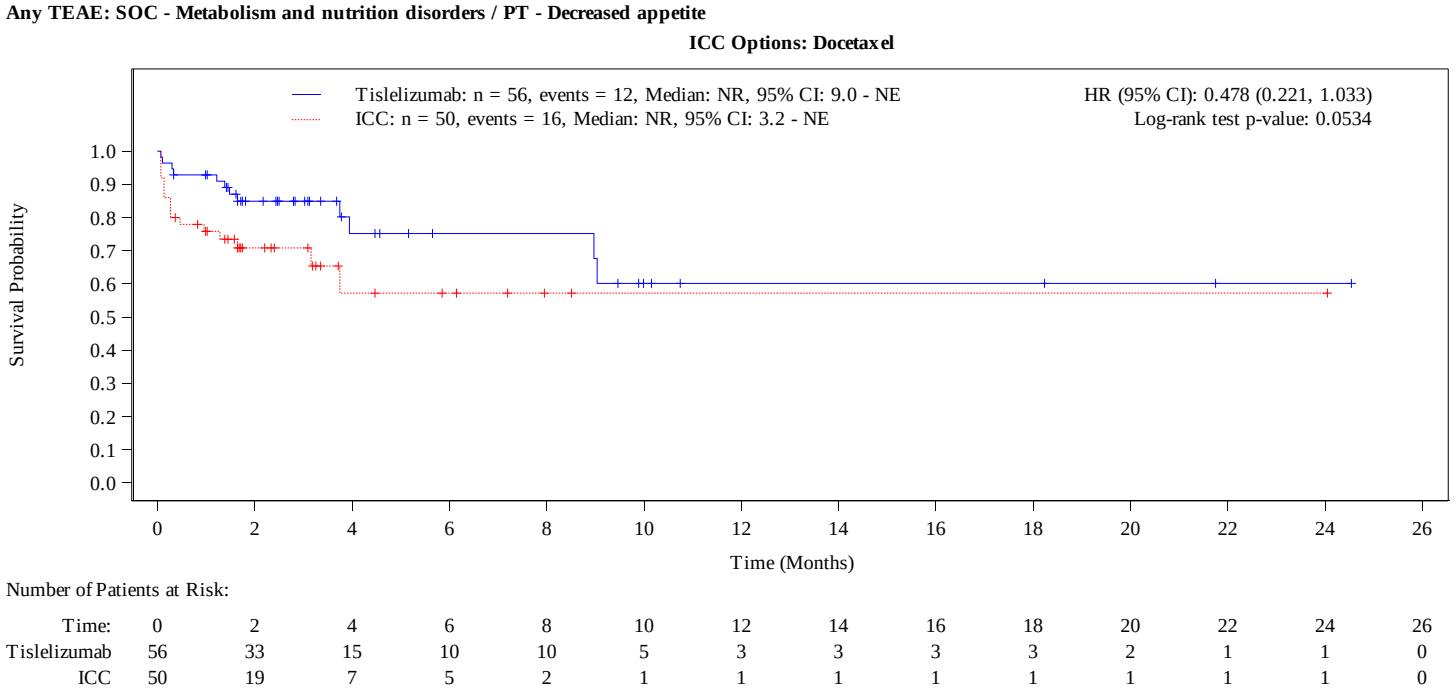


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	83	51	28	23	16	13	12	10	7	6	5	5	5	2	1	1	0
ICC	79	42	16	7	3	2	1	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-s-km-socpt-sub-safety-sa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

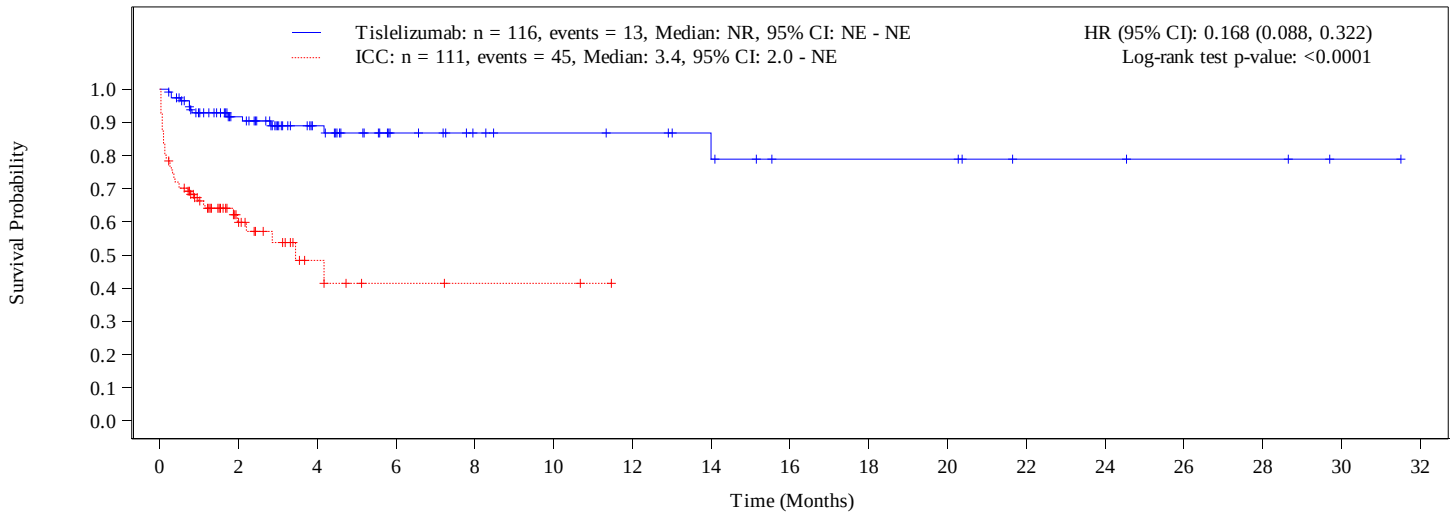


Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-s-km-socpt-sub-safety-sa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

ICC Options: Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	116	73	41	22	16	14	13	10	7	7	7	4	4	3	3	1	0
ICC	111	26	7	3	2	2	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
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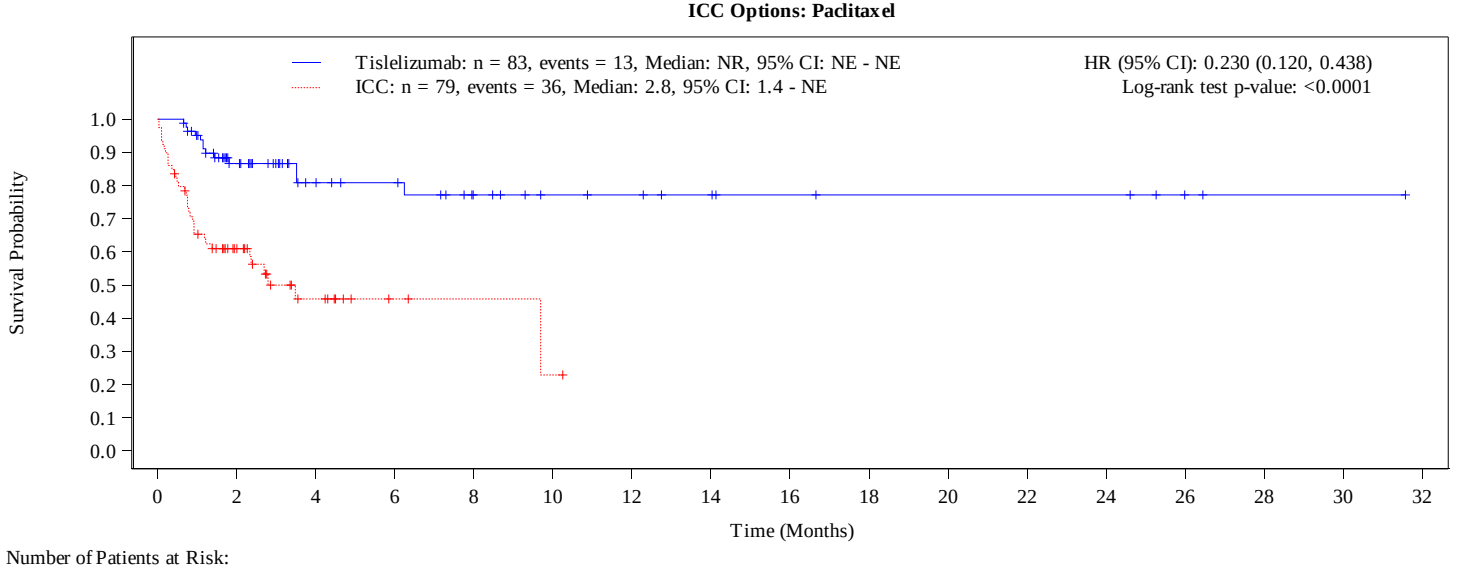
Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders



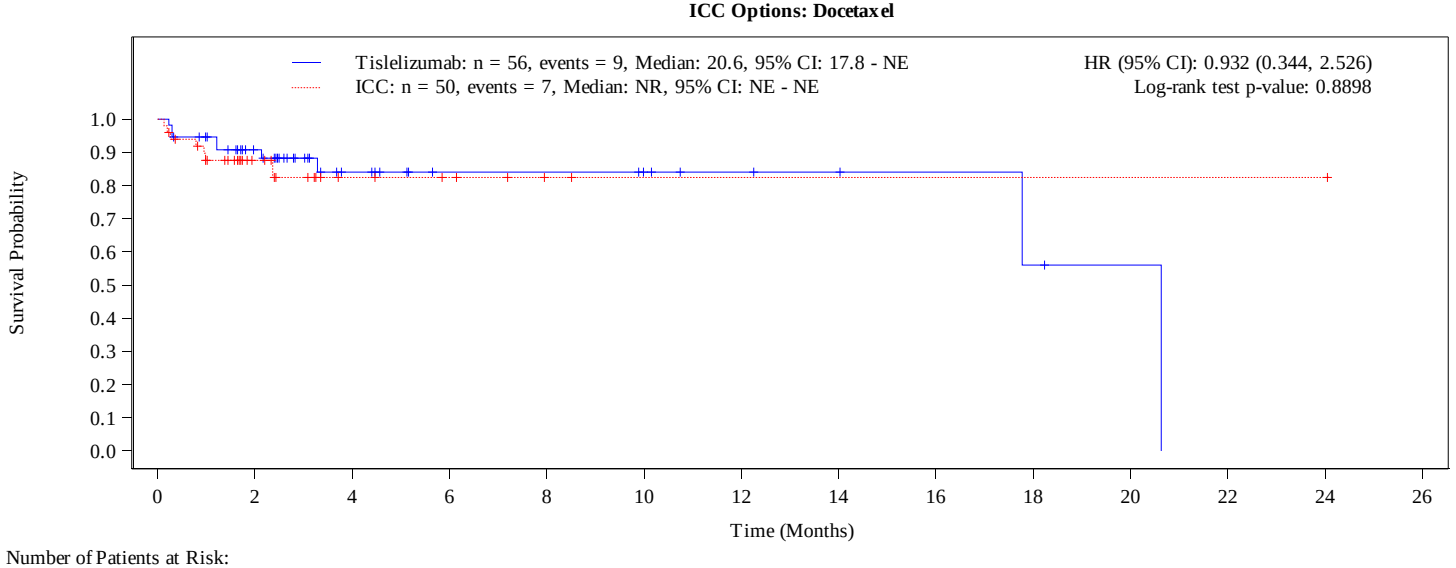
Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	83	49	26	23	15	11	10	8	6	5	5	5	5	2	1	1	0
ICC	79	31	10	3	2	1	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-s-km-socpt-sub-safety-sa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders



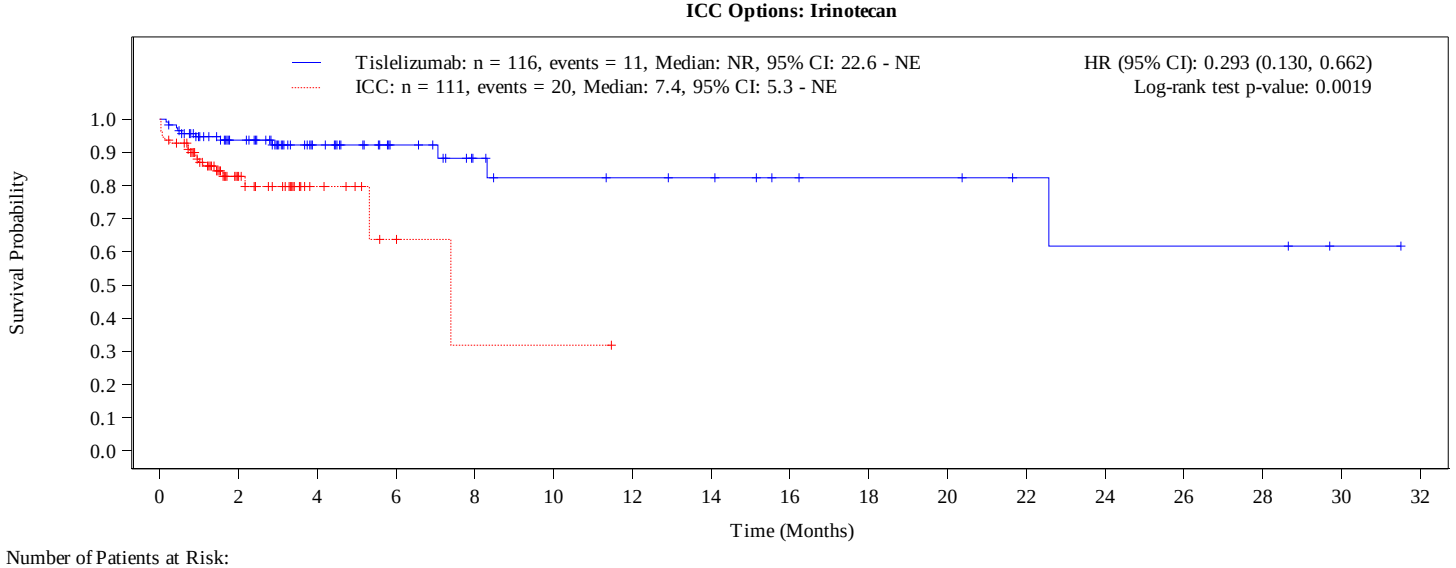
Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	56	36	17	9	9	7	5	4	3	2	1	0	0	0
ICC	50	19	8	5	2	1	1	1	1	1	1	1	1	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-s-km-socpt-sub-safety-sa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders



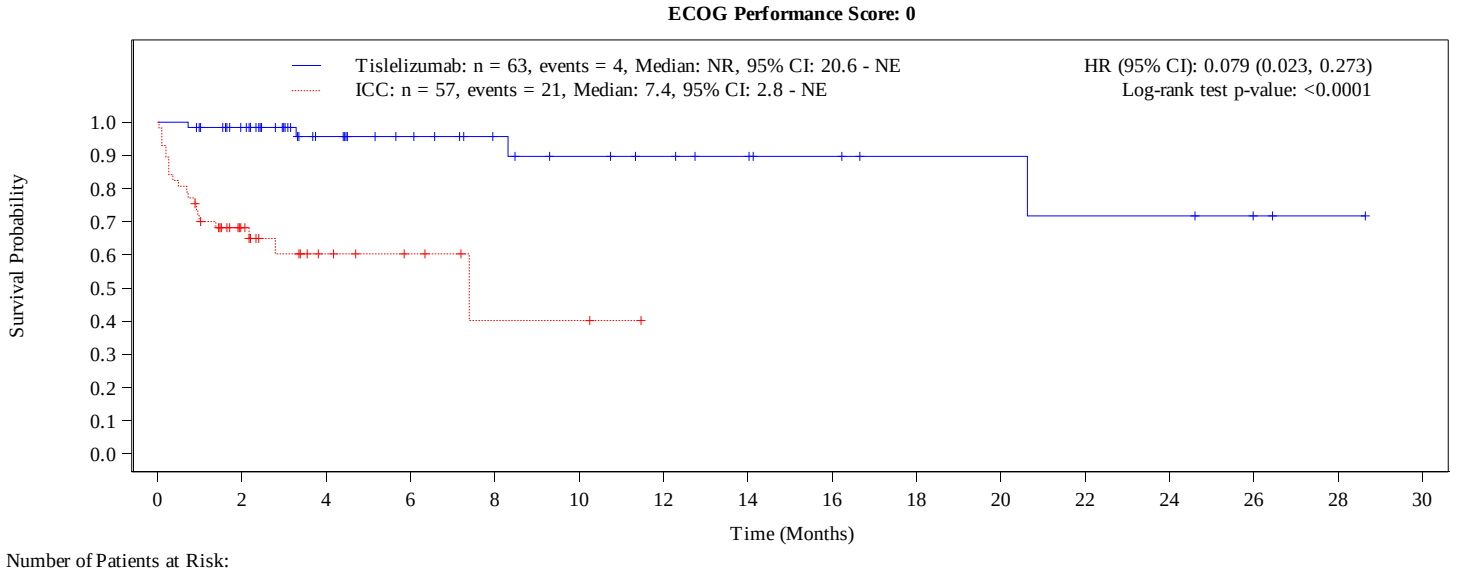
Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	116	77	43	25	16	13	11	10	7	6	6	4	3	3	3	1	0
ICC	111	31	9	3	1	1	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-s-km-socpt-sub-safety-sa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders



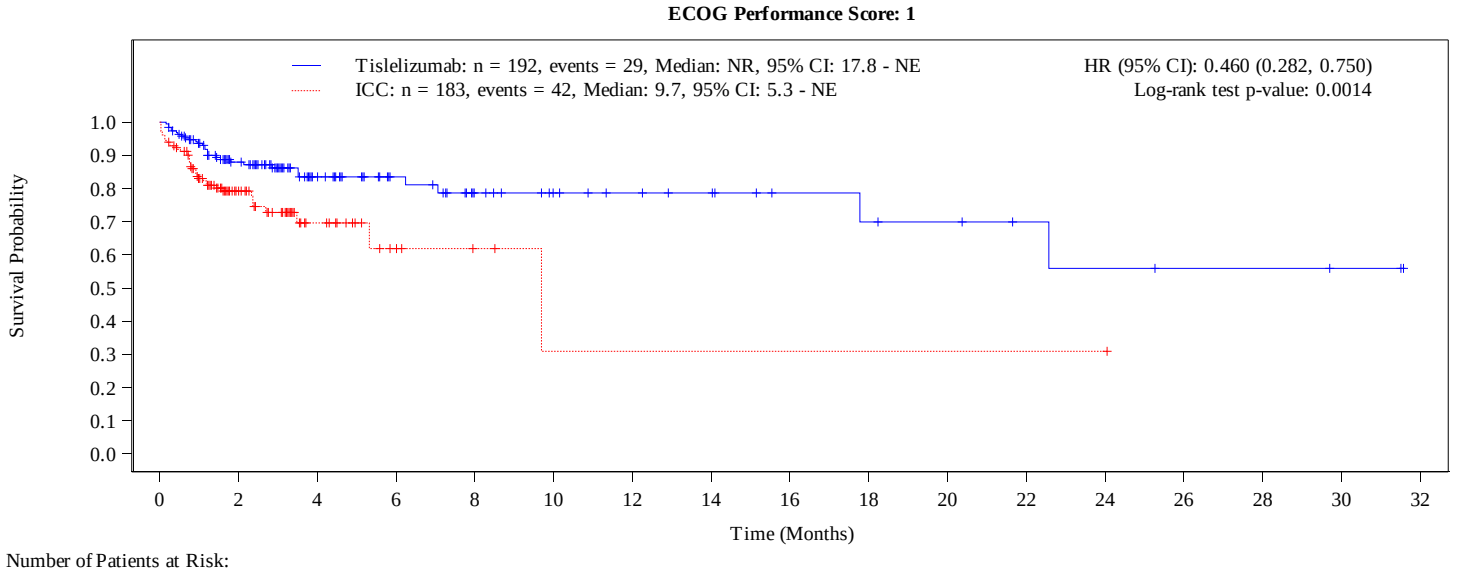
Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	63	50	31	22	16	13	11	9	7	5	5	4	4	2	1	0
ICC	57	22	9	5	2	2	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-s-km-socpt-sub-safety-sa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders



Number of Patients at Risk:

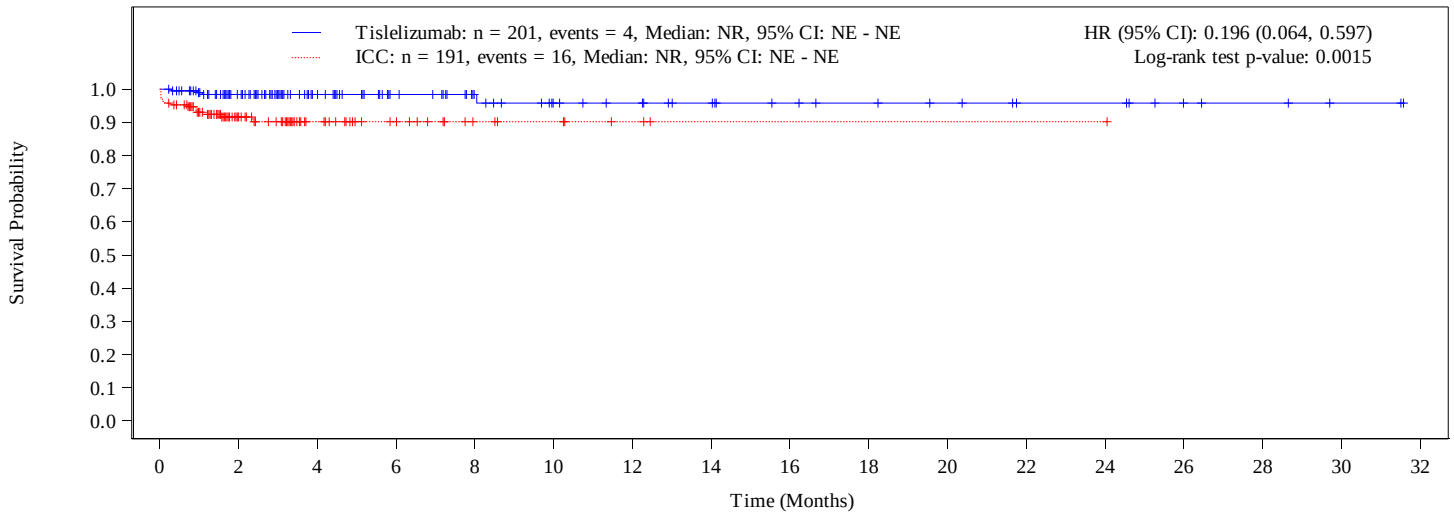
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	192	112	55	35	24	18	15	13	9	8	7	5	4	3	3	2	0
ICC	183	59	18	6	3	1	1	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-s-km-socpt-sub-safety-sa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders / PT - Dizziness

Region #1: Asia



Number of Patients at Risk:

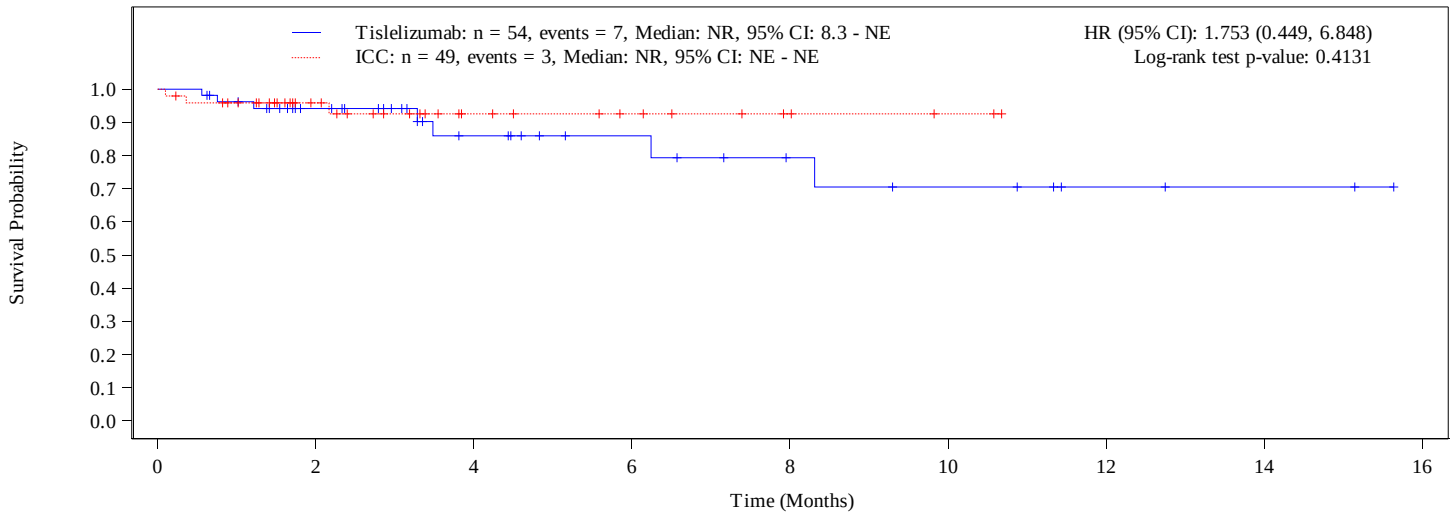
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	201	135	75	50	38	29	26	22	17	15	13	10	10	5	4	2	0
ICC	191	75	29	16	8	6	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-s-km-socpt-sub-safety-sa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders / PT - Dizziness

Region #1: Europe/North America

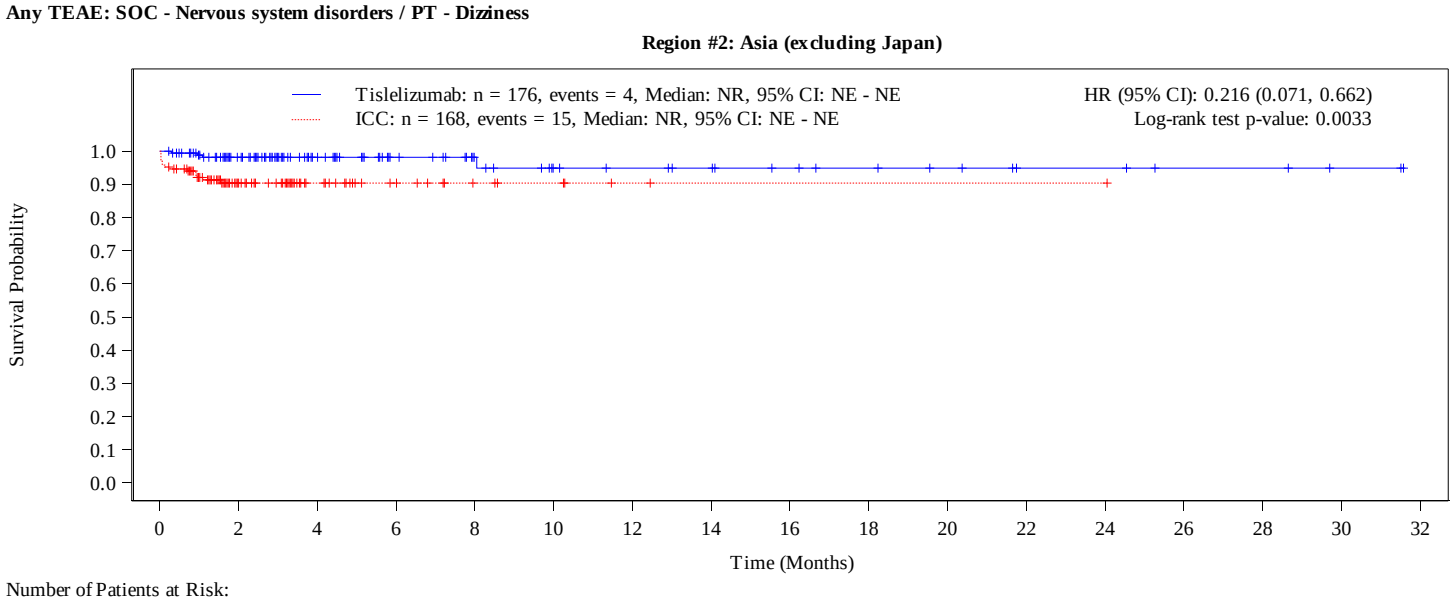


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16
Tislelizumab	54	36	19	13	9	6	3	2	0
ICC	49	30	12	8	4	2	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-s-km-socpt-sub-safety-sa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

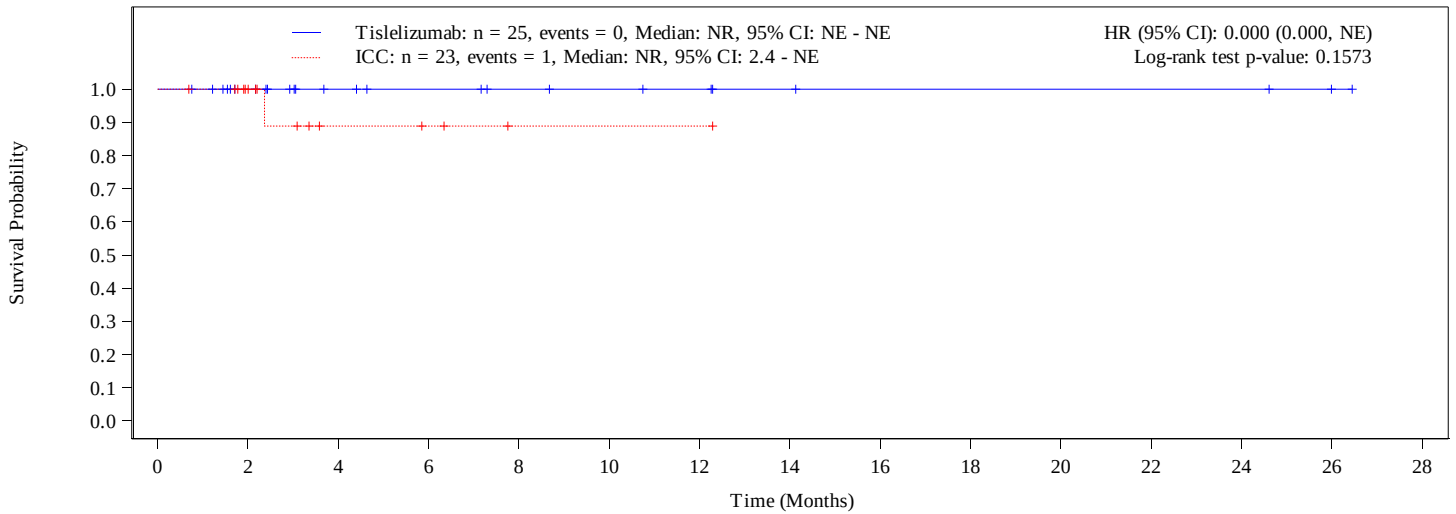


Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-s-km-socpt-sub-safety-sa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders / PT - Dizziness

Region #2: Japan

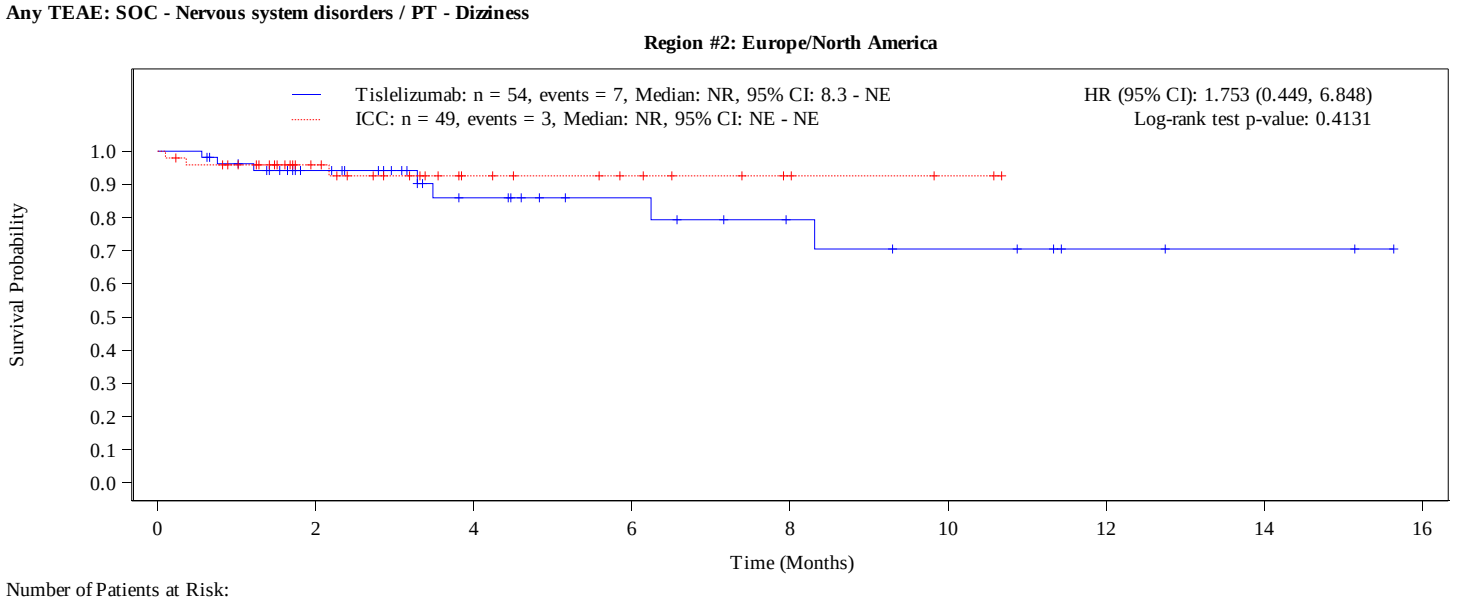


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28
Tislelizumab	25	19	12	10	8	7	6	4	3	3	3	3	3	1	0
ICC	23	13	4	3	1	1	1	0	0	0	0	0	0	0	0

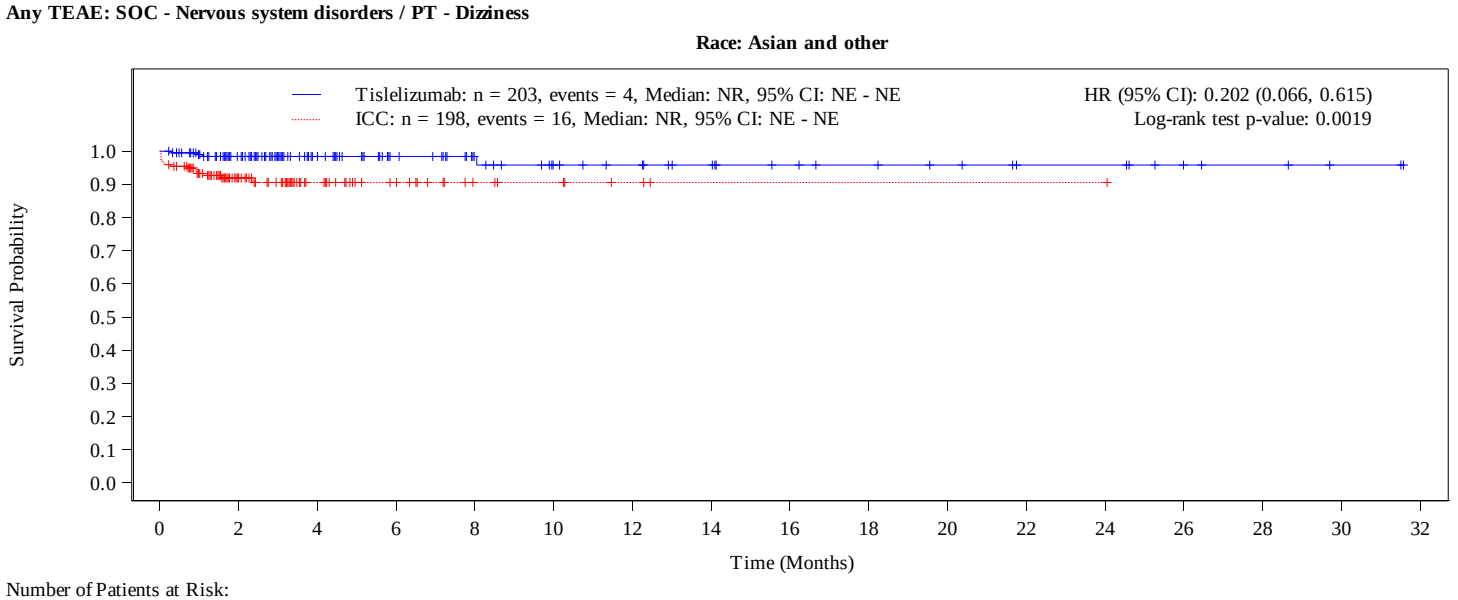
Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-s-km-socpt-sub-safety-sa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-s-km-socpt-sub-safety-sa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

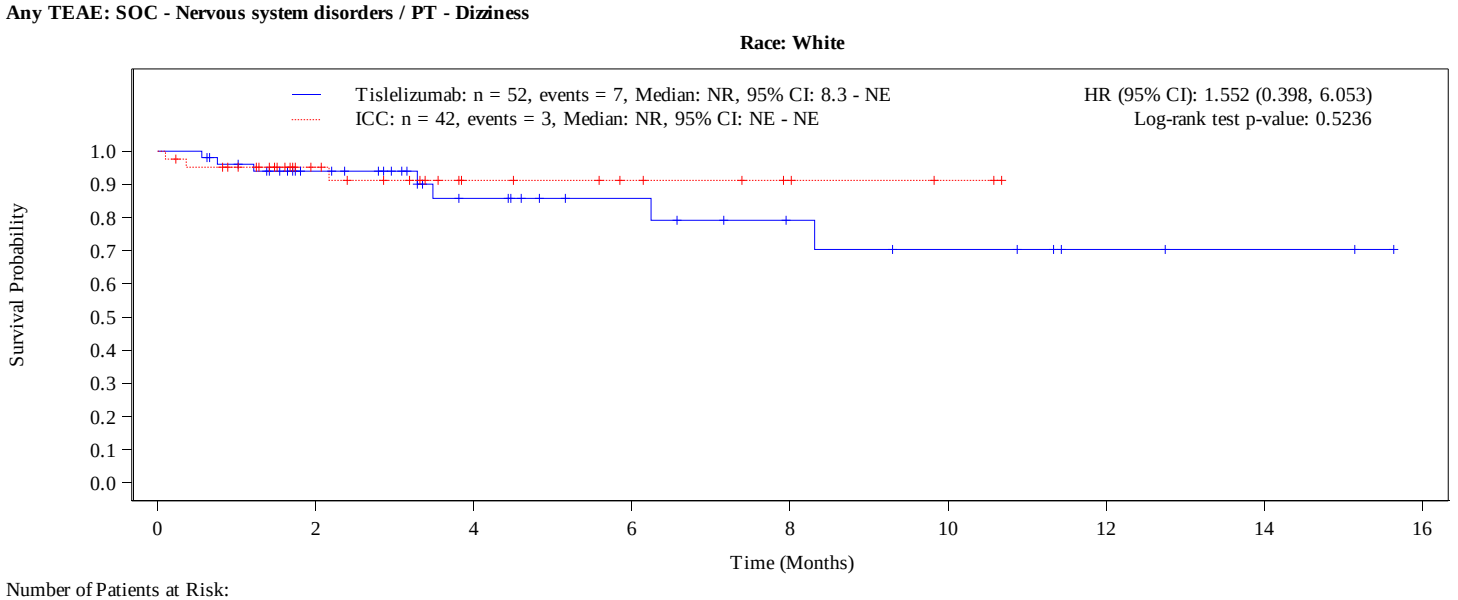


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	203	136	75	50	38	29	26	22	17	15	13	10	10	5	4	2	0
ICC	198	80	31	17	8	6	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-s-km-socpt-sub-safety-sa.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

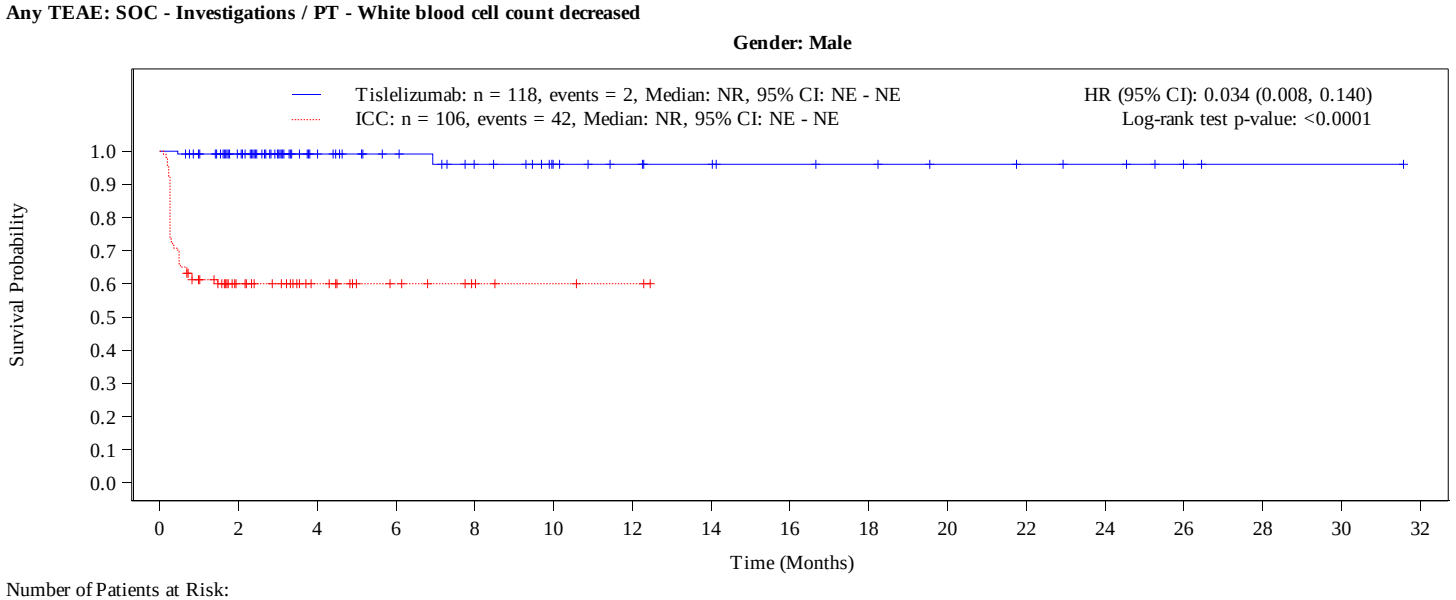


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16
Tislelizumab	52	35	19	13	9	6	3	2	0
ICC	42	25	10	7	4	2	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-s-km-socpt-sub-safety-sa.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

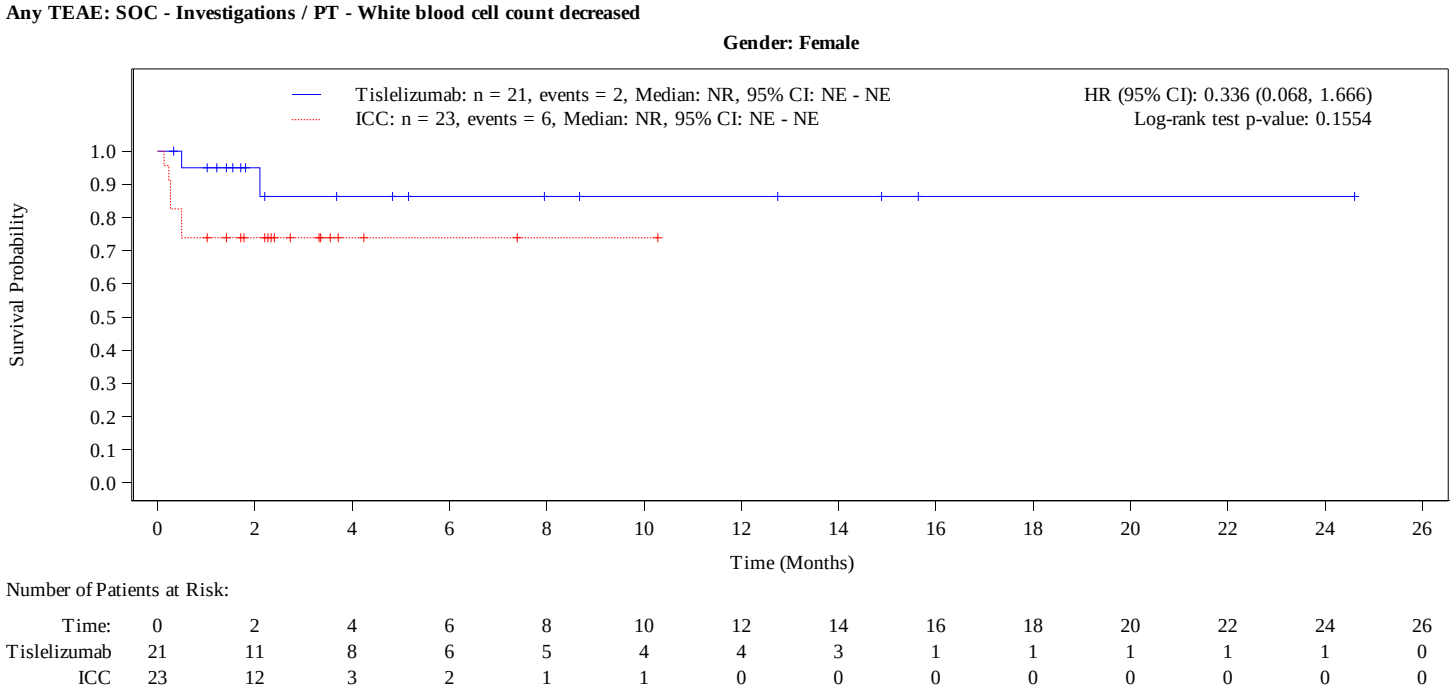


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	118	83	43	33	25	17	14	12	10	9	7	6	5	2	1	1	0
ICC	106	34	16	9	5	3	2	0	0	0	0	0	0	0	0	0	0

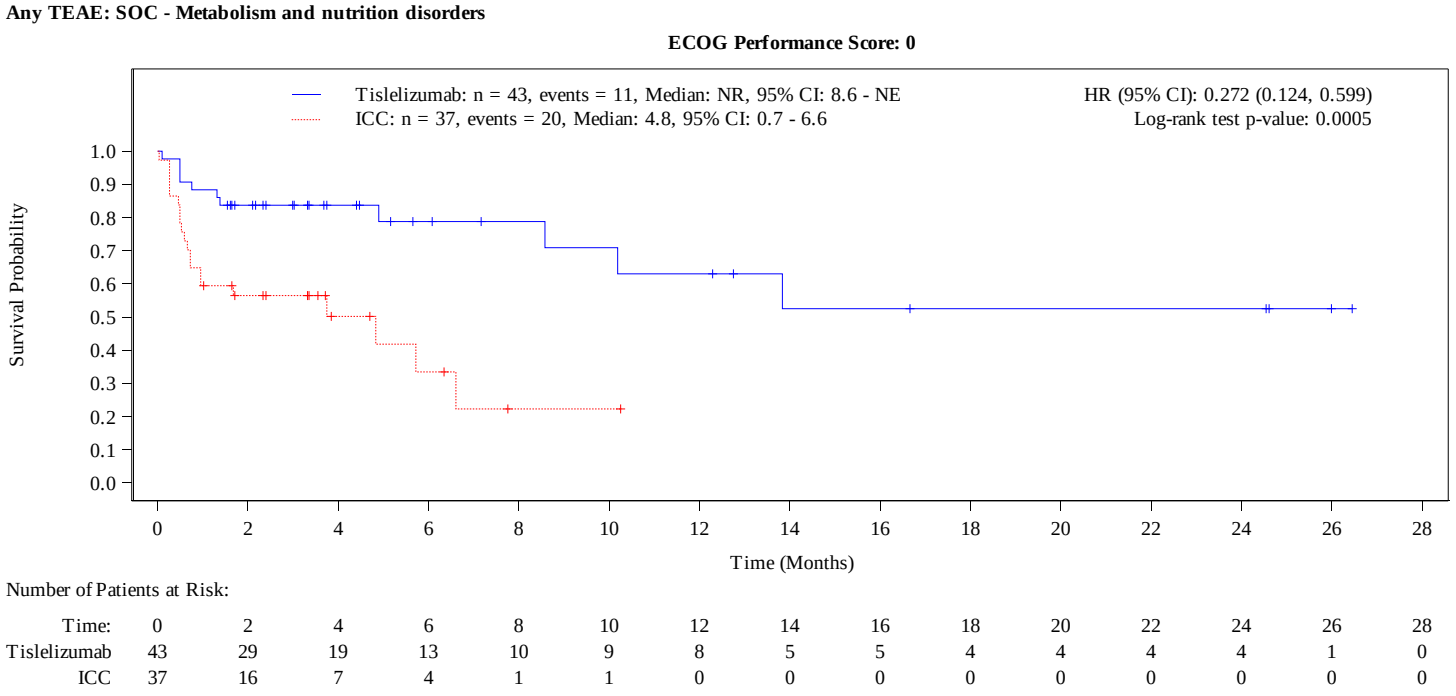
Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-b-s-km-socpt-sub-safetys-sa.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-b-s-km-socpt-sub-safetys-sa.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

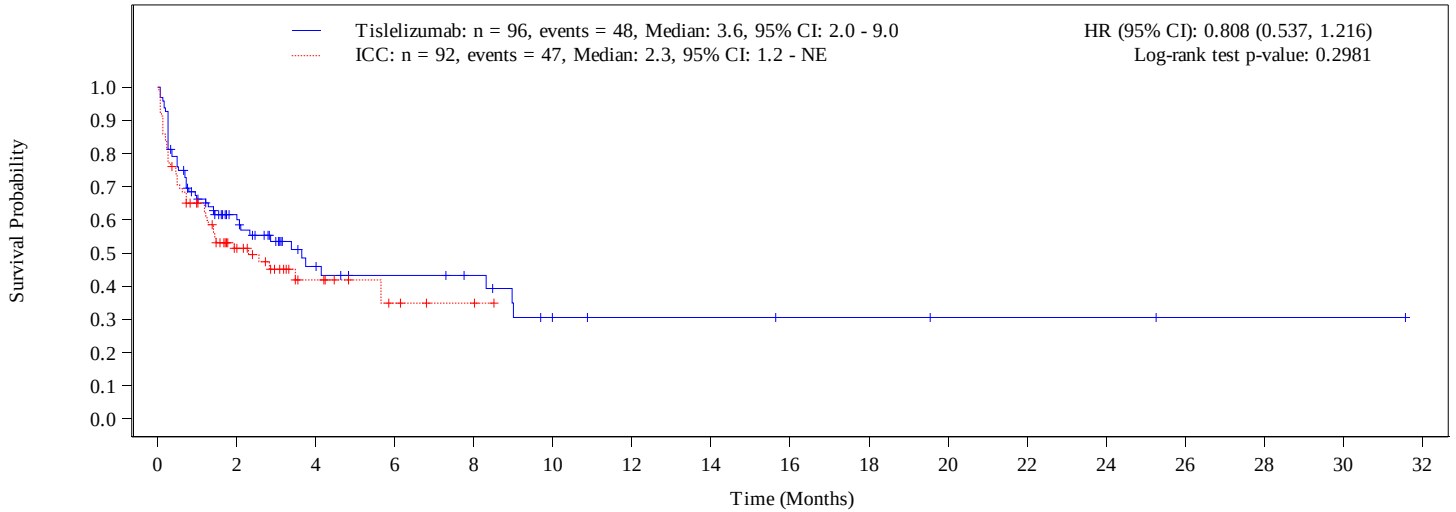


Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-b-s-km-socpt-sub-safetys-sa.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Metabolism and nutrition disorders

ECOG Performance Score: 1



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	96	40	18	14	11	5	4	4	3	3	2	2	2	1	1	1	0
ICC	92	30	11	4	2	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
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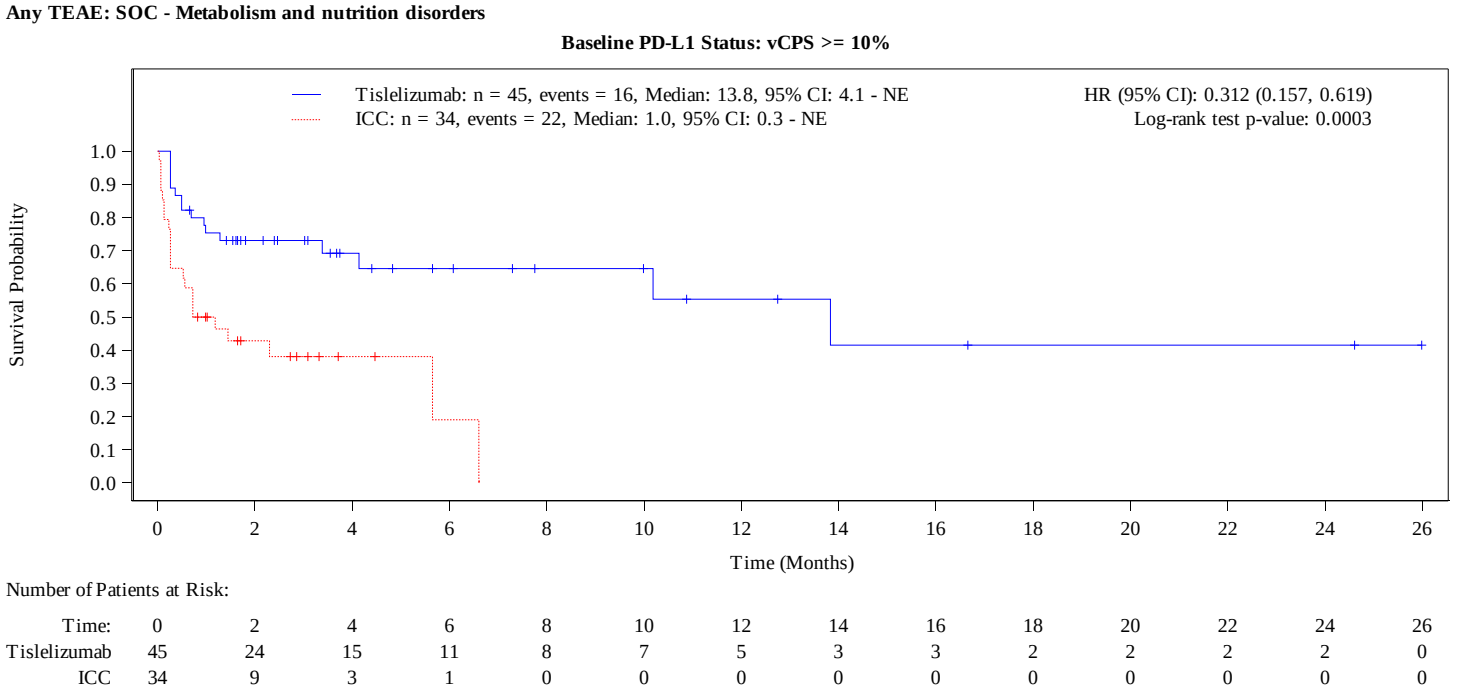
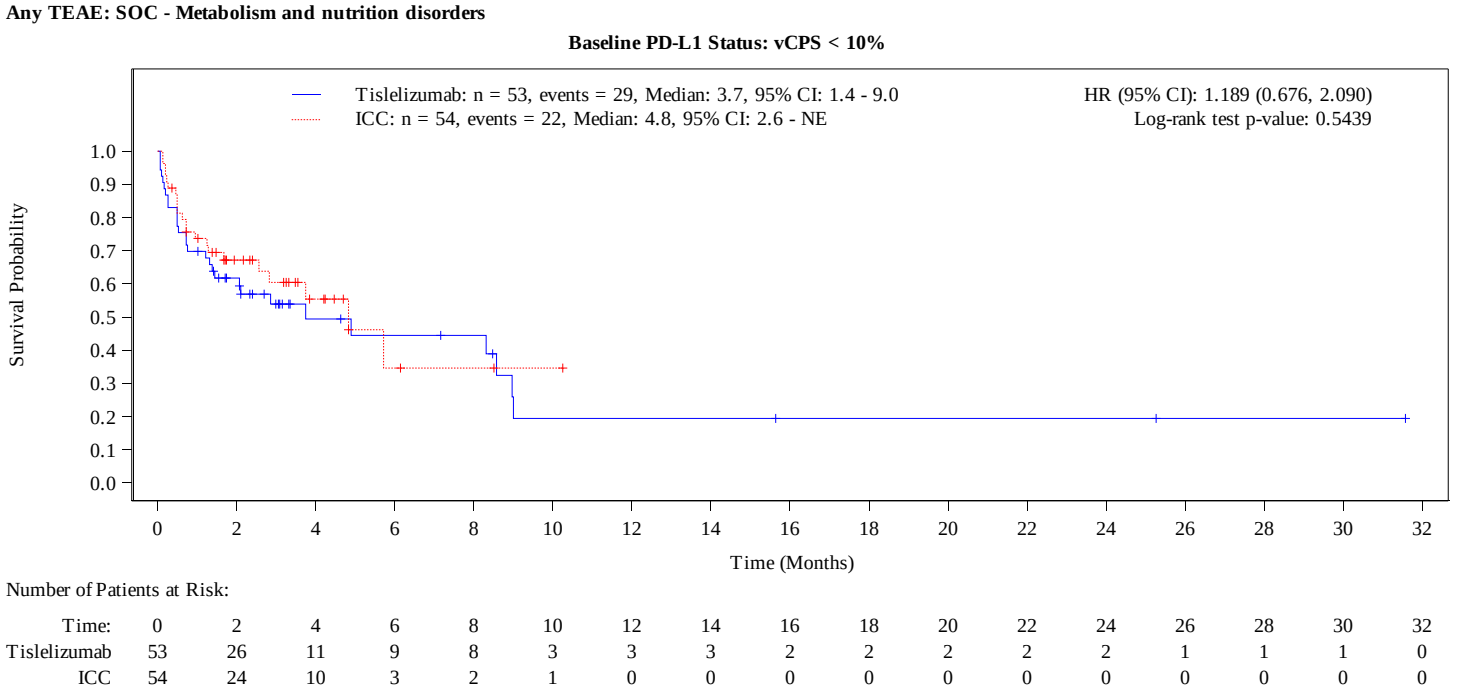
Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



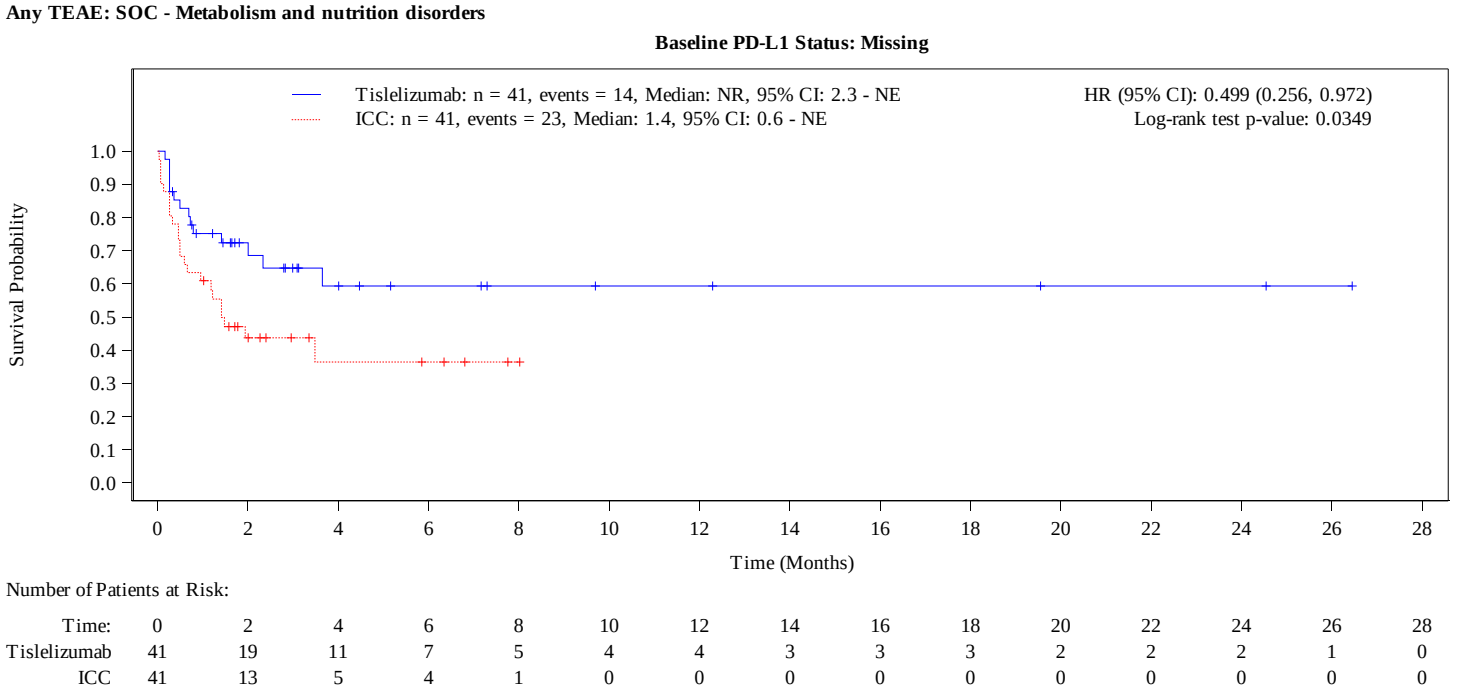
Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-b-s-km-socpt-sub-safetys-sa.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



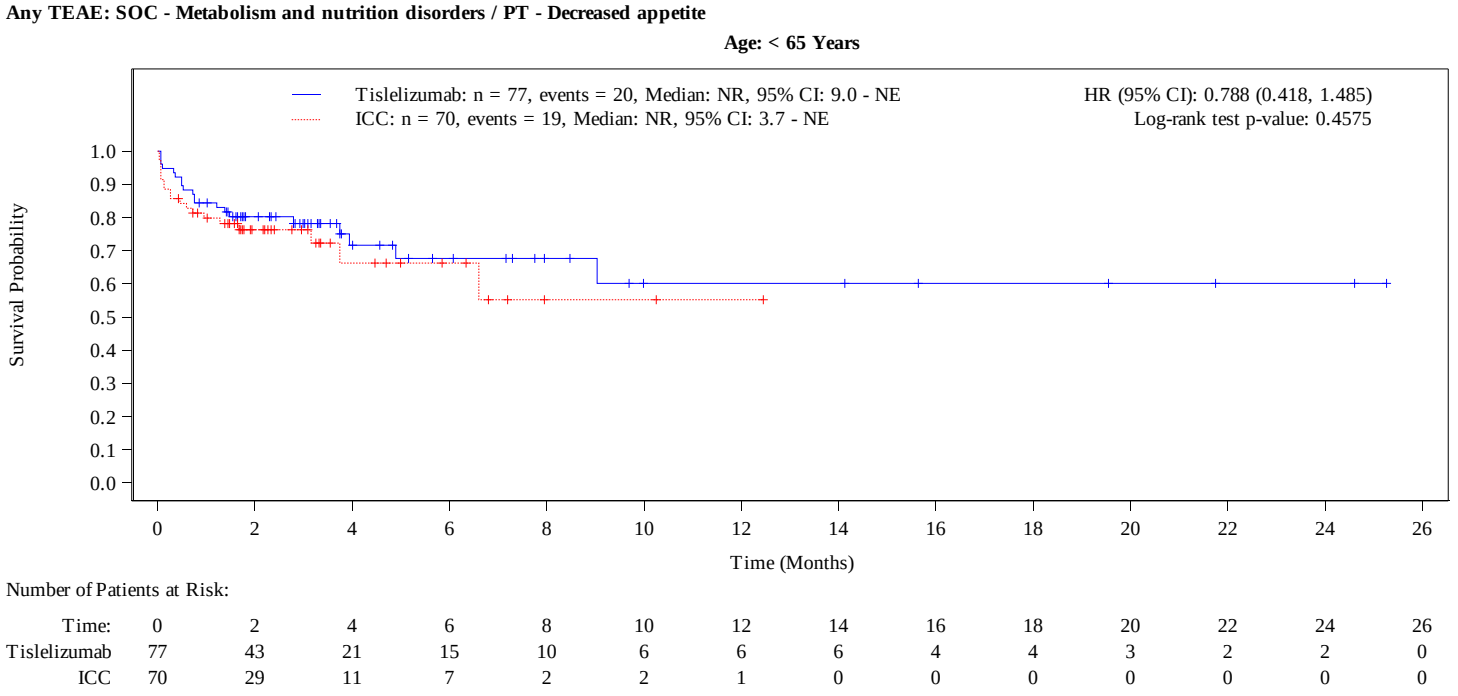
Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-b-s-km-socpt-sub-safetys-sa.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-b-s-km-socpt-sub-safetys-sa.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
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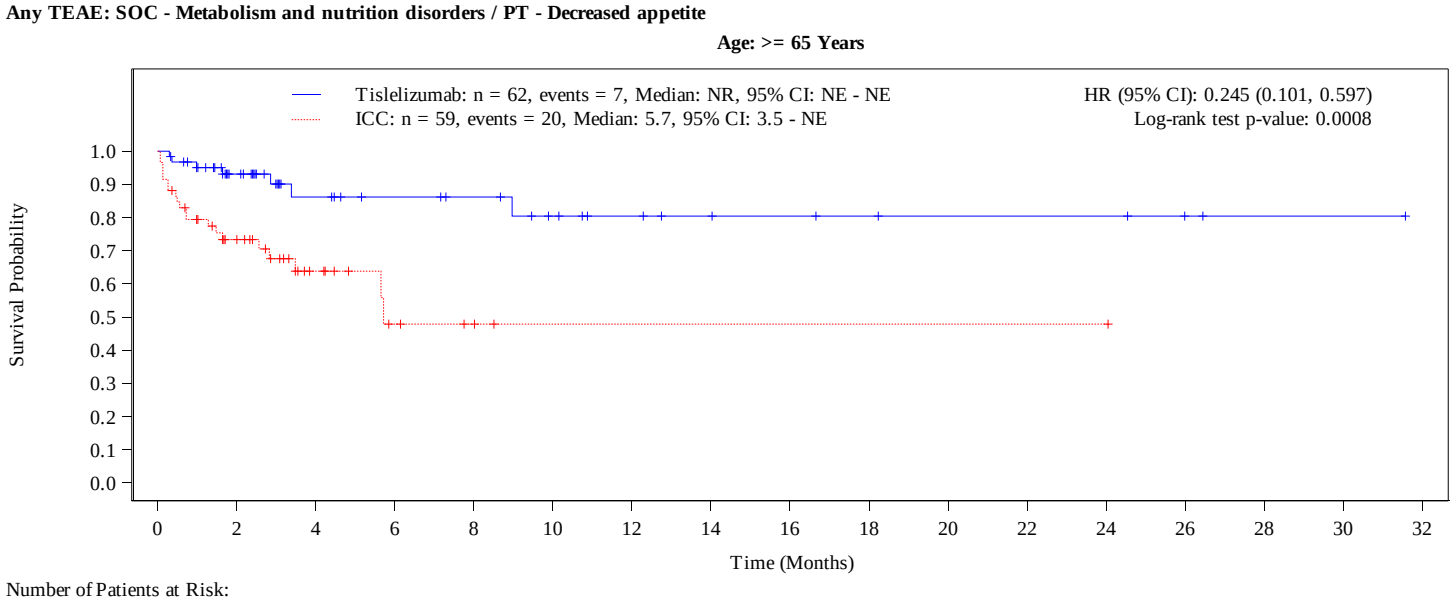
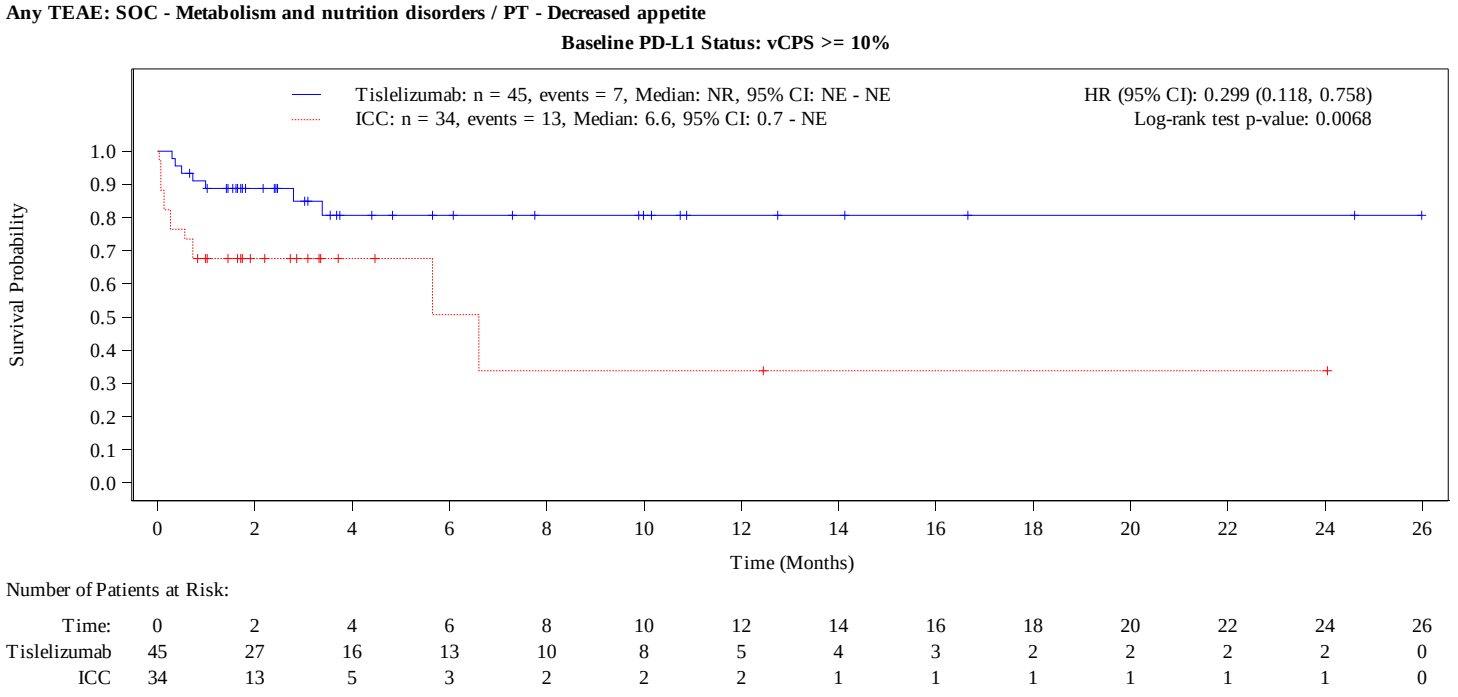
Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-b-s-km-socpt-sub-safetys-sa.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

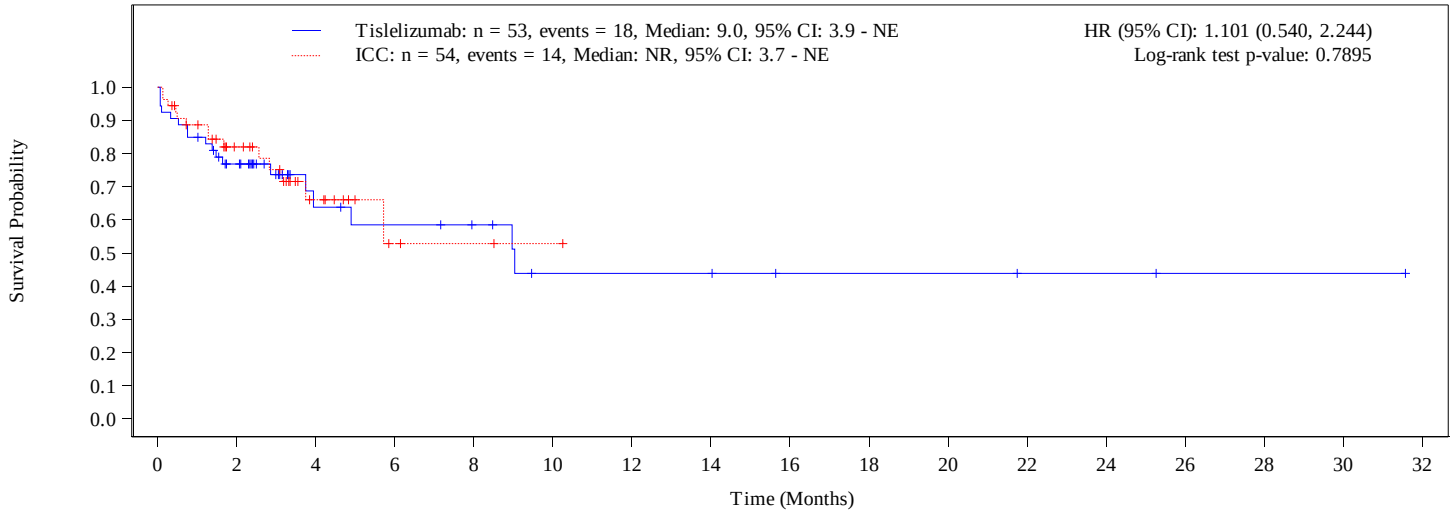


Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-b-s-km-socpt-sub-safetys-sa.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

Baseline PD-L1 Status: vCPS < 10%

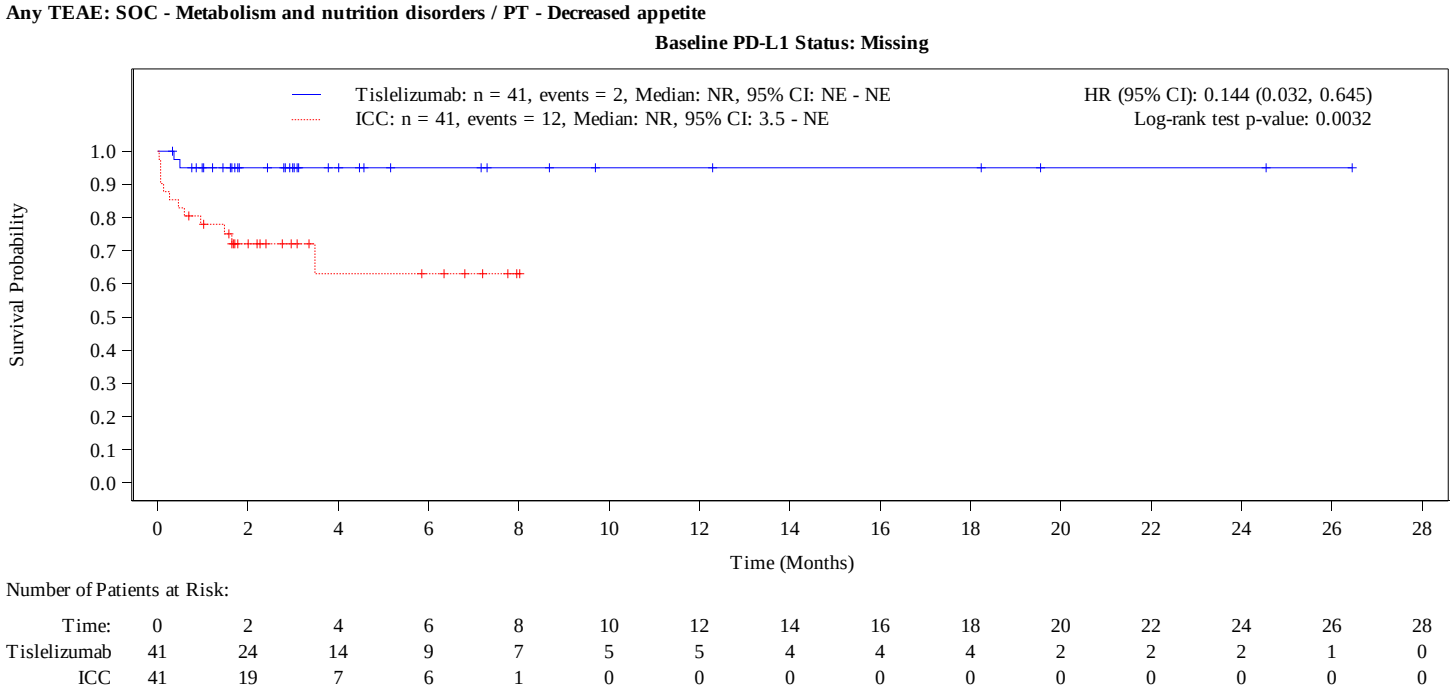


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	53	33	13	11	9	5	5	5	3	3	3	2	2	1	1	1	0
ICC	54	29	11	3	2	1	0	0	0	0	0	0	0	0	0	0	0

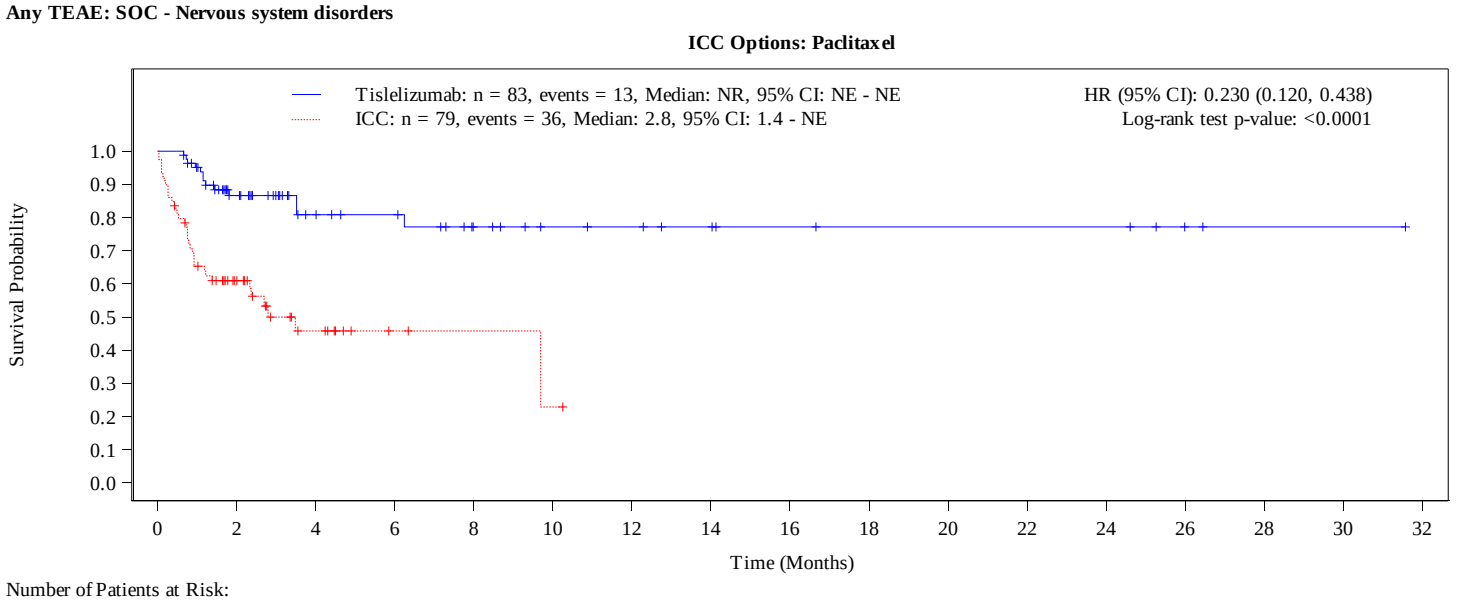
Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-b-s-km-socpt-sub-safetys-sa.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-b-s-km-socpt-sub-safetys-sa.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

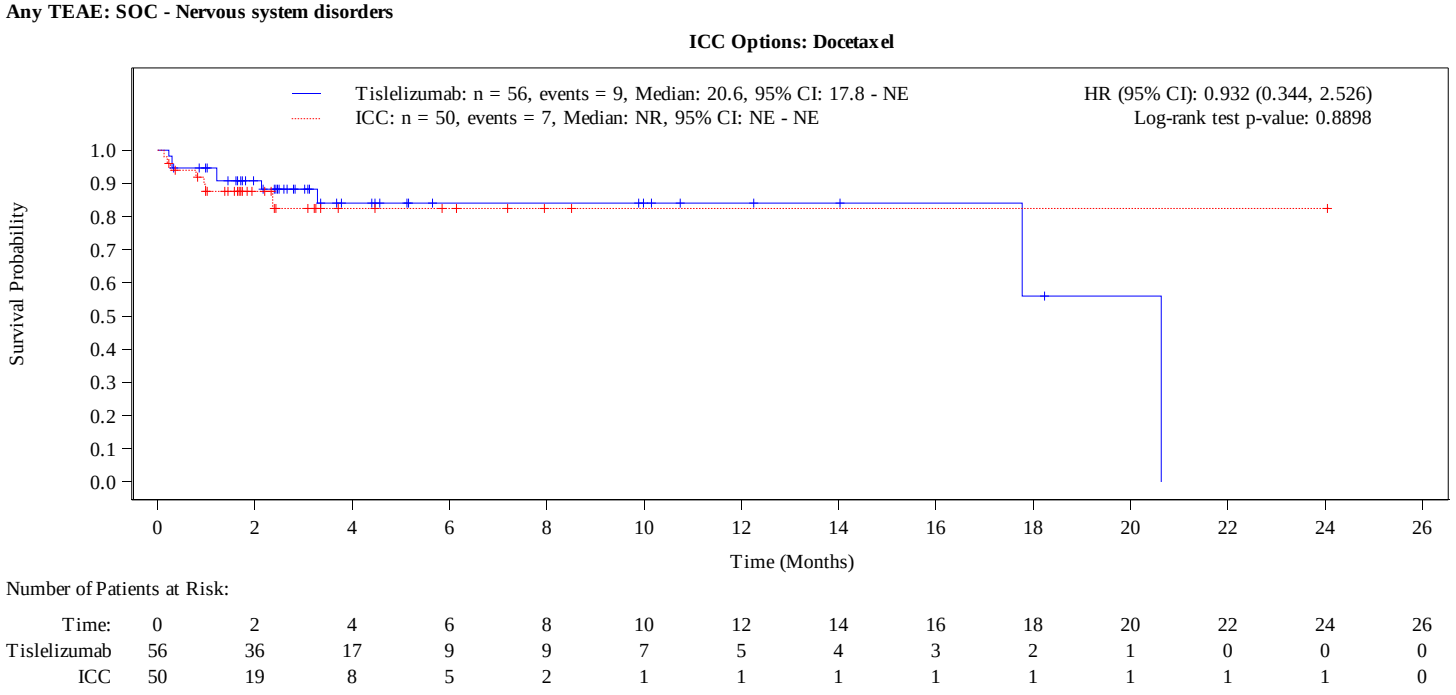


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	83	49	26	23	15	11	10	8	6	5	5	5	5	2	1	1	0
ICC	79	31	10	3	2	1	0	0	0	0	0	0	0	0	0	0	0

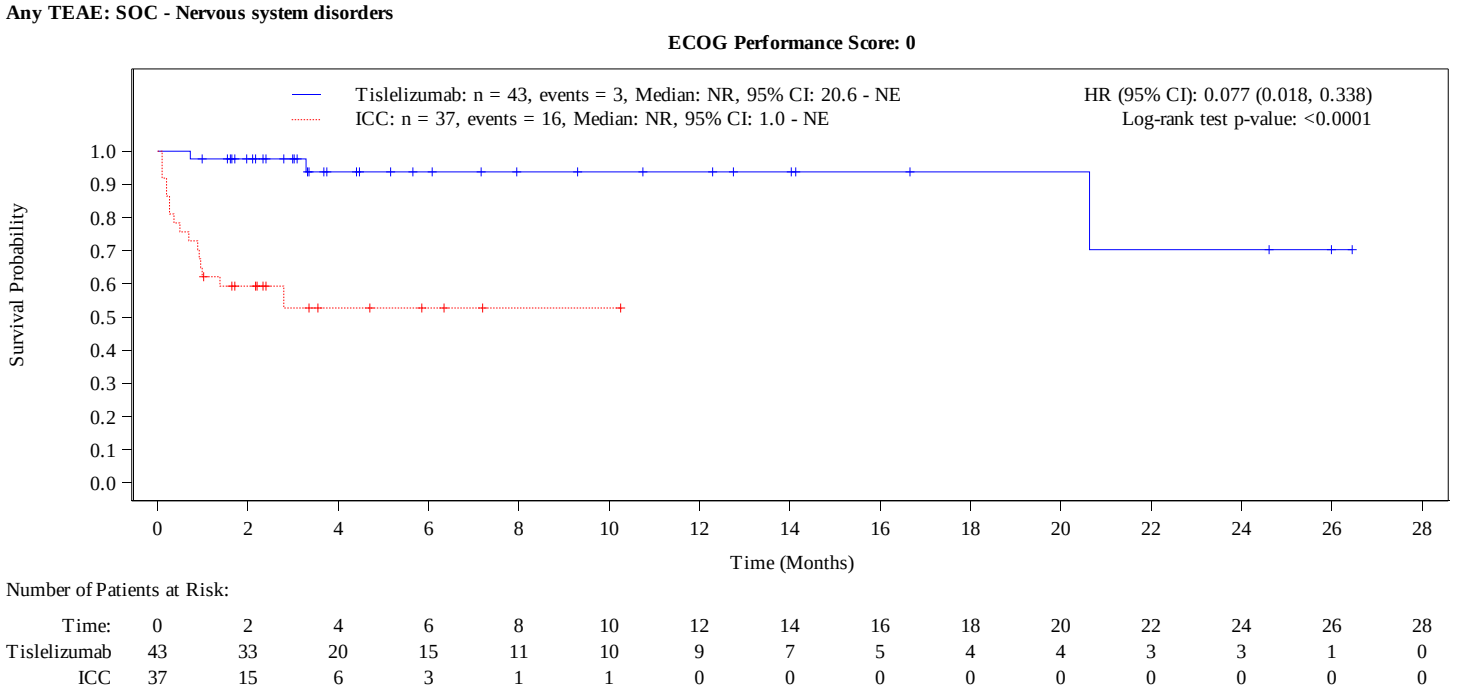
Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-b-s-km-socpt-sub-safetys-sa.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-b-s-km-socpt-sub-safetys-sa.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

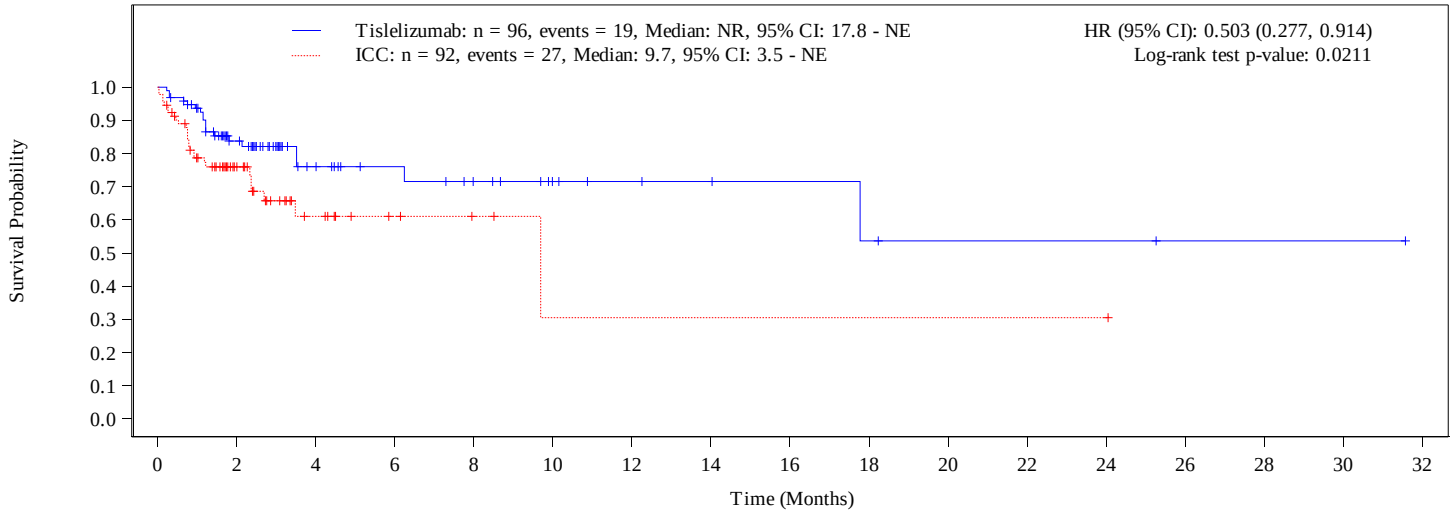


Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-b-s-km-socpt-sub-safetys-sa.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Nervous system disorders

ECOG Performance Score: 1

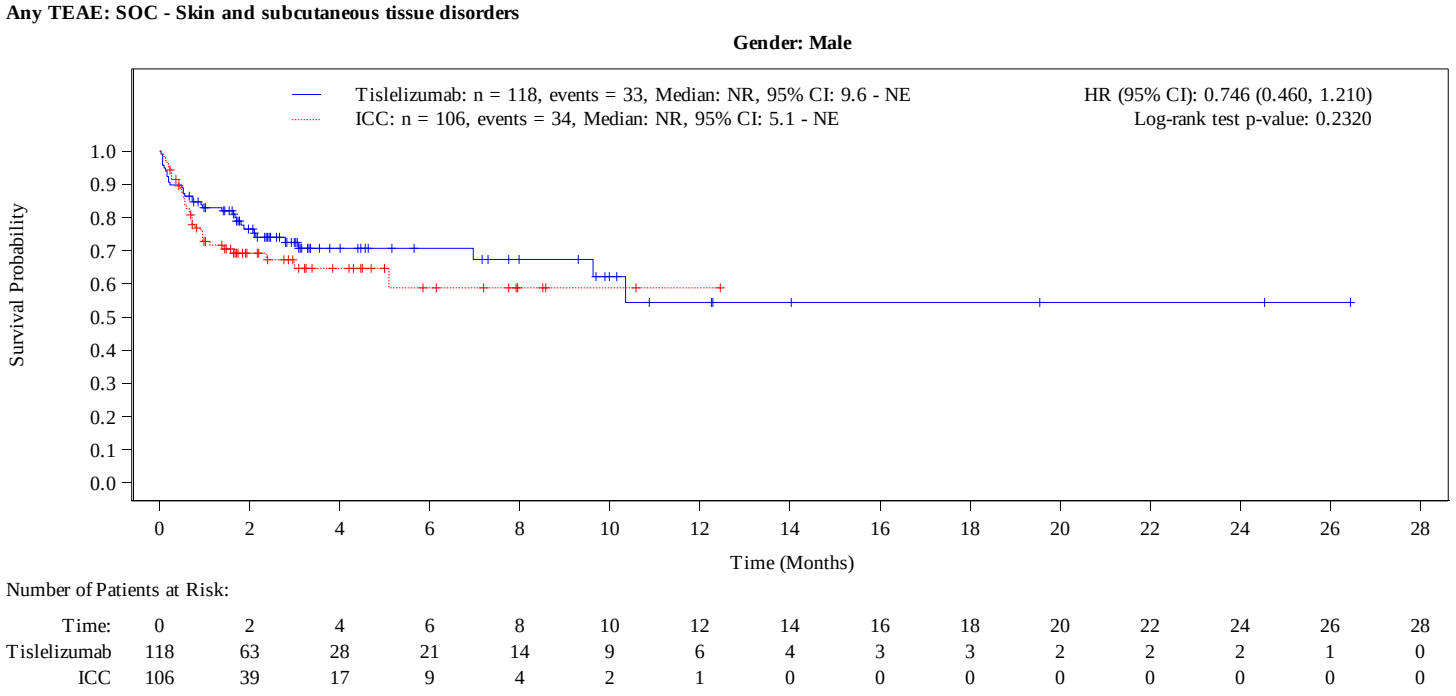


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	96	52	23	17	13	8	6	5	4	3	2	2	2	1	1	1	0
ICC	92	35	12	5	3	1	1	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-b-s-km-socpt-sub-safetys-sa.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

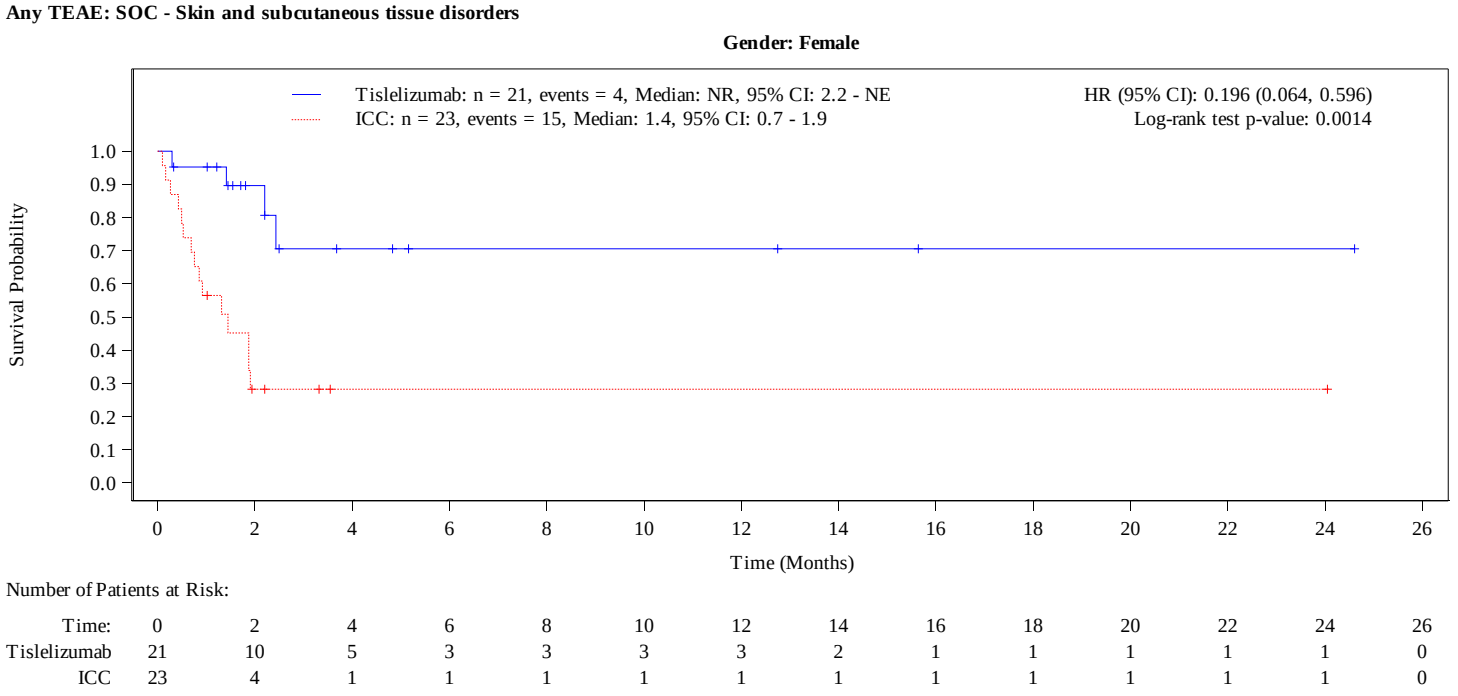


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28
Tislelizumab	118	63	28	21	14	9	6	4	3	3	2	2	2	1	0
ICC	106	39	17	9	4	2	1	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-b-s-km-socpt-sub-safetys-sa.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	21	10	5	3	3	3	3	2	1	1	1	1	1	0
ICC	23	4	1	1	1	1	1	1	1	1	1	1	1	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
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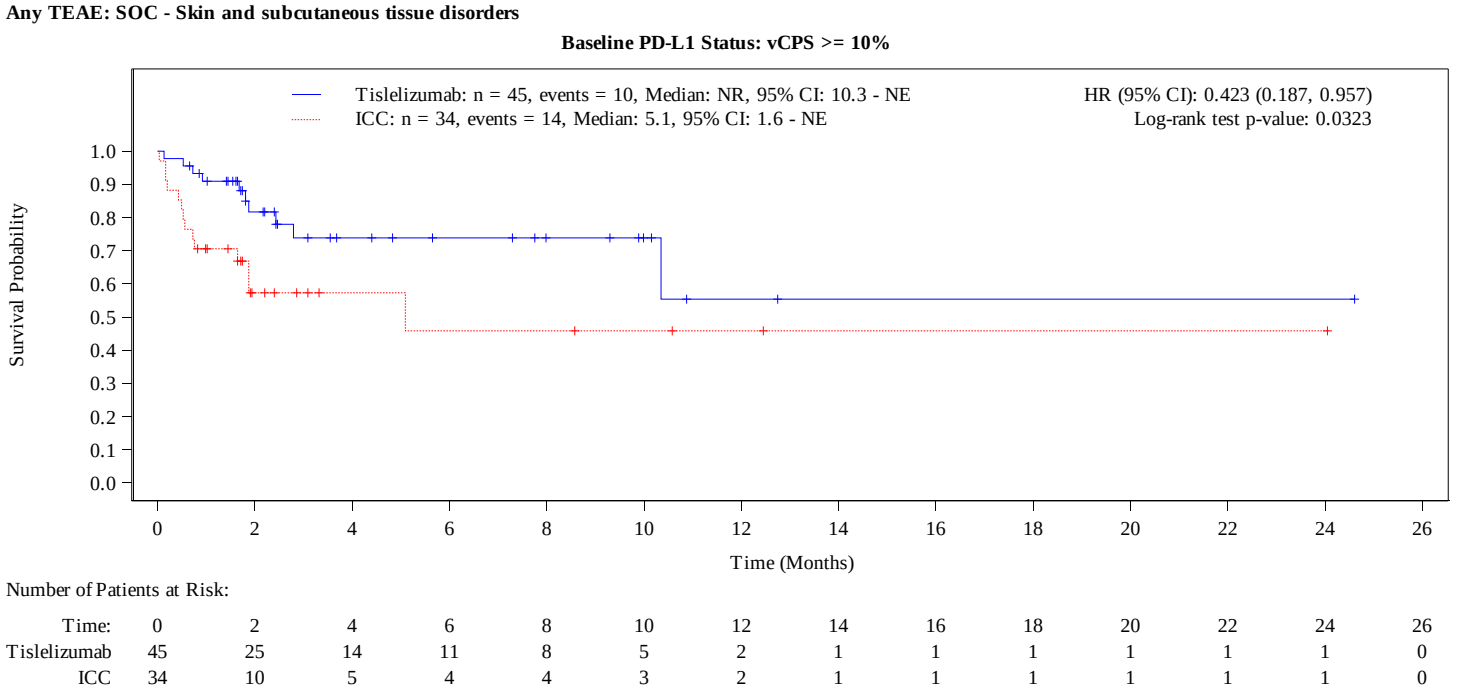
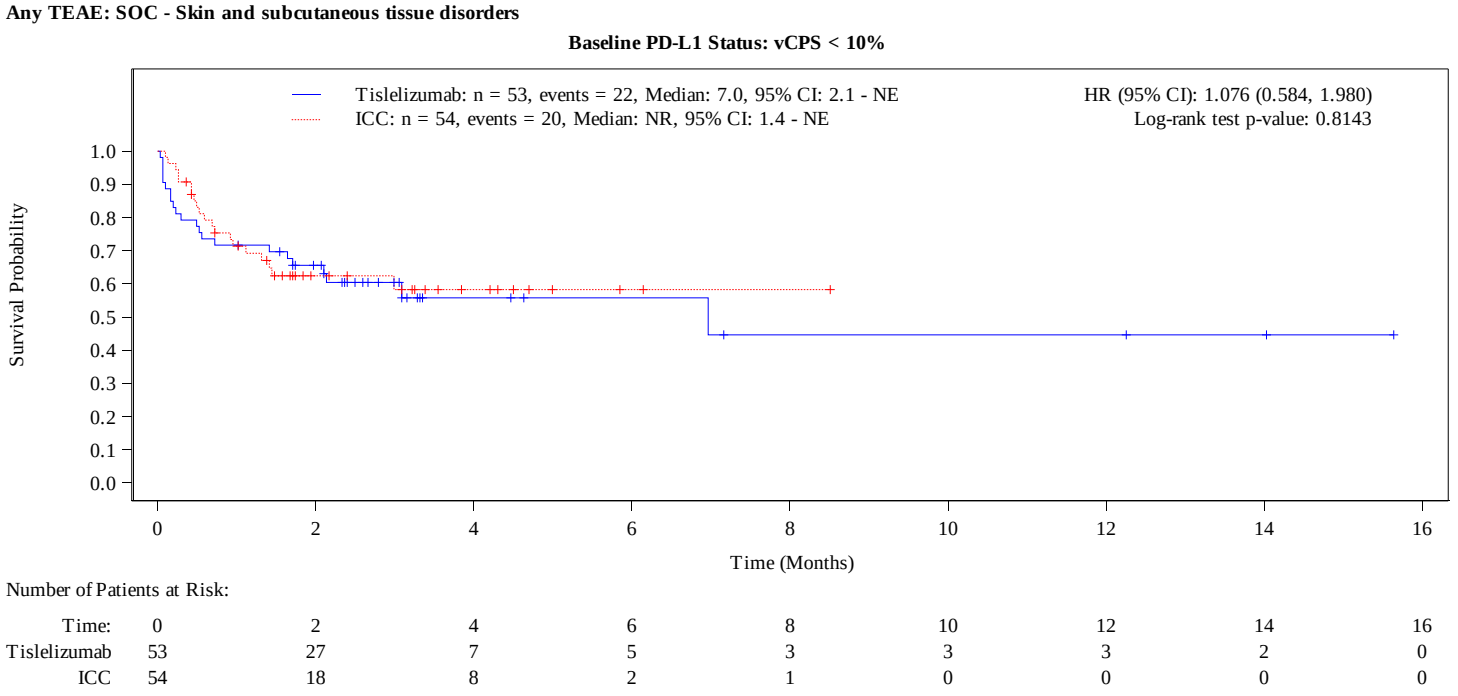
Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



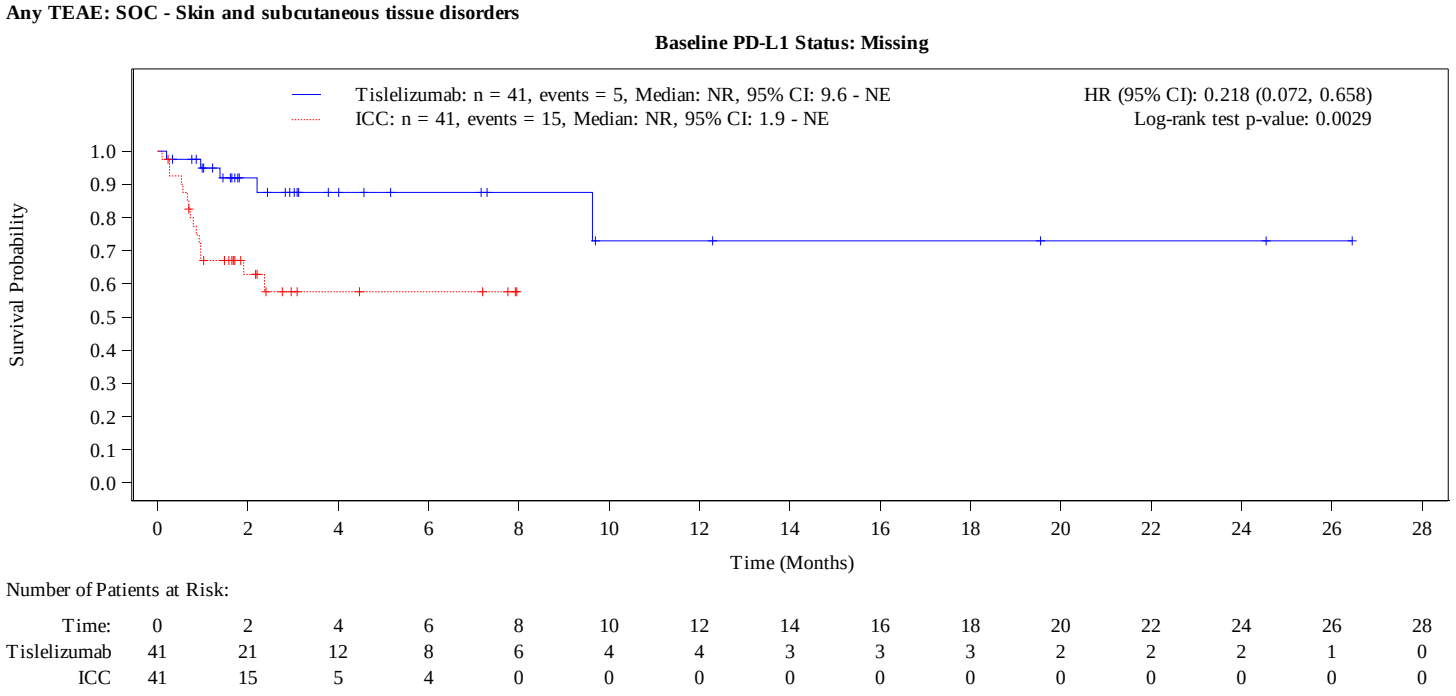
Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-b-s-km-socpt-sub-safetys-sa.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-b-s-km-socpt-sub-safetys-sa.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

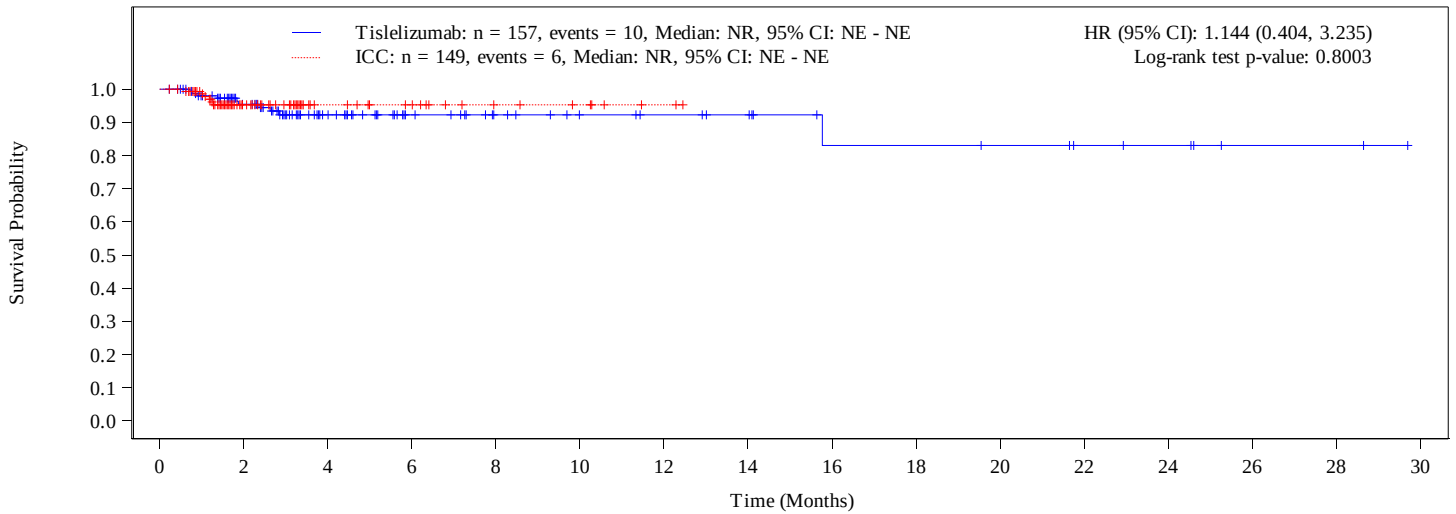


Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-02-b-s-km-socpt-sub-safetys-sa.rtf

Figure 14.3.1.3.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations / PT - Pneumonia

Age: < 65 Years



Number of Patients at Risk:

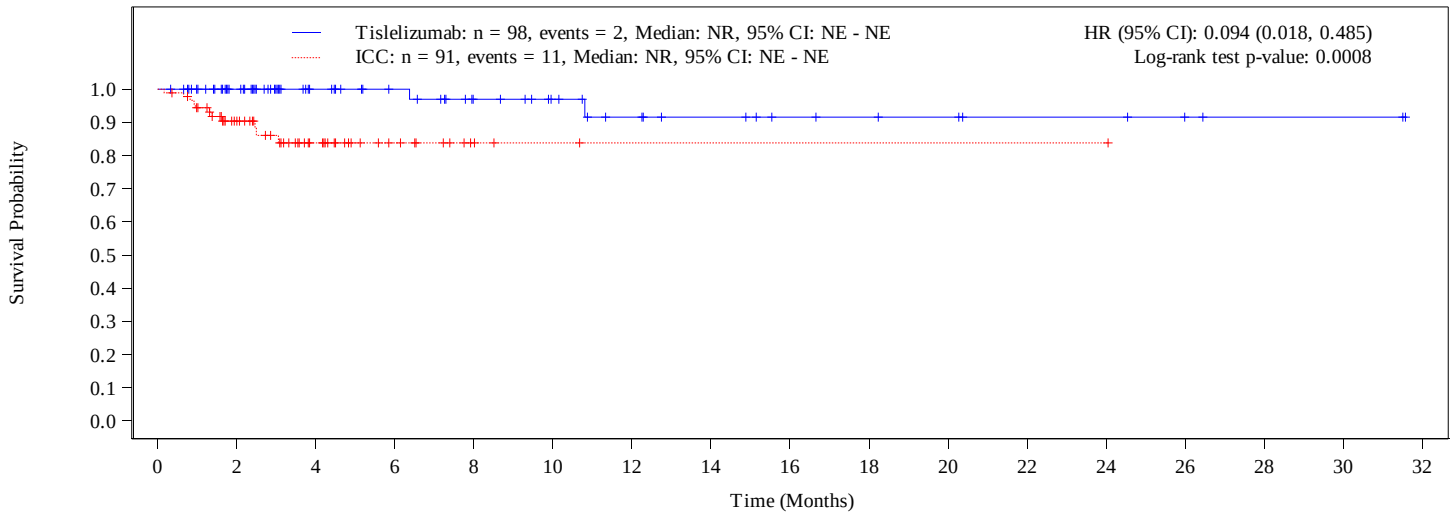
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	157	102	56	32	24	18	16	14	9	9	8	6	5	2	2	0
ICC	149	58	21	15	8	6	2	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-03-s-km-socpt-sub-g3-safety-sa.rtf

Figure 14.3.1.3.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations / PT - Pneumonia

Age: >= 65 Years

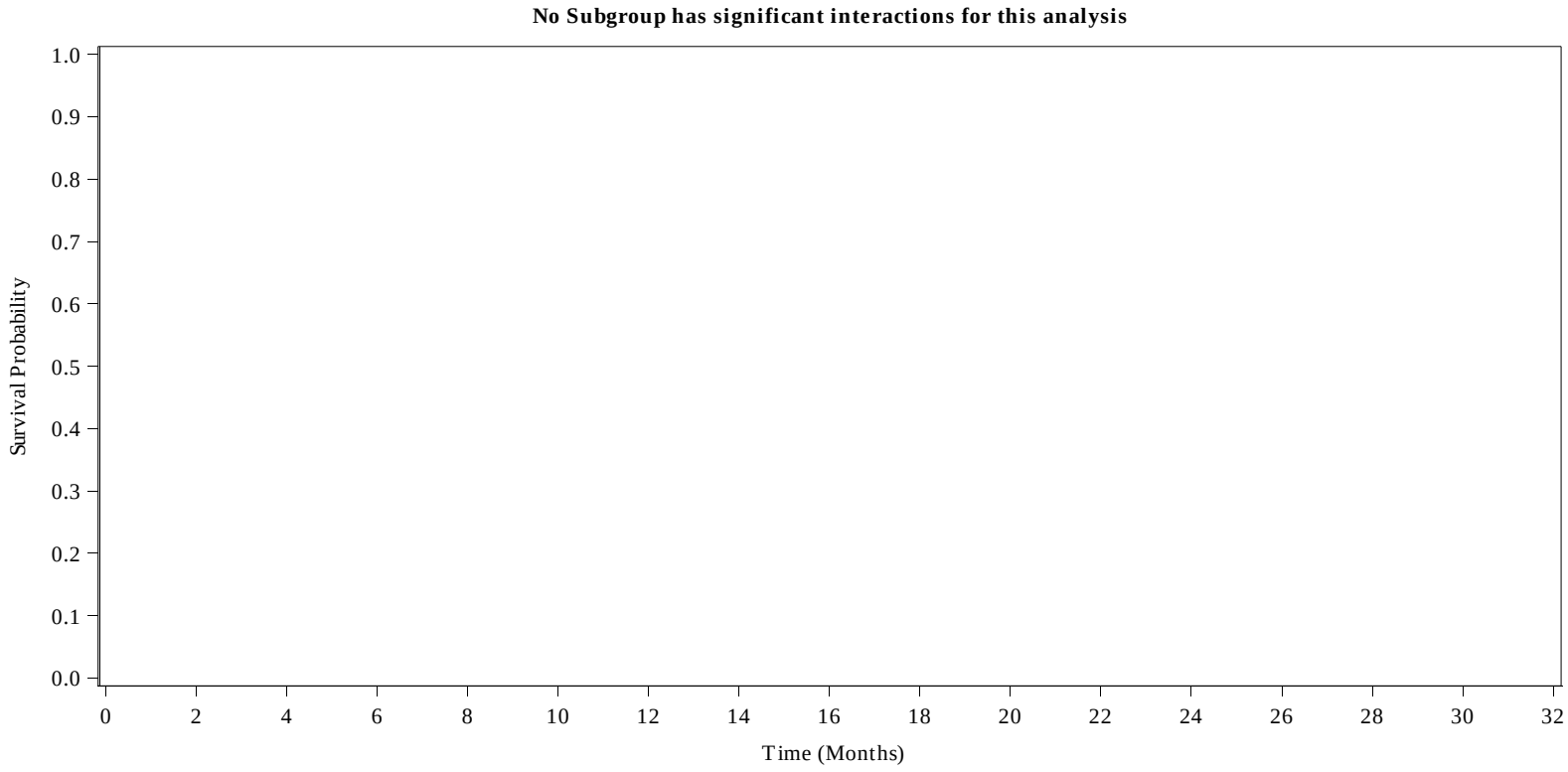


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	98	71	41	33	25	20	15	12	9	8	7	5	5	3	2	2	0
ICC	91	54	24	11	4	2	1	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 22AUG2024 01:21 f-14-03-01-03-s-km-socpt-sub-g3-safety-sa.rtf

Figure 14.3.1.3.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
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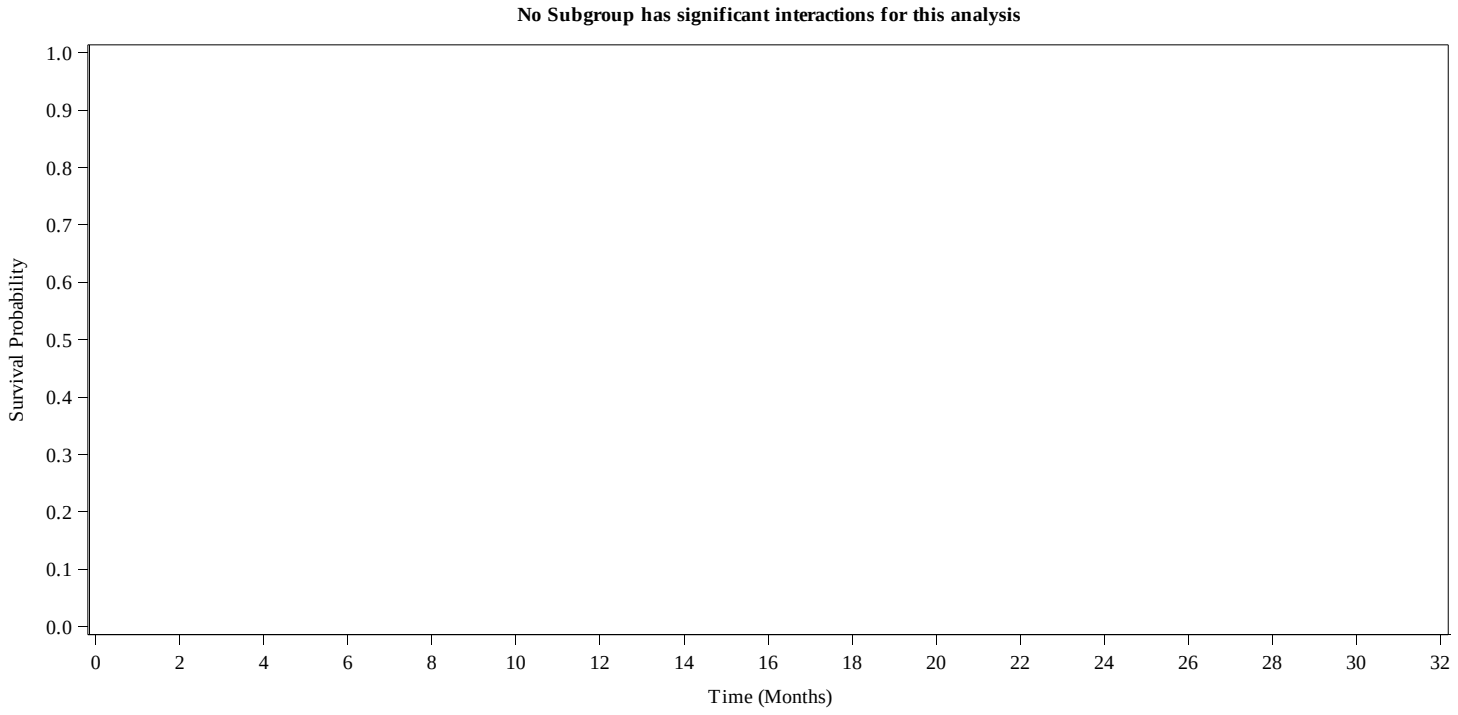
Figure 14.3.1.4.s:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
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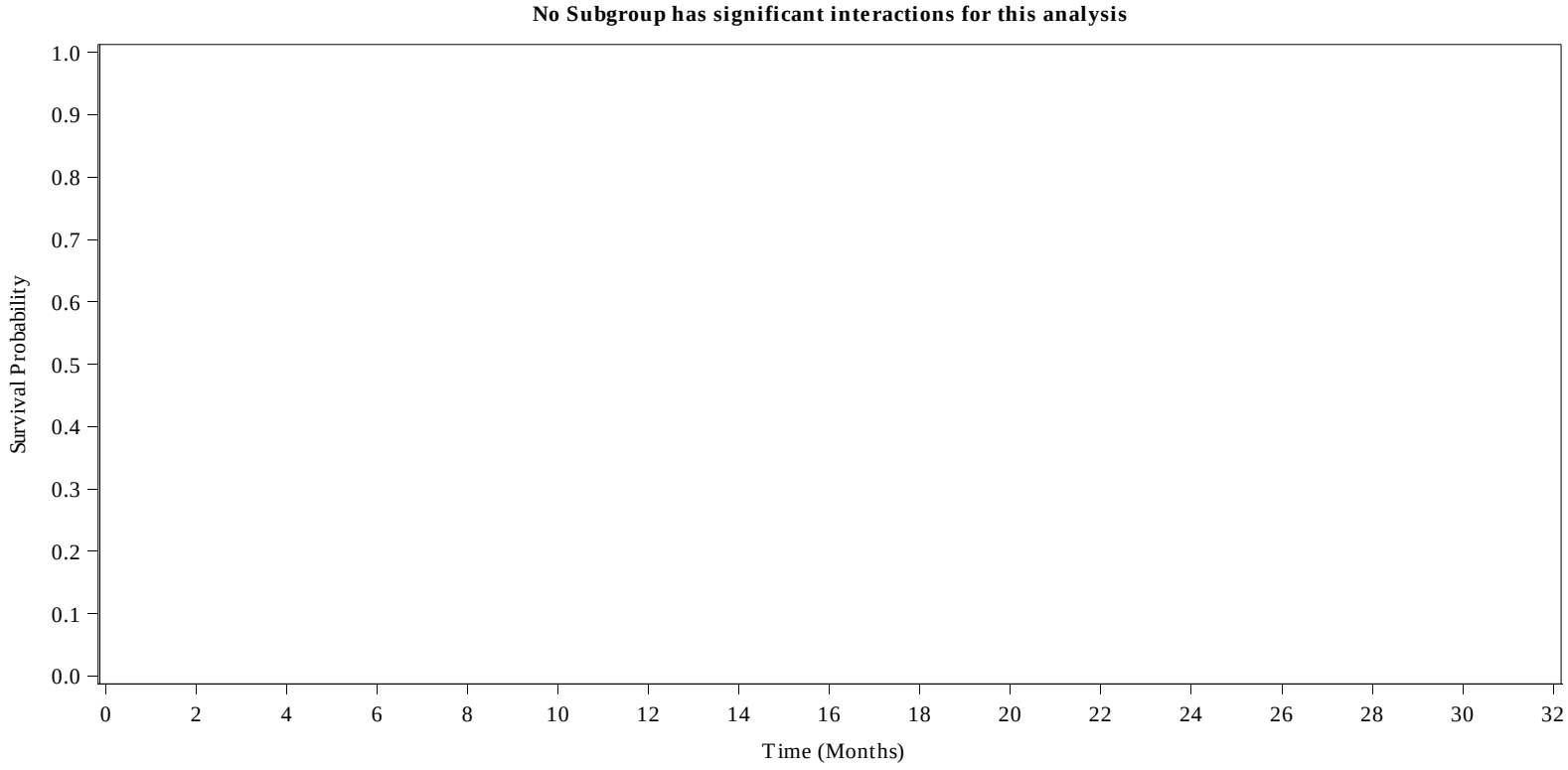
Figure 14.3.1.4.b.s:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
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Table 14.3.1.3.1:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR
Safety Analysis Set

	Tislelizumab (N = 255)			ICC (N = 240)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
IRR	255	8 (3.1)	NR (NE, NE)	240	11 (4.6)	NR (NE, NE)	0.580 (0.231, 1.459)	0.2379
IRR of Grade 1 and 2	255	8 (3.1)	NR (NE, NE)	240	11 (4.6)	NR (NE, NE)	0.580 (0.231, 1.459)	0.2379
IRR >= Grade 3	255	0 (0.0)	NR (NE, NE)	240	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Serious IRR	255	0 (0.0)	NR (NE, NE)	240	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE

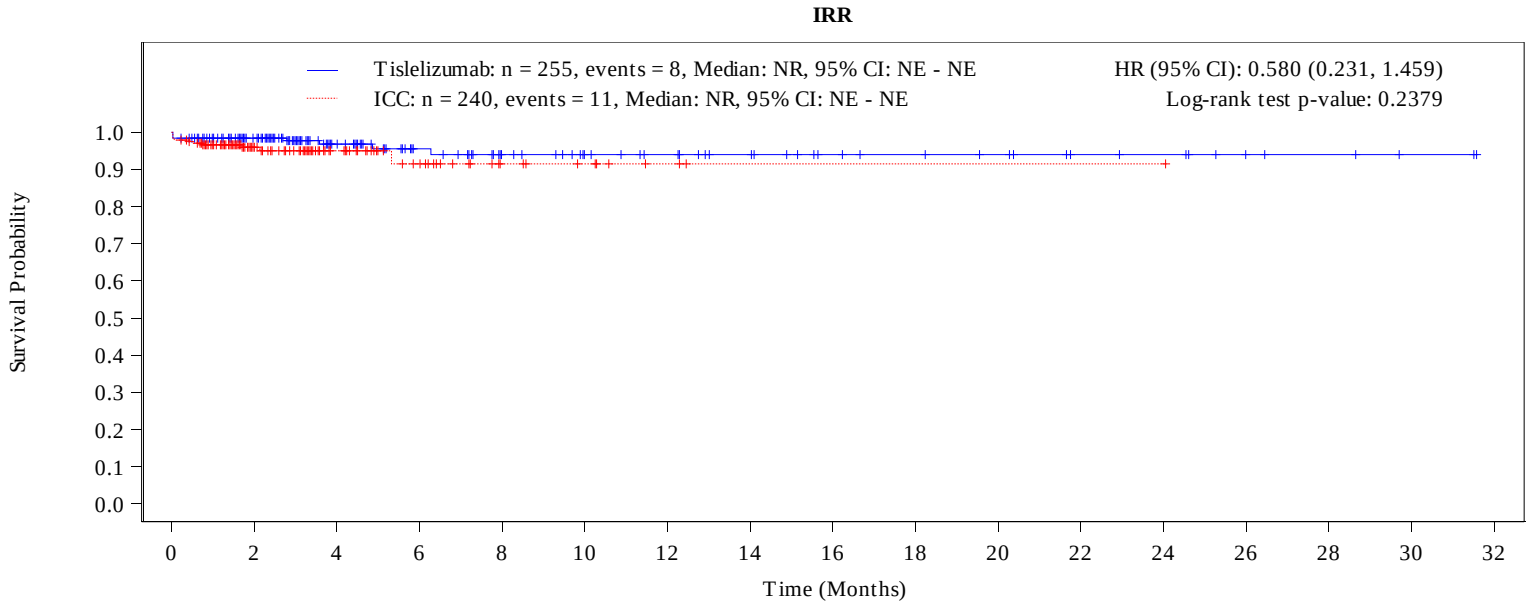
Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.
Adverse events were graded for severity using CTCAE v4.03.
Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-tte-aesi.sas 21AUG2024 19:04 t-14-03-01-03-01-tte-aesi-safety-sa.rtf

Table 14.3.1.3.1.b:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 129)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
IRR	139	8 (5.8)	NR (NE, NE)	129	7 (5.4)	NR (NE, NE)	0.977 (0.352, 2.706)	0.9634
IRR of Grade 1 and 2	139	8 (5.8)	NR (NE, NE)	129	7 (5.4)	NR (NE, NE)	0.977 (0.352, 2.706)	0.9634
IRR >= Grade 3	139	0 (0.0)	NR (NE, NE)	129	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Serious IRR	139	0 (0.0)	NR (NE, NE)	129	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.
Adverse events were graded for severity using CTCAE v4.03.
Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-tte-aesi.sas 21AUG2024 19:04 t-14-03-01-03-01-b-tte-aesi-safetys-sa.rtf

Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest: IRR
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	173	94	61	45	35	30	25	19	17	15	11	10	5	4	2	0
ICC	240	106	41	22	10	7	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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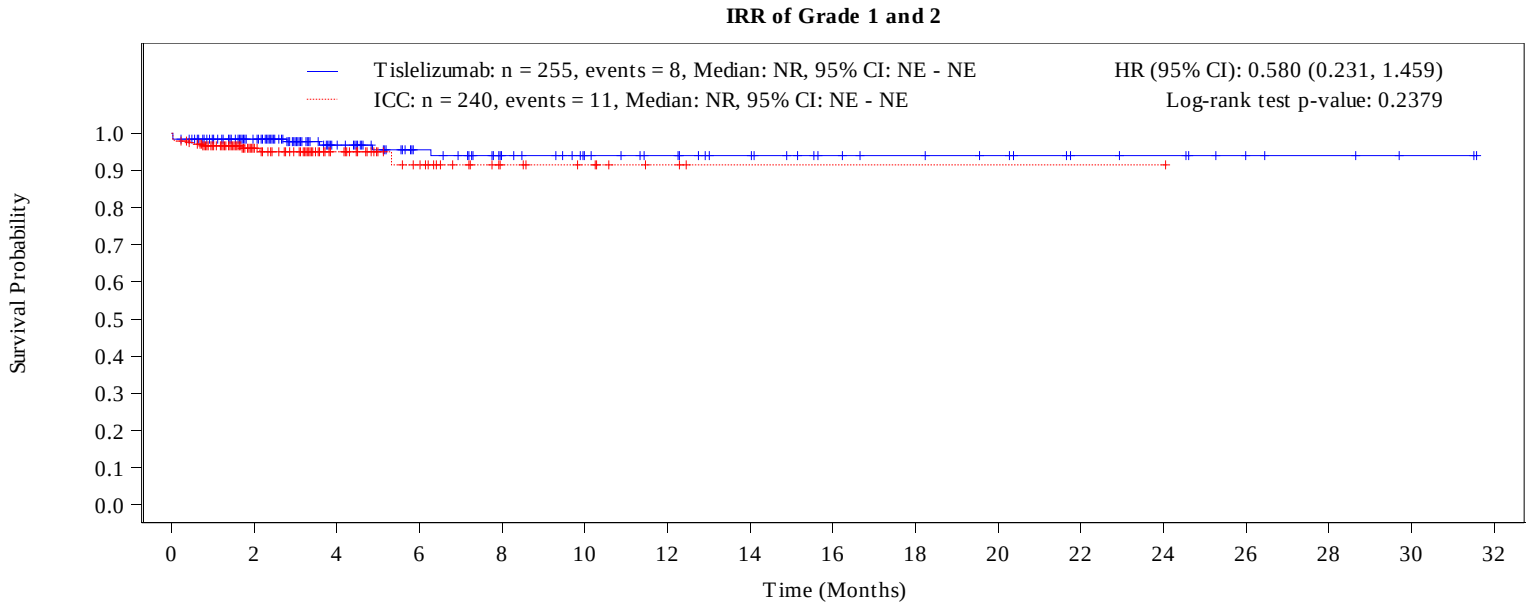
Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest: IRR
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	173	94	61	45	35	30	25	19	17	15	11	10	5	4	2	0
ICC	240	106	41	22	10	7	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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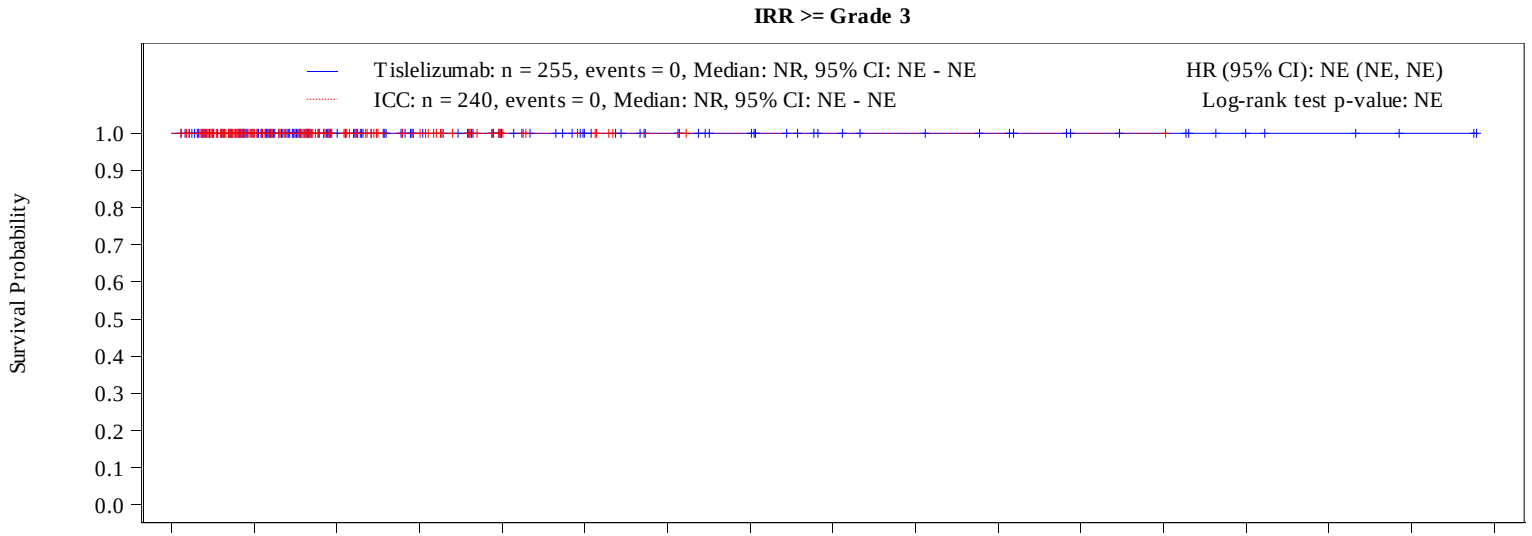
Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest: IRR
Safety Analysis Set

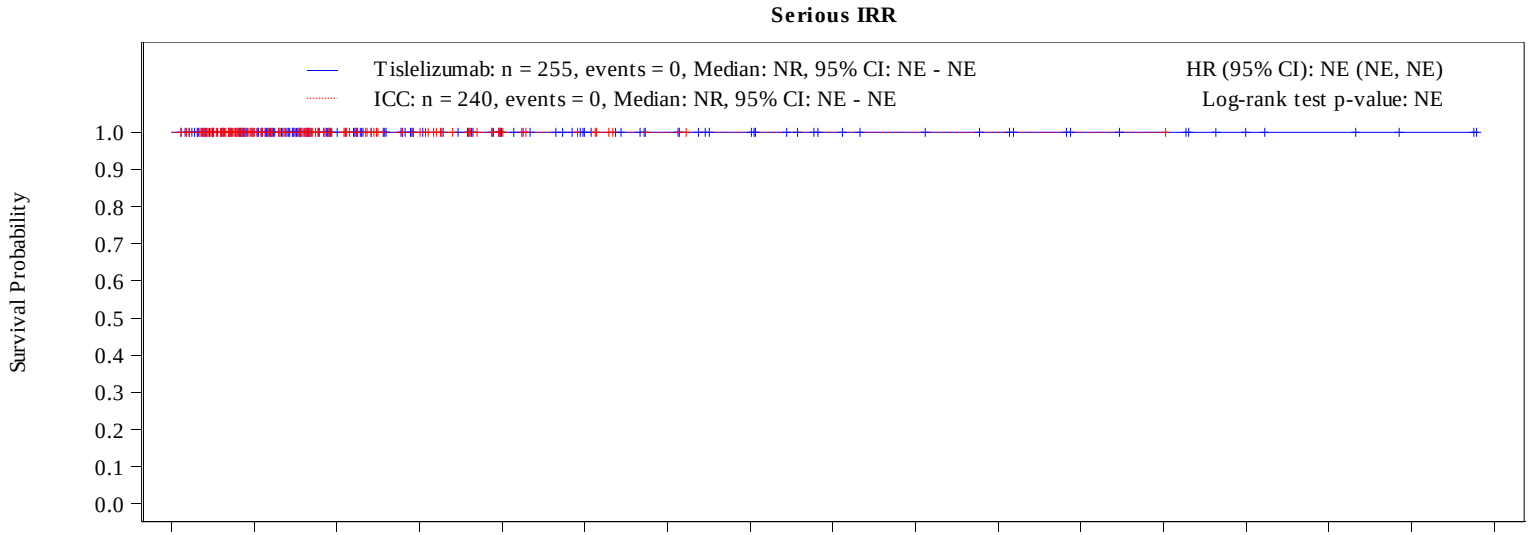


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	175	97	65	49	38	32	27	19	17	15	11	10	5	4	2	0
ICC	240	113	45	26	12	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesi.sas 22AUG2024 06:30 f-14-03-01-05-km-aesi-safety-sa.rtf

Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest: IRR
Safety Analysis Set

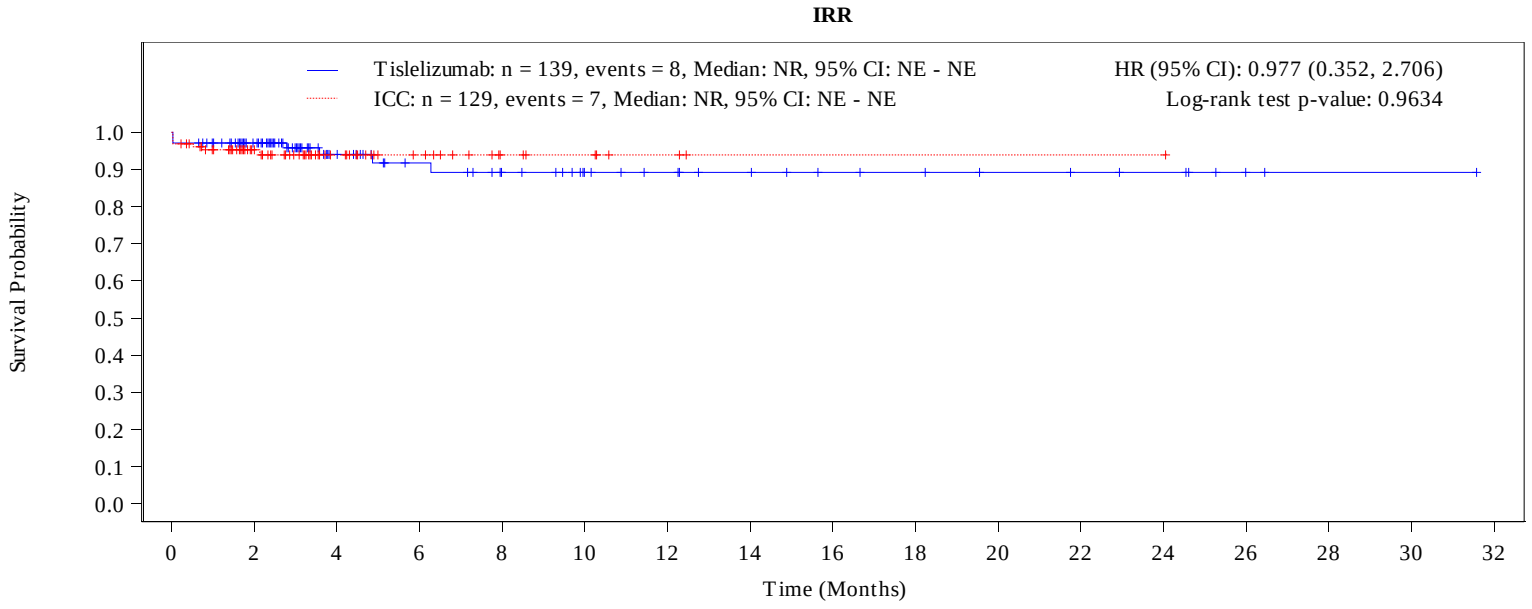


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	255	175	97	65	49	38	32	27	19	17	15	11	10	5	4	2	0
ICC	240	113	45	26	12	8	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesi.sas 22AUG2024 06:30 f-14-03-01-05-km-aesi-safety-sa.rtf

Figure 14.3.1.5.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest: IRR
Safety Analysis Set - Subpopulation without Irinotecan

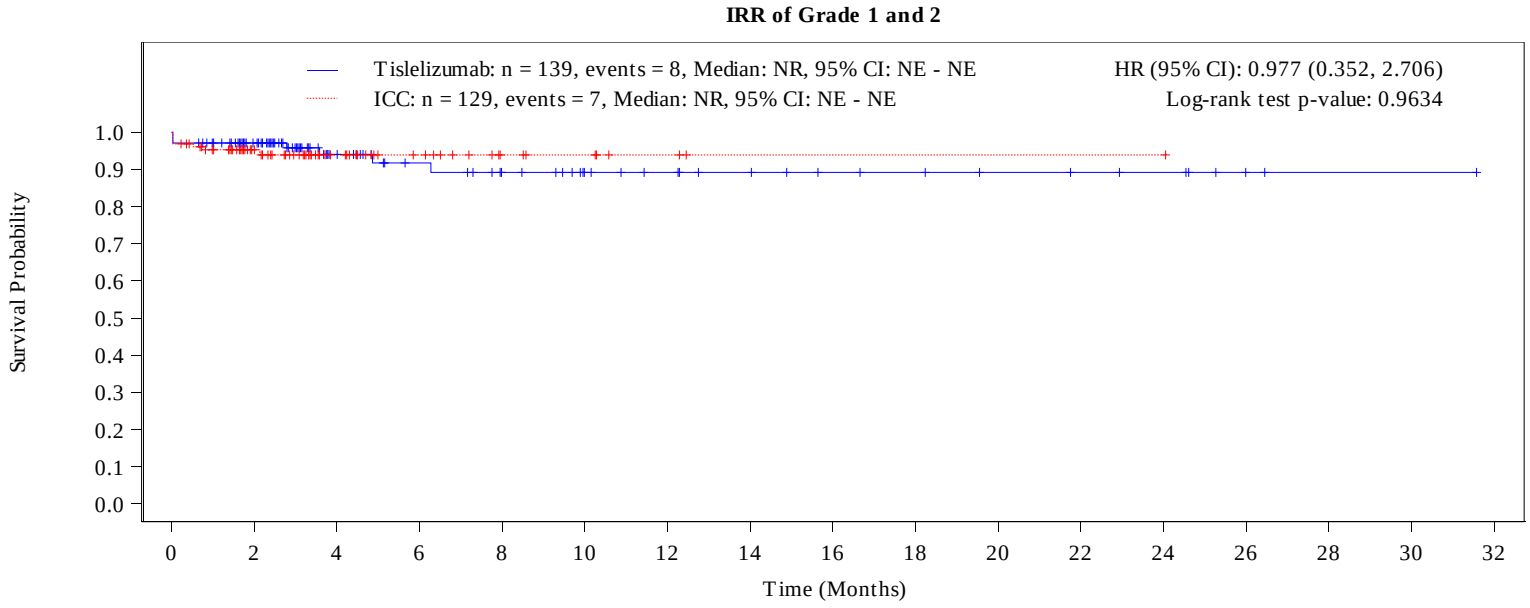


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	93	49	36	28	20	17	14	11	10	8	7	6	2	1	1	0
ICC	129	70	29	16	8	6	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesi.sas 22AUG2024 06:30 f-14-03-01-05-b-km-aesi-safetys-sa.rtf

Figure 14.3.1.5.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest: IRR
Safety Analysis Set - Subpopulation without Irinotecan

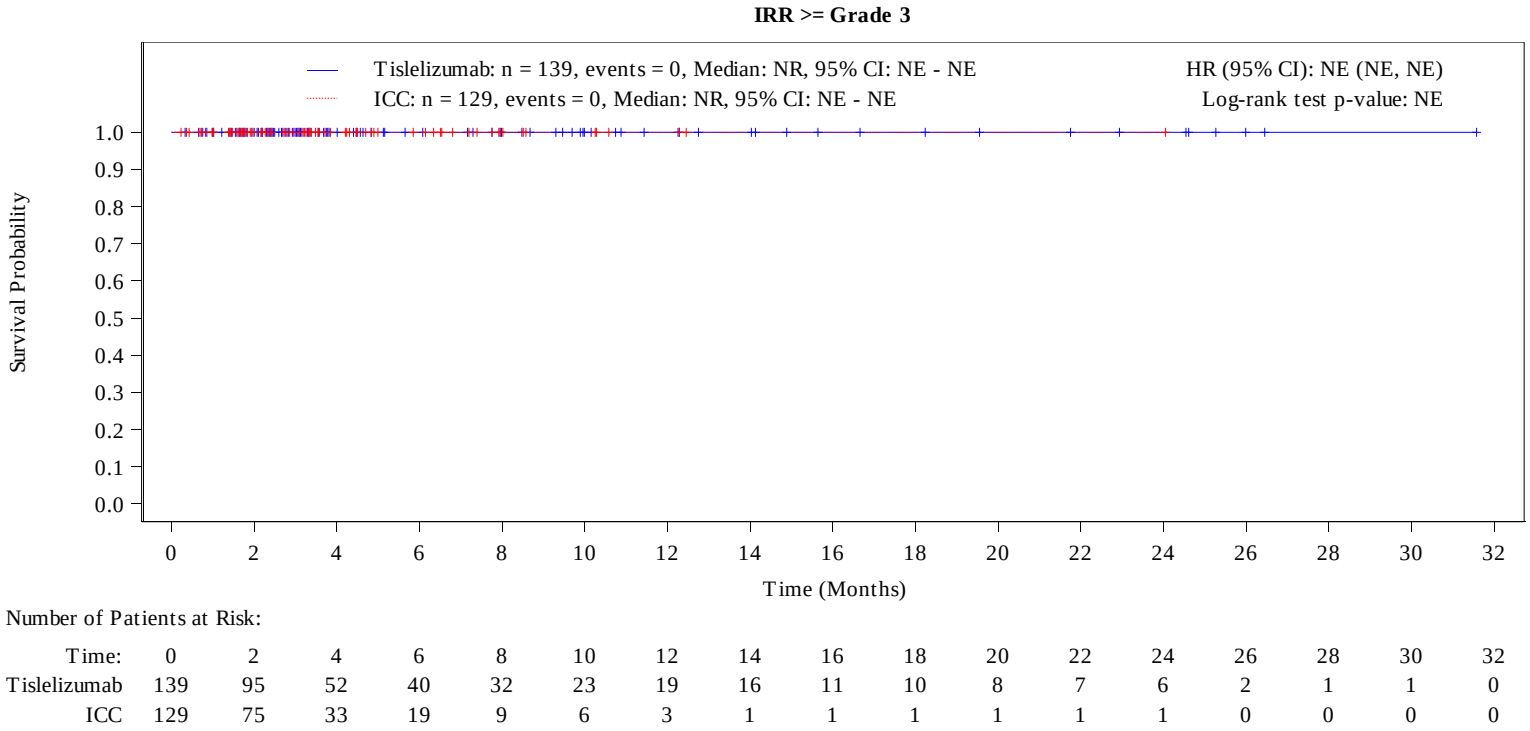


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	93	49	36	28	20	17	14	11	10	8	7	6	2	1	1	0
ICC	129	70	29	16	8	6	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesi.sas 22AUG2024 06:30 f-14-03-01-05-b-km-aesi-safetys-sa.rtf

Figure 14.3.1.5.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest: IRR
Safety Analysis Set - Subpopulation without Irinotecan

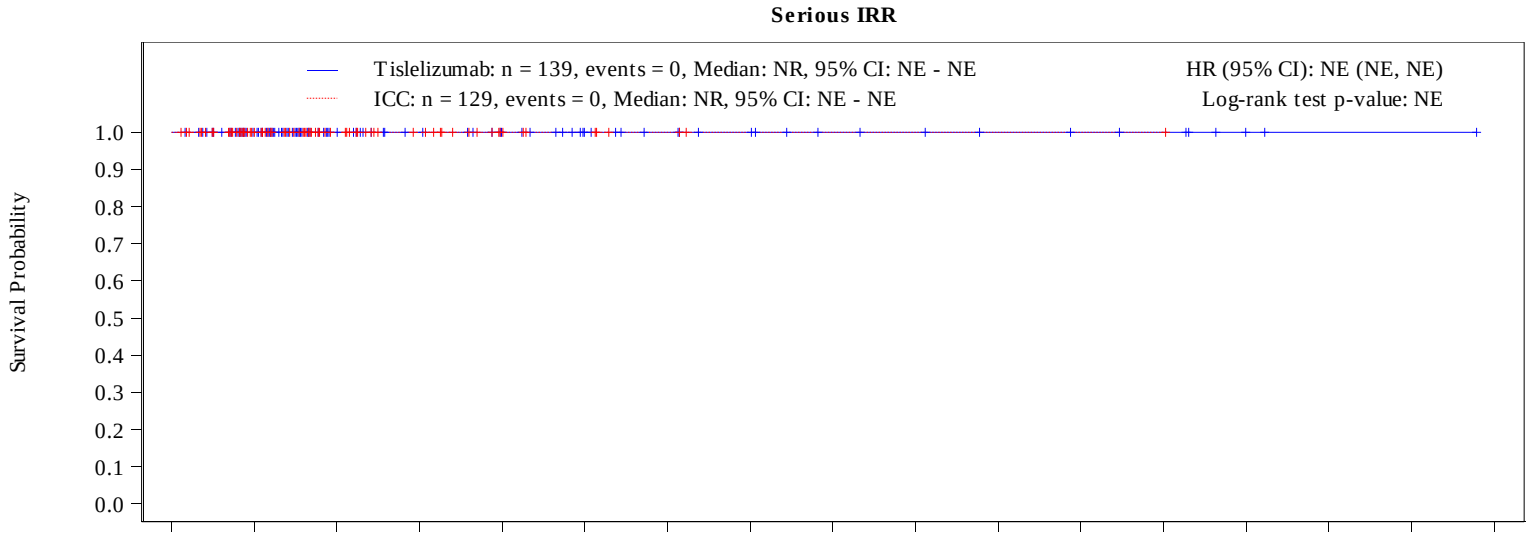


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	95	52	40	32	23	19	16	11	10	8	7	6	2	1	1	0
ICC	129	75	33	19	9	6	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesi.sas 22AUG2024 06:30 f-14-03-01-05-b-km-aesi-safetys-sa.rtf

Figure 14.3.1.5.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest: IRR
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	95	52	40	32	23	19	16	11	10	8	7	6	2	1	1	0
ICC	129	75	33	19	9	6	3	1	1	1	1	1	1	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set

IRR

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	4 (2.5)	NR (NE, NE)	149	5 (3.4)	NR (NE, NE)	0.565 (0.149, 2.147)	0.3963
>= 65 Years	98	4 (4.1)	NR (NE, NE)	91	6 (6.6)	NR (NE, NE)	0.511 (0.142, 1.846)	0.2917
Interaction								0.7883
Gender								
Male	216	6 (2.8)	NR (NE, NE)	204	8 (3.9)	NR (NE, NE)	0.500 (0.170, 1.467)	0.1977
Female	39	2 (5.1)	NR (NE, NE)	36	3 (8.3)	NR (NE, NE)	0.618 (0.103, 3.698)	0.5913
Interaction								0.8896

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set

IRR

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	5 (2.7)	NR (NE, NE)	183	9 (4.9)	NR (NE, NE)	0.371 (0.122, 1.131)	0.0702
Non-Smoker	68	3 (4.4)	NR (NE, NE)	57	2 (3.5)	NR (NE, NE)	1.271 (0.212, 7.608)	0.7912
Interaction								0.4070
ICC Options								
Paclitaxel	83	4 (4.8)	NR (NE, NE)	79	6 (7.6)	NR (NE, NE)	0.566 (0.159, 2.021)	0.3703
Docetaxel	56	4 (7.1)	NR (NE, NE)	50	1 (2.0)	NR (NE, NE)	2.920 (0.323, 26.438)	0.3173
Irinotecan	116	0 (0.0)	NR (NE, NE)	111	4 (3.6)	NR (5.3, NE)	0.000 (0.000, NE)	0.0100
Interaction								0.3827

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-aesi-subgrp.sas 22AUG2024 17:58 t-14-03-01-03-01-s-aesi-subgrp-safety-sa.rtf

Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set

IRR

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	4 (6.3)	NR (NE, NE)	57	2 (3.5)	NR (NE, NE)	1.145 (0.208, 6.318)	0.8764
1	192	4 (2.1)	NR (NE, NE)	183	9 (4.9)	NR (NE, NE)	0.394 (0.121, 1.283)	0.1070
Interaction								0.1514
Region #1								
Asia	201	8 (4.0)	NR (NE, NE)	191	6 (3.1)	NR (NE, NE)	0.988 (0.337, 2.899)	0.9824
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	5 (10.2)	NR (5.3, NE)	0.000 (0.000, NE)	0.0102
Interaction								0.9907

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set

IRR

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	5 (2.8)	NR (NE, NE)	168	6 (3.6)	NR (NE, NE)	0.654 (0.196, 2.182)	0.4846
Japan	25	3 (12.0)	NR (4.9, NE)	23	0 (0.0)	NR (NE, NE)	55301530.201 (0.000, NE)	0.1794
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	5 (10.2)	NR (5.3, NE)	0.000 (0.000, NE)	0.0102
Interaction								0.9999
Race								
Asian and other	203	8 (3.9)	NR (NE, NE)	198	7 (3.5)	NR (NE, NE)	0.884 (0.315, 2.479)	0.8145
White	52	0 (0.0)	NR (NE, NE)	42	4 (9.5)	NR (5.3, NE)	0.000 (0.000, NE)	0.0132
Interaction								0.9905

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-aesi-subgrp.sas 22AUG2024 17:58 t-14-03-01-03-01-s-aesi-subgrp-safety-sa.rtf

Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set

IRR

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	3 (3.8)	--	60	2 (3.3)	--	--	--
vCPS < 10%	100	3 (3.0)	--	119	4 (3.4)	--	--	--
Missing	75	2 (2.7)	--	61	5 (8.2)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set

IRR of Grade 1 and 2

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	157	4 (2.5)	NR (NE, NE)	149	5 (3.4)	NR (NE, NE)	0.565 (0.149, 2.147)	0.3963
>= 65 Years	98	4 (4.1)	NR (NE, NE)	91	6 (6.6)	NR (NE, NE)	0.511 (0.142, 1.846)	0.2917
Interaction								0.7883
Gender								
Male	216	6 (2.8)	NR (NE, NE)	204	8 (3.9)	NR (NE, NE)	0.500 (0.170, 1.467)	0.1977
Female	39	2 (5.1)	NR (NE, NE)	36	3 (8.3)	NR (NE, NE)	0.618 (0.103, 3.698)	0.5913
Interaction								0.8896

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-aesi-subgrp.sas 22AUG2024 17:58 t-14-03-01-03-01-s-aesi-subgrp-safety-sa.rtf

Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set

IRR of Grade 1 and 2

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	5 (2.7)	NR (NE, NE)	183	9 (4.9)	NR (NE, NE)	0.371 (0.122, 1.131)	0.0702
Non-Smoker	68	3 (4.4)	NR (NE, NE)	57	2 (3.5)	NR (NE, NE)	1.271 (0.212, 7.608)	0.7912
Interaction								0.4070
ICC Options								
Paclitaxel	83	4 (4.8)	NR (NE, NE)	79	6 (7.6)	NR (NE, NE)	0.566 (0.159, 2.021)	0.3703
Docetaxel	56	4 (7.1)	NR (NE, NE)	50	1 (2.0)	NR (NE, NE)	2.920 (0.323, 26.438)	0.3173
Irinotecan	116	0 (0.0)	NR (NE, NE)	111	4 (3.6)	NR (5.3, NE)	0.000 (0.000, NE)	0.0100
Interaction								0.3827

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set

IRR of Grade 1 and 2

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	4 (6.3)	NR (NE, NE)	57	2 (3.5)	NR (NE, NE)	1.145 (0.208, 6.318)	0.8764
1	192	4 (2.1)	NR (NE, NE)	183	9 (4.9)	NR (NE, NE)	0.394 (0.121, 1.283)	0.1070
Interaction								0.1514
Region #1								
Asia	201	8 (4.0)	NR (NE, NE)	191	6 (3.1)	NR (NE, NE)	0.988 (0.337, 2.899)	0.9824
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	5 (10.2)	NR (5.3, NE)	0.000 (0.000, NE)	0.0102
Interaction								0.9907

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set

IRR of Grade 1 and 2

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	5 (2.8)	NR (NE, NE)	168	6 (3.6)	NR (NE, NE)	0.654 (0.196, 2.182)	0.4846
Japan	25	3 (12.0)	NR (4.9, NE)	23	0 (0.0)	NR (NE, NE)	55301530.201 (0.000, NE)	0.1794
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	5 (10.2)	NR (5.3, NE)	0.000 (0.000, NE)	0.0102
Interaction								0.9999
Race								
Asian and other	203	8 (3.9)	NR (NE, NE)	198	7 (3.5)	NR (NE, NE)	0.884 (0.315, 2.479)	0.8145
White	52	0 (0.0)	NR (NE, NE)	42	4 (9.5)	NR (5.3, NE)	0.000 (0.000, NE)	0.0132
Interaction								0.9905

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set

IRR of Grade 1 and 2

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	3 (3.8)	--	60	2 (3.3)	--	--	--
vCPS < 10%	100	3 (3.0)	--	119	4 (3.4)	--	--	--
Missing	75	2 (2.7)	--	61	5 (8.2)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set

IRR >= Grade 3

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	0 (0.0)	--	149	0 (0.0)	--	--	--
>= 65 Years	98	0 (0.0)	--	91	0 (0.0)	--	--	--
Interaction								--
Gender								
Male	216	0 (0.0)	--	204	0 (0.0)	--	--	--
Female	39	0 (0.0)	--	36	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set

IRR >= Grade 3

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	0 (0.0)	--	183	0 (0.0)	--	--	--
Non-Smoker	68	0 (0.0)	--	57	0 (0.0)	--	--	--
Interaction								--
ICC Options								
Paclitaxel	83	0 (0.0)	--	79	0 (0.0)	--	--	--
Docetaxel	56	0 (0.0)	--	50	0 (0.0)	--	--	--
Irinotecan	116	0 (0.0)	--	111	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set

IRR >= Grade 3

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	0 (0.0)	--	57	0 (0.0)	--	--	--
1	192	0 (0.0)	--	183	0 (0.0)	--	--	--
Interaction								--
Region #1								
Asia	201	0 (0.0)	--	191	0 (0.0)	--	--	--
Europe/North America	54	0 (0.0)	--	49	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set

IRR >= Grade 3

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	0 (0.0)	--	168	0 (0.0)	--	--	--
Japan	25	0 (0.0)	--	23	0 (0.0)	--	--	--
Europe/North America	54	0 (0.0)	--	49	0 (0.0)	--	--	--
Interaction								--
Race								
Asian and other	203	0 (0.0)	--	198	0 (0.0)	--	--	--
White	52	0 (0.0)	--	42	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set

IRR >= Grade 3

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	0 (0.0)	--	60	0 (0.0)	--	--	--
vCPS < 10%	100	0 (0.0)	--	119	0 (0.0)	--	--	--
Missing	75	0 (0.0)	--	61	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set

Serious IRR

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	157	0 (0.0)	--	149	0 (0.0)	--	--	--
>= 65 Years	98	0 (0.0)	--	91	0 (0.0)	--	--	--
Interaction								--
Gender								
Male	216	0 (0.0)	--	204	0 (0.0)	--	--	--
Female	39	0 (0.0)	--	36	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

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Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set

Serious IRR

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	0 (0.0)	--	183	0 (0.0)	--	--	--
Non-Smoker	68	0 (0.0)	--	57	0 (0.0)	--	--	--
Interaction								--
ICC Options								
Paclitaxel	83	0 (0.0)	--	79	0 (0.0)	--	--	--
Docetaxel	56	0 (0.0)	--	50	0 (0.0)	--	--	--
Irinotecan	116	0 (0.0)	--	111	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set

Serious IRR

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	0 (0.0)	--	57	0 (0.0)	--	--	--
1	192	0 (0.0)	--	183	0 (0.0)	--	--	--
Interaction								--
Region #1								
Asia	201	0 (0.0)	--	191	0 (0.0)	--	--	--
Europe/North America	54	0 (0.0)	--	49	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set

Serious IRR

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	0 (0.0)	--	168	0 (0.0)	--	--	--
Japan	25	0 (0.0)	--	23	0 (0.0)	--	--	--
Europe/North America	54	0 (0.0)	--	49	0 (0.0)	--	--	--
Interaction								--
Race								
Asian and other	203	0 (0.0)	--	198	0 (0.0)	--	--	--
White	52	0 (0.0)	--	42	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set

Serious IRR

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	0 (0.0)	--	60	0 (0.0)	--	--	--
vCPS < 10%	100	0 (0.0)	--	119	0 (0.0)	--	--	--
Missing	75	0 (0.0)	--	61	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	4 (5.2)	--	70	2 (2.9)	--	--	--
>= 65 Years	62	4 (6.5)	--	59	5 (8.5)	--	--	--
Interaction								--
Gender								
Male	118	6 (5.1)	NR (NE, NE)	106	5 (4.7)	NR (NE, NE)	0.878 (0.266, 2.904)	0.8310
Female	21	2 (9.5)	NR (NE, NE)	23	2 (8.7)	NR (NE, NE)	1.111 (0.156, 7.887)	0.9149
Interaction								0.9889

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	5 (4.8)	NR (NE, NE)	101	6 (5.9)	NR (NE, NE)	0.617 (0.185, 2.053)	0.4247
Non-Smoker	35	3 (8.6)	NR (NE, NE)	28	1 (3.6)	NR (NE, NE)	2.432 (0.253, 23.387)	0.4207
Interaction								0.3361
ICC Options								
Paclitaxel	83	4 (4.8)	NR (NE, NE)	79	6 (7.6)	NR (NE, NE)	0.566 (0.159, 2.021)	0.3703
Docetaxel	56	4 (7.1)	NR (NE, NE)	50	1 (2.0)	NR (NE, NE)	2.920 (0.323, 26.438)	0.3173
Interaction								0.1739

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	4 (9.3)	NR (NE, NE)	37	0 (0.0)	NR (NE, NE)	54390180.131 (0.000, NE)	0.1138
1	96	4 (4.2)	NR (NE, NE)	92	7 (7.6)	NR (NE, NE)	0.527 (0.154, 1.804)	0.2930
Interaction								0.9901
Region #1								
Asia	103	8 (7.8)	NR (NE, NE)	99	4 (4.0)	NR (NE, NE)	1.623 (0.485, 5.434)	0.4237
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	3 (10.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0567
Interaction								0.9901

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	5 (6.4)	--	76	4 (5.3)	--	--	--
Japan	25	3 (12.0)	--	23	0 (0.0)	--	--	--
Europe/North America	36	0 (0.0)	--	30	3 (10.0)	--	--	--
Interaction								--
Race								
Asian and other	105	8 (7.6)	NR (NE, NE)	106	5 (4.7)	NR (NE, NE)	1.383 (0.449, 4.259)	0.5672
White	34	0 (0.0)	NR (NE, NE)	23	2 (8.7)	NR (NE, NE)	0.000 (0.000, NE)	0.0892
Interaction								0.9903

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	3 (6.7)	--	34	2 (5.9)	--	--	--
vCPS < 10%	53	3 (5.7)	--	54	1 (1.9)	--	--	--
Missing	41	2 (4.9)	--	41	4 (9.8)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR of Grade 1 and 2

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	4 (5.2)	--	70	2 (2.9)	--	--	--
>= 65 Years	62	4 (6.5)	--	59	5 (8.5)	--	--	--
Interaction								--
Gender								
Male	118	6 (5.1)	NR (NE, NE)	106	5 (4.7)	NR (NE, NE)	0.878 (0.266, 2.904)	0.8310
Female	21	2 (9.5)	NR (NE, NE)	23	2 (8.7)	NR (NE, NE)	1.111 (0.156, 7.887)	0.9149
Interaction								0.9889

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR of Grade 1 and 2

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	5 (4.8)	NR (NE, NE)	101	6 (5.9)	NR (NE, NE)	0.617 (0.185, 2.053)	0.4247
Non-Smoker	35	3 (8.6)	NR (NE, NE)	28	1 (3.6)	NR (NE, NE)	2.432 (0.253, 23.387)	0.4207
Interaction								0.3361
ICC Options								
Paclitaxel	83	4 (4.8)	NR (NE, NE)	79	6 (7.6)	NR (NE, NE)	0.566 (0.159, 2.021)	0.3703
Docetaxel	56	4 (7.1)	NR (NE, NE)	50	1 (2.0)	NR (NE, NE)	2.920 (0.323, 26.438)	0.3173
Interaction								0.1739

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR of Grade 1 and 2

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	4 (9.3)	NR (NE, NE)	37	0 (0.0)	NR (NE, NE)	54390180.131 (0.000, NE)	0.1138
1	96	4 (4.2)	NR (NE, NE)	92	7 (7.6)	NR (NE, NE)	0.527 (0.154, 1.804)	0.2930
Interaction								0.9901
Region #1								
Asia	103	8 (7.8)	NR (NE, NE)	99	4 (4.0)	NR (NE, NE)	1.623 (0.485, 5.434)	0.4237
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	3 (10.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0567
Interaction								0.9901

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR of Grade 1 and 2

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	5 (6.4)	--	76	4 (5.3)	--	--	--
Japan	25	3 (12.0)	--	23	0 (0.0)	--	--	--
Europe/North America	36	0 (0.0)	--	30	3 (10.0)	--	--	--
Interaction								--
Race								
Asian and other	105	8 (7.6)	NR (NE, NE)	106	5 (4.7)	NR (NE, NE)	1.383 (0.449, 4.259)	0.5672
White	34	0 (0.0)	NR (NE, NE)	23	2 (8.7)	NR (NE, NE)	0.000 (0.000, NE)	0.0892
Interaction								0.9903

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR of Grade 1 and 2

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	3 (6.7)	--	34	2 (5.9)	--	--	--
vCPS < 10%	53	3 (5.7)	--	54	1 (1.9)	--	--	--
Missing	41	2 (4.9)	--	41	4 (9.8)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR >= Grade 3

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	0 (0.0)	--	70	0 (0.0)	--	--	--
>= 65 Years	62	0 (0.0)	--	59	0 (0.0)	--	--	--
Interaction								--
Gender								
Male	118	0 (0.0)	--	106	0 (0.0)	--	--	--
Female	21	0 (0.0)	--	23	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR >= Grade 3

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	0 (0.0)	--	101	0 (0.0)	--	--	--
Non-Smoker	35	0 (0.0)	--	28	0 (0.0)	--	--	--
Interaction								--
ICC Options								
Paclitaxel	83	0 (0.0)	--	79	0 (0.0)	--	--	--
Docetaxel	56	0 (0.0)	--	50	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR >= Grade 3

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	0 (0.0)	--	37	0 (0.0)	--	--	--
1	96	0 (0.0)	--	92	0 (0.0)	--	--	--
Interaction								--
Region #1								
Asia	103	0 (0.0)	--	99	0 (0.0)	--	--	--
Europe/North America	36	0 (0.0)	--	30	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR >= Grade 3

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	0 (0.0)	--	76	0 (0.0)	--	--	--
Japan	25	0 (0.0)	--	23	0 (0.0)	--	--	--
Europe/North America	36	0 (0.0)	--	30	0 (0.0)	--	--	--
Interaction								--
Race								
Asian and other	105	0 (0.0)	--	106	0 (0.0)	--	--	--
White	34	0 (0.0)	--	23	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR >= Grade 3

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	0 (0.0)	--	34	0 (0.0)	--	--	--
vCPS < 10%	53	0 (0.0)	--	54	0 (0.0)	--	--	--
Missing	41	0 (0.0)	--	41	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious IRR

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	77	0 (0.0)	--	70	0 (0.0)	--	--	--
>= 65 Years	62	0 (0.0)	--	59	0 (0.0)	--	--	--
Interaction								--
Gender								
Male	118	0 (0.0)	--	106	0 (0.0)	--	--	--
Female	21	0 (0.0)	--	23	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious IRR

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	0 (0.0)	--	101	0 (0.0)	--	--	--
Non-Smoker	35	0 (0.0)	--	28	0 (0.0)	--	--	--
Interaction								--
ICC Options								
Paclitaxel	83	0 (0.0)	--	79	0 (0.0)	--	--	--
Docetaxel	56	0 (0.0)	--	50	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious IRR

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	0 (0.0)	--	37	0 (0.0)	--	--	--
1	96	0 (0.0)	--	92	0 (0.0)	--	--	--
Interaction								--
Region #1								
Asia	103	0 (0.0)	--	99	0 (0.0)	--	--	--
Europe/North America	36	0 (0.0)	--	30	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious IRR

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	0 (0.0)	--	76	0 (0.0)	--	--	--
Japan	25	0 (0.0)	--	23	0 (0.0)	--	--	--
Europe/North America	36	0 (0.0)	--	30	0 (0.0)	--	--	--
Interaction								--
Race								
Asian and other	105	0 (0.0)	--	106	0 (0.0)	--	--	--
White	34	0 (0.0)	--	23	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious IRR

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	0 (0.0)	--	34	0 (0.0)	--	--	--
vCPS < 10%	53	0 (0.0)	--	54	0 (0.0)	--	--	--
Missing	41	0 (0.0)	--	41	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 IRR included all patients with any Grade 1 or Grade 2 IRR.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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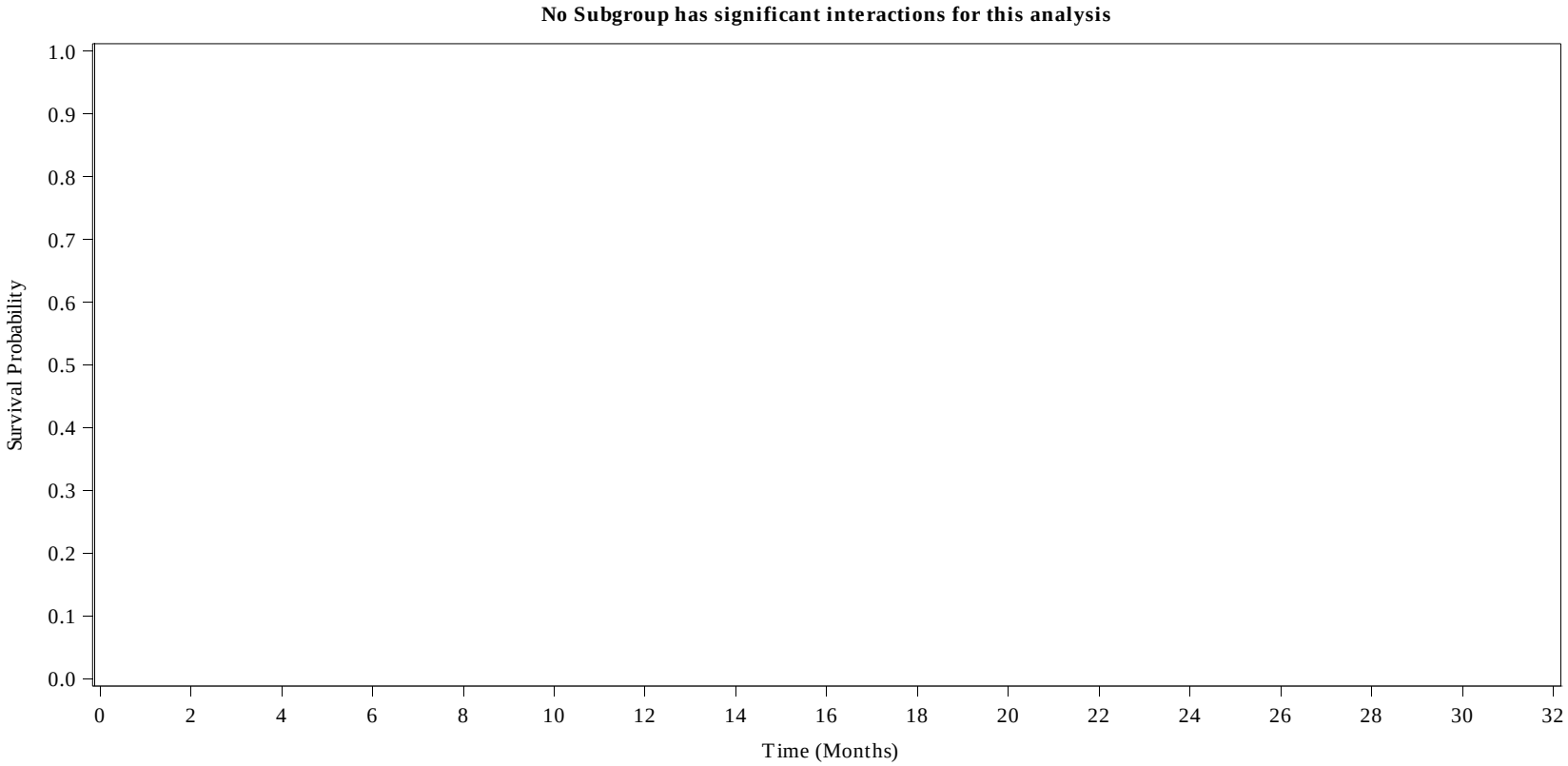
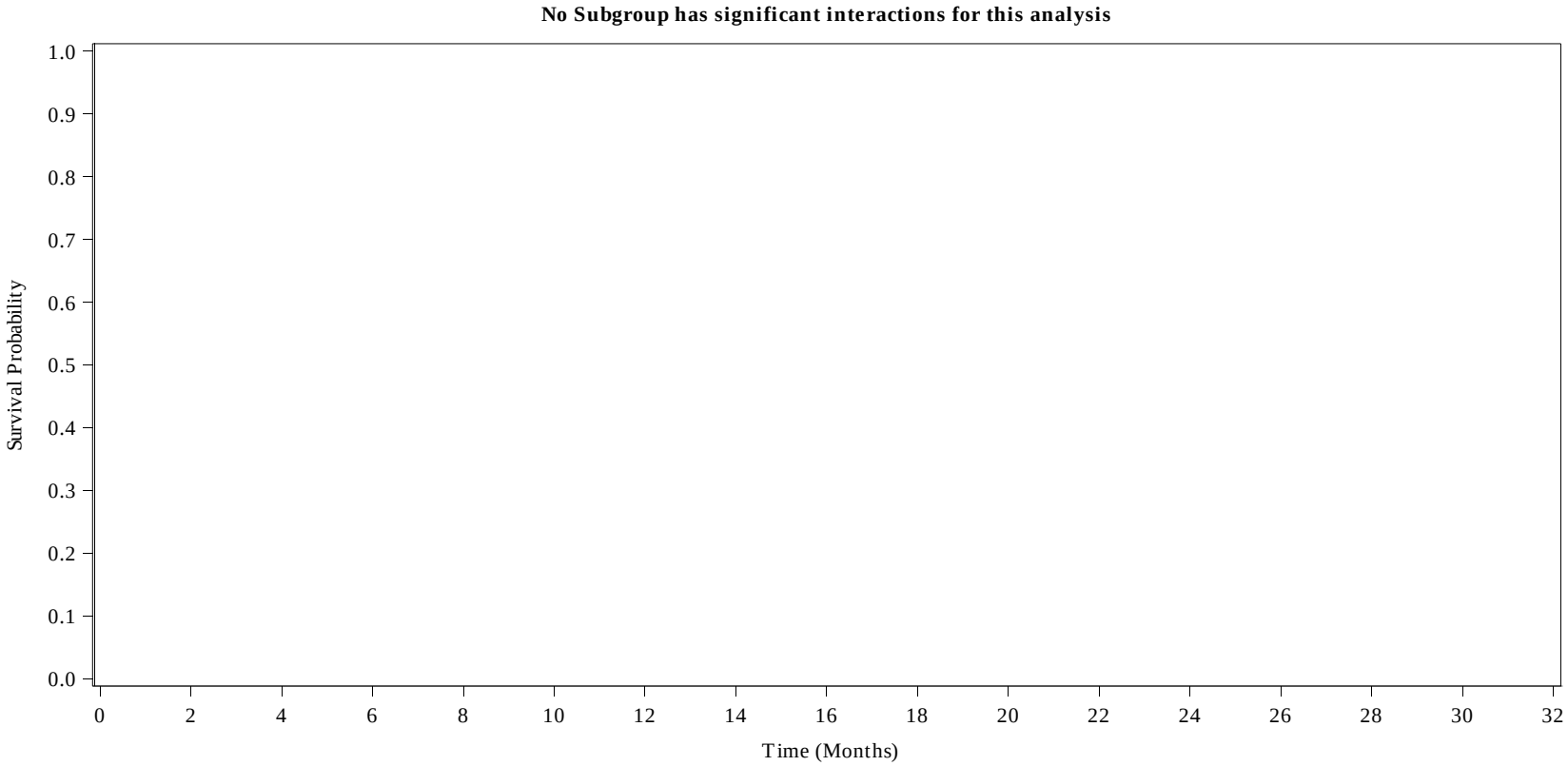
Figure 14.3.1.5.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set



Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesi-subgrp.sas 22AUG2024 05:14 f-14-03-01-05-s-km-aesi-subgrp-safety-sa.rtf

Figure 14.3.1.5.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest: IRR - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 01JUN2021. Data extraction: 24AUG2021.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesi-subgrp.sas 22AUG2024 05:14 f-14-03-01-05-b-s-km-aesi-subgrp-safetys-sa.rtf

Table 14.1.1.2.1.b:
Patient Disposition and Reasons for Discontinuation
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139) n (%)	ICC (N = 138) n (%)	Total (N = 277) n (%)
Number of Patients Randomized	139 (100.0)	138 (100.0)	277 (100.0)
Patients Randomized, but Not Treated	0 (0.0)	9 (6.5)	9 (3.2)
Primary Reason for Not Treated			
Adverse Event	0 (0.0)	2 (1.4)	2 (0.7)
Withdrawal by Subject	0 (0.0)	6 (4.3)	6 (2.2)
Other	0 (0.0)	1 (0.7)	1 (0.4)
Number of Patients Treated	139 (100.0)	129 (93.5)	268 (96.8)

Source: Listing 16.2.1.3, 16.2.1.4. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
[a] Study follow-up duration is defined as the duration from the randomization date to the study discontinuation date (due to death, consent withdrawal, lost to follow-up etc.)
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Table 14.1.1.2.1.b:
Patient Disposition and Reasons for Discontinuation
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139) n (%)	ICC (N = 138) n (%)	Total (N = 277) n (%)
Number of Patients Discontinued From Treatment	139 (100.0)	129 (93.5)	268 (96.8)
Primary Reason for Study Drug Discontinuation			
Radiographic Progression	103 (74.1)	83 (60.1)	186 (67.1)
Adverse Event	17 (12.2)	19 (13.8)	36 (13.0)
Related to COVID-19	0 (0.0)	0 (0.0)	0 (0.0)
Clinical Progression	9 (6.5)	10 (7.2)	19 (6.9)
Related to COVID-19	0 (0.0)	0 (0.0)	0 (0.0)
Study Terminated by Sponsor	5 (3.6)	0 (0.0)	5 (1.8)
Withdrawal by Subject	3 (2.2)	12 (8.7)	15 (5.4)
Physician Decision	0 (0.0)	4 (2.9)	4 (1.4)
Other	2 (1.4)	1 (0.7)	3 (1.1)
Related to COVID-19	0 (0.0)	0 (0.0)	0 (0.0)
Number of Patients Remained on Treatment	0 (0.0)	0 (0.0)	0 (0.0)

Source: Listing 16.2.1.3, 16.2.1.4. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
[a] Study follow-up duration is defined as the duration from the randomization date to the study discontinuation date (due to death, consent withdrawal, lost to follow-up etc.)
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Table 14.1.1.2.1.b:
Patient Disposition and Reasons for Discontinuation
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139) n (%)	ICC (N = 138) n (%)	Total (N = 277) n (%)
Number of Patients Discontinued From Study	139 (100.0)	138 (100.0)	277 (100.0)
Primary Reason for Study Discontinuation			
Subject Death	127 (91.4)	125 (90.6)	252 (91.0)
Related to COVID-19	0 (0.0)	0 (0.0)	0 (0.0)
Termination of The Study by Sponsor	8 (5.8)	4 (2.9)	12 (4.3)
Voluntary Withdrawal by Subject	4 (2.9)	7 (5.1)	11 (4.0)
Subject Lost to Follow-up	0 (0.0)	2 (1.4)	2 (0.7)
Related to COVID-19	0 (0.0)	0 (0.0)	0 (0.0)
Number of Patients Remained on Study	0 (0.0)	0 (0.0)	0 (0.0)
Study Follow-up Duration (months) [a]			
n	139	138	277
Mean (SD)	12.61 (11.875)	9.66 (9.795)	11.14 (10.969)
Median	8.61	6.54	7.39
Q1, Q3	3.91, 16.59	3.29, 12.25	3.68, 14.06
Min, Max	0.4, 49.8	0.1, 46.8	0.1, 49.8

Source: Listing 16.2.1.3, 16.2.1.4. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
[a] Study follow-up duration is defined as the duration from the randomization date to the study discontinuation date (due to death, consent withdrawal, lost to follow-up etc.)
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Table 14.1.2.1:
Summary of Demographics and Baseline Characteristics
ITT Analysis Set

Parameter	Tislelizumab (N = 256)	ICC (N = 256)	Total (N = 512)
Age (years)			
n	256	256	512
Mean (SD)	61.8 (8.41)	61.8 (8.02)	61.8 (8.21)
Median	62.5	63.0	63.0
Q1, Q3	55.0, 67.0	56.0, 67.0	55.5, 67.0
Min, Max	40, 86	35, 81	35, 86
Age Group, n (%)			
<65 years	152 (59.4)	158 (61.7)	310 (60.5)
>=65 years	104 (40.6)	98 (38.3)	202 (39.5)
Gender, n (%)			
Female	39 (15.2)	41 (16.0)	80 (15.6)
Male	217 (84.8)	215 (84.0)	432 (84.4)

Source: Listing 16.2.4.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; BMI = Body Mass Index; ECOG = Eastern Cooperative Oncology Group; vCPS = visually-estimated combined positive score.

Percentages were based on N.

PD-L1 positive is defined as vCPS >= 10%, PD-L1 negative is defined as vCPS < 10%, PD-L1 missing refers to the patients without sample collection, not evaluable at baseline, or scored with unqualified sample.

[a] 3 patients refused to report race and were entered with race of "unknown" by the site.

[b] 3 patients refused to report ethnicity and were entered with ethnicity of "unknown" by the site.

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Table 14.1.2.1:
Summary of Demographics and Baseline Characteristics
ITT Analysis Set

Parameter	Tislelizumab (N = 256)	ICC (N = 256)	Total (N = 512)
Race, n (%)			
Asian	201 (78.5)	207 (80.9)	408 (79.7)
Chinese	161 (62.9)	163 (63.7)	324 (63.3)
Japanese	25 (9.8)	25 (9.8)	50 (9.8)
Korean	15 (5.9)	16 (6.3)	31 (6.1)
Asian Indian	0 (0.0)	3 (1.2)	3 (0.6)
White or Caucasian	53 (20.7)	44 (17.2)	97 (18.9)
Not Reported [a]	1 (0.4)	0 (0.0)	1 (0.2)
Unknown	1 (0.4)	2 (0.8)	3 (0.6)
Black or African American	0 (0.0)	2 (0.8)	2 (0.4)
Other	0 (0.0)	1 (0.4)	1 (0.2)
Ethnicity, n (%)			
Not Hispanic or Latino	252 (98.4)	252 (98.4)	504 (98.4)
Hispanic or Latino	2 (0.8)	2 (0.8)	4 (0.8)
Not Reported [b]	1 (0.4)	0 (0.0)	1 (0.2)
Unknown	1 (0.4)	2 (0.8)	3 (0.6)

Source: Listing 16.2.4.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; BMI = Body Mass Index; ECOG = Eastern Cooperative Oncology Group; vCPS = visually-estimated combined positive score.

Percentages were based on N.

PD-L1 positive is defined as vCPS >= 10%, PD-L1 negative is defined as vCPS < 10%, PD-L1 missing refers to the patients without sample collection, not evaluable at baseline, or scored with unqualified sample.

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[b] 3 patients refused to report ethnicity and were entered with ethnicity of "unknown" by the site.

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Table 14.1.2.1:
Summary of Demographics and Baseline Characteristics
ITT Analysis Set

Parameter	Tislelizumab (N = 256)	ICC (N = 256)	Total (N = 512)
ECOG Status, n (%)			
0	66 (25.8)	61 (23.8)	127 (24.8)
1	190 (74.2)	195 (76.2)	385 (75.2)
Height (cm)			
n	254	256	510
Mean (SD)	166.89 (6.862)	166.56 (7.842)	166.72 (7.365)
Median	168.00	167.00	168.00
Q1, Q3	163.00, 172.00	162.00, 172.00	162.50, 172.00
Min, Max	147.0, 182.9	140.0, 189.0	140.0, 189.0
Weight (kg)			
n	256	256	512
Mean (SD)	59.32 (10.275)	60.15 (11.745)	59.73 (11.032)
Median	58.85	59.55	59.00
Q1, Q3	52.25, 66.00	52.00, 67.00	52.00, 66.10
Min, Max	37.5, 99.0	37.2, 105.0	37.2, 105.0

Source: Listing 16.2.4.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; BMI = Body Mass Index; ECOG = Eastern Cooperative Oncology Group; vCPS = visually-estimated combined positive score.

Percentages were based on N.

PD-L1 positive is defined as vCPS >= 10%, PD-L1 negative is defined as vCPS < 10%, PD-L1 missing refers to the patients without sample collection, not evaluable at baseline, or scored with unqualified sample.

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[b] 3 patients refused to report ethnicity and were entered with ethnicity of "unknown" by the site.

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Table 14.1.2.1:
Summary of Demographics and Baseline Characteristics
ITT Analysis Set

Parameter	Tislelizumab (N = 256)	ICC (N = 256)	Total (N = 512)
BMI (kg/m^2)			
n	254	256	510
Mean (SD)	21.27 (3.393)	21.62 (3.569)	21.45 (3.483)
Median	21.06	21.15	21.10
Q1, Q3	18.75, 23.18	18.85, 23.89	18.83, 23.48
Min, Max	14.0, 37.7	14.3, 33.1	14.0, 37.7
PD-L1 Status, n (%)			
vCPS >= 10%	80 (31.3)	62 (24.2)	142 (27.7)
vCPS < 10%	100 (39.1)	122 (47.7)	222 (43.4)
Missing	76 (29.7)	72 (28.1)	148 (28.9)
Smoking Status, n (%)			
Never	68 (26.6)	63 (24.6)	131 (25.6)
Former	162 (63.3)	159 (62.1)	321 (62.7)
Current	26 (10.2)	33 (12.9)	59 (11.5)
Missing	0 (0.0)	1 (0.4)	1 (0.2)

Source: Listing 16.2.4.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; BMI = Body Mass Index; ECOG = Eastern Cooperative Oncology Group; vCPS = visually-estimated combined positive score.
Percentages were based on N.
PD-L1 positive is defined as vCPS >= 10%, PD-L1 negative is defined as vCPS < 10%, PD-L1 missing refers to the patients without sample collection, not evaluable at baseline, or scored with unqualified sample.
[a] 3 patients refused to report race and were entered with race of "unknown" by the site.
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Table 14.1.2.1:
Summary of Demographics and Baseline Characteristics
ITT Analysis Set

Parameter	Tislelizumab (N = 256)	ICC (N = 256)	Total (N = 512)
Alcohol Consumption, n (%)			
Never	74 (28.9)	73 (28.5)	147 (28.7)
Former	146 (57.0)	151 (59.0)	297 (58.0)
Current	35 (13.7)	31 (12.1)	66 (12.9)
Missing	1 (0.4)	1 (0.4)	2 (0.4)
ICC Options, n (%)			
Paclitaxel	83 (32.4)	85 (33.2)	168 (32.8)
Docetaxel	56 (21.9)	53 (20.7)	109 (21.3)
Irinotecan	117 (45.7)	118 (46.1)	235 (45.9)
Region #1, n (%)			
Asia	201 (78.5)	203 (79.3)	404 (78.9)
Europe/North America	55 (21.5)	53 (20.7)	108 (21.1)

Source: Listing 16.2.4.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; BMI = Body Mass Index; ECOG = Eastern Cooperative Oncology Group; vCPS = visually-estimated combined positive score.
Percentages were based on N.
PD-L1 positive is defined as vCPS >= 10%, PD-L1 negative is defined as vCPS < 10%, PD-L1 missing refers to the patients without sample collection, not evaluable at baseline, or scored with unqualified sample.
[a] 3 patients refused to report race and were entered with race of "unknown" by the site.
[b] 3 patients refused to report ethnicity and were entered with ethnicity of "unknown" by the site.
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Table 14.1.2.1:
Summary of Demographics and Baseline Characteristics
ITT Analysis Set

Parameter	Tislelizumab (N = 256)	ICC (N = 256)	Total (N = 512)
Region #2, n (%)			
Asia (excluding Japan)	176 (68.8)	178 (69.5)	354 (69.1)
Japan	25 (9.8)	25 (9.8)	50 (9.8)
Europe/North America	55 (21.5)	53 (20.7)	108 (21.1)

Source: Listing 16.2.4.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; BMI = Body Mass Index; ECOG = Eastern Cooperative Oncology Group; vCPS = visually-estimated combined positive score.

Percentages were based on N.

PD-L1 positive is defined as vCPS >= 10%, PD-L1 negative is defined as vCPS < 10%, PD-L1 missing refers to the patients without sample collection, not evaluable at baseline, or scored with unqualified sample.

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Table 14.1.2.1.b:
Summary of Demographics and Baseline Characteristics
ITT Analysis Set - Subpopulation without Irinotecan

Parameter	Tislelizumab (N = 139)	ICC (N = 138)	Total (N = 277)
Age (years)			
n	139	138	277
Mean (SD)	62.1 (9.10)	62.9 (8.42)	62.5 (8.76)
Median	63.0	64.0	64.0
Q1, Q3	55.0, 69.0	58.0, 68.0	56.0, 68.0
Min, Max	40, 83	35, 81	35, 83
Age Group, n (%)			
<65 years	76 (54.7)	76 (55.1)	152 (54.9)
>=65 years	63 (45.3)	62 (44.9)	125 (45.1)
Gender, n (%)			
Female	21 (15.1)	27 (19.6)	48 (17.3)
Male	118 (84.9)	111 (80.4)	229 (82.7)

Source: Listing 16.2.4.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; BMI = Body Mass Index; ECOG = Eastern Cooperative Oncology Group; vCPS = visually-estimated combined positive score.
Percentages were based on N.
PD-L1 positive is defined as vCPS >= 10%, PD-L1 negative is defined as vCPS < 10%, PD-L1 missing refers to the patients without sample collection, not evaluable at baseline, or scored with unqualified sample.
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Table 14.1.2.1.b:
Summary of Demographics and Baseline Characteristics
ITT Analysis Set - Subpopulation without Irinotecan

Parameter	Tislelizumab (N = 139)	ICC (N = 138)	Total (N = 277)
Race, n (%)			
Asian	103 (74.1)	109 (79.0)	212 (76.5)
Chinese	66 (47.5)	66 (47.8)	132 (47.7)
Japanese	25 (18.0)	25 (18.1)	50 (18.1)
Korean	12 (8.6)	15 (10.9)	27 (9.7)
Asian Indian	0 (0.0)	3 (2.2)	3 (1.1)
White or Caucasian	34 (24.5)	24 (17.4)	58 (20.9)
Not Reported [a]	1 (0.7)	0 (0.0)	1 (0.4)
Unknown	1 (0.7)	2 (1.4)	3 (1.1)
Black or African American	0 (0.0)	2 (1.4)	2 (0.7)
Other	0 (0.0)	1 (0.7)	1 (0.4)
Ethnicity, n (%)			
Not Hispanic or Latino	135 (97.1)	134 (97.1)	269 (97.1)
Hispanic or Latino	2 (1.4)	2 (1.4)	4 (1.4)
Not Reported [b]	1 (0.7)	0 (0.0)	1 (0.4)
Unknown	1 (0.7)	2 (1.4)	3 (1.1)

Source: Listing 16.2.4.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; BMI = Body Mass Index; ECOG = Eastern Cooperative Oncology Group; vCPS = visually-estimated combined positive score.

Percentages were based on N.

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Table 14.1.2.1.b:
Summary of Demographics and Baseline Characteristics
ITT Analysis Set - Subpopulation without Irinotecan

Parameter	Tislelizumab (N = 139)	ICC (N = 138)	Total (N = 277)
ECOG Status, n (%)			
0	44 (31.7)	40 (29.0)	84 (30.3)
1	95 (68.3)	98 (71.0)	193 (69.7)
Height (cm)			
n	139	138	277
Mean (SD)	166.59 (6.813)	165.84 (7.904)	166.22 (7.373)
Median	167.00	167.00	167.00
Q1, Q3	163.00, 171.50	160.00, 170.30	162.00, 171.00
Min, Max	149.0, 182.9	140.0, 189.0	140.0, 189.0
Weight (kg)			
n	139	138	277
Mean (SD)	59.03 (10.402)	58.98 (11.154)	59.00 (10.764)
Median	58.00	58.70	58.00
Q1, Q3	52.50, 66.00	50.40, 67.00	51.80, 66.00
Min, Max	38.4, 99.0	37.2, 101.3	37.2, 101.3

Source: Listing 16.2.4.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; BMI = Body Mass Index; ECOG = Eastern Cooperative Oncology Group; vCPS = visually-estimated combined positive score.

Percentages were based on N.

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[b] 3 patients refused to report ethnicity and were entered with ethnicity of "unknown" by the site.

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Table 14.1.2.1.b:
Summary of Demographics and Baseline Characteristics
ITT Analysis Set - Subpopulation without Irinotecan

Parameter	Tislelizumab (N = 139)	ICC (N = 138)	Total (N = 277)
BMI (kg/m^2)			
n	139	138	277
Mean (SD)	21.26 (3.499)	21.40 (3.542)	21.33 (3.515)
Median	21.08	21.12	21.11
Q1, Q3	18.82, 23.05	18.66, 24.02	18.80, 23.47
Min, Max	14.2, 37.7	14.3, 32.1	14.2, 37.7
PD-L1 Status, n (%)			
vCPS >= 10%	45 (32.4)	34 (24.6)	79 (28.5)
vCPS < 10%	53 (38.1)	56 (40.6)	109 (39.4)
Missing	41 (29.5)	48 (34.8)	89 (32.1)
Smoking Status, n (%)			
Never	35 (25.2)	33 (23.9)	68 (24.5)
Former	86 (61.9)	90 (65.2)	176 (63.5)
Current	18 (12.9)	15 (10.9)	33 (11.9)

Source: Listing 16.2.4.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; BMI = Body Mass Index; ECOG = Eastern Cooperative Oncology Group; vCPS = visually-estimated combined positive score.

Percentages were based on N.

PD-L1 positive is defined as vCPS >= 10%, PD-L1 negative is defined as vCPS < 10%, PD-L1 missing refers to the patients without sample collection, not evaluable at baseline, or scored with unqualified sample.

[a] 3 patients refused to report race and were entered with race of "unknown" by the site.

[b] 3 patients refused to report ethnicity and were entered with ethnicity of "unknown" by the site.

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Table 14.1.2.1.b:
Summary of Demographics and Baseline Characteristics
ITT Analysis Set - Subpopulation without Irinotecan

Parameter	Tislelizumab (N = 139)	ICC (N = 138)	Total (N = 277)
Alcohol Consumption, n (%)			
Never	34 (24.5)	30 (21.7)	64 (23.1)
Former	80 (57.6)	88 (63.8)	168 (60.6)
Current	24 (17.3)	19 (13.8)	43 (15.5)
Missing	1 (0.7)	1 (0.7)	2 (0.7)
ICC Options, n (%)			
Paclitaxel	83 (59.7)	85 (61.6)	168 (60.6)
Docetaxel	56 (40.3)	53 (38.4)	109 (39.4)
Region #1, n (%)			
Asia	103 (74.1)	105 (76.1)	208 (75.1)
Europe/North America	36 (25.9)	33 (23.9)	69 (24.9)

Source: Listing 16.2.4.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; BMI = Body Mass Index; ECOG = Eastern Cooperative Oncology Group; vCPS = visually-estimated combined positive score.

Percentages were based on N.

PD-L1 positive is defined as vCPS >= 10%, PD-L1 negative is defined as vCPS < 10%, PD-L1 missing refers to the patients without sample collection, not evaluable at baseline, or scored with unqualified sample.

[a] 3 patients refused to report race and were entered with race of "unknown" by the site.

[b] 3 patients refused to report ethnicity and were entered with ethnicity of "unknown" by the site.

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Table 14.1.2.1.b:
Summary of Demographics and Baseline Characteristics
ITT Analysis Set - Subpopulation without Irinotecan

Parameter	Tislelizumab (N = 139)	ICC (N = 138)	Total (N = 277)
Region #2, n (%)			
Asia (excluding Japan)	78 (56.1)	80 (58.0)	158 (57.0)
Japan	25 (18.0)	25 (18.1)	50 (18.1)
Europe/North America	36 (25.9)	33 (23.9)	69 (24.9)

Source: Listing 16.2.4.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; BMI = Body Mass Index; ECOG = Eastern Cooperative Oncology Group; vCPS = visually-estimated combined positive score.

Percentages were based on N.

PD-L1 positive is defined as vCPS >= 10%, PD-L1 negative is defined as vCPS < 10%, PD-L1 missing refers to the patients without sample collection, not evaluable at baseline, or scored with unqualified sample.

[a] 3 patients refused to report race and were entered with race of "unknown" by the site.

[b] 3 patients refused to report ethnicity and were entered with ethnicity of "unknown" by the site.

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Table 14.1.3.1:
Disease History and Characteristics at Study Entry
ITT Analysis Set

Description	Tislelizumab (N = 256)	ICC (N = 256)	Total (N = 512)
Number of Patient With Metastatic Diagnosis at Study Entry, n (%)			
Yes	251 (98.0)	236 (92.2)	487 (95.1)
No	5 (2.0)	20 (7.8)	25 (4.9)
Time from Metastatic Diagnosis to Study Entry (months)			
n	251	236	487
Mean (SD)	6.72 (6.568)	7.09 (6.791)	6.90 (6.673)
Median	5.29	5.37	5.36
Q1, Q3	1.18, 9.89	1.95, 10.00	1.61, 9.92
Min, Max	0.2, 43.5	0.2, 53.0	0.2, 53.0
Prior Systemic Therapy, n (%)			
Chemotherapy	94 (36.7)	101 (39.5)	195 (38.1)
Chemo-Radiotherapy	161 (62.9)	155 (60.5)	316 (61.7)
Other *	1 (0.4)	0 (0.0)	1 (0.2)

Source: Listing 16.2.4.4. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Percentages were based on N.
Study Entry date referred to randomization date in this study.
[a] A patient was counted only once within each category, but may be counted in multiple categories.
* Other was the combination of chemotherapy and a monoclonal antibody of epidermal growth factor receptor.
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Table 14.1.3.1:
Disease History and Characteristics at Study Entry
ITT Analysis Set

Description	Tislelizumab (N = 256)	ICC (N = 256)	Total (N = 512)
Primary Site of Esophageal Cancer at Diagnosis, n (%)			
Cervical	6 (2.3)	4 (1.6)	10 (2.0)
Upper	42 (16.4)	49 (19.1)	91 (17.8)
Middle	107 (41.8)	86 (33.6)	193 (37.7)
Lower	68 (26.6)	86 (33.6)	154 (30.1)
Overlapping Lesions	11 (4.3)	9 (3.5)	20 (3.9)
Esophagus NOS	22 (8.6)	22 (8.6)	44 (8.6)
Histologic Grade at Diagnosis, n (%)			
Gx - Grade cannot be assessed	19 (7.4)	14 (5.5)	33 (6.4)
G1 - Well differentiated	23 (9.0)	16 (6.3)	39 (7.6)
G2 - Moderately differentiated	86 (33.6)	97 (37.9)	183 (35.7)
G3 - Poorly differentiated	49 (19.1)	58 (22.7)	107 (20.9)
Not Done	79 (30.9)	71 (27.7)	150 (29.3)

Source: Listing 16.2.4.4. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Percentages were based on N.
Study Entry date referred to randomization date in this study.
[a] A patient was counted only once within each category, but may be counted in multiple categories.
* Other was the combination of chemotherapy and a monoclonal antibody of epidermal growth factor receptor.
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Table 14.1.3.1:
Disease History and Characteristics at Study Entry
ITT Analysis Set

Description	Tislelizumab (N = 256)	ICC (N = 256)	Total (N = 512)
Target Lesions Sum of Diameter by Investigator (mm)			
n	237	246	483
Mean (SD)	49.30 (32.325)	49.35 (32.307)	49.33 (32.282)
Median	42.00	42.00	42.00
Q1, Q3	25.70, 66.20	23.00, 66.00	24.60, 66.00
Min, Max	10.0, 261.0	10.0, 238.0	10.0, 261.0

Source: Listing 16.2.4.4. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Percentages were based on N.
Study Entry date referred to randomization date in this study.
[a] A patient was counted only once within each category, but may be counted in multiple categories.
* Other was the combination of chemotherapy and a monoclonal antibody of epidermal growth factor receptor.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-dh.sas 05JUN2024 17:40 t-14-01-03-01-dh-itt-cl.rtf

Table 14.1.3.1:
Disease History and Characteristics at Study Entry
ITT Analysis Set

Description	Tislelizumab (N = 256)	ICC (N = 256)	Total (N = 512)
Target/Non-Target Lesion Location at Study Entry, n (%) [a]			
Lymph nodes	186 (72.7)	192 (75.0)	378 (73.8)
Lung	116 (45.3)	119 (46.5)	235 (45.9)
Esophagus	110 (43.0)	107 (41.8)	217 (42.4)
Liver	76 (29.7)	69 (27.0)	145 (28.3)
Pleura	32 (12.5)	24 (9.4)	56 (10.9)
Bone	30 (11.7)	32 (12.5)	62 (12.1)
Peritoneum	16 (6.3)	9 (3.5)	25 (4.9)
Adrenal gland	11 (4.3)	11 (4.3)	22 (4.3)
Gastroesophageal Junction	7 (2.7)	5 (2.0)	12 (2.3)
Brain	3 (1.2)	0 (0.0)	3 (0.6)
Soft tissue	3 (1.2)	4 (1.6)	7 (1.4)
Muscle	1 (0.4)	1 (0.4)	2 (0.4)
Skin	1 (0.4)	1 (0.4)	2 (0.4)
Other	40 (15.6)	50 (19.5)	90 (17.6)

Source: Listing 16.2.4.4. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Percentages were based on N.
Study Entry date referred to randomization date in this study.
[a] A patient was counted only once within each category, but may be counted in multiple categories.
* Other was the combination of chemotherapy and a monoclonal antibody of epidermal growth factor receptor.
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Table 14.1.3.1:
Disease History and Characteristics at Study Entry
ITT Analysis Set

Description	Tislelizumab (N = 256)	ICC (N = 256)	Total (N = 512)
Time from Initial Cancer Diagnosis to Study Entry (months)			
n	256	256	512
Mean (SD)	14.51 (14.212)	15.86 (16.885)	15.18 (15.605)
Median	10.14	10.07	10.12
Q1, Q3	6.80, 15.49	6.59, 18.76	6.65, 17.69
Min, Max	2.0, 119.8	2.1, 170.5	2.0, 170.5

Source: Listing 16.2.4.4. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Percentages were based on N.
Study Entry date referred to randomization date in this study.
[a] A patient was counted only once within each category, but may be counted in multiple categories.
* Other was the combination of chemotherapy and a monoclonal antibody of epidermal growth factor receptor.
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Table 14.1.3.1.b:
Disease History and Characteristics at Study Entry
ITT Analysis Set - Subpopulation without Irinotecan

Description	Tislelizumab (N = 139)	ICC (N = 138)	Total (N = 277)
Number of Patient With Metastatic Diagnosis at Study Entry, n (%)			
Yes	137 (98.6)	125 (90.6)	262 (94.6)
No	2 (1.4)	13 (9.4)	15 (5.4)
Time from Metastatic Diagnosis to Study Entry (months)			
n	137	125	262
Mean (SD)	6.15 (5.301)	7.36 (6.789)	6.73 (6.075)
Median	4.99	6.21	5.29
Q1, Q3	1.41, 9.56	1.64, 10.32	1.45, 9.92
Min, Max	0.3, 26.5	0.2, 34.4	0.2, 34.4
Prior Systemic Therapy, n (%)			
Chemotherapy	49 (35.3)	61 (44.2)	110 (39.7)
Chemo-Radiotherapy	90 (64.7)	77 (55.8)	167 (60.3)

Source: Listing 16.2.4.4. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Study Entry date referred to randomization date in this study.
[a] A patient was counted only once within each category, but may be counted in multiple categories.
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Table 14.1.3.1.b:
Disease History and Characteristics at Study Entry
ITT Analysis Set - Subpopulation without Irinotecan

Description	Tislelizumab (N = 139)	ICC (N = 138)	Total (N = 277)
Primary Site of Esophageal Cancer at Diagnosis, n (%)			
Cervical	4 (2.9)	3 (2.2)	7 (2.5)
Upper	22 (15.8)	26 (18.8)	48 (17.3)
Middle	59 (42.4)	42 (30.4)	101 (36.5)
Lower	35 (25.2)	49 (35.5)	84 (30.3)
Overlapping Lesions	6 (4.3)	4 (2.9)	10 (3.6)
Esophagus NOS	13 (9.4)	14 (10.1)	27 (9.7)
Histologic Grade at Diagnosis, n (%)			
Gx - Grade cannot be assessed	16 (11.5)	12 (8.7)	28 (10.1)
G1 - Well differentiated	15 (10.8)	9 (6.5)	24 (8.7)
G2 - Moderately differentiated	48 (34.5)	56 (40.6)	104 (37.5)
G3 - Poorly differentiated	26 (18.7)	32 (23.2)	58 (20.9)
Not Done	34 (24.5)	29 (21.0)	63 (22.7)

Source: Listing 16.2.4.4. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Study Entry date referred to randomization date in this study.
[a] A patient was counted only once within each category, but may be counted in multiple categories.
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Table 14.1.3.1.b:
Disease History and Characteristics at Study Entry
ITT Analysis Set - Subpopulation without Irinotecan

Description	Tislelizumab (N = 139)	ICC (N = 138)	Total (N = 277)
Target Lesions Sum of Diameter by Investigator (mm)			
n	125	131	256
Mean (SD)	49.24 (35.087)	51.01 (36.609)	50.14 (35.815)
Median	41.40	41.00	41.20
Q1, Q3	23.00, 66.90	21.40, 66.00	22.00, 66.45
Min, Max	10.0, 261.0	12.0, 238.0	10.0, 261.0

Source: Listing 16.2.4.4. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Study Entry date referred to randomization date in this study.
[a] A patient was counted only once within each category, but may be counted in multiple categories.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-dh.sas 05JUN2024 17:40 t-14-01-03-01-b-dh-itts-cl.rtf

Table 14.1.3.1.b:
Disease History and Characteristics at Study Entry
ITT Analysis Set - Subpopulation without Irinotecan

Description	Tislelizumab (N = 139)	ICC (N = 138)	Total (N = 277)
Target/Non-Target Lesion Location at Study Entry, n (%) [a]			
Lymph nodes	100 (71.9)	99 (71.7)	199 (71.8)
Esophagus	66 (47.5)	59 (42.8)	125 (45.1)
Lung	62 (44.6)	61 (44.2)	123 (44.4)
Liver	34 (24.5)	40 (29.0)	74 (26.7)
Pleura	19 (13.7)	14 (10.1)	33 (11.9)
Bone	15 (10.8)	16 (11.6)	31 (11.2)
Peritoneum	9 (6.5)	6 (4.3)	15 (5.4)
Adrenal gland	6 (4.3)	5 (3.6)	11 (4.0)
Gastroesophageal Junction	4 (2.9)	3 (2.2)	7 (2.5)
Soft tissue	3 (2.2)	2 (1.4)	5 (1.8)
Brain	2 (1.4)	0 (0.0)	2 (0.7)
Skin	1 (0.7)	0 (0.0)	1 (0.4)
Muscle	0 (0.0)	1 (0.7)	1 (0.4)
Other	22 (15.8)	24 (17.4)	46 (16.6)

Source: Listing 16.2.4.4. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Study Entry date referred to randomization date in this study.
[a] A patient was counted only once within each category, but may be counted in multiple categories.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-dh.sas 05JUN2024 17:40 t-14-01-03-01-b-dh-itts-cl.rtf

Table 14.1.3.1.b:
Disease History and Characteristics at Study Entry
ITT Analysis Set - Subpopulation without Irinotecan

Description	Tislelizumab (N = 139)	ICC (N = 138)	Total (N = 277)
Time from Initial Cancer Diagnosis to Study Entry (months)			
n	139	138	277
Mean (SD)	15.26 (16.413)	14.52 (13.109)	14.89 (14.837)
Median	10.12	9.92	9.99
Q1, Q3	6.87, 15.57	6.08, 18.33	6.64, 17.02
Min, Max	2.0, 119.8	2.1, 79.4	2.0, 119.8

Source: Listing 16.2.4.4. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Study Entry date referred to randomization date in this study.
[a] A patient was counted only once within each category, but may be counted in multiple categories.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-dh.sas 05JUN2024 17:40 t-14-01-03-01-b-dh-itts-cl.rtf

Table 14.1.5.1.b:
Prior Anti-Cancer Systemic Therapy
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)	ICC (N = 138)	Total (N = 277)
Patients With at Least One Prior Systemic Therapy, n (%)	139 (100.0)	138 (100.0)	277 (100.0)
Patients With Prior Line of Platinum-based Systemic Therapy [a], n (%)	131 (94.2)	135 (97.8)	266 (96.0)
Number of Prior Line of Systemic Therapies [b], n (%)			
0	0 (0.0)	1 (0.7)	1 (0.4)
1	139 (100.0)	137 (99.3)	276 (99.6)
Prior Neo-Adjuvant/Adjuvant Treatment or Definitive Chemoradiotherapy as First Line Systemic Therapies [c], n (%)			
Neo-Adjuvant/Adjuvant Treatment	27 (19.4)	16 (11.6)	43 (15.5)
Definitive Chemoradiotherapy	16 (11.5)	20 (14.5)	36 (13.0)

Source: Listing 16.2.4.7. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
[a] Platinum-based regimen in the first-line systemic therapy was requested for enrollment eligibility since Protocol Amendment version 3.0.
[b] Based on protocol deviation of inclusion criteria #4 and exclusion criteria #1 identified in the study.
[c] Neoadjuvant/adjuvant chemotherapy or chemoradiotherapy, or definitive chemoradiotherapy received by patients who had disease progression during treatment or <= 6 months (180 days) of cessation of treatment was counted as one prior line. Definitive chemoradiotherapy data were provided based on medical review on relevant data collected in the EDC.
[d] Study Entry date referred to randomization date in this study.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-pr-cst-fp1.sas 05JUN2024 17:44 t-14-01-05-01-b-pr-cst-fp1-itts-cl.rtf

Table 14.1.5.1.b:
Prior Anti-Cancer Systemic Therapy
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)	ICC (N = 138)	Total (N = 277)
Duration of Last Prior Anti-Cancer Systemic Therapy (months)			
n	139	138	277
Mean (SD)	3.35 (3.203)	3.51 (3.723)	3.43 (3.467)
Median	2.73	2.73	2.73
Q1, Q3	1.12, 4.50	1.05, 4.70	1.12, 4.63
Min, Max	0.0, 17.1	0.0, 28.8	0.0, 28.8
Time From End of Last Prior Anti-Cancer Systemic Therapy to Study Entry [d] (months)			
n	139	138	277
Mean (SD)	4.33 (3.551)	4.09 (4.272)	4.21 (3.922)
Median	3.42	2.43	2.73
Q1, Q3	1.58, 6.21	1.45, 5.45	1.48, 5.78
Min, Max	0.6, 18.5	0.5, 30.4	0.5, 30.4

Source: Listing 16.2.4.7. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

Percentages were based on N.

[a] Platinum-based regimen in the first-line systemic therapy was requested for enrollment eligibility since Protocol Amendment version 3.0.

[b] Based on protocol deviation of inclusion criteria #4 and exclusion criteria #1 identified in the study.

[c] Neoadjuvant/adjuvant chemotherapy or chemoradiotherapy, or definitive chemoradiotherapy received by patients who had disease progression during treatment or <= 6 months (180 days) of cessation of treatment was counted as one prior line. Definitive chemoradiotherapy data were provided based on medical review on relevant data collected in the EDC.

[d] Study Entry date referred to randomization date in this study.

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Table 14.1.5.1.4.b:
Last Prior Anti-Cancer Systemic Therapy Before Study Entry
ITT Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 138) n (%)	Total (N = 277) n (%)
Platinum Compounds	131 (94.2)	135 (97.8)	266 (96.0)
Cisplatin	75 (54.0)	85 (61.6)	160 (57.8)
Nedaplatin	28 (20.1)	18 (13.0)	46 (16.6)
Oxaliplatin	20 (14.4)	25 (18.1)	45 (16.2)
Carboplatin	8 (5.8)	7 (5.1)	15 (5.4)
Lobaplatin	3 (2.2)	5 (3.6)	8 (2.9)
Pyrimidine Analogues	103 (74.1)	111 (80.4)	214 (77.3)
Fluorouracil	80 (57.6)	75 (54.3)	155 (56.0)
Capecitabine	13 (9.4)	19 (13.8)	32 (11.6)
Tegafur	8 (5.8)	5 (3.6)	13 (4.7)
Gimeracil;oteracil Potassium;tegafur	3 (2.2)	10 (7.2)	13 (4.7)
Tegafur;uracil	3 (2.2)	2 (1.4)	5 (1.8)
Gemcitabine	0 (0.0)	2 (1.4)	2 (0.7)

Source: Listing 16.2.4.7. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.5.1.4.b:
Last Prior Anti-Cancer Systemic Therapy Before Study Entry
ITT Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 138) n (%)	Total (N = 277) n (%)
Taxanes	43 (30.9)	34 (24.6)	77 (27.8)
Paclitaxel	21 (15.1)	17 (12.3)	38 (13.7)
Docetaxel	17 (12.2)	14 (10.1)	31 (11.2)
Paclitaxel Liposome	5 (3.6)	2 (1.4)	7 (2.5)
Paclitaxel Nanoparticle Albumin-Bound	0 (0.0)	1 (0.7)	1 (0.4)
Detoxifying Agents For Antineoplastic Treatment	20 (14.4)	16 (11.6)	36 (13.0)
Folinic Acid	14 (10.1)	12 (8.7)	26 (9.4)
Calcium Folinate	2 (1.4)	2 (1.4)	4 (1.4)
Levofolinic Acid	2 (1.4)	0 (0.0)	2 (0.7)
Calcium Levofolinate	1 (0.7)	1 (0.7)	2 (0.7)
Gimeracil	1 (0.7)	1 (0.7)	2 (0.7)
Oteracil Potassium	1 (0.7)	1 (0.7)	2 (0.7)
Anthracyclines And Related Substances	2 (1.4)	2 (1.4)	4 (1.4)
Epirubicin	2 (1.4)	2 (1.4)	4 (1.4)
Folic Acid Analogues	2 (1.4)	3 (2.2)	5 (1.8)
Raltitrexed	2 (1.4)	3 (2.2)	5 (1.8)

Source: Listing 16.2.4.7. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.5.1.4.b:
Last Prior Anti-Cancer Systemic Therapy Before Study Entry
ITT Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 138) n (%)	Total (N = 277) n (%)
Topoisomerase 1 (Top1) Inhibitors	2 (1.4)	1 (0.7)	3 (1.1)
Irinotecan	2 (1.4)	1 (0.7)	3 (1.1)
Combinations Of Antineoplastic Agents	1 (0.7)	0 (0.0)	1 (0.4)
Fluorouracil;folinic Acid;oxaliplatin	1 (0.7)	0 (0.0)	1 (0.4)
Nitrogen Mustard Analogues	1 (0.7)	0 (0.0)	1 (0.4)
Cyclophosphamide	1 (0.7)	0 (0.0)	1 (0.4)
Vascular Endothelial Growth Factor Receptor (Vegfr) Tyrosine Kinase Inhibitors	1 (0.7)	0 (0.0)	1 (0.4)
Rivoceranib Mesylate	1 (0.7)	0 (0.0)	1 (0.4)
Egfr (Epidermal Growth Factor Receptor) Inhibitors	0 (0.0)	4 (2.9)	4 (1.4)
Cetuximab	0 (0.0)	1 (0.7)	1 (0.4)
Nimotuzumab	0 (0.0)	3 (2.2)	3 (1.1)
Other Antineoplastic Agents	0 (0.0)	1 (0.7)	1 (0.4)
Endostatin	0 (0.0)	1 (0.7)	1 (0.4)

Source: Listing 16.2.4.7. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.5.1.4.b:
Last Prior Anti-Cancer Systemic Therapy Before Study Entry
ITT Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 138) n (%)	Total (N = 277) n (%)
Other Cytotoxic Antibiotics	0 (0.0)	1 (0.7)	1 (0.4)
Bleomycin	0 (0.0)	1 (0.7)	1 (0.4)
Various	0 (0.0)	2 (1.4)	2 (0.7)
Blinded Therapy	0 (0.0)	2 (1.4)	2 (0.7)

Source: Listing 16.2.4.7. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-prlst.sas 05JUN2024 17:44 t-14-01-05-01-04-b-prlst-itts-cl.rtf

Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Patients With at Least One Prior Medication	63 (45.3)	74 (57.4)	137 (51.1)
Proton Pump Inhibitors	12 (8.6)	18 (14.0)	30 (11.2)
Pantoprazole Sodium Sesquihydrate	4 (2.9)	0 (0.0)	4 (1.5)
Rabeprazole Sodium	3 (2.2)	1 (0.8)	4 (1.5)
Lansoprazole	2 (1.4)	3 (2.3)	5 (1.9)
Omeprazole	2 (1.4)	2 (1.6)	4 (1.5)
Pantoprazole	2 (1.4)	3 (2.3)	5 (1.9)
Ilaprazole	1 (0.7)	0 (0.0)	1 (0.4)
Omeprazole Sodium	1 (0.7)	5 (3.9)	6 (2.2)
Esomeprazole	0 (0.0)	3 (2.3)	3 (1.1)
Esomeprazole Magnesium	0 (0.0)	1 (0.8)	1 (0.4)
Vonoprazan Fumarate	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Glucocorticoids	11 (7.9)	17 (13.2)	28 (10.4)
Dexamethasone	10 (7.2)	16 (12.4)	26 (9.7)
Prednisone	2 (1.4)	0 (0.0)	2 (0.7)
Hydrocortisone	1 (0.7)	0 (0.0)	1 (0.4)
Prednisolone	0 (0.0)	1 (0.8)	1 (0.4)
Electrolyte Solutions	8 (5.8)	6 (4.7)	14 (5.2)
Potassium Chloride	6 (4.3)	5 (3.9)	11 (4.1)
Sodium Chloride	2 (1.4)	2 (1.6)	4 (1.5)
Magnesium Sulfate	0 (0.0)	2 (1.6)	2 (0.7)
Solutions For Parenteral Nutrition	8 (5.8)	8 (6.2)	16 (6.0)
Glucose	3 (2.2)	0 (0.0)	3 (1.1)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Alanine;arginine;calcium Chloride Dihydrate;fish Oil;glucose Monohydrate;glycine;glycine Max Oil;histidine;isoleucine;leucine;lysine Hydrochloride;magnesium Sulfate Heptahydrate;medium-Chain Triglycerides;methionine;olea Europaea Oil;phenylalanine;potassium Chloride;proline;serine;sodium Acetate Trihydrate;sodium Glycerophosphate;threonine;tryptophan, L-;tyrosine;valine;zinc Sulfate Heptahydrate	2 (1.4)	1 (0.8)	3 (1.1)
Amino Acids Nos	1 (0.7)	3 (2.3)	4 (1.5)
Amino Acids Nos;copper;electrolytes Nos;glucose;iodine;iron;manganese;vitamins Nos;zinc	1 (0.7)	0 (0.0)	1 (0.4)
Dl-Alpha Tocopheryl Acetate;glycerol;glycine Max Seed Oil;lecithin;medium-Chain Triglycerides	1 (0.7)	0 (0.0)	1 (0.4)
Fats Nos	1 (0.7)	1 (0.8)	2 (0.7)
Alanine;arginine;aspartic Acid;calcium Chloride Dihydrate;glucose;glutamic Acid;glycine;glycine Max Seed Oil;histidine;isoleucine;leucine;lysine Acetate;magnesium Chloride Hexahydrate;methionine;olea Europaea Oil;phenylalanine;potassium Chloride;proline;serine;sodium Acetate Trihydrate;sodium Glycerophosphate;threonine;tryptophan, L-;tyrosine;valine	0 (0.0)	1 (0.8)	1 (0.4)
Alanine;arginine;aspartic Acid;calcium Chloride;glucose Monohydrate;glutamic Acid;glycine;glycine Max Seed Oil;histidine Hydrochloride;isoleucine;leucine;lysine Hydrochloride;magnesium Acetate Tetrahydrate;medium-Chain Triglycerides;methionine;phenylalanine;potassium Acetate;proline;serine;sodium Acetate;sodium Chloride;sodium Hydroxide;sodium Phosphate Monobasic (Dihydrate);threonine;tryptophan, L-;valine;zinc Acetate Dihydrate	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Alanine;arginine;aspartic Acid;cysteine;glutamic Acid;glycine;histidine;isoleucine;leucine;lysine Acetate;methionine;phenylalanine;proline;serine;threonine;tryptophan, L-;tyrosine;valine	0 (0.0)	1 (0.8)	1 (0.4)
Alanine;arginine;aspartic Acid;cystine;glutamic Acid;glycine;histidine;isoleucine;leucine;lysine Acetate;methionine;phenylalanine;proline;serine;threonine;tryptophan, L-;tyrosine;valine	0 (0.0)	2 (1.6)	2 (0.7)
Alanine;arginine;calcium Chloride Dihydrate;fish Oil;glucose Monohydrate;glycine;glycine Max Seed Oil;histidine;isoleucine;leucine;lysine Acetate;magnesium Sulfate Heptahydrate;methionine;olea Europaea Oil;phenylalanine;potassium Chloride;proline;serine;sodium Acetate Trihydrate;sodium Glycerophosphate;taurine;threonine;triglycerides;tryptophan, L-;tyrosine;valine;zinc Sulfate Heptahydrate	0 (0.0)	1 (0.8)	1 (0.4)
Alanine;arginine;calcium Chloride;fish Oil;glucose Monohydrate;glycine;glycine Max Seed Oil;histidine;isoleucine;leucine;lysine Acetate;magnesium Sulfate;medium-Chain Triglycerides;methionine;olea Europaea Oil;phenylalanine;potassium Chloride;proline;serine;sodium Acetate;sodium Glycerophosphate;taurine;threonine;tryptophan, L-;tyrosine;valine;zinc Sulfate	0 (0.0)	1 (0.8)	1 (0.4)
Amino Acids Nos;carbohydrates Nos;minerals Nos;vitamins Nos	0 (0.0)	1 (0.8)	1 (0.4)
Fish Oil;glycine Max Seed Oil;olea Europaea Oil;triglycerides	0 (0.0)	1 (0.8)	1 (0.4)
Glycerol;glycine Max Seed Oil;lecithin	0 (0.0)	2 (1.6)	2 (0.7)
Glycerol;glycine Max Seed Oil;lecithin;medium-Chain Triglycerides	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Natural Opium Alkaloids	7 (5.0)	6 (4.7)	13 (4.9)
Morphine Hydrochloride	3 (2.2)	3 (2.3)	6 (2.2)
Oxycodone Hydrochloride	3 (2.2)	2 (1.6)	5 (1.9)
Hydromorphone Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Morphine Sulfate	1 (0.7)	1 (0.8)	2 (0.7)
Oxycodone	1 (0.7)	1 (0.8)	2 (0.7)
Unspecified Herbal And Traditional Medicine	7 (5.0)	15 (11.6)	22 (8.2)
Acorus Calamus Var. Angustatus Rhizome;amber (Fossilized Tree Resin);angelica Sinensis Root;atractylodes Macrocephala, Rhizoma;codonopsis Spp. Root;glycyrrhiza Spp. Root With Rhizome;ligusticum Chuanxiong Rhizome;paeonia Lactiflora Root;polygala Spp. Root;poria Cocos Sclerotium;rehmannia Glutinosa Root Tuber;scutellaria Baicalensis Root;ziziphus Jujuba Var. Spinosa Seed	1 (0.7)	0 (0.0)	1 (0.4)
Agaricus Blazei;centella Asiatica Leaf;citrus Aurantium Peel;cordyceps Sinensis;cuminum Cyminum;curcuma Longa Rhizome;cymbopogon Citratus;elettaria Cardamomum Fruit;foeniculum Vulgare Seed;illicium Verum Oil;pimpinella Anisum Seed;salvia Officinalis Leaf;syzygium Aromaticum;zingiber Officinale Root	1 (0.7)	0 (0.0)	1 (0.4)
Astragalus Mongholicus Root;eleutherococcus Senticosus Root With Rhizome;mylabris Spp.;panax Ginseng Root	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Astragalus Mongholicus Root;oxymatrine;panax Ginseng Dry Extract	1 (0.7)	0 (0.0)	1 (0.4)
Bupleurum Chinense Root;citrus Aurantium Fruit Peel;glycyrrhiza Uralensis Root With Rhizome;paeonia Lactiflora Sun Dried Root;saposhnikovia Divaricata Root;zingiber Officinale Rhizome	1 (0.7)	0 (0.0)	1 (0.4)
Hericium Erinaceus	1 (0.7)	0 (0.0)	1 (0.4)
Panax Notoginseng	1 (0.7)	1 (0.8)	2 (0.7)
Panax Notoginseng Root Total Saponin Extract	1 (0.7)	0 (0.0)	1 (0.4)
Unspecified Herbal And Traditional Medicine	1 (0.7)	1 (0.8)	2 (0.7)
Angelica Dahurica Var. Formosana Root;arisaema Consanguineum Rhizome;atractylodes Lancea Rhizome;citrus Aurantium Fruit Peel;curcuma Longa Rhizome;glycyrrhiza Uralensis Root With Rhizome;magnolia Officinalis Bark;phellodendron Amurense Bark;rheum Palmatum Root With Rhizome;trichosanthes Kirilowii Root	0 (0.0)	1 (0.8)	1 (0.4)
Arctium Lappa Fruit;cicada Slough;ephedra Spp. Herb;eriobotrya Japonica Leaf;perilla Frutescens Fruit;perilla Frutescens Leaf;peucedanum Praeruptorum Root;pheretima Spp.;schisandra Chinensis Fruit	0 (0.0)	1 (0.8)	1 (0.4)
Arisaema Spp. Tuber;coptis Spp. Rhizome;fritillaria Cirrhosa Bulb;herbal Nos;rheum Spp. Root With Rhizome	0 (0.0)	1 (0.8)	1 (0.4)
Astragalus Mongholicus Root;bear Bile;cornus Officinalis Fruit;curcuma Spp. Rhizome;eleutherococcus Senticosus Root With Rhizome;glycyrrhiza Spp. Root With Rhizome;ligustrum Lucidum Fruit;mylabris Spp.;panax Ginseng Root With Rhizome;scutellaria Barbata Whole Plant;sparganium Stoloniferum Tuber	0 (0.0)	1 (0.8)	1 (0.4)
Astragalus Mongholicus Root;codonopsis Pilosula Root	0 (0.0)	3 (2.3)	3 (1.1)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Astragalus Spp. Root;citrus Aurantium Fruit Peel;codonopsis Spp. Root;cyperus Rotundus Rhizome;dioscorea Oppositifolia Rhizome;glycyrrhiza Spp. Root With Rhizome;paeonia Lactiflora Root;prunus Mume Smoke Treated Unripe Fruit	0 (0.0)	1 (0.8)	1 (0.4)
Baicalin;buffalo Horn;cholic Acid;concha Margaritifera;gardenia Jasminoides Fruit;hyodeoxycholic Acid;isatis Tinctoria Root;lonicera Japonica Flower	0 (0.0)	1 (0.8)	1 (0.4)
Benzoic Acid;camphor;glycyrrhiza Uralensis Root With Rhizome;illicium Verum Oil;papaver Somniferum Tincture	0 (0.0)	1 (0.8)	1 (0.4)
Bidens Biternata;caffeine;chlorphenamine Maleate;chrysanthemum Indicum Flower;ilex Asprella Root;melicope Pteleifolia;mentha Canadensis Oil;paracetamol	0 (0.0)	1 (0.8)	1 (0.4)
Calcium Sulfate Dihydrate;dryopteris Crassirhizoma Rhizome;ephedra Spp. Herb;forsythia Suspensa;glycyrrhiza Spp. Root With Rhizome;houttuynia Cordata Herb;isatis Tinctoria Root;lonicera Japonica Flower;menthol;pogostemon Cablin Herb;prunus Spp. Seed;rheum Spp. Root With Rhizome;rhodiola Crenulata Root With Rhizome	0 (0.0)	1 (0.8)	1 (0.4)
Marsdenia Tenacissima Stem	0 (0.0)	1 (0.8)	1 (0.4)
Papaver Somniferum Tincture	0 (0.0)	1 (0.8)	1 (0.4)
Periplaneta Americana	0 (0.0)	1 (0.8)	1 (0.4)
Smilax Spp. Tuber;sophora Flavescens Root	0 (0.0)	1 (0.8)	1 (0.4)
Ulmus Spp.	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Propionic Acid Derivatives	6 (4.3)	4 (3.1)	10 (3.7)
Flurbiprofen Axetil	2 (1.4)	0 (0.0)	2 (0.7)
Apronal;caffeine;ibuprofen	1 (0.7)	0 (0.0)	1 (0.4)
Arginine Hydrochloride;ibuprofen	1 (0.7)	0 (0.0)	1 (0.4)
Flurbiprofen	1 (0.7)	0 (0.0)	1 (0.4)
Ibuprofen	1 (0.7)	1 (0.8)	2 (0.7)
Loxoprofen Sodium	1 (0.7)	2 (1.6)	3 (1.1)
Loxoprofen	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Third-Generation Cephalosporins	6 (4.3)	2 (1.6)	8 (3.0)
Cefoperazone Sodium;sulbactam Sodium	2 (1.4)	0 (0.0)	2 (0.7)
Cefotaxime	1 (0.7)	0 (0.0)	1 (0.4)
Ceftazidime	1 (0.7)	0 (0.0)	1 (0.4)
Ceftriaxone	1 (0.7)	2 (1.6)	3 (1.1)
Ceftriaxone Sodium	1 (0.7)	0 (0.0)	1 (0.4)
Cefixime	0 (0.0)	1 (0.8)	1 (0.4)
Contact Laxatives	5 (3.6)	4 (3.1)	9 (3.4)
Bisacodyl	2 (1.4)	1 (0.8)	3 (1.1)
Senna Alexandrina Leaf	2 (1.4)	1 (0.8)	3 (1.1)
Sennoside A+b	1 (0.7)	0 (0.0)	1 (0.4)
Ricinus Communis Oil	0 (0.0)	1 (0.8)	1 (0.4)
Sennoside A+b Calcium	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (Gord)	5 (3.6)	3 (2.3)	8 (3.0)
Calcium Carbonate;sodium Alginate;sodium Bicarbonate	2 (1.4)	0 (0.0)	2 (0.7)
Polaprezinc	1 (0.7)	0 (0.0)	1 (0.4)
Rebamipide	1 (0.7)	1 (0.8)	2 (0.7)
Sodium Alginate	1 (0.7)	1 (0.8)	2 (0.7)
Sucralfate	1 (0.7)	1 (0.8)	2 (0.7)
Other Plain Vitamin Preparations	5 (3.6)	5 (3.9)	10 (3.7)
Pyridoxine Hydrochloride	4 (2.9)	5 (3.9)	9 (3.4)
Panthenol	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Solutions Affecting The Electrolyte Balance	5 (3.6)	10 (7.8)	15 (5.6)
Glucose;sodium Chloride	2 (1.4)	3 (2.3)	5 (1.9)
Electrolytes Nos;glucose	1 (0.7)	3 (2.3)	4 (1.5)
Fructose;glucose;magnesium Chloride;potassium Chloride;sodium Bisulfite;sodium Chloride;sodium Lactate;sodium Phosphate Monobasic	1 (0.7)	0 (0.0)	1 (0.4)
Sodium Chloride	1 (0.7)	2 (1.6)	3 (1.1)
Calcium Chloride;potassium Chloride;sodium Chloride;sodium Lactate;sorbitol	0 (0.0)	2 (1.6)	2 (0.7)
Potassium Chloride;sodium Chloride	0 (0.0)	1 (0.8)	1 (0.4)
Substituted Alkylamines	5 (3.6)	1 (0.8)	6 (2.2)
Chlorphenamine Maleate	5 (3.6)	0 (0.0)	5 (1.9)
Chlorphenamine	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Acetic Acid Derivatives And Related Substances	4 (2.9)	1 (0.8)	5 (1.9)
Aceclofenac	1 (0.7)	0 (0.0)	1 (0.4)
Diclofenac	1 (0.7)	1 (0.8)	2 (0.7)
Diclofenac Potassium	1 (0.7)	0 (0.0)	1 (0.4)
Indometacin	1 (0.7)	0 (0.0)	1 (0.4)
Amides	4 (2.9)	7 (5.4)	11 (4.1)
Lidocaine	2 (1.4)	2 (1.6)	4 (1.5)
Lidocaine Hydrochloride	2 (1.4)	5 (3.9)	7 (2.6)
Lidocaine Hydrochloride;menthol	0 (0.0)	1 (0.8)	1 (0.4)
Anilides	4 (2.9)	5 (3.9)	9 (3.4)
Paracetamol	3 (2.2)	4 (3.1)	7 (2.6)
Diclofenac Sodium;paracetamol	1 (0.7)	0 (0.0)	1 (0.4)
Propacetamol Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Ascorbic Acid (Vitamin C), Plain	4 (2.9)	5 (3.9)	9 (3.4)
Ascorbic Acid	4 (2.9)	5 (3.9)	9 (3.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Fluoroquinolones	4 (2.9)	6 (4.7)	10 (3.7)
Levofloxacin	2 (1.4)	3 (2.3)	5 (1.9)
Levofloxacin Hydrochloride	1 (0.7)	1 (0.8)	2 (0.7)
Levofloxacin Lactate	1 (0.7)	1 (0.8)	2 (0.7)
Moxifloxacin	0 (0.0)	1 (0.8)	1 (0.4)
Moxifloxacin Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Heparin Group	4 (2.9)	3 (2.3)	7 (2.6)
Enoxaparin Sodium	2 (1.4)	1 (0.8)	3 (1.1)
Heparin Sodium	1 (0.7)	2 (1.6)	3 (1.1)
Low Molecular Weight Heparin, Calcium Salt	1 (0.7)	0 (0.0)	1 (0.4)
Opioids In Combination With Non-Opioid Analgesics	4 (2.9)	2 (1.6)	6 (2.2)
Paracetamol;tramadol Hydrochloride	2 (1.4)	1 (0.8)	3 (1.1)
Codeine Phosphate;ibuprofen	1 (0.7)	1 (0.8)	2 (0.7)
Codeine Phosphate;paracetamol	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Osmotically Acting Laxatives	4 (2.9)	6 (4.7)	10 (3.7)
Mannitol	2 (1.4)	3 (2.3)	5 (1.9)
Electrolytes Nos;macrogol	1 (0.7)	0 (0.0)	1 (0.4)
Lactulose	1 (0.7)	0 (0.0)	1 (0.4)
Magnesium Oxide	1 (0.7)	0 (0.0)	1 (0.4)
Macrogol	0 (0.0)	1 (0.8)	1 (0.4)
Macrogol 3350;potassium Chloride;sodium Bicarbonate;sodium Chloride	0 (0.0)	1 (0.8)	1 (0.4)
Macrogol 4000;potassium Chloride;sodium Bicarbonate;sodium Chloride;sodium Sulfate Anhydrous	0 (0.0)	1 (0.8)	1 (0.4)
Other Opioids	4 (2.9)	3 (2.3)	7 (2.6)
Tramadol Hydrochloride	2 (1.4)	2 (1.6)	4 (1.5)
Bucinnazine Hydrochloride	1 (0.7)	1 (0.8)	2 (0.7)
Tramadol	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Propulsives	4 (2.9)	6 (4.7)	10 (3.7)
Metoclopramide	2 (1.4)	1 (0.8)	3 (1.1)
Itopride Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Mosapride	1 (0.7)	0 (0.0)	1 (0.4)
Mosapride Citrate	1 (0.7)	4 (3.1)	5 (1.9)
Metoclopramide Dihydrochloride	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Serotonin (5ht3) Antagonists	4 (2.9)	9 (7.0)	13 (4.9)
Granisetron	1 (0.7)	0 (0.0)	1 (0.4)
Palonosetron	1 (0.7)	2 (1.6)	3 (1.1)
Sodium Chloride;tropisetron	1 (0.7)	0 (0.0)	1 (0.4)
Tropisetron	1 (0.7)	1 (0.8)	2 (0.7)
Dolasetron Mesilate	0 (0.0)	1 (0.8)	1 (0.4)
Granisetron Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Ondansetron	0 (0.0)	1 (0.8)	1 (0.4)
Ondansetron Hydrochloride;sodium Chloride	0 (0.0)	1 (0.8)	1 (0.4)
Palonosetron Hydrochloride	0 (0.0)	2 (1.6)	2 (0.7)
Tropisetron Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Sulfonamides, Plain	4 (2.9)	5 (3.9)	9 (3.4)
Furosemide	4 (2.9)	4 (3.1)	8 (3.0)
Torasemide	0 (0.0)	2 (1.6)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Amino Acids	3 (2.2)	4 (3.1)	7 (2.6)
Tranexamic Acid	2 (1.4)	1 (0.8)	3 (1.1)
Aminomethylbenzoic Acid	1 (0.7)	0 (0.0)	1 (0.4)
Alanyl Glutamine	0 (0.0)	2 (1.6)	2 (0.7)
Sodium Chloride;tranexamic Acid	0 (0.0)	1 (0.8)	1 (0.4)
Benzodiazepine Derivatives	3 (2.2)	4 (3.1)	7 (2.6)
Alprazolam	1 (0.7)	0 (0.0)	1 (0.4)
Diazepam	1 (0.7)	1 (0.8)	2 (0.7)
Lorazepam	1 (0.7)	0 (0.0)	1 (0.4)
Midazolam	1 (0.7)	1 (0.8)	2 (0.7)
Estazolam	0 (0.0)	1 (0.8)	1 (0.4)
Oxazepam	0 (0.0)	1 (0.8)	1 (0.4)
Colony Stimulating Factors	3 (2.2)	2 (1.6)	5 (1.9)
Granulocyte Colony Stimulating Factor	3 (2.2)	2 (1.6)	5 (1.9)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Combinations Of Penicillins, Incl. Beta-Lactamase Inhibitors	3 (2.2)	2 (1.6)	5 (1.9)
Amoxicillin;clavulanate Potassium	1 (0.7)	1 (0.8)	2 (0.7)
Ampicillin Sodium;sulbactam Sodium	1 (0.7)	0 (0.0)	1 (0.4)
Mezlocillin;sulbactam	1 (0.7)	0 (0.0)	1 (0.4)
Piperacillin Sodium;tazobactam Sodium	0 (0.0)	1 (0.8)	1 (0.4)
H2-Receptor Antagonists	3 (2.2)	4 (3.1)	7 (2.6)
Famotidine	3 (2.2)	2 (1.6)	5 (1.9)
Cimetidine	0 (0.0)	2 (1.6)	2 (0.7)
Other General Anesthetics	3 (2.2)	0 (0.0)	3 (1.1)
Propofol	3 (2.2)	0 (0.0)	3 (1.1)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Phenylpiperidine Derivatives	3 (2.2)	4 (3.1)	7 (2.6)
Fentanyl	3 (2.2)	0 (0.0)	3 (1.1)
Fentanyl Citrate	0 (0.0)	1 (0.8)	1 (0.4)
Pethidine	0 (0.0)	1 (0.8)	1 (0.4)
Pethidine Hydrochloride	0 (0.0)	2 (1.6)	2 (0.7)
Piperazine Derivatives	3 (2.2)	0 (0.0)	3 (1.1)
Levocetirizine	2 (1.4)	0 (0.0)	2 (0.7)
Cetirizine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Antiemetics And Antinauseants	2 (1.4)	5 (3.9)	7 (2.6)
Metoclopramide	1 (0.7)	2 (1.6)	3 (1.1)
Metoclopramide Hydrochloride	1 (0.7)	2 (1.6)	3 (1.1)
Metoclopramide Dihydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Antiinfectives And Antiseptics For Local Oral Treatment	2 (1.4)	0 (0.0)	2 (0.7)
Nystatin	2 (1.4)	0 (0.0)	2 (0.7)
Neomycin	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
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Percentages were based on N.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Combinations And Complexes Of Aluminium, Calcium And Magnesium Compounds	2 (1.4)	0 (0.0)	2 (0.7)
Aluminium Hydroxide Gel, Dried;magnesium Carbonate	1 (0.7)	0 (0.0)	1 (0.4)
Hydrotalcite	1 (0.7)	0 (0.0)	1 (0.4)
Corticosteroids For Local Oral Treatment	2 (1.4)	0 (0.0)	2 (0.7)
Dexamethasone	1 (0.7)	0 (0.0)	1 (0.4)
Triamcinolone	1 (0.7)	0 (0.0)	1 (0.4)
Diazepines, Oxazepines, Thiazepines And Oxepines	2 (1.4)	1 (0.8)	3 (1.1)
Olanzapine	2 (1.4)	1 (0.8)	3 (1.1)
Enemas	2 (1.4)	1 (0.8)	3 (1.1)
Sodium Chloride	1 (0.7)	0 (0.0)	1 (0.4)
Sodium Phosphate Dibasic;sodium Phosphate Monobasic	1 (0.7)	0 (0.0)	1 (0.4)
Soft Soap	1 (0.7)	1 (0.8)	2 (0.7)
Glycerol	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Insulins And Analogues	2 (1.4)	1 (0.8)	3 (1.1)
Insulin	2 (1.4)	1 (0.8)	3 (1.1)
Macrolides	2 (1.4)	0 (0.0)	2 (0.7)
Clarithromycin	1 (0.7)	0 (0.0)	1 (0.4)
Spiramycin	1 (0.7)	0 (0.0)	1 (0.4)
Medical Gases	2 (1.4)	0 (0.0)	2 (0.7)
Oxygen	2 (1.4)	0 (0.0)	2 (0.7)
Opium Alkaloids And Derivatives	2 (1.4)	2 (1.6)	4 (1.5)
Codeine	1 (0.7)	0 (0.0)	1 (0.4)
Dextromethorphan	1 (0.7)	0 (0.0)	1 (0.4)
Dextromethorphan Hydrobromide	0 (0.0)	2 (1.6)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Opium Derivatives And Expectorants	2 (1.4)	2 (1.6)	4 (1.5)
Opium Derivatives And Expectorants	2 (1.4)	1 (0.8)	3 (1.1)
Camphor;glycyrrhiza Glabra;illicium Verum Oil;papaver Somniferum;sodium Benzoate	0 (0.0)	1 (0.8)	1 (0.4)
Other Blood Products	2 (1.4)	3 (2.3)	5 (1.9)
Red Blood Cells, Concentrated	2 (1.4)	0 (0.0)	2 (0.7)
Blood, Whole	0 (0.0)	2 (1.6)	2 (0.7)
Red Blood Cells	0 (0.0)	1 (0.8)	1 (0.4)
Peripheral Opioid Receptor Antagonists	2 (1.4)	0 (0.0)	2 (0.7)
Naldemedine Tosilate	1 (0.7)	0 (0.0)	1 (0.4)
Naloxegol	1 (0.7)	0 (0.0)	1 (0.4)
Watersoluble, Nephrotropic, Low Osmolar X-Ray Contrast Media	2 (1.4)	1 (0.8)	3 (1.1)
Iohexol	2 (1.4)	1 (0.8)	3 (1.1)
Ioversol	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Alpha-Adrenoreceptor Antagonists	1 (0.7)	0 (0.0)	1 (0.4)
Tamsulosin Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Amino Acids/Carbohydrates/Minerals/Vitamins, Combinations	1 (0.7)	0 (0.0)	1 (0.4)
Amino Acids Nos;carbohydrates Nos;fats Nos;minerals Nos;vitamins Nos	1 (0.7)	0 (0.0)	1 (0.4)
Aminoalkyl Ethers	1 (0.7)	2 (1.6)	3 (1.1)
Diphenhydramine	1 (0.7)	1 (0.8)	2 (0.7)
Diphenhydramine Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Anesthetics, Local	1 (0.7)	0 (0.0)	1 (0.4)
Lidocaine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Angiotensin Ii Receptor Blockers (Arbs), Plain	1 (0.7)	1 (0.8)	2 (0.7)
Valsartan	1 (0.7)	0 (0.0)	1 (0.4)
Losartan	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
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Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 05JUN2024 17:40 t-14-01-06-b-cm-prmed-safetys-cl.rtf

Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Antidiarrheal Microorganisms	1 (0.7)	3 (2.3)	4 (1.5)
Bifidobacterium Longum;enterococcus Faecalis;lactobacillus Acidophilus	1 (0.7)	1 (0.8)	2 (0.7)
Bacillus Mesentericus;clostridium Butyricum;enterococcus Faecalis	0 (0.0)	1 (0.8)	1 (0.4)
Bacillus Subtilis;enterococcus Faecalis;lactobacillus Acidophilus	0 (0.0)	1 (0.8)	1 (0.4)
Antihemorrhagics	1 (0.7)	0 (0.0)	1 (0.4)
Antihemorrhagics	1 (0.7)	0 (0.0)	1 (0.4)
Antiinfectives For Systemic Use	1 (0.7)	1 (0.8)	2 (0.7)
Andrographolide Sulfonate Sodium	1 (0.7)	1 (0.8)	2 (0.7)
Antiinflammatory Preparations, Non-Steroids For Topical Use	1 (0.7)	1 (0.8)	2 (0.7)
Ketoprofen	1 (0.7)	1 (0.8)	2 (0.7)
Appetite Stimulants	1 (0.7)	3 (2.3)	4 (1.5)
Carnitine Hydrochloride;cyanocobalamin;cyproheptadine Orotate;lysine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Megestrol Acetate	1 (0.7)	2 (1.6)	3 (1.1)
Megestrol	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Belladonna Alkaloids, Semisynthetic, Quaternary Ammonium Compounds	1 (0.7)	1 (0.8)	2 (0.7)
Cimetropium Bromide	1 (0.7)	1 (0.8)	2 (0.7)
Benzothiazepine Derivatives	1 (0.7)	0 (0.0)	1 (0.4)
Diltiazem Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Beta-Lactamase Resistant Penicillins	1 (0.7)	0 (0.0)	1 (0.4)
Dicloxacillin Sodium Monohydrate	1 (0.7)	0 (0.0)	1 (0.4)
Bile Acids And Derivatives	1 (0.7)	0 (0.0)	1 (0.4)
Ursodeoxycholic Acid	1 (0.7)	0 (0.0)	1 (0.4)
Bisphosphonates	1 (0.7)	1 (0.8)	2 (0.7)
Zoledronic Acid	1 (0.7)	1 (0.8)	2 (0.7)
Blood And Related Products	1 (0.7)	1 (0.8)	2 (0.7)
Blood, Calf, Deprot., Lmw Portion	1 (0.7)	1 (0.8)	2 (0.7)

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Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Combinations Of Sulfonamides And Trimethoprim, Incl. Derivatives	1 (0.7)	1 (0.8)	2 (0.7)
Sulfamethoxazole;trimethoprim	1 (0.7)	1 (0.8)	2 (0.7)
Coxibs	1 (0.7)	0 (0.0)	1 (0.4)
Celecoxib	1 (0.7)	0 (0.0)	1 (0.4)
Detoxifying Agents For Antineoplastic Treatment	1 (0.7)	0 (0.0)	1 (0.4)
Amifostine	1 (0.7)	0 (0.0)	1 (0.4)
Dihydropyridine Derivatives	1 (0.7)	1 (0.8)	2 (0.7)
Amlodipine Besilate	1 (0.7)	0 (0.0)	1 (0.4)
Lercanidipine Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Diphenylmethane Derivatives	1 (0.7)	0 (0.0)	1 (0.4)
Hydroxyzine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)

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Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Enzyme Preparations	1 (0.7)	1 (0.8)	2 (0.7)
Pancreatin	1 (0.7)	0 (0.0)	1 (0.4)
Azintamide;cellulase;dimeticone;pancreatin	0 (0.0)	1 (0.8)	1 (0.4)
Enzymes	1 (0.7)	0 (0.0)	1 (0.4)
Pronase	1 (0.7)	0 (0.0)	1 (0.4)
First-Generation Cephalosporins	1 (0.7)	1 (0.8)	2 (0.7)
Cefadroxil	1 (0.7)	0 (0.0)	1 (0.4)
Cefazolin Sodium	0 (0.0)	1 (0.8)	1 (0.4)
Folic Acid And Derivatives	1 (0.7)	0 (0.0)	1 (0.4)
Folinic Acid	1 (0.7)	0 (0.0)	1 (0.4)
I.V. Solution Additives	1 (0.7)	0 (0.0)	1 (0.4)
Calcium Chloride Dihydrate;glucose;potassium Chloride;sodium Acetate;sodium Chloride	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Insulins And Analogues For Injection, Intermediate-Acting	1 (0.7)	0 (0.0)	1 (0.4)
Insulin Human Injection, Isophane	1 (0.7)	0 (0.0)	1 (0.4)
Iron, Parenteral Preparations	1 (0.7)	1 (0.8)	2 (0.7)
Saccharated Iron Oxide	1 (0.7)	1 (0.8)	2 (0.7)
Liver Therapy	1 (0.7)	5 (3.9)	6 (2.2)
Diisopropylamine Dichloroacetate;gluconate Sodium	1 (0.7)	0 (0.0)	1 (0.4)
Magnesium Isoglycyrrhizinate	0 (0.0)	5 (3.9)	5 (1.9)
Mucolytics	1 (0.7)	4 (3.1)	5 (1.9)
Bromhexine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Ambroxol Hydrochloride	0 (0.0)	4 (3.1)	4 (1.5)
Other Agents For Local Oral Treatment	1 (0.7)	0 (0.0)	1 (0.4)
Lidocaine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)

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Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Aminoglycosides	1 (0.7)	1 (0.8)	2 (0.7)
Gentamicin;procaine	1 (0.7)	0 (0.0)	1 (0.4)
Etimicin Sulfate	0 (0.0)	1 (0.8)	1 (0.4)
Other Antianemic Preparations	1 (0.7)	1 (0.8)	2 (0.7)
Erythropoietin Human	1 (0.7)	1 (0.8)	2 (0.7)
Other Antibiotics For Topical Use	1 (0.7)	0 (0.0)	1 (0.4)
Neomycin;tyrothricin	1 (0.7)	0 (0.0)	1 (0.4)
Other Antiemetics	1 (0.7)	2 (1.6)	3 (1.1)
Hydroxyzine	1 (0.7)	0 (0.0)	1 (0.4)
Difenidol	0 (0.0)	1 (0.8)	1 (0.4)
Fosaprepitant	0 (0.0)	1 (0.8)	1 (0.4)
Other Antihistamines For Systemic Use	1 (0.7)	0 (0.0)	1 (0.4)
Cyproheptadine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Cough Suppressants	1 (0.7)	0 (0.0)	1 (0.4)
Tipepidine Hibenzate	1 (0.7)	0 (0.0)	1 (0.4)
Other Drugs For Disorders Of The Musculo-Skeletal System	1 (0.7)	1 (0.8)	2 (0.7)
Polypeptide;polysaccharides Nos	1 (0.7)	1 (0.8)	2 (0.7)
Other Drugs For Functional Gastrointestinal Disorders	1 (0.7)	1 (0.8)	2 (0.7)
Simeticone	1 (0.7)	0 (0.0)	1 (0.4)
Flopropione	0 (0.0)	1 (0.8)	1 (0.4)
Other Immunostimulants	1 (0.7)	1 (0.8)	2 (0.7)
Agaricus Blazei;ascorbic Acid;cordyceps Sinensis;glutathione;zinc Sulfate	1 (0.7)	0 (0.0)	1 (0.4)
Peptides Nos;thymalfasin	0 (0.0)	1 (0.8)	1 (0.4)
Other Ophthalmologicals	1 (0.7)	1 (0.8)	2 (0.7)
Cyanocobalamin	1 (0.7)	0 (0.0)	1 (0.4)
Nepidermin	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Systemic Hemostatics	1 (0.7)	0 (0.0)	1 (0.4)
Etamsilate	1 (0.7)	0 (0.0)	1 (0.4)
Penicillins With Extended Spectrum	1 (0.7)	2 (1.6)	3 (1.1)
Amoxicillin	1 (0.7)	1 (0.8)	2 (0.7)
Piperacillin	0 (0.0)	1 (0.8)	1 (0.4)
Progestogens	1 (0.7)	0 (0.0)	1 (0.4)
Medroxyprogesterone	1 (0.7)	0 (0.0)	1 (0.4)
Pyrazolones	1 (0.7)	1 (0.8)	2 (0.7)
Aminophenazone;barbital;phenazone	1 (0.7)	1 (0.8)	2 (0.7)
Rauwolfia Alkaloids And Diuretics In Combination	1 (0.7)	0 (0.0)	1 (0.4)
Dihydralazine Sulfate;hydrochlorothiazide;reserpine;triamterene	1 (0.7)	0 (0.0)	1 (0.4)

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Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Selective Beta-2-Adrenoreceptor Agonists	1 (0.7)	1 (0.8)	2 (0.7)
Terbutaline	1 (0.7)	0 (0.0)	1 (0.4)
Terbutaline Sulfate	0 (0.0)	1 (0.8)	1 (0.4)
Sulfonamides	1 (0.7)	0 (0.0)	1 (0.4)
Sulfamethoxazole	1 (0.7)	0 (0.0)	1 (0.4)
Sympathomimetics	1 (0.7)	0 (0.0)	1 (0.4)
Ebastine;pseudoephedrine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Synthetic Anticholinergics, Esters With Tertiary Amino Group	1 (0.7)	0 (0.0)	1 (0.4)
Dicycloverine	1 (0.7)	0 (0.0)	1 (0.4)
Testosterone-5-Alpha Reductase Inhibitors	1 (0.7)	0 (0.0)	1 (0.4)
Finasteride	1 (0.7)	0 (0.0)	1 (0.4)
Various Alimentary Tract And Metabolism Products	1 (0.7)	0 (0.0)	1 (0.4)
Morinda Citrifolia;selenium	1 (0.7)	0 (0.0)	1 (0.4)

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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Vitamin B1, Plain	1 (0.7)	0 (0.0)	1 (0.4)
Thiamine	1 (0.7)	0 (0.0)	1 (0.4)
Watersoluble, Nephrotropic, High Osmolar X-Ray Contrast Media	1 (0.7)	0 (0.0)	1 (0.4)
Meglumine Amidotrizoate;sodium Amidotrizoate	1 (0.7)	0 (0.0)	1 (0.4)
Xanthines	1 (0.7)	0 (0.0)	1 (0.4)
Ambroxol Acefyllinate	1 (0.7)	0 (0.0)	1 (0.4)
Xanthines And Adrenergics	1 (0.7)	0 (0.0)	1 (0.4)
Aminophylline;chlorphenamine Maleate;methoxyphenamine Hydrochloride;noscapine	1 (0.7)	0 (0.0)	1 (0.4)
Antibiotics	0 (0.0)	1 (0.8)	1 (0.4)
Tobramycin	0 (0.0)	1 (0.8)	1 (0.4)
Anticholinergics	0 (0.0)	1 (0.8)	1 (0.4)
Phenylephrine Hydrochloride;tropicamide	0 (0.0)	1 (0.8)	1 (0.4)

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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Antidotes	0 (0.0)	1 (0.8)	1 (0.4)
Glutathione	0 (0.0)	1 (0.8)	1 (0.4)
Beta Blocking Agents	0 (0.0)	1 (0.8)	1 (0.4)
Carteolol Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Beta Blocking Agents, Selective	0 (0.0)	1 (0.8)	1 (0.4)
Metoprolol	0 (0.0)	1 (0.8)	1 (0.4)
Bile And Liver Therapy	0 (0.0)	2 (1.6)	2 (0.7)
Bicyclol	0 (0.0)	2 (1.6)	2 (0.7)
Blood Substitutes And Plasma Protein Fractions	0 (0.0)	1 (0.8)	1 (0.4)
Albumin Human	0 (0.0)	1 (0.8)	1 (0.4)
Calcium, Combinations With Vitamin D And/Or Other Drugs	0 (0.0)	1 (0.8)	1 (0.4)
Calcium Carbonate;colecalciferol	0 (0.0)	1 (0.8)	1 (0.4)

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Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Carbapenems	0 (0.0)	1 (0.8)	1 (0.4)
Meropenem	0 (0.0)	1 (0.8)	1 (0.4)
Colouring Agents	0 (0.0)	1 (0.8)	1 (0.4)
Fluorescein Sodium	0 (0.0)	1 (0.8)	1 (0.4)
Combinations Of Vitamins	0 (0.0)	1 (0.8)	1 (0.4)
Combinations Of Vitamins	0 (0.0)	1 (0.8)	1 (0.4)
Corticosteroids	0 (0.0)	1 (0.8)	1 (0.4)
Budesonide	0 (0.0)	1 (0.8)	1 (0.4)
Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (Gord)	0 (0.0)	1 (0.8)	1 (0.4)
Teprenone	0 (0.0)	1 (0.8)	1 (0.4)
Esters Of Aminobenzoic Acid	0 (0.0)	1 (0.8)	1 (0.4)
Tetracaine Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 05JUN2024 17:40 t-14-01-06-b-cm-prmed-safetys-cl.rtf

Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Expectorants	0 (0.0)	1 (0.8)	1 (0.4)
Fudosteine	0 (0.0)	1 (0.8)	1 (0.4)
Fat/Carbohydrates/Proteins/Minerals/Vitamins, Combinations	0 (0.0)	3 (2.3)	3 (1.1)
Ascorbic Acid;biotin;calcium Citrate;calcium Pantothenate;cyanocobalamin;ferrous Sulfate;fibre, Dietary;folic Acid;glycine Max Seed Oil;magnesium Carbonate;maltodextrin;nicotinamide;potassium Citrate;proteins Nos;pyridoxine Hydrochloride;retinol;riboflavin;sodium Chloride;sucrose;thiamine Hydrochloride;tocopheryl Acetate;whey Protein;zea Mays Starch	0 (0.0)	1 (0.8)	1 (0.4)
Casein;fats Nos;fibre, Dietary;maltodextrin;minerals Nos;vitamins Nos	0 (0.0)	2 (1.6)	2 (0.7)
Imidazole Derivatives	0 (0.0)	2 (1.6)	2 (0.7)
Metronidazole	0 (0.0)	1 (0.8)	1 (0.4)
Ornidazole	0 (0.0)	1 (0.8)	1 (0.4)
Insulins And Analogues For Injection, Fast-Acting	0 (0.0)	1 (0.8)	1 (0.4)
Insulin Human	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 05JUN2024 17:40 t-14-01-06-b-cm-prmed-safetys-cl.rtf

Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Insulins And Analogues For Injection, Long-Acting	0 (0.0)	1 (0.8)	1 (0.4)
Insulin Glargine	0 (0.0)	1 (0.8)	1 (0.4)
Local Anesthetics	0 (0.0)	1 (0.8)	1 (0.4)
Cinchocaine Hydrochloride;policresulen	0 (0.0)	1 (0.8)	1 (0.4)
Nucleoside And Nucleotide Reverse Transcriptase Inhibitors	0 (0.0)	2 (1.6)	2 (0.7)
Entecavir	0 (0.0)	1 (0.8)	1 (0.4)
Tenofovir Disoproxil Fumarate	0 (0.0)	1 (0.8)	1 (0.4)
Other Analgesics And Antipyretics	0 (0.0)	2 (1.6)	2 (0.7)
Gabapentin	0 (0.0)	1 (0.8)	1 (0.4)
Pregabalin	0 (0.0)	1 (0.8)	1 (0.4)
Other Cicatrizants	0 (0.0)	1 (0.8)	1 (0.4)
Trafermin	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 05JUN2024 17:40 t-14-01-06-b-cm-prmed-safetys-cl.rtf

Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Diagnostic Agents	0 (0.0)	1 (0.8)	1 (0.4)
Indocyanine Green	0 (0.0)	1 (0.8)	1 (0.4)
Other Drugs Affecting Bone Structure And Mineralization	0 (0.0)	1 (0.8)	1 (0.4)
Denosumab	0 (0.0)	1 (0.8)	1 (0.4)
Other Drugs For Constipation	0 (0.0)	1 (0.8)	1 (0.4)
Prucalopride	0 (0.0)	1 (0.8)	1 (0.4)
Other Intestinal Adsorbents	0 (0.0)	2 (1.6)	2 (0.7)
Montmorillonite	0 (0.0)	2 (1.6)	2 (0.7)
Other Irrigating Solutions	0 (0.0)	1 (0.8)	1 (0.4)
Mannitol	0 (0.0)	1 (0.8)	1 (0.4)
Other Mineral Products	0 (0.0)	1 (0.8)	1 (0.4)
Magnesium Aspartate;potassium Aspartate	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 05JUN2024 17:40 t-14-01-06-b-cm-prmed-safetys-cl.rtf

Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Plant Alkaloids And Natural Products	0 (0.0)	1 (0.8)	1 (0.4)
Ginsenoside Rg3	0 (0.0)	1 (0.8)	1 (0.4)
Other Urologicals	0 (0.0)	1 (0.8)	1 (0.4)
Tiopronin	0 (0.0)	1 (0.8)	1 (0.4)
Phenothiazines With Aliphatic Side-Chain	0 (0.0)	1 (0.8)	1 (0.4)
Chlorpromazine	0 (0.0)	1 (0.8)	1 (0.4)
Phenylalkylamine Derivatives	0 (0.0)	1 (0.8)	1 (0.4)
Verapamil Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Phosphodiesterase Inhibitors	0 (0.0)	1 (0.8)	1 (0.4)
Bucladesine Calcium	0 (0.0)	1 (0.8)	1 (0.4)
Platinum Compounds	0 (0.0)	1 (0.8)	1 (0.4)
Cisplatin	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 05JUN2024 17:40 t-14-01-06-b-cm-prmed-safetys-cl.rtf

Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Potassium	0 (0.0)	3 (2.3)	3 (1.1)
Potassium Chloride	0 (0.0)	2 (1.6)	2 (0.7)
Potassium Gluconate	0 (0.0)	1 (0.8)	1 (0.4)
Pyrimidine Analogues	0 (0.0)	1 (0.8)	1 (0.4)
Gemcitabine Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Second-Generation Cephalosporins	0 (0.0)	2 (1.6)	2 (0.7)
Cefmetazole Sodium	0 (0.0)	1 (0.8)	1 (0.4)
Cefuroxime	0 (0.0)	1 (0.8)	1 (0.4)
Solutions Producing Osmotic Diuresis	0 (0.0)	1 (0.8)	1 (0.4)
Mannitol	0 (0.0)	1 (0.8)	1 (0.4)
Vasopressin Antagonists	0 (0.0)	1 (0.8)	1 (0.4)
Tolvaptan	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 05JUN2024 17:40 t-14-01-06-b-cm-prmed-safetys-cl.rtf

Table 14.1.6.b:
Prior Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Vitamin B-Complex, Plain	0 (0.0)	1 (0.8)	1 (0.4)
Vitamin B Complex	0 (0.0)	1 (0.8)	1 (0.4)
Vitamins	0 (0.0)	2 (1.6)	2 (0.7)
Fat Soluble Vitamins Nos	0 (0.0)	1 (0.8)	1 (0.4)
Vitamins Nos	0 (0.0)	1 (0.8)	1 (0.4)
Vitamins With Minerals	0 (0.0)	1 (0.8)	1 (0.4)
Minerals Nos;vitamins Nos	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Prior medications are defined as medications that stopped before the first dose of study drug.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 05JUN2024 17:40 t-14-01-06-b-cm-prmed-safetys-cl.rtf

Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Patients With at Least One Concomitant Medication	136 (97.8)	127 (98.4)	263 (98.1)
Proton Pump Inhibitors	83 (59.7)	91 (70.5)	174 (64.9)
Lansoprazole	21 (15.1)	23 (17.8)	44 (16.4)
Esomeprazole	17 (12.2)	16 (12.4)	33 (12.3)
Omeprazole	17 (12.2)	21 (16.3)	38 (14.2)
Pantoprazole Sodium Sesquihydrate	13 (9.4)	21 (16.3)	34 (12.7)
Vonoprazan Fumarate	8 (5.8)	6 (4.7)	14 (5.2)
Pantoprazole	7 (5.0)	10 (7.8)	17 (6.3)
Rabeprazole Sodium	7 (5.0)	8 (6.2)	15 (5.6)
Esomeprazole Magnesium	6 (4.3)	6 (4.7)	12 (4.5)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 05JUN2024 17:40 t-14-01-07-01-b-cm-gen-safetys-cl.rtf

Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Omeprazole Sodium	6 (4.3)	9 (7.0)	15 (5.6)
Esomeprazole Sodium	4 (2.9)	5 (3.9)	9 (3.4)
Rabeprazole	2 (1.4)	0 (0.0)	2 (0.7)
Dexlansoprazole	1 (0.7)	1 (0.8)	2 (0.7)
Ilaprazole	1 (0.7)	4 (3.1)	5 (1.9)
Omeprazole Magnesium	1 (0.7)	2 (1.6)	3 (1.1)
Esomeprazole Magnesium Dihydrate	0 (0.0)	1 (0.8)	1 (0.4)
Glucocorticoids	55 (39.6)	115 (89.1)	170 (63.4)
Dexamethasone	24 (17.3)	105 (81.4)	129 (48.1)
Prednisolone	19 (13.7)	9 (7.0)	28 (10.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Methylprednisolone	13 (9.4)	8 (6.2)	21 (7.8)
Hydrocortisone	10 (7.2)	10 (7.8)	20 (7.5)
Budesonide	6 (4.3)	4 (3.1)	10 (3.7)
Prednisone	6 (4.3)	2 (1.6)	8 (3.0)
Cortisone	4 (2.9)	1 (0.8)	5 (1.9)
Betamethasone	2 (1.4)	6 (4.7)	8 (3.0)
Methylprednisolone Sodium Succinate	1 (0.7)	2 (1.6)	3 (1.1)
Beclometasone Dipropionate	0 (0.0)	1 (0.8)	1 (0.4)
Betamethasone Sodium Phosphate	0 (0.0)	2 (1.6)	2 (0.7)
Dexamethasone Sodium Phosphate	0 (0.0)	2 (1.6)	2 (0.7)
Hydrocortisone Sodium Succinate	0 (0.0)	2 (1.6)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Anilides	52 (37.4)	42 (32.6)	94 (35.1)
Paracetamol	49 (35.3)	38 (29.5)	87 (32.5)
Amantadine Hydrochloride;caffeine;chlorphenamine Maleate;cow Bezoar;paracetamol	1 (0.7)	1 (0.8)	2 (0.7)
Chlorphenamine Maleate;dextromethorphan;paracetamol;pseudoephedrine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Propacetamol Hydrochloride	1 (0.7)	3 (2.3)	4 (1.5)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Natural Opium Alkaloids	50 (36.0)	39 (30.2)	89 (33.2)
Oxycodone Hydrochloride	22 (15.8)	21 (16.3)	43 (16.0)
Morphine	12 (8.6)	6 (4.7)	18 (6.7)
Morphine Hydrochloride	11 (7.9)	10 (7.8)	21 (7.8)
Morphine Sulfate	8 (5.8)	5 (3.9)	13 (4.9)
Oxycodone	7 (5.0)	4 (3.1)	11 (4.1)
Naloxone Hydrochloride;oxycodone Hydrochloride	4 (2.9)	3 (2.3)	7 (2.6)
Hydromorphone Hydrochloride	3 (2.2)	1 (0.8)	4 (1.5)
Codeine	1 (0.7)	0 (0.0)	1 (0.4)
Codeine Phosphate	1 (0.7)	0 (0.0)	1 (0.4)
Naloxone;oxycodone	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Osmotically Acting Laxatives	43 (30.9)	31 (24.0)	74 (27.6)
Magnesium Oxide	21 (15.1)	13 (10.1)	34 (12.7)
Lactulose	16 (11.5)	8 (6.2)	24 (9.0)
Macrogol 3350;potassium Chloride;sodium Bicarbonate;sodium Chloride	6 (4.3)	8 (6.2)	14 (5.2)
Macrogol	3 (2.2)	1 (0.8)	4 (1.5)
Macrogol 3350	1 (0.7)	0 (0.0)	1 (0.4)
Macrogol 4000	1 (0.7)	2 (1.6)	3 (1.1)
Sodium Phosphate	1 (0.7)	0 (0.0)	1 (0.4)
Magnesium Hydroxide	0 (0.0)	1 (0.8)	1 (0.4)
Mannitol	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Unspecified Herbal And Traditional Medicine	35 (25.2)	28 (21.7)	63 (23.5)
Unspecified Herbal And Traditional Medicine	8 (5.8)	3 (2.3)	11 (4.1)
Astragalus Mongholicus Root;cibotium Barometz Rhizome;eclipta Prostrata Herb;fallopia Multiflora Root Tuber;ligustrum Lucidum Fruit;morus Alba Fruit;paeonia Lactiflora Root	6 (4.3)	4 (3.1)	10 (3.7)
Periplaneta Americana	3 (2.2)	0 (0.0)	3 (1.1)
Sanguisorba Officinalis Root	3 (2.2)	2 (1.6)	5 (1.9)
Alisma Orientale Rhizome;angelica Sinensis Root;asarum Spp. Root With Rhizome;astragalus Spp. Root;cuscuta Spp. Seed;deer Horn;gastrodia Elata Tuber;lycium Barbarum Fruit;panax Ginseng Root;rehmannia Glutinosa Root Tuber;senna Spp. Seed	2 (1.4)	0 (0.0)	2 (0.7)
Astragalus Mongholicus Root;oxymatrine;panax Ginseng Dry Extract	2 (1.4)	1 (0.8)	3 (1.1)
Cinnamomum Cassia Stem Bark;ferrous Sulfate;juglans Regia Seed;panax Quinquefolius Root;sea Horse;ziziphus Jujuba Fruit	2 (1.4)	0 (0.0)	2 (0.7)
Coix Lacryma-Jobi Subsp. Ma-Yuen Seed	2 (1.4)	0 (0.0)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
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Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 05JUN2024 17:40 t-14-01-07-01-b-cm-gen-safetys-cl.rtf

Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Cynanchum Stauntonii Root With Rhizome;eriobotrya Japonica Leaf;menthol;morus Alba Root Bark;papaver Somniferum Peel;platycodon Grandiflorus Root;stemona Sessilifolia Root Tuber	2 (1.4)	1 (0.8)	3 (1.1)
Panax Notoginseng	2 (1.4)	2 (1.6)	4 (1.5)
Panax Notoginseng Root Total Saponin Extract	2 (1.4)	2 (1.6)	4 (1.5)
Abelmoschus Manihot Flower	1 (0.7)	0 (0.0)	1 (0.4)
Aconitum Carmichaelii Root;panax Ginseng Root	1 (0.7)	1 (0.8)	2 (0.7)
Aconitum Kusnezoffii Root;herbal Nos	1 (0.7)	0 (0.0)	1 (0.4)
Agrimonia Pilosa Herb;forsythia Suspensa Fruit;glycyrrhiza Spp. Root With Rhizome;indigo;paeonia X Suffruticosa Root Bark	1 (0.7)	0 (0.0)	1 (0.4)
Alisma Orientale Rhizome;amomum Spp. Fruit;astragalus Mongholicus Root;bombyx Mori;citrus Aurantium Fruit Peel;codonopsis Spp. Root;crataegus Pinnatifida Fruit;dioscorea Oppositifolia Rhizome;eleutherococcus Senticosus Root With Rhizome;epimedium Spp. Leaf;lycium Barbarum Fruit;morus Alba Fruit;pinellia Ternata Rhizome;polygonatum Spp. Rhizome;poria Cocos Sclerotium;rehmannia Glutinosa Root Tuber;strychnos Nux-Vomica Seed	1 (0.7)	1 (0.8)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Anemarrhena Asphodeloides Rhizome;angelica Sinensis Root;animal Bone Marrow;arachis Hypogaea Seed Coat;asini Corii Colla;astragalus Mongholicus Root;atractylodes Macrocephala, Rhizoma;blood, Deer;chicken's Gizzard-Membrane;codonopsis Spp. Root;crataegus Pinnatifida Fruit;deer Horn;deer Velvet;fallopia Multiflora Root Tuber;hordeum Vulgare Sprout;paeonia Lactiflora Root;placenta;poria Cocos Sclerotium;rehmannia Glutinosa Root Tuber;rheum Spp. Root With Rhizome;turtle Carapace;ziziphus Jujuba Fruit	1 (0.7)	0 (0.0)	1 (0.4)
Angelica Sinensis Root;asini Corii Colla;astragalus Mongholicus Root;epimedium Brevicornu Herb;lespedeza Buergeri;sophora Flavescens Root;ziziphus Jujuba Fruit	1 (0.7)	1 (0.8)	2 (0.7)
Arctium Lappa Fruit;cicada Slough;ephedra Spp. Herb;eriobotrya Japonica Leaf;perilla Frutescens Fruit;perilla Frutescens Leaf;peucedanum Praeruptorum Root;pheretima Spp.;schisandra Chinensis Fruit	1 (0.7)	1 (0.8)	2 (0.7)
Arctium Lappa Fruit;cow Bezoar;forsythia Suspensa Fruit;glycine Max Fermented Seed;glycyrrhiza Spp. Root With Rhizome;lonicera Spp. Flower Bud;lophatherum Gracile Leaf With Stem;phragmites Communis Rhizome;platycodon Grandiflorus Root;schizonepeta Tenuifolia Herb	1 (0.7)	0 (0.0)	1 (0.4)
Arisaema Spp. Tuber;coptis Spp. Rhizome;fritillaria Cirrhosa Bulb;herbal Nos;rheum Spp. Root With Rhizome	1 (0.7)	0 (0.0)	1 (0.4)
Artemisia Annua Herb;gardenia Jasminoides Fruit;lonicera Japonica Flower Bud	1 (0.7)	0 (0.0)	1 (0.4)

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Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Artemisia Argyi Leaf	1 (0.7)	0 (0.0)	1 (0.4)
Artemisia Spp. Herb;bupleurum Spp. Root;isatis Tinctoria Root;schisandra Chinensis Fruit;swine Bile;vigna Radiata Seed	1 (0.7)	0 (0.0)	1 (0.4)
Aster Ageratoides Whole Plant;firmiana Simplex Root;metagentiana Rhodantha Whole Plant;peucedanum Praeruptorum Root;scleromitrion Diffusum Whole Plant;scutellaria Baicalensis Root;stemona Spp. Root Tuber	1 (0.7)	0 (0.0)	1 (0.4)
Astragalus Mongholicus Root;blood, Pig;ziziphus Jujuba Fruit	1 (0.7)	0 (0.0)	1 (0.4)
Astragalus Mongholicus Root;eleutherococcus Senticosus Root With Rhizome;mylabris Spp.;panax Ginseng Root	1 (0.7)	0 (0.0)	1 (0.4)
Atractylodes Spp. Rhizome;ferrous Sulfate Heptahydrate	1 (0.7)	0 (0.0)	1 (0.4)
Aucklandia Costus Root;citrus Aurantium Submature Fruit;magnolia Officinalis Bark;rheum Spp. Root With Rhizome	1 (0.7)	0 (0.0)	1 (0.4)
Benzoic Acid;camphor;glycyrrhiza Uralensis Root With Rhizome;illicium Verum Oil;papaver Somniferum Tincture	1 (0.7)	0 (0.0)	1 (0.4)
Bidens Biternata;caffeine;chlorphenamine Maleate;chrysanthemum Indicum Flower;ilex Asprella Root;melicope Pteleifolia;mentha Canadensis Oil;paracetamol	1 (0.7)	1 (0.8)	2 (0.7)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Cinnamomum Camphora Root;euphorbia Spp. Herb;exallage Chrysotricha;liquidambar Formosana Leaf;mosla Chinensis Herb	1 (0.7)	0 (0.0)	1 (0.4)
Coptis Spp. Rhizome;hedera Helix Leaf	1 (0.7)	0 (0.0)	1 (0.4)
Corydalis Yanhusuo Tuber;ipomoea Nil Seed	1 (0.7)	1 (0.8)	2 (0.7)
Fritillaria Spp. Bulb;glycyrrhiza Spp. Root With Rhizome;mentha Canadensis Herb;ophiopogon Japonicus Root Tuber;paeonia Lactiflora Root;paeonia X Suffruticosa Root Bark;rehmannia Glutinosa Root Tuber;scrophularia Ningpoensis Root	1 (0.7)	0 (0.0)	1 (0.4)
Ganoderma Lucidum	1 (0.7)	0 (0.0)	1 (0.4)
Ginseng Nos	1 (0.7)	0 (0.0)	1 (0.4)
Glycyrrhiza Glabra Extract	1 (0.7)	0 (0.0)	1 (0.4)
Glycyrrhiza Spp. Root;rheum Spp. Rhizome	1 (0.7)	0 (0.0)	1 (0.4)
Isatis Tinctoria Root	1 (0.7)	0 (0.0)	1 (0.4)
Jacobaea Cannabifolia Herb	1 (0.7)	1 (0.8)	2 (0.7)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Lonicera Japonica Flower Bud;scutellaria Baicalensis Root	1 (0.7)	0 (0.0)	1 (0.4)
Ophiopogon Japonicus Root Tuber;panax Ginseng	1 (0.7)	0 (0.0)	1 (0.4)
Ophiopogon Japonicus Root Tuber;panax Ginseng Root With Rhizome;schisandra Chinensis Fruit	1 (0.7)	0 (0.0)	1 (0.4)
Panax Ginseng Root;zanthoxylum Piperitum Pericarp;zingiber Officinale Processed Rhizome	1 (0.7)	0 (0.0)	1 (0.4)
Platycodon Grandiflorus	1 (0.7)	0 (0.0)	1 (0.4)
Salvia Miltiorrhiza Root	1 (0.7)	0 (0.0)	1 (0.4)
Sesamum Indicum Seed Oil	1 (0.7)	0 (0.0)	1 (0.4)
Sophora Flavescens Root	1 (0.7)	0 (0.0)	1 (0.4)
Achyranthes Bidentata Root;angelica Sinensis Root;astragalus Spp. Root;boswellia Sacra;carthamus Tinctorius Flower;cinnamomum Cassia Twig;commiphora Myrrha Resin;leech;ligusticum Chuanxiong Rhizome;mesobuthus Martensii;morus Alba Twig;paeonia Officinalis Subsp. Officinalis Root;pheretima Spp.;prunus Persica Seed;salvia Miltiorrhiza Root With Rhizome;spatholobus Suberectus Stem	0 (0.0)	1 (0.8)	1 (0.4)
Aloe Spp.	0 (0.0)	1 (0.8)	1 (0.4)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Angelica Dahurica Var. Formosana Root;arisaema Consanguineum Rhizome;atractylodes Lancea Rhizome;citrus Aurantium Fruit Peel;curcuma Longa Rhizome;glycyrrhiza Uralensis Root With Rhizome;magnolia Officinalis Bark;phellodendron Amurense Bark;rheum Palmatum Root With Rhizome;trichosanthes Kirilowii Root	0 (0.0)	3 (2.3)	3 (1.1)
Angelica Sinensis Root;carthamus Tinctorius Flower;ligusticum Chuanxiong Rhizome;paeonia Lactiflora Sun Dried Root;salvia Miltiorrhiza Root	0 (0.0)	1 (0.8)	1 (0.4)
Angelica Sinensis Root;cistanche Deserticola Stem;senna Alexandrina Leaf	0 (0.0)	1 (0.8)	1 (0.4)
Arachis Hypogaea	0 (0.0)	1 (0.8)	1 (0.4)
Arctium Lappa Fruit;forsythia Suspensa Fruit;glycine Max Fermented Seed;glycyrrhiza Spp. Root With Rhizome;lonicera Japonica Flower Bud;lophatherum Gracile Leaf With Stem;mentha Canadensis Herb;platycodon Grandiflorus Root;schizonepeta Tenuifolia Herb	0 (0.0)	1 (0.8)	1 (0.4)
Areca Catechu Seed;aucklandia Costus Root;citrus Aurantium Unripe Fruit;lindera Aggregata Root	0 (0.0)	1 (0.8)	1 (0.4)
Artemisia Argyi	0 (0.0)	1 (0.8)	1 (0.4)
Asini Corii Colla;borneol;ethanol;sorbic Acid	0 (0.0)	1 (0.8)	1 (0.4)
Astragalus Mongholicus Root;codonopsis Pilosula Root	0 (0.0)	1 (0.8)	1 (0.4)

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Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Atractylodes Lancea Rhizome;citrus Aurantium Peel;glycyrrhiza Spp. Root;panax Ginseng Root;pinellia Ternata Tuber;poria Cocos Sclerotium;zingiber Officinale Rhizome;ziziphus Jujuba Fruit	0 (0.0)	1 (0.8)	1 (0.4)
Baicalin;buffalo Horn;cholic Acid;concha Margaritifera;gardenia Jasminoides Fruit;hyodeoxycholic Acid;isatis Tinctoria Root;lonicera Japonica Flower	0 (0.0)	1 (0.8)	1 (0.4)
Bioflavonoids Nos;d-Mannose;vaccinium Macrocarpon	0 (0.0)	1 (0.8)	1 (0.4)
Bupleurum Spp. Root	0 (0.0)	1 (0.8)	1 (0.4)
Calcium Sulfate Dihydrate;dryopteris Crassirhizoma Rhizome;ephedra Spp. Herb;forsythia Suspensa;glycyrrhiza Spp. Root With Rhizome;houttuynia Cordata Herb;isatis Tinctoria Root;lonicera Japonica Flower;menthol;pogostemon Cablin Herb;prunus Spp. Seed;rheum Spp. Root With Rhizome;rhodiola Crenulata Root With Rhizome	0 (0.0)	1 (0.8)	1 (0.4)
Cannabis Sativa Fruit;citrus Aurantium Submature Fruit;magnolia Officinalis Bark;paeonia Lactiflora Root;prunus Spp. Seed;rheum Spp. Root With Rhizome	0 (0.0)	1 (0.8)	1 (0.4)
Ficus Carica	0 (0.0)	1 (0.8)	1 (0.4)
Pelargonium Sidoides Root Ethanol Extract	0 (0.0)	1 (0.8)	1 (0.4)
Platycodon Grandiflorus Root Fluid Extract	0 (0.0)	1 (0.8)	1 (0.4)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Sanguisorba Officinalis	0 (0.0)	1 (0.8)	1 (0.4)
Smilax Spp. Tuber;sophora Flavescens Root	0 (0.0)	1 (0.8)	1 (0.4)
Vitis Vinifera Extract	0 (0.0)	1 (0.8)	1 (0.4)
Solutions For Parenteral Nutrition	34 (24.5)	27 (20.9)	61 (22.8)
Amino Acids Nos	11 (7.9)	5 (3.9)	16 (6.0)
Glucose	10 (7.2)	7 (5.4)	17 (6.3)
Fats Nos	7 (5.0)	7 (5.4)	14 (5.2)
Amino Acids Nos;electrolytes Nos;glucose;thiamine Hydrochloride	6 (4.3)	5 (3.9)	11 (4.1)
Alanine;arginine;aspartic Acid;cysteine;glutamic Acid;glycine;histidine;isoleucine;leucine;lysine Acetate;methionine;phenylalanine;proline;serine;threonine;tryptophan, L-;tyrosine;valine	3 (2.2)	0 (0.0)	3 (1.1)

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Safety Analysis Set - Subpopulation without Irinotecan

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Alanine;arginine;calcium Chloride;fish Oil;glucose Monohydrate;glycine;glycine Max Seed Oil;histidine;isoleucine;leucine;lysine Acetate;magnesium Sulfate;medium-Chain Triglycerides;methionine;olea Europaea Oil;phenylalanine;potassium Chloride;proline;serine;sodium Acetate;sodium Glycerophosphate;taurine;threonine;tryptophan, L-;tyrosine;valine;zinc Sulfate	3 (2.2)	1 (0.8)	4 (1.5)
Amino Acids Nos;fats Nos;glucose	3 (2.2)	0 (0.0)	3 (1.1)
Solutions For Parenteral Nutrition	3 (2.2)	1 (0.8)	4 (1.5)
Alanine;arginine;aspartic Acid;calcium Chloride;glucose;glutamic Acid;glycine;glycine Max Seed Oil;histidine;isoleucine;leucine;lysine Hydrochloride;magnesium Sulfate;methionine;phenylalanine;potassium Chloride;proline;serine;sodium Acetate;sodium Glycerophosphate;threonine;tryptophan, L-;tyrosine;valine	2 (1.4)	1 (0.8)	3 (1.1)
Alanine;arginine;calcium Chloride Dihydrate;fish Oil;glucose Monohydrate;glycine;glycine Max Oil;histidine;isoleucine;leucine;lysine Hydrochloride;magnesium Sulfate Heptahydrate;medium-Chain Triglycerides;methionine;olea Europaea Oil;phenylalanine;potassium Chloride;proline;serine;sodium Acetate Trihydrate;sodium Glycerophosphate;threonine;tryptophan, L-;tyrosine;valine;zinc Sulfate Heptahydrate	2 (1.4)	1 (0.8)	3 (1.1)
Amino Acids Nos;copper;electrolytes Nos;glucose;iodine;iron;manganese;vitamins Nos;zinc	2 (1.4)	1 (0.8)	3 (1.1)
Glycerol;glycine Max Seed Oil;lecithin	2 (1.4)	0 (0.0)	2 (0.7)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Acetylcysteine;alanine;arginine;ascorbic Acid;aspartic Acid;biotin;calcium Chloride Dihydrate;cyanocobalamin;folic Acid;glucose;glutamic Acid;glycine;histidine;isoleucine;leucine;lysine Hydrochloride;magnesium Sulfate Heptahydrate;methionine;nicotinamide;panthenol;phenylalanine;potassium Phosphate Dibasic;proline;pyridoxine Hydrochloride;riboflavin Sodium Phosphate;serine;sodium Chloride;sodium Lactate;thiamine Hydrochloride;threonine;tryptophan, L-;tyrosine;valine;zinc Sulfate Heptahydrate	1 (0.7)	0 (0.0)	1 (0.4)
Alanine;arginine;aspartic Acid;calcium Chloride Dihydrate;glucose;glutamic Acid;glycerol;glycine;glycine Max Seed Oil;histidine;isoleucine;leucine;lysine Hydrochloride;magnesium Sulfate Heptahydrate;methionine;phenylalanine;phospholipids Egg;potassium Chloride;proline;serine;sodium Acetate Trihydrate;sodium Glycerophosphate;threonine;tryptophan, L-;tyrosine;valine	1 (0.7)	0 (0.0)	1 (0.4)
Amino Acids Nos;carbohydrates Nos;electrolytes Nos	1 (0.7)	0 (0.0)	1 (0.4)
Amino Acids Nos;electrolytes Nos;glucose	1 (0.7)	0 (0.0)	1 (0.4)
Amino Acids Nos;electrolytes Nos;glucose;lipids Nos	1 (0.7)	0 (0.0)	1 (0.4)
Amino Acids Nos;glucose	1 (0.7)	0 (0.0)	1 (0.4)
Amino Acids Nos;xylitol	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
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Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Dl-Alpha Tocopheryl Acetate;glycerol;glycine Max Seed Oil;lecithin;medium-Chain Triglycerides	1 (0.7)	0 (0.0)	1 (0.4)
Fish Oil;glycine Max Seed Oil;olea Europaea Oil;triglycerides	1 (0.7)	1 (0.8)	2 (0.7)
Glycerol;glycine Max Seed Oil;lecithin;medium-Chain Triglycerides	1 (0.7)	0 (0.0)	1 (0.4)
Triglycerides	1 (0.7)	0 (0.0)	1 (0.4)
Alanine;arginine Hydrochloride;aspartic Acid;calcium Gluconate;cysteine;glucose;glutamic Acid;glycine;histidine;isoleucine;leucine;lysine Hydrochloride;magnesium Sulfate;methionine;phenylalanine;potassium Phosphate Dibasic;proline;serine;sodium Chloride;sodium Lactate;threonine;tryptophan, L-;tyrosine;valine;zinc Sulfate	0 (0.0)	1 (0.8)	1 (0.4)
Alanine;arginine Hydrochloride;aspartic Acid;cystine;glycine;histidine Hydrochloride;isoleucine;lysine Hydrochloride;methionine;phenylalanine;proline;serine;sodium Bisulfite;sorbitol;threonine;tryptophan, L-;valine	0 (0.0)	1 (0.8)	1 (0.4)
Alanine;arginine;aspartic Acid;calcium Chloride Dihydrate;glucose;glutamic Acid;glycine;glycine Max Seed Oil;histidine;isoleucine;leucine;lysine Acetate;magnesium Chloride Hexahydrate;methionine;olea Europaea Oil;phenylalanine;potassium Chloride;proline;serine;sodium Acetate Trihydrate;sodium Glycerophosphate;threonine;tryptophan, L-;tyrosine;valine	0 (0.0)	1 (0.8)	1 (0.4)
Amino Acids Nos;electrolytes Nos;fatty Acid Glycerides;glucose	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Carbohydrates Nos;electrolytes Nos	0 (0.0)	2 (1.6)	2 (0.7)
Fructose	0 (0.0)	2 (1.6)	2 (0.7)
Glycerol;glycine Max Seed Oil;medium-Chain Triglycerides;phospholipids Egg	0 (0.0)	1 (0.8)	1 (0.4)
Invert Sugar	0 (0.0)	1 (0.8)	1 (0.4)
Solutions Affecting The Electrolyte Balance	31 (22.3)	35 (27.1)	66 (24.6)
Sodium Chloride	14 (10.1)	6 (4.7)	20 (7.5)
Electrolytes Nos;glucose	5 (3.6)	7 (5.4)	12 (4.5)
Glucose;sodium Chloride	5 (3.6)	5 (3.9)	10 (3.7)
Calcium Chloride Dihydrate;potassium Chloride;sodium Chloride;sodium Lactate	3 (2.2)	4 (3.1)	7 (2.6)
Calcium Chloride;potassium Chloride;sodium Chloride;sodium Lactate;sorbitol	3 (2.2)	3 (2.3)	6 (2.2)
Potassium Chloride;sodium Chloride	3 (2.2)	0 (0.0)	3 (1.1)
Fructose;glucose;magnesium Chloride;potassium Chloride;sodium Bisulfite;sodium Chloride;sodium Lactate;sodium Phosphate Monobasic	2 (1.4)	6 (4.7)	8 (3.0)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Solutions Affecting The Electrolyte Balance	2 (1.4)	1 (0.8)	3 (1.1)
Calcium Chloride Dihydrate;maltose Monohydrate;potassium Chloride;sodium Chloride;sodium Lactate	1 (0.7)	1 (0.8)	2 (0.7)
Calcium Chloride Dihydrate;potassium Chloride;sodium Acetate Trihydrate;sodium Chloride	1 (0.7)	1 (0.8)	2 (0.7)
Calcium Chloride;glucose	1 (0.7)	0 (0.0)	1 (0.4)
Calcium Gluconate Monohydrate;glucose;magnesium Chloride Hexahydrate;potassium Chloride;sodium Acetate;sodium Chloride;sodium Citrate Dihydrate	1 (0.7)	1 (0.8)	2 (0.7)
Electrolytes Nos	1 (0.7)	2 (1.6)	3 (1.1)
Glucose;potassium Chloride	1 (0.7)	0 (0.0)	1 (0.4)
Glucose;potassium Chloride;sodium Chloride	1 (0.7)	0 (0.0)	1 (0.4)
Glucose;potassium Chloride;sodium Chloride;sodium Lactate	1 (0.7)	2 (1.6)	3 (1.1)
Glucose;sodium Chloride;sodium Lactate	1 (0.7)	2 (1.6)	3 (1.1)
Calcium Chloride Dihydrate;glucose;potassium Chloride;sodium Acetate	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Calcium Chloride;potassium Chloride;sodium Acetate;sodium Chloride	0 (0.0)	1 (0.8)	1 (0.4)
Potassium Chloride;sodium Chloride;sodium Lactate	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
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Concomitant medications include medications that either
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Fluoroquinolones	30 (21.6)	29 (22.5)	59 (22.0)
Levofloxacin	21 (15.1)	14 (10.9)	35 (13.1)
Levofloxacin Hydrochloride	5 (3.6)	4 (3.1)	9 (3.4)
Ciprofloxacin	2 (1.4)	1 (0.8)	3 (1.1)
Levofloxacin Lactate	2 (1.4)	1 (0.8)	3 (1.1)
Moxifloxacin Hydrochloride	2 (1.4)	5 (3.9)	7 (2.6)
Ofloxacin	2 (1.4)	2 (1.6)	4 (1.5)
Enoxacin Gluconate	1 (0.7)	0 (0.0)	1 (0.4)
Moxifloxacin	1 (0.7)	2 (1.6)	3 (1.1)
Ciprofloxacin Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Norfloxacin	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
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Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Phenylpiperidine Derivatives	29 (20.9)	21 (16.3)	50 (18.7)
Fentanyl	20 (14.4)	16 (12.4)	36 (13.4)
Fentanyl Citrate	13 (9.4)	9 (7.0)	22 (8.2)
Pethidine	1 (0.7)	0 (0.0)	1 (0.4)
Pethidine Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Benzodiazepine Derivatives	28 (20.1)	28 (21.7)	56 (20.9)
Alprazolam	8 (5.8)	6 (4.7)	14 (5.2)
Lorazepam	5 (3.6)	4 (3.1)	9 (3.4)
Midazolam	5 (3.6)	5 (3.9)	10 (3.7)
Brotizolam	3 (2.2)	4 (3.1)	7 (2.6)
Diazepam	3 (2.2)	4 (3.1)	7 (2.6)
Flunitrazepam	3 (2.2)	0 (0.0)	3 (1.1)
Oxazepam	3 (2.2)	1 (0.8)	4 (1.5)
Clonazepam	2 (1.4)	1 (0.8)	3 (1.1)
Estazolam	2 (1.4)	4 (3.1)	6 (2.2)
Bromazepam	1 (0.7)	0 (0.0)	1 (0.4)
Etizolam	0 (0.0)	2 (1.6)	2 (0.7)
Lormetazepam	0 (0.0)	3 (2.3)	3 (1.1)

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Table 14.1.7.1.b:
Concomitant Medication
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Prazepam	0 (0.0)	2 (1.6)	2 (0.7)
Combinations Of Penicillins, Incl. Beta-Lactamase Inhibitors	27 (19.4)	23 (17.8)	50 (18.7)
Amoxicillin;clavulanate Potassium	10 (7.2)	10 (7.8)	20 (7.5)
Piperacillin Sodium;tazobactam Sodium	10 (7.2)	5 (3.9)	15 (5.6)
Ampicillin Sodium;sulbactam Sodium	5 (3.6)	4 (3.1)	9 (3.4)
Amoxicillin Trihydrate;clavulanate Potassium	2 (1.4)	1 (0.8)	3 (1.1)
Amoxicillin;clavulanic Acid	2 (1.4)	3 (2.3)	5 (1.9)
Mezlocillin;sulbactam	1 (0.7)	0 (0.0)	1 (0.4)
Piperacillin Sodium;sulbactam Sodium	1 (0.7)	0 (0.0)	1 (0.4)
Piperacillin Sodium;tazobactam	1 (0.7)	0 (0.0)	1 (0.4)
Piperacillin;tazobactam	1 (0.7)	4 (3.1)	5 (1.9)
Sultamicillin	0 (0.0)	1 (0.8)	1 (0.4)
Mucolytics	27 (19.4)	25 (19.4)	52 (19.4)

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Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Ambroxol Hydrochloride	10 (7.2)	9 (7.0)	19 (7.1)
Acetylcysteine	8 (5.8)	9 (7.0)	17 (6.3)
Carbocisteine	6 (4.3)	3 (2.3)	9 (3.4)
Bromhexine Hydrochloride	4 (2.9)	1 (0.8)	5 (1.9)
Ambroxol	2 (1.4)	1 (0.8)	3 (1.1)
Ambroxol Hydrochloride;sodium Chloride	2 (1.4)	2 (1.6)	4 (1.5)
Bromhexine	2 (1.4)	0 (0.0)	2 (0.7)
Erdosteine	2 (1.4)	4 (3.1)	6 (2.2)
Bromhexine Hydrochloride;glucose	1 (0.7)	0 (0.0)	1 (0.4)
Chymotrypsin	1 (0.7)	0 (0.0)	1 (0.4)
Mesna	1 (0.7)	0 (0.0)	1 (0.4)
Sodium Chloride	1 (0.7)	0 (0.0)	1 (0.4)
Ambroxol Hydrochloride;glucose	0 (0.0)	1 (0.8)	1 (0.4)

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Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
L-Carbocisteine	0 (0.0)	1 (0.8)	1 (0.4)
Propulsives	26 (18.7)	30 (23.3)	56 (20.9)
Mosapride Citrate	11 (7.9)	7 (5.4)	18 (6.7)
Domperidone	9 (6.5)	10 (7.8)	19 (7.1)
Metoclopramide	4 (2.9)	3 (2.3)	7 (2.6)
Metoclopramide Hydrochloride	3 (2.2)	4 (3.1)	7 (2.6)
Levosulpiride	2 (1.4)	2 (1.6)	4 (1.5)
Mosapride	2 (1.4)	0 (0.0)	2 (0.7)
Metoclopramide Dihydrochloride	1 (0.7)	8 (6.2)	9 (3.4)
Alizapride Hydrochloride	0 (0.0)	3 (2.3)	3 (1.1)
Domperidone Maleate	0 (0.0)	1 (0.8)	1 (0.4)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Electrolyte Solutions	24 (17.3)	19 (14.7)	43 (16.0)
Potassium Chloride	19 (13.7)	14 (10.9)	33 (12.3)
Calcium Gluconate	7 (5.0)	2 (1.6)	9 (3.4)
Sodium Chloride	7 (5.0)	4 (3.1)	11 (4.1)
Magnesium Sulfate	6 (4.3)	2 (1.6)	8 (3.0)
Sodium Glycerophosphate	2 (1.4)	0 (0.0)	2 (0.7)
Potassium Phosphate Monobasic	1 (0.7)	0 (0.0)	1 (0.4)
Sodium Bicarbonate	1 (0.7)	2 (1.6)	3 (1.1)
Calcium Chloride;potassium Chloride;sodium Chloride	0 (0.0)	1 (0.8)	1 (0.4)
Calcium Gluconate;calcium Saccharate	0 (0.0)	1 (0.8)	1 (0.4)
Chromic Chloride Hexahydrate;copper Chloride Dihydrate;ferric Chloride Hexahydrate;manganese Chloride Tetrahydrate;potassium Iodide;sodium Fluoride;sodium Molybdate Dihydrate;sodium Selenite;zinc Chloride Potassium	0 (0.0)	1 (0.8)	1 (0.4)
Potassium Phosphate Dibasic;potassium Phosphate Monobasic	0 (0.0)	2 (1.6)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Thyroid Hormones	24 (17.3)	4 (3.1)	28 (10.4)
Levothyroxine Sodium	16 (11.5)	4 (3.1)	20 (7.5)
Levothyroxine	8 (5.8)	0 (0.0)	8 (3.0)
Thyroid	1 (0.7)	0 (0.0)	1 (0.4)
Antiemetics And Antinauseants	22 (15.8)	21 (16.3)	43 (16.0)
Metoclopramide	14 (10.1)	14 (10.9)	28 (10.4)
Metoclopramide Hydrochloride	8 (5.8)	5 (3.9)	13 (4.9)
Metoclopramide Dihydrochloride	0 (0.0)	4 (3.1)	4 (1.5)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Contact Laxatives	22 (15.8)	13 (10.1)	35 (13.1)
Bisacodyl	8 (5.8)	4 (3.1)	12 (4.5)
Sennoside A+b	7 (5.0)	0 (0.0)	7 (2.6)
Sennoside A+b Calcium	5 (3.6)	5 (3.9)	10 (3.7)
Senna Alexandrina Leaf	2 (1.4)	0 (0.0)	2 (0.7)
Sodium Picosulfate	2 (1.4)	3 (2.3)	5 (1.9)
Ricinus Communis Oil	1 (0.7)	0 (0.0)	1 (0.4)
Senna Alexandrina	0 (0.0)	2 (1.6)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Third-Generation Cephalosporins	22 (15.8)	19 (14.7)	41 (15.3)
Cefoperazone Sodium;sulbactam Sodium	5 (3.6)	5 (3.9)	10 (3.7)
Ceftazidime	4 (2.9)	5 (3.9)	9 (3.4)
Ceftriaxone Sodium	3 (2.2)	7 (5.4)	10 (3.7)
Cefcapene Pivoxil Hydrochloride Hydrate	2 (1.4)	2 (1.6)	4 (1.5)
Cefoperazone Sodium;tazobactam Sodium	2 (1.4)	0 (0.0)	2 (0.7)
Ceftriaxone	2 (1.4)	0 (0.0)	2 (0.7)
Cefcapene Pivoxil Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Cefixime	1 (0.7)	0 (0.0)	1 (0.4)
Cefotaxime	1 (0.7)	1 (0.8)	2 (0.7)
Cefpodoxime Proxetil	1 (0.7)	0 (0.0)	1 (0.4)
Ceftriaxone Sodium Sesquaterhydrate	1 (0.7)	0 (0.0)	1 (0.4)
Cefditoren Pivoxil	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Cefotaxime Sodium	0 (0.0)	2 (1.6)	2 (0.7)
H2-Receptor Antagonists	20 (14.4)	72 (55.8)	92 (34.3)
Famotidine	10 (7.2)	24 (18.6)	34 (12.7)
Ranitidine	5 (3.6)	14 (10.9)	19 (7.1)
Cimetidine	3 (2.2)	25 (19.4)	28 (10.4)
Ranitidine Hydrochloride	3 (2.2)	13 (10.1)	16 (6.0)
Nizatidine	0 (0.0)	1 (0.8)	1 (0.4)
Ranitidine Bismuth Citrate	0 (0.0)	1 (0.8)	1 (0.4)
Roxatidine Acetate	0 (0.0)	1 (0.8)	1 (0.4)
Roxatidine Acetate Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Opioids	19 (13.7)	17 (13.2)	36 (13.4)
Tramadol Hydrochloride	12 (8.6)	9 (7.0)	21 (7.8)
Tramadol	4 (2.9)	3 (2.3)	7 (2.6)
Dezocine	2 (1.4)	2 (1.6)	4 (1.5)
Bucinnazine Hydrochloride	1 (0.7)	1 (0.8)	2 (0.7)
Naloxone;tilidine	0 (0.0)	1 (0.8)	1 (0.4)
Tapentadol Hydrochloride	0 (0.0)	2 (1.6)	2 (0.7)
Amino Acids	18 (12.9)	13 (10.1)	31 (11.6)
Tranexamic Acid	12 (8.6)	7 (5.4)	19 (7.1)
Alanyl Glutamine	5 (3.6)	4 (3.1)	9 (3.4)
Aminomethylbenzoic Acid	3 (2.2)	1 (0.8)	4 (1.5)
Sodium Chloride;tranexamic Acid	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Opioids In Combination With Non-Opioid Analgesics	18 (12.9)	27 (20.9)	45 (16.8)
Paracetamol;tramadol Hydrochloride	9 (6.5)	14 (10.9)	23 (8.6)
Codeine Phosphate;ibuprofen;paracetamol	4 (2.9)	4 (3.1)	8 (3.0)
Codeine Phosphate;ibuprofen	3 (2.2)	1 (0.8)	4 (1.5)
Oxycodone;paracetamol	3 (2.2)	1 (0.8)	4 (1.5)
Codeine Phosphate;paracetamol	0 (0.0)	2 (1.6)	2 (0.7)
Codeine;paracetamol	0 (0.0)	1 (0.8)	1 (0.4)
Dihydrocodeine Bitartrate;paracetamol	0 (0.0)	3 (2.3)	3 (1.1)
Oxycodone Hydrochloride;paracetamol	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Opium Alkaloids And Derivatives	18 (12.9)	22 (17.1)	40 (14.9)
Codeine Phosphate	8 (5.8)	10 (7.8)	18 (6.7)
Codeine	4 (2.9)	3 (2.3)	7 (2.6)
Dextromethorphan Hydrobromide	4 (2.9)	5 (3.9)	9 (3.4)
Dextromethorphan	2 (1.4)	0 (0.0)	2 (0.7)
Chlorphenamine Maleate;dihydrocodeine Phosphate;methylephedrine Hydrochloride-Dl	1 (0.7)	1 (0.8)	2 (0.7)
Dextromethorphan Hydrobromide;lysozyme Hydrochloride;potassium Cresolsulfonate	1 (0.7)	0 (0.0)	1 (0.4)
Dihydrocodeine	1 (0.7)	1 (0.8)	2 (0.7)
Dihydrocodeine Bitartrate	1 (0.7)	0 (0.0)	1 (0.4)
Ammonium Chloride;chlorphenamine Maleate;dihydrocodeine Bitartrate;methylephedrine Hydrochloride-Dl	0 (0.0)	4 (3.1)	4 (1.5)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
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Percentages were based on N.
Concomitant medications include medications that either
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Analgesics And Antipyretics	18 (12.9)	17 (13.2)	35 (13.1)
Pregabalin	10 (7.2)	10 (7.8)	20 (7.5)
Gabapentin	4 (2.9)	6 (4.7)	10 (3.7)
Nefopam Hydrochloride	2 (1.4)	0 (0.0)	2 (0.7)
Mirogabalin Besilate	1 (0.7)	1 (0.8)	2 (0.7)
Nefopam	1 (0.7)	0 (0.0)	1 (0.4)
Clonidine Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Duloxetine	0 (0.0)	1 (0.8)	1 (0.4)
Duloxetine Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
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Percentages were based on N.
Concomitant medications include medications that either
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Propionic Acid Derivatives	17 (12.2)	22 (17.1)	39 (14.6)
Ibuprofen	5 (3.6)	6 (4.7)	11 (4.1)
Loxoprofen Sodium Dihydrate	5 (3.6)	4 (3.1)	9 (3.4)
Naproxen	3 (2.2)	4 (3.1)	7 (2.6)
Dexketoprofen	2 (1.4)	0 (0.0)	2 (0.7)
Loxoprofen Sodium	2 (1.4)	6 (4.7)	8 (3.0)
Dexketoprofen Trometamol	1 (0.7)	0 (0.0)	1 (0.4)
Flurbiprofen Axetil	1 (0.7)	4 (3.1)	5 (1.9)
Loxoprofen	1 (0.7)	1 (0.8)	2 (0.7)
Chlorphenamine Maleate;ibuprofen;zinc Gluconate	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Appetite Stimulants	16 (11.5)	10 (7.8)	26 (9.7)
Megestrol Acetate	9 (6.5)	6 (4.7)	15 (5.6)
Megestrol	6 (4.3)	4 (3.1)	10 (3.7)
Carnitine Hydrochloride;cyanocobalamin;cyproheptadine Orotate;lysine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Serotonin (5ht3) Antagonists	16 (11.5)	69 (53.5)	85 (31.7)
Ondansetron	5 (3.6)	5 (3.9)	10 (3.7)
Palonosetron	3 (2.2)	8 (6.2)	11 (4.1)
Granisetron Hydrochloride	2 (1.4)	9 (7.0)	11 (4.1)
Ondansetron Hydrochloride	2 (1.4)	6 (4.7)	8 (3.0)
Tropisetron	2 (1.4)	4 (3.1)	6 (2.2)
Azasetron Hydrochloride	1 (0.7)	2 (1.6)	3 (1.1)
Glucose;granisetron Hydrochloride	1 (0.7)	1 (0.8)	2 (0.7)
Palonosetron Hydrochloride	1 (0.7)	19 (14.7)	20 (7.5)

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Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Tropisetron Hydrochloride	1 (0.7)	14 (10.9)	15 (5.6)
Azasetron Hydrochloride;sodium Chloride	0 (0.0)	1 (0.8)	1 (0.4)
Dolasetron	0 (0.0)	1 (0.8)	1 (0.4)
Dolasetron Mesilate	0 (0.0)	9 (7.0)	9 (3.4)
Granisetron	0 (0.0)	3 (2.3)	3 (1.1)
Ramosetron	0 (0.0)	3 (2.3)	3 (1.1)
Ramosetron Hydrochloride	0 (0.0)	2 (1.6)	2 (0.7)
Sodium Chloride;tropisetron Hydrochloride	0 (0.0)	2 (1.6)	2 (0.7)
Tropisetron Mesylate	0 (0.0)	1 (0.8)	1 (0.4)
Sulfonamides, Plain	16 (11.5)	19 (14.7)	35 (13.1)
Furosemide	15 (10.8)	16 (12.4)	31 (11.6)
Azosemide	1 (0.7)	0 (0.0)	1 (0.4)
Indapamide	0 (0.0)	1 (0.8)	1 (0.4)
Torasemide	0 (0.0)	3 (2.3)	3 (1.1)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Benzodiazepine Related Drugs	14 (10.1)	9 (7.0)	23 (8.6)
Zopiclone	6 (4.3)	3 (2.3)	9 (3.4)
Zolpidem Tartrate	5 (3.6)	5 (3.9)	10 (3.7)
Zolpidem	2 (1.4)	2 (1.6)	4 (1.5)
Eszopiclone	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 05JUN2024 17:40 t-14-01-07-01-b-cm-gen-safetys-cl.rtf

Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Heparin Group	13 (9.4)	7 (5.4)	20 (7.5)
Tinzaparin Sodium	3 (2.2)	1 (0.8)	4 (1.5)
Enoxaparin	2 (1.4)	1 (0.8)	3 (1.1)
Heparin	2 (1.4)	1 (0.8)	3 (1.1)
Dalteparin Sodium	1 (0.7)	0 (0.0)	1 (0.4)
Heparin Sodium	1 (0.7)	1 (0.8)	2 (0.7)
Low Molecular Weight Heparin, Calcium Salt	1 (0.7)	0 (0.0)	1 (0.4)
Low Molecular Weight Heparin, Sodium Salt	1 (0.7)	0 (0.0)	1 (0.4)
Sulodexide	1 (0.7)	0 (0.0)	1 (0.4)
Tinzaparin	1 (0.7)	0 (0.0)	1 (0.4)
Enoxaparin Sodium	0 (0.0)	1 (0.8)	1 (0.4)
Nadroparin Calcium	0 (0.0)	2 (1.6)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 05JUN2024 17:40 t-14-01-07-01-b-cm-gen-safetys-cl.rtf

Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Antihistamines For Systemic Use	13 (9.4)	10 (7.8)	23 (8.6)
Desloratadine	3 (2.2)	1 (0.8)	4 (1.5)
Fexofenadine Hydrochloride	3 (2.2)	4 (3.1)	7 (2.6)
Azelastine	2 (1.4)	0 (0.0)	2 (0.7)
Bepotastine Besilate	2 (1.4)	0 (0.0)	2 (0.7)
Bilastine	2 (1.4)	1 (0.8)	3 (1.1)
Cyproheptadine Hydrochloride	2 (1.4)	0 (0.0)	2 (0.7)
Loratadine	2 (1.4)	2 (1.6)	4 (1.5)
Epinastine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Fexofenadine	1 (0.7)	2 (1.6)	3 (1.1)
Ketotifen	1 (0.7)	0 (0.0)	1 (0.4)
Mebhydrolin	1 (0.7)	0 (0.0)	1 (0.4)
Ebastine	0 (0.0)	2 (1.6)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
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(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (Gord)	13 (9.4)	17 (13.2)	30 (11.2)
Sucralfate	4 (2.9)	4 (3.1)	8 (3.0)
Rebamipide	3 (2.2)	4 (3.1)	7 (2.6)
Sodium Alginate	3 (2.2)	1 (0.8)	4 (1.5)
Alginic Acid;aluminium Hydroxide;magnesium Carbonate;silicon Dioxide	1 (0.7)	0 (0.0)	1 (0.4)
Aloe Vera;calendula Officinalis;honey;hyaluronic Acid;matricaria Recutita;propolis;sodium Alginate	1 (0.7)	0 (0.0)	1 (0.4)
Calcium Carbonate;sodium Alginate;sodium Bicarbonate	1 (0.7)	1 (0.8)	2 (0.7)
Irsogladine Maleate	1 (0.7)	0 (0.0)	1 (0.4)
Levoglutamide;sodium Gualenate	1 (0.7)	2 (1.6)	3 (1.1)
Polaprezinc	1 (0.7)	4 (3.1)	5 (1.9)
Sodium Gualenate	1 (0.7)	1 (0.8)	2 (0.7)
Bismuth Pectin	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 05JUN2024 17:40 t-14-01-07-01-b-cm-gen-safetys-cl.rtf

Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Insulins And Analogues For Injection, Fast-Acting	12 (8.6)	1 (0.8)	13 (4.9)
Insulin	7 (5.0)	0 (0.0)	7 (2.6)
Insulin Aspart	4 (2.9)	0 (0.0)	4 (1.5)
Insulin Human	3 (2.2)	0 (0.0)	3 (1.1)
Insulin Lispro	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 05JUN2024 17:40 t-14-01-07-01-b-cm-gen-safetys-cl.rtf

Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Liver Therapy	12 (8.6)	9 (7.0)	21 (7.8)
Cysteine Hydrochloride;glycine;glycyrrhizic Acid, Ammonium Salt	4 (2.9)	3 (2.3)	7 (2.6)
Magnesium Isoglycyrrhizinate	4 (2.9)	3 (2.3)	7 (2.6)
Polyene Phosphatidylcholine	3 (2.2)	1 (0.8)	4 (1.5)
Diammonium Glycyrrhizinate	2 (1.4)	2 (1.6)	4 (1.5)
Dl-Methionine;glycine;glycyrrhizic Acid, Ammonium Salt	1 (0.7)	1 (0.8)	2 (0.7)
Ornithine Aspartate	1 (0.7)	0 (0.0)	1 (0.4)
Tiopronin	1 (0.7)	0 (0.0)	1 (0.4)
Diisopropylamine Dichloroacetate	0 (0.0)	1 (0.8)	1 (0.4)
Diisopropylamine Dichloroacetate;gluconate Sodium	0 (0.0)	2 (1.6)	2 (0.7)
Inosine	0 (0.0)	1 (0.8)	1 (0.4)
Liver Therapy	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Plain Vitamin Preparations	12 (8.6)	16 (12.4)	28 (10.4)
Pyridoxine Hydrochloride	11 (7.9)	15 (11.6)	26 (9.7)
Biotin	1 (0.7)	0 (0.0)	1 (0.4)
Dexpanthenol	1 (0.7)	0 (0.0)	1 (0.4)
Riboflavin	1 (0.7)	0 (0.0)	1 (0.4)
Riboflavin Sodium Phosphate	1 (0.7)	0 (0.0)	1 (0.4)
Vitamin B Nos	0 (0.0)	1 (0.8)	1 (0.4)
Platelet Aggregation Inhibitors Excl. Heparin	12 (8.6)	8 (6.2)	20 (7.5)
Acetylsalicylic Acid	6 (4.3)	4 (3.1)	10 (3.7)
Acetylsalicylate Lysine	2 (1.4)	2 (1.6)	4 (1.5)
Clopidogrel Bisulfate	2 (1.4)	2 (1.6)	4 (1.5)
Alprostadil	1 (0.7)	0 (0.0)	1 (0.4)
Cilostazol	1 (0.7)	0 (0.0)	1 (0.4)
Clopidogrel	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Selective Beta-2-Adrenoreceptor Agonists	12 (8.6)	4 (3.1)	16 (6.0)
Salbutamol	6 (4.3)	1 (0.8)	7 (2.6)
Terbutaline	2 (1.4)	0 (0.0)	2 (0.7)
Tulobuterol	2 (1.4)	0 (0.0)	2 (0.7)
Salbutamol Sulfate	1 (0.7)	0 (0.0)	1 (0.4)
Terbutaline Sulfate	1 (0.7)	2 (1.6)	3 (1.1)
Procaterol Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Acetic Acid Derivatives And Related Substances	11 (7.9)	9 (7.0)	20 (7.5)
Diclofenac Potassium	3 (2.2)	1 (0.8)	4 (1.5)
Diclofenac	2 (1.4)	1 (0.8)	3 (1.1)
Diclofenac Sodium	2 (1.4)	3 (2.3)	5 (1.9)
Aceclofenac	1 (0.7)	1 (0.8)	2 (0.7)
Acemetacin	1 (0.7)	1 (0.8)	2 (0.7)
Indometacin	1 (0.7)	2 (1.6)	3 (1.1)
Ketorolac Tromethamine	1 (0.7)	1 (0.8)	2 (0.7)
Antidotes	11 (7.9)	13 (10.1)	24 (9.0)
Glutathione	7 (5.0)	12 (9.3)	19 (7.1)
Flumazenil	2 (1.4)	0 (0.0)	2 (0.7)
Acetylcysteine	1 (0.7)	1 (0.8)	2 (0.7)
Glutathione Sodium	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Blood Substitutes And Plasma Protein Fractions	11 (7.9)	6 (4.7)	17 (6.3)
Albumin Human	7 (5.0)	4 (3.1)	11 (4.1)
Albumin Nos	5 (3.6)	2 (1.6)	7 (2.6)
Dextran	1 (0.7)	0 (0.0)	1 (0.4)
Succinylated Gelatin	0 (0.0)	1 (0.8)	1 (0.4)
Combinations And Complexes Of Aluminium, Calcium And Magnesium Compounds	11 (7.9)	13 (10.1)	24 (9.0)
Hydrotalcite	5 (3.6)	3 (2.3)	8 (3.0)
Almagate	4 (2.9)	3 (2.3)	7 (2.6)
Aluminium Hydroxide;calcium Carbonate;magnesium Carbonate;oxetacaine	1 (0.7)	0 (0.0)	1 (0.4)
Aluminium;magnesium	1 (0.7)	7 (5.4)	8 (3.0)
Magaldrate	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Corticosteroids, Potent (Group Iii)	11 (7.9)	10 (7.8)	21 (7.8)
Betamethasone Valerate	4 (2.9)	1 (0.8)	5 (1.9)
Diflucortolone Valerate	3 (2.2)	2 (1.6)	5 (1.9)
Betamethasone	2 (1.4)	1 (0.8)	3 (1.1)
Betamethasone Dipropionate	2 (1.4)	1 (0.8)	3 (1.1)
Difluprednate	1 (0.7)	1 (0.8)	2 (0.7)
Fluocinonide	1 (0.7)	0 (0.0)	1 (0.4)
Mometasone Furoate	1 (0.7)	1 (0.8)	2 (0.7)
Betamethasone Butyrate Propionate	0 (0.0)	1 (0.8)	1 (0.4)
Diflucortolone	0 (0.0)	1 (0.8)	1 (0.4)
Hydrocortisone	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Coxibs	11 (7.9)	8 (6.2)	19 (7.1)
Celecoxib	9 (6.5)	7 (5.4)	16 (6.0)
Etoricoxib	1 (0.7)	0 (0.0)	1 (0.4)
Imrecoxib	1 (0.7)	1 (0.8)	2 (0.7)
Hmg Coa Reductase Inhibitors	11 (7.9)	7 (5.4)	18 (6.7)
Atorvastatin	4 (2.9)	1 (0.8)	5 (1.9)
Atorvastatin Calcium	2 (1.4)	1 (0.8)	3 (1.1)
Rosuvastatin Calcium	2 (1.4)	1 (0.8)	3 (1.1)
Simvastatin	2 (1.4)	2 (1.6)	4 (1.5)
Pitavastatin	1 (0.7)	0 (0.0)	1 (0.4)
Pitavastatin Calcium	1 (0.7)	0 (0.0)	1 (0.4)
Pravastatin	0 (0.0)	1 (0.8)	1 (0.4)
Rosuvastatin	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Antiinflammatory Preparations, Non-Steroids For Topical Use	10 (7.2)	8 (6.2)	18 (6.7)
Ketoprofen	3 (2.2)	1 (0.8)	4 (1.5)
Flurbiprofen	2 (1.4)	0 (0.0)	2 (0.7)
Loxoprofen Sodium	2 (1.4)	0 (0.0)	2 (0.7)
Loxoprofen Sodium Dihydrate	2 (1.4)	3 (2.3)	5 (1.9)
Esflurbiprofen;mentha Spp. Oil	1 (0.7)	0 (0.0)	1 (0.4)
Etofenamate	1 (0.7)	0 (0.0)	1 (0.4)
Diclofenac Diethylamine	0 (0.0)	1 (0.8)	1 (0.4)
Diclofenac Sodium	0 (0.0)	1 (0.8)	1 (0.4)
Indometacin	0 (0.0)	2 (1.6)	2 (0.7)
Ascorbic Acid (Vitamin C), Plain	10 (7.2)	10 (7.8)	20 (7.5)
Ascorbic Acid	10 (7.2)	10 (7.8)	20 (7.5)
Fat/Carbohydrates/Proteins/Minerals/Vitamins, Combinations	10 (7.2)	13 (10.1)	23 (8.6)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 05JUN2024 17:40 t-14-01-07-01-b-cm-gen-safetys-cl.rtf

Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Ascorbic Acid;biotin;calcium;carbohydrates Nos;chloride;colecalciferol;copper;cyanocobalamin;fats Nos;folic Acid;iron;magnesium;manganese;nicotinamide;pantothenic Acid;phosphorus;potassium;proteins Nos;pyridoxine;retinol;riboflavin;sodium;thiamine;tocopherol;zinc	3 (2.2)	5 (3.9)	8 (3.0)
Casein;herbal Oil Nos;maltodextrin;minerals Nos;trace Elements Nos;vitamins Nos	3 (2.2)	1 (0.8)	4 (1.5)
Ascorbic Acid;biotin;calcium Citrate;calcium Pantothenate;cyanocobalamin;ferrous Sulfate;fibre, Dietary;folic Acid;glycine Max Seed Oil;magnesium Carbonate;maltodextrin;nicotinamide;potassium Citrate;proteins Nos;pyridoxine Hydrochloride;retinol;riboflavin;sodium Chloride;sucrose;thiamine Hydrochloride;tocopheryl Acetate;whey Protein;zea Mays Starch	2 (1.4)	3 (2.3)	5 (1.9)
Carbohydrates Nos;electrolytes Nos;lipids Nos;proteins Nos;vitamins Nos	2 (1.4)	2 (1.6)	4 (1.5)
Fat/Carbohydrates/Proteins/Minerals/Vitamins, Combinations	1 (0.7)	0 (0.0)	1 (0.4)
Ascorbic Acid;biotin;calcium;carbohydrates Nos;chlorine;choline;chromium;copper;fats Nos;folic Acid;fructooligosaccharides;iron;levocarnitine;magnesium;manganese;molybdenum;nicotinic Acid;pantothenic Acid;phosphorus;potassium;proteins Nos;pyridoxine Hydrochloride;retinol;riboflavin;selenium;sodium;taurine;vitamin B1 Nos;vitamin B12 Nos;vitamin D Nos;vitamin E Nos;vitamin K Nos;zinc	0 (0.0)	1 (0.8)	1 (0.4)
Carbohydrates Nos;fats Nos;minerals Nos;proteins Nos;vitamins Nos	0 (0.0)	1 (0.8)	1 (0.4)
Carbohydrates Nos;fatty Acids Nos;minerals Nos;proteins Nos;vitamins Nos	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
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Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 05JUN2024 17:40 t-14-01-07-01-b-cm-gen-safetys-cl.rtf

Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Casein;fats Nos;fibre, Dietary;maltodextrin;minerals Nos;vitamins Nos	0 (0.0)	1 (0.8)	1 (0.4)
General Nutrients	10 (7.2)	10 (7.8)	20 (7.5)
Nutrients Nos	4 (2.9)	4 (3.1)	8 (3.0)
General Nutrients	3 (2.2)	5 (3.9)	8 (3.0)
Trace Elements Nos	3 (2.2)	1 (0.8)	4 (1.5)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Opium Derivatives And Expectorants	10 (7.2)	5 (3.9)	15 (5.6)
Ammonia;benzoic Acid;camphor;glycerol;glycyrrhiza Spp. Root With Rhizome;guaifenesin;illicium Verum Oil;papaver Somniferum Tincture	4 (2.9)	1 (0.8)	5 (1.9)
Chlorphenamine Maleate;codeine Phosphate;glycyrrhizic Acid;methylephedrine Hydrochloride-Dl	2 (1.4)	0 (0.0)	2 (0.7)
Opium Derivatives And Expectorants	2 (1.4)	1 (0.8)	3 (1.1)
Dextromethorphan;guaifenesin;phenylephrine	1 (0.7)	0 (0.0)	1 (0.4)
Ephedrine Hydrochloride;guaifenesin;pholcodine	1 (0.7)	0 (0.0)	1 (0.4)
Camphor;glycyrrhiza Glabra;illicium Verum Oil;papaver Somniferum;sodium Benzoate	0 (0.0)	1 (0.8)	1 (0.4)
Chlorphenamine Maleate;dihydrocodeine Bitartrate;guaifenesin;methylephedrine Hydrochloride-Dl	0 (0.0)	1 (0.8)	1 (0.4)
Papaver Somniferum Powder;platycodon Grandiflorus;potassium Sulfate	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Agents For Local Oral Treatment	10 (7.2)	6 (4.7)	16 (6.0)
Sodium Gualenate Hydrate	4 (2.9)	2 (1.6)	6 (2.2)
Lidocaine	3 (2.2)	2 (1.6)	5 (1.9)
Benzydamine	1 (0.7)	0 (0.0)	1 (0.4)
Calcium Chloride;carmellose Sodium;magnesium Chloride;potassium Chloride;potassium Phosphate Dibasic;sodium Chloride;sorbitol	1 (0.7)	0 (0.0)	1 (0.4)
Sucralfate	1 (0.7)	0 (0.0)	1 (0.4)
Triester Glycerol Oxide	1 (0.7)	0 (0.0)	1 (0.4)
Benzydamine Hydrochloride	0 (0.0)	2 (1.6)	2 (0.7)
Lidocaine Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Antiemetics	10 (7.2)	10 (7.8)	20 (7.5)
Prochlorperazine Maleate	4 (2.9)	1 (0.8)	5 (1.9)
Metopimazine	3 (2.2)	0 (0.0)	3 (1.1)
Aprepitant	1 (0.7)	3 (2.3)	4 (1.5)
Difenidol	1 (0.7)	0 (0.0)	1 (0.4)
Promethazine	1 (0.7)	0 (0.0)	1 (0.4)
Dimenhydrinate	0 (0.0)	1 (0.8)	1 (0.4)
Diphenhydramine	0 (0.0)	1 (0.8)	1 (0.4)
Diphenhydramine Hydrochloride	0 (0.0)	2 (1.6)	2 (0.7)
Fosaprepitant Meglumine	0 (0.0)	1 (0.8)	1 (0.4)
Hyoscine Hydrobromide	0 (0.0)	1 (0.8)	1 (0.4)
Promethazine Hydrochloride	0 (0.0)	2 (1.6)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Blood Products	10 (7.2)	13 (10.1)	23 (8.6)
Blood, Whole	4 (2.9)	1 (0.8)	5 (1.9)
Blood Plasma	3 (2.2)	0 (0.0)	3 (1.1)
Red Blood Cells, Concentrated	2 (1.4)	1 (0.8)	3 (1.1)
Platelets	1 (0.7)	0 (0.0)	1 (0.4)
Red Blood Cells	1 (0.7)	7 (5.4)	8 (3.0)
Red Blood Cells, Leucocyte Depleted	1 (0.7)	4 (3.1)	5 (1.9)
Other Systemic Hemostatics	10 (7.2)	4 (3.1)	14 (5.2)
Haemocoagulase	5 (3.6)	2 (1.6)	7 (2.6)
Etamsilate	4 (2.9)	1 (0.8)	5 (1.9)
Recombinant Human Thrombopoietin	2 (1.4)	0 (0.0)	2 (0.7)
Carbazochrome	1 (0.7)	0 (0.0)	1 (0.4)
Carbazochrome Sodium Sulfonate	1 (0.7)	2 (1.6)	3 (1.1)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
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Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Substituted Alkylamines	10 (7.2)	35 (27.1)	45 (16.8)
Chlorphenamine	4 (2.9)	13 (10.1)	17 (6.3)
Chlorphenamine Maleate	4 (2.9)	5 (3.9)	9 (3.4)
Dexchlorpheniramine Maleate	2 (1.4)	14 (10.9)	16 (6.0)
Dexchlorpheniramine	0 (0.0)	2 (1.6)	2 (0.7)
Pheniramine	0 (0.0)	2 (1.6)	2 (0.7)
Carbapenems	9 (6.5)	5 (3.9)	14 (5.2)
Meropenem	5 (3.6)	2 (1.6)	7 (2.6)
Meropenem Trihydrate	3 (2.2)	2 (1.6)	5 (1.9)
Cilastatin Sodium;imipenem	1 (0.7)	0 (0.0)	1 (0.4)
Imipenem	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Direct Factor Xa Inhibitors	9 (6.5)	5 (3.9)	14 (5.2)
Apixaban	5 (3.6)	4 (3.1)	9 (3.4)
Rivaroxaban	3 (2.2)	2 (1.6)	5 (1.9)
Edoxaban	2 (1.4)	0 (0.0)	2 (0.7)
Edoxaban Tosilate	2 (1.4)	0 (0.0)	2 (0.7)
Medical Gases	9 (6.5)	8 (6.2)	17 (6.3)
Oxygen	9 (6.5)	8 (6.2)	17 (6.3)
Other Cough Suppressants	9 (6.5)	1 (0.8)	10 (3.7)
Tipepidine Hibenzate	6 (4.3)	0 (0.0)	6 (2.2)
Benzonatate	1 (0.7)	1 (0.8)	2 (0.7)
Cloperastine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Helicidine	1 (0.7)	0 (0.0)	1 (0.4)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Second-Generation Cephalosporins	9 (6.5)	2 (1.6)	11 (4.1)
Cefaclor	3 (2.2)	1 (0.8)	4 (1.5)
Cefuroxime Sodium	3 (2.2)	0 (0.0)	3 (1.1)
Cefmetazole Sodium	1 (0.7)	1 (0.8)	2 (0.7)
Cefonicid	1 (0.7)	0 (0.0)	1 (0.4)
Cefonicid Sodium	1 (0.7)	0 (0.0)	1 (0.4)
Cefoxitin Sodium	0 (0.0)	1 (0.8)	1 (0.4)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Adrenergics In Combination With Anticholinergics Incl. Triple Combinations With Corticosteroids	8 (5.8)	1 (0.8)	9 (3.4)
Beclometasone Dipropionate;formoterol Fumarate;glycopyrronium Bromide	2 (1.4)	0 (0.0)	2 (0.7)
Ipratropium Bromide;salbutamol Sulfate	2 (1.4)	0 (0.0)	2 (0.7)
Ipratropium;salbutamol	2 (1.4)	0 (0.0)	2 (0.7)
Fenoterol Hydrobromide;ipratropium Bromide	1 (0.7)	1 (0.8)	2 (0.7)
Glycopyrronium Bromide;indacaterol Maleate	1 (0.7)	0 (0.0)	1 (0.4)
Ipratropium Bromide;salbutamol	1 (0.7)	0 (0.0)	1 (0.4)
Olodaterol Hydrochloride;tiotropium Bromide Monohydrate	1 (0.7)	0 (0.0)	1 (0.4)
Alpha-Adrenoreceptor Antagonists	8 (5.8)	6 (4.7)	14 (5.2)
Tamsulosin Hydrochloride	6 (4.3)	3 (2.3)	9 (3.4)
Alfuzosin	1 (0.7)	0 (0.0)	1 (0.4)
Tamsulosin	1 (0.7)	1 (0.8)	2 (0.7)
Terazosin Hydrochloride	1 (0.7)	1 (0.8)	2 (0.7)
Doxazosin	0 (0.0)	1 (0.8)	1 (0.4)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Anticholinergics	8 (5.8)	3 (2.3)	11 (4.1)
Ipratropium Bromide	2 (1.4)	0 (0.0)	2 (0.7)
Ipratropium	1 (0.7)	0 (0.0)	1 (0.4)
Phenylephrine Hydrochloride;tropicamide	1 (0.7)	0 (0.0)	1 (0.4)
Tiotropium	1 (0.7)	1 (0.8)	2 (0.7)
Tiotropium Bromide	1 (0.7)	1 (0.8)	2 (0.7)
Tropicamide	1 (0.7)	0 (0.0)	1 (0.4)
Umeclidinium Bromide	1 (0.7)	0 (0.0)	1 (0.4)
Ipratropium Bromide Monohydrate	0 (0.0)	1 (0.8)	1 (0.4)

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Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
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unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 05JUN2024 17:40 t-14-01-07-01-b-cm-gen-safetys-cl.rtf

Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Antidiarrheal Microorganisms	8 (5.8)	7 (5.4)	15 (5.6)
Bacillus Subtilis;enterococcus Faecalis;lactobacillus Acidophilus	2 (1.4)	0 (0.0)	2 (0.7)
Bifidobacterium Bifidum;bifidobacterium Infantis	2 (1.4)	1 (0.8)	3 (1.1)
Bifidobacterium Nos	1 (0.7)	0 (0.0)	1 (0.4)
Enterococcus Faecalis	1 (0.7)	1 (0.8)	2 (0.7)
Lactobacillus Helveticus;lactobacillus Rhamnosus	1 (0.7)	0 (0.0)	1 (0.4)
Saccharomyces Boulardii	1 (0.7)	0 (0.0)	1 (0.4)
Bacillus Lichenformis	0 (0.0)	1 (0.8)	1 (0.4)
Bacillus Mesentericus;clostridium Butyricum;enterococcus Faecalis	0 (0.0)	1 (0.8)	1 (0.4)
Bifidobacterium Lactis	0 (0.0)	1 (0.8)	1 (0.4)
Bifidobacterium Longum;enterococcus Faecalis;lactobacillus Acidophilus	0 (0.0)	1 (0.8)	1 (0.4)
Bifidobacterium Longum;lactobacillus Bulgaricus;streptococcus Thermophilus	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Beta Blocking Agents, Selective	8 (5.8)	11 (8.5)	19 (7.1)
Bisoprolol	4 (2.9)	4 (3.1)	8 (3.0)
Bisoprolol Fumarate	2 (1.4)	1 (0.8)	3 (1.1)
Atenolol	1 (0.7)	1 (0.8)	2 (0.7)
Metoprolol Tartrate	1 (0.7)	2 (1.6)	3 (1.1)
Acebutolol	0 (0.0)	1 (0.8)	1 (0.4)
Esmolol Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Metoprolol	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Bisphosphonates	8 (5.8)	10 (7.8)	18 (6.7)
Zoledronic Acid	6 (4.3)	9 (7.0)	15 (5.6)
Clodronate Disodium	1 (0.7)	0 (0.0)	1 (0.4)
Glucose;pamidronate Disodium	1 (0.7)	0 (0.0)	1 (0.4)
Ibandronate Monosodium Monohydrate	1 (0.7)	0 (0.0)	1 (0.4)
Ibandronate Sodium	1 (0.7)	0 (0.0)	1 (0.4)
Disodium Incadronate	0 (0.0)	1 (0.8)	1 (0.4)
Corticosteroids, Moderately Potent (Group Ii)	8 (5.8)	2 (1.6)	10 (3.7)
Desonide	4 (2.9)	1 (0.8)	5 (1.9)
Hydrocortisone Butyrate	3 (2.2)	0 (0.0)	3 (1.1)
Dexamethasone	1 (0.7)	0 (0.0)	1 (0.4)
Dexamethasone Sodium Phosphate	0 (0.0)	1 (0.8)	1 (0.4)

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Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Aminoglycosides	8 (5.8)	1 (0.8)	9 (3.4)
Amikacin	5 (3.6)	0 (0.0)	5 (1.9)
Gentamicin	2 (1.4)	1 (0.8)	3 (1.1)
Etimicin Sulfate	1 (0.7)	0 (0.0)	1 (0.4)
Other Emollients And Protectives	8 (5.8)	3 (2.3)	11 (4.1)
Heparinoid	4 (2.9)	0 (0.0)	4 (1.5)
Mucopolysaccharide Polysulfuric Acid Ester	2 (1.4)	1 (0.8)	3 (1.1)
Ceramide;methyl Caprooyl Tyrosinate;phytosterols Nos;squalane;stearic Acid	1 (0.7)	0 (0.0)	1 (0.4)
Glycerol;paraffin, Liquid;white Soft Paraffin	1 (0.7)	1 (0.8)	2 (0.7)
Glycerol;paraffin, Liquid;petrolatum	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Ophthalmologicals	8 (5.8)	3 (2.3)	11 (4.1)
Pirenoxine	4 (2.9)	0 (0.0)	4 (1.5)
Cyanocobalamin	3 (2.2)	0 (0.0)	3 (1.1)
Hyaluronate Sodium	1 (0.7)	2 (1.6)	3 (1.1)
Hypromellose	1 (0.7)	0 (0.0)	1 (0.4)
Potassium Iodide;sodium Iodide	1 (0.7)	0 (0.0)	1 (0.4)
Rebamipide	1 (0.7)	0 (0.0)	1 (0.4)
Trehalose	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Piperazine Derivatives	8 (5.8)	11 (8.5)	19 (7.1)
Cetirizine Hydrochloride	3 (2.2)	3 (2.3)	6 (2.2)
Levocetirizine Dihydrochloride	3 (2.2)	3 (2.3)	6 (2.2)
Buclizine Hydrochloride	1 (0.7)	1 (0.8)	2 (0.7)
Hydroxyzine	1 (0.7)	0 (0.0)	1 (0.4)
Hydroxyzine Hydrochloride	1 (0.7)	1 (0.8)	2 (0.7)
Levocetirizine	1 (0.7)	2 (1.6)	3 (1.1)
Cetirizine	0 (0.0)	1 (0.8)	1 (0.4)
Antipropulsives	7 (5.0)	13 (10.1)	20 (7.5)
Loperamide	5 (3.6)	4 (3.1)	9 (3.4)
Loperamide Hydrochloride	2 (1.4)	9 (7.0)	11 (4.1)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
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Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Biguanides	7 (5.0)	3 (2.3)	10 (3.7)
Metformin Hydrochloride	4 (2.9)	2 (1.6)	6 (2.2)
Metformin	3 (2.2)	1 (0.8)	4 (1.5)
Diazepines, Oxazepines, Thiazepines And Oxepines	7 (5.0)	6 (4.7)	13 (4.9)
Olanzapine	4 (2.9)	2 (1.6)	6 (2.2)
Quetiapine Fumarate	2 (1.4)	1 (0.8)	3 (1.1)
Quetiapine	1 (0.7)	2 (1.6)	3 (1.1)
Asenapine Maleate	0 (0.0)	1 (0.8)	1 (0.4)
Enemas	7 (5.0)	6 (4.7)	13 (4.9)
Glycerol	6 (4.3)	6 (4.7)	12 (4.5)
Sodium Chloride	1 (0.7)	1 (0.8)	2 (0.7)
Soft Soap	1 (0.7)	0 (0.0)	1 (0.4)
Enemas	0 (0.0)	1 (0.8)	1 (0.4)

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Table 14.1.7.1.b:
Concomitant Medication
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Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Iron Bivalent, Oral Preparations	7 (5.0)	7 (5.4)	14 (5.2)
Ferrous Sulfate	3 (2.2)	2 (1.6)	5 (1.9)
Ferrous Fumarate	1 (0.7)	2 (1.6)	3 (1.1)
Ferrous Glycine Sulfate	1 (0.7)	0 (0.0)	1 (0.4)
Ferrous Sodium Citrate	1 (0.7)	1 (0.8)	2 (0.7)
Ferrous Succinate	1 (0.7)	1 (0.8)	2 (0.7)
Ferrous Gluconate	0 (0.0)	1 (0.8)	1 (0.4)
Other Drugs For Functional Gastrointestinal Disorders	7 (5.0)	3 (2.3)	10 (3.7)
Simeticone	3 (2.2)	0 (0.0)	3 (1.1)
Dimeticone	2 (1.4)	2 (1.6)	4 (1.5)
Phloroglucinol;trimethylphloroglucinol	2 (1.4)	0 (0.0)	2 (0.7)
Phloroglucinol	1 (0.7)	0 (0.0)	1 (0.4)
Atractylodes Macrocephala, Rhizoma;glycyrrhiza Spp. Root With Rhizome;levoglutamide;panax Ginseng Root With Rhizome;poria Cocos Sclerotium	0 (0.0)	1 (0.8)	1 (0.4)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Immunostimulants	7 (5.0)	7 (5.4)	14 (5.2)
Leucogen	3 (2.2)	2 (1.6)	5 (1.9)
Lentinan	1 (0.7)	0 (0.0)	1 (0.4)
Mannatide	1 (0.7)	0 (0.0)	1 (0.4)
Polypeptide	1 (0.7)	0 (0.0)	1 (0.4)
Thymopentin	1 (0.7)	1 (0.8)	2 (0.7)
Amino Acids Nos;nucleic Acid Nos;polysaccharides Nos	0 (0.0)	1 (0.8)	1 (0.4)
Amino Acids Nos;peptides Nos;trace Elements Nos	0 (0.0)	1 (0.8)	1 (0.4)
Deoxyribonucleotide Sodium	0 (0.0)	1 (0.8)	1 (0.4)
Nucleotides Nos;polypeptide	0 (0.0)	1 (0.8)	1 (0.4)
Thymalfasin	0 (0.0)	2 (1.6)	2 (0.7)

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Concomitant Medication
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Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Penicillins With Extended Spectrum	7 (5.0)	7 (5.4)	14 (5.2)
Amoxicillin	5 (3.6)	6 (4.7)	11 (4.1)
Amoxicillin Trihydrate	1 (0.7)	2 (1.6)	3 (1.1)
Ampicillin	1 (0.7)	0 (0.0)	1 (0.4)
Piperacillin	1 (0.7)	1 (0.8)	2 (0.7)
Peripheral Opioid Receptor Antagonists	7 (5.0)	0 (0.0)	7 (2.6)
Naldemedine Tosilate	6 (4.3)	0 (0.0)	6 (2.2)
Naloxegol	1 (0.7)	0 (0.0)	1 (0.4)
Vitamins	7 (5.0)	5 (3.9)	12 (4.5)
Vitamins Nos	5 (3.6)	1 (0.8)	6 (2.2)
Water Soluble Vitamins Nos	2 (1.4)	2 (1.6)	4 (1.5)
Fat Soluble Vitamins Nos	1 (0.7)	0 (0.0)	1 (0.4)
Ergocalciferol;phytomenadione;retinol Palmitate;vitamin E Nos	0 (0.0)	2 (1.6)	2 (0.7)

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Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Xanthines	7 (5.0)	4 (3.1)	11 (4.1)
Doxofylline	4 (2.9)	1 (0.8)	5 (1.9)
Diprophylline	2 (1.4)	1 (0.8)	3 (1.1)
Theobromine	1 (0.7)	0 (0.0)	1 (0.4)
Theophylline	1 (0.7)	0 (0.0)	1 (0.4)
Aminophylline	0 (0.0)	2 (1.6)	2 (0.7)

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Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Adrenergic And Dopaminergic Agents	6 (4.3)	6 (4.7)	12 (4.5)
Norepinephrine	4 (2.9)	1 (0.8)	5 (1.9)
Midodrine Hydrochloride	2 (1.4)	1 (0.8)	3 (1.1)
Dopamine	1 (0.7)	0 (0.0)	1 (0.4)
Epinephrine	1 (0.7)	3 (2.3)	4 (1.5)
Metaraminol Tartrate	1 (0.7)	0 (0.0)	1 (0.4)
Norepinephrine Bitartrate	1 (0.7)	1 (0.8)	2 (0.7)
Dopamine Hydrochloride	0 (0.0)	2 (1.6)	2 (0.7)
Etilefrine Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Norepinephrine Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Cardiac Preparations	6 (4.3)	8 (6.2)	14 (5.2)
Adenosine	2 (1.4)	0 (0.0)	2 (0.7)
Ivabradine	1 (0.7)	0 (0.0)	1 (0.4)
Levocarnitine	1 (0.7)	2 (1.6)	3 (1.1)
Magnesium Tanshinoate B	1 (0.7)	0 (0.0)	1 (0.4)
Meglumine Adenosine Cyclophosphate	1 (0.7)	0 (0.0)	1 (0.4)
Phosphocreatine Sodium	0 (0.0)	4 (3.1)	4 (1.5)
Tanshinone Iia Sodium Sulfonate	0 (0.0)	1 (0.8)	1 (0.4)
Ubidecarenone	0 (0.0)	1 (0.8)	1 (0.4)
Adrenergics In Combination With Corticosteroids Or Other Drugs, Excl. Anticholinergics	5 (3.6)	0 (0.0)	5 (1.9)
Beclometasone Dipropionate;formoterol Fumarate	2 (1.4)	0 (0.0)	2 (0.7)
Fluticasone Furoate;vilanterol Trifenatate	1 (0.7)	0 (0.0)	1 (0.4)
Fluticasone Propionate;salmeterol Xinafoate	1 (0.7)	0 (0.0)	1 (0.4)
Fluticasone;salmeterol	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Amides	5 (3.6)	15 (11.6)	20 (7.5)
Lidocaine	3 (2.2)	5 (3.9)	8 (3.0)
Lidocaine;prilocaine	2 (1.4)	0 (0.0)	2 (0.7)
Lidocaine Hydrochloride	1 (0.7)	7 (5.4)	8 (3.0)
Ropivacaine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Bupivacaine	0 (0.0)	1 (0.8)	1 (0.4)
Epinephrine;lidocaine	0 (0.0)	1 (0.8)	1 (0.4)
Lidocaine Hydrochloride;menthol	0 (0.0)	1 (0.8)	1 (0.4)
Aminoalkyl Ethers	5 (3.6)	19 (14.7)	24 (9.0)
Diphenhydramine	3 (2.2)	4 (3.1)	7 (2.6)
Diphenhydramine Hydrochloride	3 (2.2)	15 (11.6)	18 (6.7)
Dimenhydrinate	0 (0.0)	1 (0.8)	1 (0.4)
Piprinhydrinate	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Angiotensin Ii Receptor Blockers (Arbs), Plain	5 (3.6)	6 (4.7)	11 (4.1)
Candesartan	1 (0.7)	1 (0.8)	2 (0.7)
Candesartan Cilexetil	1 (0.7)	0 (0.0)	1 (0.4)
Olmesartan Medoxomil	1 (0.7)	0 (0.0)	1 (0.4)
Telmisartan	1 (0.7)	0 (0.0)	1 (0.4)
Valsartan	1 (0.7)	2 (1.6)	3 (1.1)
Azilsartan	0 (0.0)	1 (0.8)	1 (0.4)
Losartan	0 (0.0)	1 (0.8)	1 (0.4)
Losartan Potassium	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Antibiotics	5 (3.6)	2 (1.6)	7 (2.6)
Nystatin	2 (1.4)	0 (0.0)	2 (0.7)
Amphotericin B	1 (0.7)	0 (0.0)	1 (0.4)
Erythromycin	1 (0.7)	0 (0.0)	1 (0.4)
Tetracycline Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Chloramphenicol	0 (0.0)	1 (0.8)	1 (0.4)
Tetracycline	0 (0.0)	1 (0.8)	1 (0.4)
Belladonna Alkaloids, Semisynthetic, Quaternary Ammonium Compounds	5 (3.6)	6 (4.7)	11 (4.1)
Hyoscine	3 (2.2)	1 (0.8)	4 (1.5)
Hyoscine Butylbromide	2 (1.4)	3 (2.3)	5 (1.9)
Butylscopolamine	0 (0.0)	1 (0.8)	1 (0.4)
Cimetropium Bromide	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Bile Acids And Derivatives	5 (3.6)	3 (2.3)	8 (3.0)
Ursodeoxycholic Acid	5 (3.6)	3 (2.3)	8 (3.0)
Bile And Liver Therapy	5 (3.6)	2 (1.6)	7 (2.6)
Bicyclol	5 (3.6)	2 (1.6)	7 (2.6)
Calcium, Combinations With Vitamin D And/Or Other Drugs	5 (3.6)	4 (3.1)	9 (3.4)
Calcium Carbonate;colecalciferol	3 (2.2)	2 (1.6)	5 (1.9)
Calcium Carbonate;colecalciferol;magnesium Carbonate	1 (0.7)	2 (1.6)	3 (1.1)
Calcium;colecalciferol	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Colony Stimulating Factors	5 (3.6)	49 (38.0)	54 (20.1)
Granulocyte Colony Stimulating Factor	4 (2.9)	31 (24.0)	35 (13.1)
Granulocyte Macrophage Colony Stimulating Factor	1 (0.7)	2 (1.6)	3 (1.1)
Pegylated Granulocyte Colony Stimulating Factor	1 (0.7)	5 (3.9)	6 (2.2)
Filgrastim	0 (0.0)	16 (12.4)	16 (6.0)
Lenograstim	0 (0.0)	4 (3.1)	4 (1.5)
Pegfilgrastim	0 (0.0)	1 (0.8)	1 (0.4)
Combinations Of Sulfonamides And Trimethoprim, Incl. Derivatives	5 (3.6)	3 (2.3)	8 (3.0)
Sulfamethoxazole;trimethoprim	5 (3.6)	3 (2.3)	8 (3.0)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Enzyme Preparations	5 (3.6)	2 (1.6)	7 (2.6)
Azintamide;cellulase;dimeticone;pancreatin	1 (0.7)	1 (0.8)	2 (0.7)
Enzymes Nos;pancreatin	1 (0.7)	0 (0.0)	1 (0.4)
Pancreatin	1 (0.7)	0 (0.0)	1 (0.4)
Pancrelipase	1 (0.7)	0 (0.0)	1 (0.4)
Pepsin	1 (0.7)	0 (0.0)	1 (0.4)
Enzymes Nos	0 (0.0)	1 (0.8)	1 (0.4)
Glycopeptide Antibacterials	5 (3.6)	4 (3.1)	9 (3.4)
Teicoplanin	3 (2.2)	1 (0.8)	4 (1.5)
Vancomycin	2 (1.4)	1 (0.8)	3 (1.1)
Vancomycin Hydrochloride	0 (0.0)	2 (1.6)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Antibiotics For Topical Use	5 (3.6)	8 (6.2)	13 (4.9)
Mupirocin	2 (1.4)	2 (1.6)	4 (1.5)
Fusidate Sodium	1 (0.7)	0 (0.0)	1 (0.4)
Gentamicin	1 (0.7)	1 (0.8)	2 (0.7)
Neomycin	1 (0.7)	0 (0.0)	1 (0.4)
Bacitracin;neomycin Sulfate;polymyxin B Sulfate	0 (0.0)	1 (0.8)	1 (0.4)
Fusidic Acid	0 (0.0)	4 (3.1)	4 (1.5)
Gentamicin Sulfate	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Drugs For Constipation	5 (3.6)	2 (1.6)	7 (2.6)
Lubiprostone	3 (2.2)	0 (0.0)	3 (1.1)
Linaclotide	2 (1.4)	0 (0.0)	2 (0.7)
Sodium Bicarbonate;sodium Phosphate Monobasic (Anhydrous)	1 (0.7)	2 (1.6)	3 (1.1)
Other Mineral Products	5 (3.6)	3 (2.3)	8 (3.0)
Magnesium Aspartate;potassium Aspartate	2 (1.4)	2 (1.6)	4 (1.5)
Sodium Phosphate	2 (1.4)	0 (0.0)	2 (0.7)
Phosphoric Acid;sodium Phosphate Dibasic	1 (0.7)	0 (0.0)	1 (0.4)
Calcium Phosphate Monobasic;magnesium Glycerophosphate;phosphoric Acid;sodium Phosphate Dibasic	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Nervous System Drugs	5 (3.6)	6 (4.7)	11 (4.1)
Mecobalamin	4 (2.9)	6 (4.7)	10 (3.7)
Edaravone	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Potassium	5 (3.6)	5 (3.9)	10 (3.7)
Potassium Chloride	3 (2.2)	2 (1.6)	5 (1.9)
Magnesium;potassium Aspartate	1 (0.7)	0 (0.0)	1 (0.4)
Potassium Gluconate	1 (0.7)	1 (0.8)	2 (0.7)
Potassium Magnesium Aspartate	1 (0.7)	0 (0.0)	1 (0.4)
Potassium Aspartate	0 (0.0)	1 (0.8)	1 (0.4)
Potassium Citrate	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Pyrazolones	5 (3.6)	5 (3.9)	10 (3.7)
Aminophenazone;barbital;phenazone	3 (2.2)	2 (1.6)	5 (1.9)
Metamizole	2 (1.4)	1 (0.8)	3 (1.1)
Metamizole Sodium	0 (0.0)	2 (1.6)	2 (0.7)
Various Alimentary Tract And Metabolism Products	5 (3.6)	4 (3.1)	9 (3.4)
Coenzyme A;nadide	1 (0.7)	2 (1.6)	3 (1.1)
Glucurolactone	1 (0.7)	0 (0.0)	1 (0.4)
Probiotics Nos	1 (0.7)	0 (0.0)	1 (0.4)
Sodium Bicarbonate	1 (0.7)	0 (0.0)	1 (0.4)
Thioctic Acid Tromethamine	1 (0.7)	0 (0.0)	1 (0.4)
Acetylcarnitine;citicoline;pantothenic Acid;pyridoxine Hydrochloride;riboflavin;thioctic Acid;vitamin B1 Nos;vitamin B12 Nos	0 (0.0)	1 (0.8)	1 (0.4)
Zinc Acetate Dihydrate	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Aldosterone Antagonists	4 (2.9)	2 (1.6)	6 (2.2)
Spironolactone	4 (2.9)	2 (1.6)	6 (2.2)
Butyrophenone Derivatives	4 (2.9)	3 (2.3)	7 (2.6)
Haloperidol	4 (2.9)	3 (2.3)	7 (2.6)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Corticosteroids	4 (2.9)	1 (0.8)	5 (1.9)
Aluminium Acetate;hydrocortisone Acetate;lidocaine;zinc Oxide	1 (0.7)	0 (0.0)	1 (0.4)
Beclometasone Dipropionate	1 (0.7)	0 (0.0)	1 (0.4)
Fluticasone Furoate	1 (0.7)	0 (0.0)	1 (0.4)
Triamcinolone	1 (0.7)	0 (0.0)	1 (0.4)
Escherichia Coli;hydrocortisone	0 (0.0)	1 (0.8)	1 (0.4)
Corticosteroids, Plain	4 (2.9)	0 (0.0)	4 (1.5)
Fluorometholone	2 (1.4)	0 (0.0)	2 (0.7)
Prednisolone	2 (1.4)	0 (0.0)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 05JUN2024 17:40 t-14-01-07-01-b-cm-gen-safetys-cl.rtf

Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Dihydropyridine Derivatives	4 (2.9)	12 (9.3)	16 (6.0)
Amlodipine	1 (0.7)	4 (3.1)	5 (1.9)
Amlodipine Besilate	1 (0.7)	1 (0.8)	2 (0.7)
Lercanidipine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Nifedipine	1 (0.7)	4 (3.1)	5 (1.9)
Amlodipine Camsilate	0 (0.0)	1 (0.8)	1 (0.4)
Felodipine	0 (0.0)	1 (0.8)	1 (0.4)
Lacidipine	0 (0.0)	1 (0.8)	1 (0.4)
Drugs For Treatment Of Hyperkalemia And Hyperphosphatemia	4 (2.9)	0 (0.0)	4 (1.5)
Calcium Polystyrene Sulfonate	4 (2.9)	0 (0.0)	4 (1.5)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
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Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 05JUN2024 17:40 t-14-01-07-01-b-cm-gen-safetys-cl.rtf

Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Expectorants	4 (2.9)	0 (0.0)	4 (1.5)
Fudosteine	3 (2.2)	0 (0.0)	3 (1.1)
Ammonium Chloride;glycyrrhiza Glabra	1 (0.7)	0 (0.0)	1 (0.4)
First-Generation Cephalosporins	4 (2.9)	2 (1.6)	6 (2.2)
Cefazolin Sodium	2 (1.4)	2 (1.6)	4 (1.5)
Cefazedone	1 (0.7)	0 (0.0)	1 (0.4)
Cefazolin Sodium Pentahydrate	1 (0.7)	0 (0.0)	1 (0.4)
Influenza Vaccines	4 (2.9)	1 (0.8)	5 (1.9)
Influenza Vaccine	4 (2.9)	1 (0.8)	5 (1.9)
Insulins And Analogues For Injection, Long-Acting	4 (2.9)	2 (1.6)	6 (2.2)
Insulin Glargine	4 (2.9)	1 (0.8)	5 (1.9)
Insulin Glargine Biosimilar 1	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Macrolides	4 (2.9)	5 (3.9)	9 (3.4)
Azithromycin	3 (2.2)	2 (1.6)	5 (1.9)
Roxithromycin	1 (0.7)	0 (0.0)	1 (0.4)
Clarithromycin	0 (0.0)	3 (2.3)	3 (1.1)
Nucleoside And Nucleotide Reverse Transcriptase Inhibitors	4 (2.9)	7 (5.4)	11 (4.1)
Entecavir	3 (2.2)	3 (2.3)	6 (2.2)
Tenofovir	1 (0.7)	2 (1.6)	3 (1.1)
Lamivudine	0 (0.0)	1 (0.8)	1 (0.4)
Tenofovir Disoproxil Fumarate	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Centrally Acting Agents	4 (2.9)	2 (1.6)	6 (2.2)
Eperisone Hydrochloride	3 (2.2)	1 (0.8)	4 (1.5)
Baclofen	1 (0.7)	1 (0.8)	2 (0.7)
Other Dermatologicals	4 (2.9)	3 (2.3)	7 (2.6)
Guaiazulene	3 (2.2)	2 (1.6)	5 (1.9)
Hyaluronic Acid	1 (0.7)	0 (0.0)	1 (0.4)
Magnesium Sulfate	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Hypnotics And Sedatives	4 (2.9)	5 (3.9)	9 (3.4)
Alimemazine Tartrate	2 (1.4)	0 (0.0)	2 (0.7)
Suvorexant	2 (1.4)	2 (1.6)	4 (1.5)
Clomethiazole	0 (0.0)	1 (0.8)	1 (0.4)
Dexmedetomidine Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Hyoscine	0 (0.0)	1 (0.8)	1 (0.4)
Phenothiazine Derivatives	4 (2.9)	13 (10.1)	17 (6.3)
Mequitazine	2 (1.4)	0 (0.0)	2 (0.7)
Promethazine Hydrochloride	2 (1.4)	11 (8.5)	13 (4.9)
Promethazine	0 (0.0)	3 (2.3)	3 (1.1)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
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Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Sodium	4 (2.9)	4 (3.1)	8 (3.0)
Sodium Chloride	4 (2.9)	4 (3.1)	8 (3.0)
Softeners, Emollients	4 (2.9)	0 (0.0)	4 (1.5)
Paraffin, Liquid	3 (2.2)	0 (0.0)	3 (1.1)
Paraffin;sodium Picosulfate	1 (0.7)	0 (0.0)	1 (0.4)
Stomatological Preparations	4 (2.9)	2 (1.6)	6 (2.2)
Sodium Bicarbonate	4 (2.9)	2 (1.6)	6 (2.2)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
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Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Sulfonylureas	4 (2.9)	1 (0.8)	5 (1.9)
Glimepiride	3 (2.2)	0 (0.0)	3 (1.1)
Glipizide	1 (0.7)	1 (0.8)	2 (0.7)
Triazole And Tetrazole Derivatives	4 (2.9)	2 (1.6)	6 (2.2)
Fluconazole	3 (2.2)	2 (1.6)	5 (1.9)
Voriconazole	1 (0.7)	0 (0.0)	1 (0.4)
Watersoluble, Nephrotropic, Low Osmolar X-Ray Contrast Media	4 (2.9)	0 (0.0)	4 (1.5)
Ioversol	2 (1.4)	0 (0.0)	2 (0.7)
Iodixanol	1 (0.7)	0 (0.0)	1 (0.4)
Iohexol	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
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Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Ace Inhibitors, Plain	3 (2.2)	4 (3.1)	7 (2.6)
Ramipril	2 (1.4)	1 (0.8)	3 (1.1)
Captopril	1 (0.7)	2 (1.6)	3 (1.1)
Enalapril	1 (0.7)	1 (0.8)	2 (0.7)
Alpha- And Beta-Adrenoreceptor Agonists	3 (2.2)	0 (0.0)	3 (1.1)
Epinephrine	2 (1.4)	0 (0.0)	2 (0.7)
Ephedrine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Anesthetics, Local	3 (2.2)	2 (1.6)	5 (1.9)
Lidocaine	3 (2.2)	1 (0.8)	4 (1.5)
Dyclonine Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Antiinfectives And Antiseptics For Local Oral Treatment	3 (2.2)	6 (4.7)	9 (3.4)
Amphotericin B	1 (0.7)	1 (0.8)	2 (0.7)
Chlorhexidine Gluconate	1 (0.7)	1 (0.8)	2 (0.7)
Nystatin	1 (0.7)	2 (1.6)	3 (1.1)
Cetylpyridinium Chloride	0 (0.0)	1 (0.8)	1 (0.4)
Cetylpyridinium Chloride;chlorhexidine Gluconate	0 (0.0)	1 (0.8)	1 (0.4)
Chlorhexidine	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Antiinfectives For Systemic Use	3 (2.2)	1 (0.8)	4 (1.5)
Andrographolide Sulfonate Sodium	3 (2.2)	1 (0.8)	4 (1.5)
Corticosteroids, Very Potent (Group Iv)	3 (2.2)	1 (0.8)	4 (1.5)
Clobetasol Propionate	2 (1.4)	1 (0.8)	3 (1.1)
Clobetasol	1 (0.7)	0 (0.0)	1 (0.4)
Diphenylmethane Derivatives	3 (2.2)	2 (1.6)	5 (1.9)
Hydroxyzine Hydrochloride	2 (1.4)	2 (1.6)	4 (1.5)
Hydroxyzine	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
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Percentages were based on N.
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Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Imidazole And Triazole Derivatives	3 (2.2)	1 (0.8)	4 (1.5)
Econazole Nitrate;triamcinolone Acetonide	2 (1.4)	0 (0.0)	2 (0.7)
Bifonazole	1 (0.7)	0 (0.0)	1 (0.4)
Clobetasol Propionate;ketoconazole	1 (0.7)	0 (0.0)	1 (0.4)
Isoconazole Nitrate	1 (0.7)	0 (0.0)	1 (0.4)
Miconazole	0 (0.0)	1 (0.8)	1 (0.4)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Imidazole Derivatives	3 (2.2)	3 (2.3)	6 (2.2)
Econazole	1 (0.7)	0 (0.0)	1 (0.4)
Econazole Nitrate	1 (0.7)	0 (0.0)	1 (0.4)
Metronidazole	1 (0.7)	1 (0.8)	2 (0.7)
Sertaconazole	1 (0.7)	0 (0.0)	1 (0.4)
Tinidazole	1 (0.7)	0 (0.0)	1 (0.4)
Ornidazole	0 (0.0)	2 (1.6)	2 (0.7)
Iron, Parenteral Preparations	3 (2.2)	4 (3.1)	7 (2.6)
Ferric Carboxymaltose	1 (0.7)	1 (0.8)	2 (0.7)
Iron	1 (0.7)	0 (0.0)	1 (0.4)
Saccharated Iron Oxide	1 (0.7)	3 (2.3)	4 (1.5)

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Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Mineralocorticoids	3 (2.2)	0 (0.0)	3 (1.1)
Fludrocortisone Acetate	3 (2.2)	0 (0.0)	3 (1.1)
Opioid Anesthetics	3 (2.2)	3 (2.3)	6 (2.2)
Fentanyl	3 (2.2)	0 (0.0)	3 (1.1)
Remifentanil Hydrochloride	1 (0.7)	1 (0.8)	2 (0.7)
Sufentanil Citrate	0 (0.0)	2 (1.6)	2 (0.7)
Organic Nitrates	3 (2.2)	2 (1.6)	5 (1.9)
Glyceryl Trinitrate	2 (1.4)	2 (1.6)	4 (1.5)
Isosorbide Mononitrate	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Antianemic Preparations	3 (2.2)	6 (4.7)	9 (3.4)
Erythropoietin Human	2 (1.4)	4 (3.1)	6 (2.2)
Darbepoetin Alfa	1 (0.7)	1 (0.8)	2 (0.7)
Epoetin Alfa	0 (0.0)	2 (1.6)	2 (0.7)
Other Antibacterials	3 (2.2)	1 (0.8)	4 (1.5)
Fosfomycin	1 (0.7)	1 (0.8)	2 (0.7)
Fosfomycin Sodium	1 (0.7)	0 (0.0)	1 (0.4)
Linezolid	1 (0.7)	0 (0.0)	1 (0.4)
Other Antipsoriatics For Topical Use	3 (2.2)	0 (0.0)	3 (1.1)
Betamethasone;calcipotriol	3 (2.2)	0 (0.0)	3 (1.1)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Antivirals	3 (2.2)	1 (0.8)	4 (1.5)
Lysozyme Chloride	2 (1.4)	0 (0.0)	2 (0.7)
Dehydroandrographolide Succinate Potassium Sodium	1 (0.7)	1 (0.8)	2 (0.7)
Other General Anesthetics	3 (2.2)	3 (2.3)	6 (2.2)
Propofol	3 (2.2)	2 (1.6)	5 (1.9)
Etomidate	1 (0.7)	1 (0.8)	2 (0.7)
Other Viral Vaccines	3 (2.2)	0 (0.0)	3 (1.1)
Tozinameran	2 (1.4)	0 (0.0)	2 (0.7)
Elasomeran	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Oxazol, Thiazine, And Triazine Derivatives	3 (2.2)	0 (0.0)	3 (1.1)
Chlorzoxazone	3 (2.2)	0 (0.0)	3 (1.1)
Phosphodiesterase Inhibitors	3 (2.2)	3 (2.3)	6 (2.2)
Bucladesine Calcium	3 (2.2)	3 (2.3)	6 (2.2)
Protein Supplements	3 (2.2)	1 (0.8)	4 (1.5)
Protein Hydrolysate	2 (1.4)	0 (0.0)	2 (0.7)
Proteins Nos	1 (0.7)	1 (0.8)	2 (0.7)
Whey Protein	0 (0.0)	1 (0.8)	1 (0.4)
Selective Serotonin Reuptake Inhibitors	3 (2.2)	1 (0.8)	4 (1.5)
Citalopram	2 (1.4)	0 (0.0)	2 (0.7)
Sertraline	1 (0.7)	0 (0.0)	1 (0.4)
Fluvoxamine Maleate	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Somatostatin And Analogues	3 (2.2)	2 (1.6)	5 (1.9)
Octreotide Acetate	2 (1.4)	1 (0.8)	3 (1.1)
Somatostatin	1 (0.7)	1 (0.8)	2 (0.7)
Sulfonamides	3 (2.2)	2 (1.6)	5 (1.9)
Sulfamethoxazole	3 (2.2)	2 (1.6)	5 (1.9)
Vitamin B1 In Combination With Vitamin B6 And/Or Vitamin B12	3 (2.2)	2 (1.6)	5 (1.9)
Cyanocobalamin;pyridoxine Hydrochloride;thiamine Disulfide Phosphate	2 (1.4)	2 (1.6)	4 (1.5)
Cyanocobalamin;pyridoxine Hydrochloride;riboflavin;thiamine Mononitrate	1 (0.7)	0 (0.0)	1 (0.4)
Vitamin K	3 (2.2)	2 (1.6)	5 (1.9)
Phytomenadione	3 (2.2)	2 (1.6)	5 (1.9)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Xanthines And Adrenergics	3 (2.2)	1 (0.8)	4 (1.5)
Aminophylline;chlorphenamine Maleate;methoxyphenamine Hydrochloride;noscapine	3 (2.2)	1 (0.8)	4 (1.5)
Alpha Glucosidase Inhibitors	2 (1.4)	0 (0.0)	2 (0.7)
Acarbose	2 (1.4)	0 (0.0)	2 (0.7)
Amino Acids And Derivatives	2 (1.4)	1 (0.8)	3 (1.1)
Ademetionine 1,4-Butanedisulfonate	2 (1.4)	1 (0.8)	3 (1.1)
Ademetionine	1 (0.7)	0 (0.0)	1 (0.4)
Angiotensin Ii Receptor Blockers (Arbs) And Calcium Channel Blockers	2 (1.4)	2 (1.6)	4 (1.5)
Amlodipine Besilate;olmesartan Medoxomil	1 (0.7)	0 (0.0)	1 (0.4)
Amlodipine;valsartan	1 (0.7)	0 (0.0)	1 (0.4)
Amlodipine;losartan Potassium	0 (0.0)	1 (0.8)	1 (0.4)
Lercanidipine;valsartan	0 (0.0)	1 (0.8)	1 (0.4)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Angiotensin Ii Receptor Blockers (Arbs) And Diuretics	2 (1.4)	0 (0.0)	2 (0.7)
Hydrochlorothiazide;irbesartan	1 (0.7)	0 (0.0)	1 (0.4)
Hydrochlorothiazide;valsartan	1 (0.7)	0 (0.0)	1 (0.4)
Antiarrhythmics, Class Iii	2 (1.4)	4 (3.1)	6 (2.2)
Amiodarone Hydrochloride	2 (1.4)	2 (1.6)	4 (1.5)
Amiodarone	0 (0.0)	2 (1.6)	2 (0.7)
Benzomorphan Derivatives	2 (1.4)	1 (0.8)	3 (1.1)
Pentazocine	2 (1.4)	1 (0.8)	3 (1.1)
Benzothiazepine Derivatives	2 (1.4)	0 (0.0)	2 (0.7)
Diltiazem Hydrochloride	2 (1.4)	0 (0.0)	2 (0.7)

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Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Beta Blocking Agents	2 (1.4)	0 (0.0)	2 (0.7)
Carteolol Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Timolol Maleate	1 (0.7)	0 (0.0)	1 (0.4)
Calcitonin Preparations	2 (1.4)	0 (0.0)	2 (0.7)
Calcitonin	1 (0.7)	0 (0.0)	1 (0.4)
Elcatonin	1 (0.7)	0 (0.0)	1 (0.4)
Corticosteroids, Moderately Potent, Other Combinations	2 (1.4)	0 (0.0)	2 (0.7)
Camphor;dexamethasone Acetate;menthol	2 (1.4)	0 (0.0)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Dipeptidyl Peptidase 4 (Dpp-4) Inhibitors	2 (1.4)	1 (0.8)	3 (1.1)
Sitagliptin Phosphate	1 (0.7)	0 (0.0)	1 (0.4)
Vildagliptin	1 (0.7)	0 (0.0)	1 (0.4)
Linagliptin	0 (0.0)	1 (0.8)	1 (0.4)
Drugs For Constipation	2 (1.4)	1 (0.8)	3 (1.1)
Drugs For Constipation	2 (1.4)	1 (0.8)	3 (1.1)
Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (Gord)	2 (1.4)	3 (2.3)	5 (1.9)
Gentamicin Sulfate;procaine Hydrochloride;vitamin B12 Nos	1 (0.7)	0 (0.0)	1 (0.4)
Teprenone	1 (0.7)	2 (1.6)	3 (1.1)
Montmorillonite	0 (0.0)	1 (0.8)	1 (0.4)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Drugs For Urinary Frequency And Incontinence	2 (1.4)	1 (0.8)	3 (1.1)
Solifenacin Succinate	1 (0.7)	0 (0.0)	1 (0.4)
Trospium Chloride	1 (0.7)	0 (0.0)	1 (0.4)
Vibegron	1 (0.7)	0 (0.0)	1 (0.4)
Mirabegron	0 (0.0)	1 (0.8)	1 (0.4)
Emollients And Protectives	2 (1.4)	1 (0.8)	3 (1.1)
Emollients And Protectives	2 (1.4)	1 (0.8)	3 (1.1)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Enzymes	2 (1.4)	2 (1.6)	4 (1.5)
Bromelains;cysteine	1 (0.7)	0 (0.0)	1 (0.4)
Kallidinogenase	1 (0.7)	0 (0.0)	1 (0.4)
Bromelains;trypsin	0 (0.0)	1 (0.8)	1 (0.4)
Hyaluronidase	0 (0.0)	1 (0.8)	1 (0.4)
Magnesium	2 (1.4)	0 (0.0)	2 (0.7)
Magnesium	1 (0.7)	0 (0.0)	1 (0.4)
Magnesium Aspartate	1 (0.7)	0 (0.0)	1 (0.4)

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Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Nucleosides And Nucleotides Excl. Reverse Transcriptase Inhibitors	2 (1.4)	3 (2.3)	5 (1.9)
Ganciclovir	1 (0.7)	1 (0.8)	2 (0.7)
Valaciclovir Hydrochloride	1 (0.7)	1 (0.8)	2 (0.7)
Vidarabine	1 (0.7)	0 (0.0)	1 (0.4)
Aciclovir	0 (0.0)	1 (0.8)	1 (0.4)
Valaciclovir	0 (0.0)	1 (0.8)	1 (0.4)
Other Alimentary Tract And Metabolism Products	2 (1.4)	1 (0.8)	3 (1.1)
Clostridium Butyricum	2 (1.4)	1 (0.8)	3 (1.1)

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Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Antidepressants	2 (1.4)	7 (5.4)	9 (3.4)
Duloxetine Hydrochloride	1 (0.7)	1 (0.8)	2 (0.7)
Mirtazapine	1 (0.7)	0 (0.0)	1 (0.4)
Trazodone	1 (0.7)	3 (2.3)	4 (1.5)
Mianserin	0 (0.0)	1 (0.8)	1 (0.4)
Trazodone Hydrochloride	0 (0.0)	2 (1.6)	2 (0.7)
Other Antidiarrheals	2 (1.4)	0 (0.0)	2 (0.7)
Racecadotril	2 (1.4)	0 (0.0)	2 (0.7)
Other Antifungals For Topical Use	2 (1.4)	0 (0.0)	2 (0.7)
Methyl Salicylate;tolnaftate	1 (0.7)	0 (0.0)	1 (0.4)
Selenium Sulfide	1 (0.7)	0 (0.0)	1 (0.4)

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Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 05JUN2024 17:40 t-14-01-07-01-b-cm-gen-safetys-cl.rtf

Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Antiinflammatory And Antirheumatic Agents, Non-Steroids	2 (1.4)	0 (0.0)	2 (0.7)
Benzydamine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Rabbit Vaccinia Extract	1 (0.7)	0 (0.0)	1 (0.4)
Other Antipruritics	2 (1.4)	1 (0.8)	3 (1.1)
Doxepin	2 (1.4)	0 (0.0)	2 (0.7)
Calamine;glycerol;zinc Oxide	0 (0.0)	1 (0.8)	1 (0.4)
Other Capillary Stabilizing Agents	2 (1.4)	0 (0.0)	2 (0.7)
Escin Sodium	2 (1.4)	0 (0.0)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
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unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 05JUN2024 17:40 t-14-01-07-01-b-cm-gen-safetys-cl.rtf

Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Cardiac Combination Products	2 (1.4)	1 (0.8)	3 (1.1)
Ligustrazine Hydrochloride;salvia Miltiorrhiza Root With Rhizome	2 (1.4)	0 (0.0)	2 (0.7)
Aceglutamide;carthamus Tinctorius Flower	1 (0.7)	0 (0.0)	1 (0.4)
Ligustrazine;salvia Miltiorrhiza	1 (0.7)	0 (0.0)	1 (0.4)
Magnesium Aspartate;potassium Aspartate	0 (0.0)	1 (0.8)	1 (0.4)
Other Intestinal Adsorbents	2 (1.4)	8 (6.2)	10 (3.7)
Diosmectite	1 (0.7)	2 (1.6)	3 (1.1)
Montmorillonite	1 (0.7)	6 (4.7)	7 (2.6)
Other Local Anesthetics	2 (1.4)	0 (0.0)	2 (0.7)
Dyclonine	1 (0.7)	0 (0.0)	1 (0.4)
Dyclonine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 05JUN2024 17:40 t-14-01-07-01-b-cm-gen-safetys-cl.rtf

Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Oxicams	2 (1.4)	0 (0.0)	2 (0.7)
Meloxicam	2 (1.4)	0 (0.0)	2 (0.7)
Parasympathomimetics	2 (1.4)	0 (0.0)	2 (0.7)
Carbachol	1 (0.7)	0 (0.0)	1 (0.4)
Neostigmine	1 (0.7)	0 (0.0)	1 (0.4)
Phenothiazines With Aliphatic Side-Chain	2 (1.4)	1 (0.8)	3 (1.1)
Chlorpromazine	1 (0.7)	1 (0.8)	2 (0.7)
Chlorpromazine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Progestogens	2 (1.4)	0 (0.0)	2 (0.7)
Medroxyprogesterone Acetate	2 (1.4)	0 (0.0)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Solutions Producing Osmotic Diuresis	2 (1.4)	4 (3.1)	6 (2.2)
Mannitol	2 (1.4)	1 (0.8)	3 (1.1)
Fructose;glycerol	0 (0.0)	1 (0.8)	1 (0.4)
Glucose;mannitol;sodium Chloride	0 (0.0)	2 (1.6)	2 (0.7)
Synthetic Anticholinergics, Esters With Tertiary Amino Group	2 (1.4)	0 (0.0)	2 (0.7)
Trimebutine	1 (0.7)	0 (0.0)	1 (0.4)
Trimebutine Maleate	1 (0.7)	0 (0.0)	1 (0.4)
Taxanes	2 (1.4)	0 (0.0)	2 (0.7)
Paclitaxel	2 (1.4)	0 (0.0)	2 (0.7)
Testosterone-5-Alpha Reductase Inhibitors	2 (1.4)	0 (0.0)	2 (0.7)
Dutasteride	1 (0.7)	0 (0.0)	1 (0.4)
Finasteride	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Tests For Allergic Diseases	2 (1.4)	2 (1.6)	4 (1.5)
Antibacterial Skin Test	2 (1.4)	2 (1.6)	4 (1.5)
Tetanus Vaccines	2 (1.4)	0 (0.0)	2 (0.7)
Tetanus Vaccine	1 (0.7)	0 (0.0)	1 (0.4)
Tetanus Vaccine Toxoid	1 (0.7)	0 (0.0)	1 (0.4)
Tetracyclines	2 (1.4)	1 (0.8)	3 (1.1)
Minocycline Hydrochloride	1 (0.7)	1 (0.8)	2 (0.7)
Tigecycline	1 (0.7)	0 (0.0)	1 (0.4)
Thiazides, Plain	2 (1.4)	2 (1.6)	4 (1.5)
Hydrochlorothiazide	2 (1.4)	1 (0.8)	3 (1.1)
Bendroflumethiazide	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Vitamin B1, Plain	2 (1.4)	1 (0.8)	3 (1.1)
Thiamine	1 (0.7)	1 (0.8)	2 (0.7)
Thiamine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Vitamin D And Analogues	2 (1.4)	4 (3.1)	6 (2.2)
Calcifediol	1 (0.7)	0 (0.0)	1 (0.4)
Colecalciferol	1 (0.7)	3 (2.3)	4 (1.5)
Vitamin D Nos	1 (0.7)	0 (0.0)	1 (0.4)
Alfacalcidol	0 (0.0)	1 (0.8)	1 (0.4)
Zinc Products	2 (1.4)	0 (0.0)	2 (0.7)
Zinc Oxide	2 (1.4)	0 (0.0)	2 (0.7)
Ace Inhibitors And Calcium Channel Blockers	1 (0.7)	1 (0.8)	2 (0.7)
Amlodipine Besilate;perindopril Arginine	1 (0.7)	1 (0.8)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Alpha And Beta Blocking Agents	1 (0.7)	0 (0.0)	1 (0.4)
Carvedilol	1 (0.7)	0 (0.0)	1 (0.4)
Amino Acids/Carbohydrates/Minerals/Vitamins, Combinations	1 (0.7)	0 (0.0)	1 (0.4)
Amino Acids Nos;carbohydrates Nos;fats Nos;minerals Nos;vitamins Nos	1 (0.7)	0 (0.0)	1 (0.4)
Anesthetics For Topical Use	1 (0.7)	1 (0.8)	2 (0.7)
Benzocaine;chlorphenamine Maleate	1 (0.7)	1 (0.8)	2 (0.7)
Cinchocaine Hydrochloride;diphenhydramine;zinc Oxide	1 (0.7)	0 (0.0)	1 (0.4)
Angiotensin Ii Receptor Blockers (Arbs), Other Combinations	1 (0.7)	0 (0.0)	1 (0.4)
Amlodipine Besilate;hydrochlorothiazide;valsartan	1 (0.7)	0 (0.0)	1 (0.4)
Antacids With Antiflatulents	1 (0.7)	0 (0.0)	1 (0.4)
Aluminium Hydroxide Gel, Dried;magnesium Hydroxide;simeticone	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Antacids With Sodium Bicarbonate	1 (0.7)	1 (0.8)	2 (0.7)
Sodium Alginate;sodium Bicarbonate	1 (0.7)	0 (0.0)	1 (0.4)
Antacids With Sodium Bicarbonate	0 (0.0)	1 (0.8)	1 (0.4)
Antacids, Other Combinations	1 (0.7)	0 (0.0)	1 (0.4)
Aluminium Hydroxide-Magnesium Carbonate;lidocaine Hydrochloride;magnesium Hydroxide;magnesium Trisilicate	1 (0.7)	0 (0.0)	1 (0.4)
Antiarrhythmics, Class Ic	1 (0.7)	2 (1.6)	3 (1.1)
Pilsicainide Hydrochloride	1 (0.7)	1 (0.8)	2 (0.7)
Flecainide	0 (0.0)	1 (0.8)	1 (0.4)
Antibacterials For Systemic Use	1 (0.7)	1 (0.8)	2 (0.7)
Antibiotics	1 (0.7)	1 (0.8)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Antihistamines For Topical Use	1 (0.7)	1 (0.8)	2 (0.7)
Diphenhydramine	1 (0.7)	1 (0.8)	2 (0.7)
Antiinflammatory Agents, Non-Steroids	1 (0.7)	0 (0.0)	1 (0.4)
Bromfenac Sodium	1 (0.7)	0 (0.0)	1 (0.4)
Antiinflammatory And Antirheumatic Products, Non-Steroids	1 (0.7)	0 (0.0)	1 (0.4)
Nsaids	1 (0.7)	0 (0.0)	1 (0.4)
Antipruritics, Incl. Antihistamines, Anesthetics, Etc.	1 (0.7)	1 (0.8)	2 (0.7)
Cetirizine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Camphor;chlorphenamine Maleate;hexachlorophene;lidocaine Hydrochloride;menthol;methyl Salicylate	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Antiseptics	1 (0.7)	1 (0.8)	2 (0.7)
Azulene	1 (0.7)	0 (0.0)	1 (0.4)
Sodium Bicarbonate;sodium Gualenate	0 (0.0)	1 (0.8)	1 (0.4)
Antivirals	1 (0.7)	5 (3.9)	6 (2.2)
Ganciclovir	1 (0.7)	1 (0.8)	2 (0.7)
Aciclovir	0 (0.0)	4 (3.1)	4 (1.5)
Beta Blocking Agents, Non-Selective	1 (0.7)	0 (0.0)	1 (0.4)
Propranolol	1 (0.7)	0 (0.0)	1 (0.4)
Beta-Lactamase Inhibitors	1 (0.7)	1 (0.8)	2 (0.7)
Sulbactam	1 (0.7)	0 (0.0)	1 (0.4)
Clavulanic Acid	0 (0.0)	1 (0.8)	1 (0.4)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Biguanides And Amidines	1 (0.7)	0 (0.0)	1 (0.4)
Chlorhexidine Gluconate	1 (0.7)	0 (0.0)	1 (0.4)
Bioflavonoids	1 (0.7)	1 (0.8)	2 (0.7)
Scutellarein Glucuronide	1 (0.7)	1 (0.8)	2 (0.7)
Blood And Related Products	1 (0.7)	2 (1.6)	3 (1.1)
Blood, Calf, Deprot., Lmw Portion	1 (0.7)	2 (1.6)	3 (1.1)
Blood Coagulation Factors	1 (0.7)	0 (0.0)	1 (0.4)
Thrombin	1 (0.7)	0 (0.0)	1 (0.4)
Blood Substitutes And Perfusion Solutions	1 (0.7)	2 (1.6)	3 (1.1)
Carbohydrates Nos;potassium Chloride;sodium Chloride;sodium Lactate	1 (0.7)	2 (1.6)	3 (1.1)

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Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Carbamide Products	1 (0.7)	0 (0.0)	1 (0.4)
Urea	1 (0.7)	0 (0.0)	1 (0.4)
Carbohydrates	1 (0.7)	1 (0.8)	2 (0.7)
Glucose	1 (0.7)	1 (0.8)	2 (0.7)
Choline Esters	1 (0.7)	2 (1.6)	3 (1.1)
Bethanechol Chloride	1 (0.7)	2 (1.6)	3 (1.1)
Corticosteroids And Antiinfectives In Combination	1 (0.7)	1 (0.8)	2 (0.7)
Betamethasone Sodium Phosphate;neomycin Sulfate	1 (0.7)	0 (0.0)	1 (0.4)
Betamethasone Sodium Phosphate;neomycin	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Corticosteroids For Local Oral Treatment	1 (0.7)	7 (5.4)	8 (3.0)
Triamcinolone	1 (0.7)	0 (0.0)	1 (0.4)
Dexamethasone	0 (0.0)	3 (2.3)	3 (1.1)
Triamcinolone Acetonide	0 (0.0)	4 (3.1)	4 (1.5)
Corticosteroids For Systemic Use	1 (0.7)	0 (0.0)	1 (0.4)
Corticosteroid Nos	1 (0.7)	0 (0.0)	1 (0.4)
Corticosteroids, Potent, Combinations With Antibiotics	1 (0.7)	1 (0.8)	2 (0.7)
Betamethasone;gentamicin	1 (0.7)	1 (0.8)	2 (0.7)
Corticosteroids, Potent, Other Combinations	1 (0.7)	0 (0.0)	1 (0.4)
Betamethasone Dipropionate;salicylic Acid	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Corticosteroids, Weak, Other Combinations	1 (0.7)	1 (0.8)	2 (0.7)
Crotamiton;hydrocortisone	1 (0.7)	1 (0.8)	2 (0.7)
Detoxifying Agents For Antineoplastic Treatment	1 (0.7)	0 (0.0)	1 (0.4)
Calcium Folinate	1 (0.7)	0 (0.0)	1 (0.4)
Fibrates	1 (0.7)	1 (0.8)	2 (0.7)
Fenofibrate	1 (0.7)	0 (0.0)	1 (0.4)
Bezafibrate	0 (0.0)	1 (0.8)	1 (0.4)
Folic Acid And Derivatives	1 (0.7)	1 (0.8)	2 (0.7)
Folic Acid	1 (0.7)	0 (0.0)	1 (0.4)
Folinic Acid	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
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Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Fourth-Generation Cephalosporins	1 (0.7)	2 (1.6)	3 (1.1)
Cefepime	1 (0.7)	0 (0.0)	1 (0.4)
Cefepime Hydrochloride	0 (0.0)	2 (1.6)	2 (0.7)
Homeopathic Preparation	1 (0.7)	1 (0.8)	2 (0.7)
Apis Mellifica	1 (0.7)	0 (0.0)	1 (0.4)
Achillea Millefolium;aconitum Napellus;arnica Montana;atropa Belladonna;bellis Perennis;calcium Sulfide;calendula Officinalis;echinacea Angustifolia;echinacea Purpurea;hamamelis Virginiana;hypericum Perforatum;matricaria Recutita;mercurius Solubilis Hahnemanni;symphytum Officinale	0 (0.0)	1 (0.8)	1 (0.4)
Imidazoline Receptor Agonists In Combination With Diuretics	1 (0.7)	0 (0.0)	1 (0.4)
Clonidine Hydrochloride;dihydralazine Sulfate;hydrochlorothiazide	1 (0.7)	0 (0.0)	1 (0.4)
Immunoglobulins, Normal Human	1 (0.7)	0 (0.0)	1 (0.4)
Immunoglobulin Human Normal	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Insulins And Analogues	1 (0.7)	3 (2.3)	4 (1.5)
Insulin	1 (0.7)	3 (2.3)	4 (1.5)
Insulins And Analogues For Injection, Intermediate- Or Long-Acting Combined With Fast-Acting	1 (0.7)	0 (0.0)	1 (0.4)
Insulin Aspart;insulin Degludec	1 (0.7)	0 (0.0)	1 (0.4)
Insulins And Analogues For Injection, Intermediate-Acting	1 (0.7)	0 (0.0)	1 (0.4)
Insulin Human Injection, Isophane	1 (0.7)	0 (0.0)	1 (0.4)
Interleukin Inhibitors	1 (0.7)	0 (0.0)	1 (0.4)
Tocilizumab	1 (0.7)	0 (0.0)	1 (0.4)
Interleukins	1 (0.7)	1 (0.8)	2 (0.7)
Oprelvekin	1 (0.7)	1 (0.8)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Iron In Other Combinations	1 (0.7)	0 (0.0)	1 (0.4)
Ascorbic Acid;ferric Pyrophosphate	1 (0.7)	0 (0.0)	1 (0.4)
Iron Preparations	1 (0.7)	0 (0.0)	1 (0.4)
Iron	1 (0.7)	0 (0.0)	1 (0.4)
Leukotriene Receptor Antagonists	1 (0.7)	0 (0.0)	1 (0.4)
Montelukast Sodium	1 (0.7)	0 (0.0)	1 (0.4)
Lincosamides	1 (0.7)	2 (1.6)	3 (1.1)
Clindamycin Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Clindamycin Phosphate	0 (0.0)	2 (1.6)	2 (0.7)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
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Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Local Anesthetics	1 (0.7)	1 (0.8)	2 (0.7)
Proxymetacaine Hydrochloride	1 (0.7)	0 (0.0)	1 (0.4)
Benzocaine;bismuth Subgallate;diphenhydramine Hydrochloride;zinc Oxide	0 (0.0)	1 (0.8)	1 (0.4)
Magnesium Compounds	1 (0.7)	0 (0.0)	1 (0.4)
Magnesium Oxide	1 (0.7)	0 (0.0)	1 (0.4)
Morphinan Derivatives	1 (0.7)	0 (0.0)	1 (0.4)
Butorphanol	1 (0.7)	0 (0.0)	1 (0.4)
Multivitamins, Plain	1 (0.7)	3 (2.3)	4 (1.5)
Ascorbic Acid;biotin;colecalciferol;dexpanthenol;folic Acid;nicotinamide;pyridoxine Hydrochloride;retinol Palmitate;riboflavin;vitamin B1 Nos;vitamin B12 Nos;vitamin E Nos	1 (0.7)	3 (2.3)	4 (1.5)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Neuraminidase Inhibitors	1 (0.7)	1 (0.8)	2 (0.7)
Oseltamivir Phosphate	1 (0.7)	1 (0.8)	2 (0.7)
Other Agents For Treatment Of Hemorrhoids And Anal Fissures For Topical Use	1 (0.7)	0 (0.0)	1 (0.4)
Chondrus Crispus;titanium Dioxide;zinc Oxide	1 (0.7)	0 (0.0)	1 (0.4)
Other Antiallergics	1 (0.7)	0 (0.0)	1 (0.4)
Ketotifen Fumarate	1 (0.7)	0 (0.0)	1 (0.4)
Other Antiepileptics	1 (0.7)	1 (0.8)	2 (0.7)
Levetiracetam	1 (0.7)	1 (0.8)	2 (0.7)
Other Antimycotics For Systemic Use	1 (0.7)	0 (0.0)	1 (0.4)
Anidulafungin	1 (0.7)	0 (0.0)	1 (0.4)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Blood Glucose Lowering Drugs, Excl. Insulins	1 (0.7)	0 (0.0)	1 (0.4)
Nateglinide	1 (0.7)	0 (0.0)	1 (0.4)
Other Cephalosporins And Penems	1 (0.7)	0 (0.0)	1 (0.4)
Faropenem Sodium	1 (0.7)	0 (0.0)	1 (0.4)
Other Combinations Of Nutrients	1 (0.7)	0 (0.0)	1 (0.4)
Carbohydrates Nos;fats Nos;fibre, Dietary;minerals Nos;proteins Nos;vitamins Nos	1 (0.7)	0 (0.0)	1 (0.4)
Other Drugs Affecting Bone Structure And Mineralization	1 (0.7)	1 (0.8)	2 (0.7)
Denosumab	1 (0.7)	1 (0.8)	2 (0.7)
Other Gynecologicals	1 (0.7)	0 (0.0)	1 (0.4)
Hyaluronate Sodium;malva Sylvestris;matricaria Recutita	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Intestinal Antiinfectives	1 (0.7)	0 (0.0)	1 (0.4)
Berberine Tannate;scopolia Spp.	1 (0.7)	0 (0.0)	1 (0.4)
Other Nutrients	1 (0.7)	2 (1.6)	3 (1.1)
Other Nutrients	1 (0.7)	2 (1.6)	3 (1.1)
Other Parasympathomimetics	1 (0.7)	0 (0.0)	1 (0.4)
Choline Alfoscerate	1 (0.7)	0 (0.0)	1 (0.4)
Other Psychostimulants And Nootropics	1 (0.7)	0 (0.0)	1 (0.4)
Oxiracetam	1 (0.7)	0 (0.0)	1 (0.4)
Other Quaternary Ammonium Compounds	1 (0.7)	1 (0.8)	2 (0.7)
Rocuronium Bromide	1 (0.7)	0 (0.0)	1 (0.4)
Atracurium Besilate	0 (0.0)	1 (0.8)	1 (0.4)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Sclerosing Agents	1 (0.7)	0 (0.0)	1 (0.4)
Talc	1 (0.7)	0 (0.0)	1 (0.4)
Other Surgical Aids	1 (0.7)	0 (0.0)	1 (0.4)
Calcium Chloride Dihydrate;magnesium Chloride Hexahydrate;potassium Chloride;sodium Acetate Trihydrate;sodium Chloride;sodium Citrate Dihydrate	1 (0.7)	0 (0.0)	1 (0.4)
Other Systemic Drugs For Obstructive Airway Diseases	1 (0.7)	0 (0.0)	1 (0.4)
Asarone	1 (0.7)	0 (0.0)	1 (0.4)
Other Urologicals	1 (0.7)	0 (0.0)	1 (0.4)
Piperazine Ferulate	1 (0.7)	0 (0.0)	1 (0.4)
Other Vasodilators Used In Cardiac Diseases	1 (0.7)	0 (0.0)	1 (0.4)
Nicorandil	1 (0.7)	0 (0.0)	1 (0.4)

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Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Polymyxins	1 (0.7)	0 (0.0)	1 (0.4)
Colistin	1 (0.7)	0 (0.0)	1 (0.4)
Preparations Inhibiting Uric Acid Production	1 (0.7)	4 (3.1)	5 (1.9)
Febuxostat	1 (0.7)	2 (1.6)	3 (1.1)
Allopurinol	0 (0.0)	2 (1.6)	2 (0.7)
Progestogens And Estrogens, Fixed Combinations	1 (0.7)	0 (0.0)	1 (0.4)
Estriol;lactobacillus Acidophilus;progesterone	1 (0.7)	0 (0.0)	1 (0.4)
Proteinase Inhibitors	1 (0.7)	0 (0.0)	1 (0.4)
Ulinastatin	1 (0.7)	0 (0.0)	1 (0.4)
Quinoline Derivatives And Related Substances	1 (0.7)	0 (0.0)	1 (0.4)
Praziquantel	1 (0.7)	0 (0.0)	1 (0.4)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Rabies Vaccines	1 (0.7)	0 (0.0)	1 (0.4)
Rabies Vaccine	1 (0.7)	0 (0.0)	1 (0.4)
Salicylic Acid And Derivatives	1 (0.7)	0 (0.0)	1 (0.4)
Acetylsalicylate Lysine	1 (0.7)	0 (0.0)	1 (0.4)
Salicylic Acid Preparations	1 (0.7)	0 (0.0)	1 (0.4)
Salicylic Acid	1 (0.7)	0 (0.0)	1 (0.4)
Selective Immunosuppressants	1 (0.7)	0 (0.0)	1 (0.4)
Apremilast	1 (0.7)	0 (0.0)	1 (0.4)
Selective Serotonin (5ht1) Agonists	1 (0.7)	0 (0.0)	1 (0.4)
Eletriptan	1 (0.7)	0 (0.0)	1 (0.4)

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Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Silver Compounds	1 (0.7)	0 (0.0)	1 (0.4)
Silver Compounds	1 (0.7)	0 (0.0)	1 (0.4)
Soft Paraffin And Fat Products	1 (0.7)	1 (0.8)	2 (0.7)
White Soft Paraffin	1 (0.7)	1 (0.8)	2 (0.7)
Steroid Antibacterials	1 (0.7)	0 (0.0)	1 (0.4)
Fusidic Acid	1 (0.7)	0 (0.0)	1 (0.4)
Streptogramins	1 (0.7)	0 (0.0)	1 (0.4)
Pristinamycin	1 (0.7)	0 (0.0)	1 (0.4)
Sympathomimetics	1 (0.7)	1 (0.8)	2 (0.7)
Loratadine;pseudoephedrine Sulfate	1 (0.7)	0 (0.0)	1 (0.4)
Pseudoephedrine Hydrochloride;triprolidine Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-cm.sas 05JUN2024 17:40 t-14-01-07-01-b-cm-gen-safetys-cl.rtf

Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Tetracycline And Derivatives	1 (0.7)	1 (0.8)	2 (0.7)
Oxytetracycline Hydrochloride;polymyxin B Sulfate	1 (0.7)	0 (0.0)	1 (0.4)
Tetracycline Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Viscoelastic Substances	1 (0.7)	0 (0.0)	1 (0.4)
Hyaluronate Sodium	1 (0.7)	0 (0.0)	1 (0.4)
Vitamin B-Complex With Vitamin C	1 (0.7)	0 (0.0)	1 (0.4)
Ascorbic Acid;vitamin B Complex	1 (0.7)	0 (0.0)	1 (0.4)
Vitamin B-Complex, Plain	1 (0.7)	0 (0.0)	1 (0.4)
Vitamin B Complex	1 (0.7)	0 (0.0)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Vitamin B12 (Cyanocobalamin And Analogues)	1 (0.7)	3 (2.3)	4 (1.5)
Vitamin B12 Nos	1 (0.7)	1 (0.8)	2 (0.7)
Cyanocobalamin	0 (0.0)	1 (0.8)	1 (0.4)
Mecobalamin	0 (0.0)	1 (0.8)	1 (0.4)
Vitamins With Minerals	1 (0.7)	2 (1.6)	3 (1.1)
Minerals Nos;vitamins Nos	1 (0.7)	2 (1.6)	3 (1.1)
All Other Therapeutic Products	0 (0.0)	1 (0.8)	1 (0.4)
All Other Therapeutic Products	0 (0.0)	1 (0.8)	1 (0.4)
Aluminium Compounds	0 (0.0)	5 (3.9)	5 (1.9)
Aluminium Phosphate Gel	0 (0.0)	5 (3.9)	5 (1.9)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
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Percentages were based on N.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Belladonna Alkaloids, Tertiary Amines	0 (0.0)	6 (4.7)	6 (2.2)
Atropine	0 (0.0)	3 (2.3)	3 (1.1)
Atropine Sulfate	0 (0.0)	1 (0.8)	1 (0.4)
Raceanisodamine Hydrochloride	0 (0.0)	2 (1.6)	2 (0.7)
Beta-Lactam Antibacterials, Penicillins	0 (0.0)	1 (0.8)	1 (0.4)
Penicillin Nos	0 (0.0)	1 (0.8)	1 (0.4)
Beta-Lactamase Sensitive Penicillins	0 (0.0)	2 (1.6)	2 (0.7)
Benzylpenicillin Sodium	0 (0.0)	2 (1.6)	2 (0.7)
Bulk-Forming Laxatives	0 (0.0)	1 (0.8)	1 (0.4)
Plantago Spp.	0 (0.0)	1 (0.8)	1 (0.4)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Calcium	0 (0.0)	1 (0.8)	1 (0.4)
Calcium Carbonate	0 (0.0)	1 (0.8)	1 (0.4)
Carbamic Acid Esters	0 (0.0)	1 (0.8)	1 (0.4)
Methocarbamol	0 (0.0)	1 (0.8)	1 (0.4)
Carboxamide Derivatives	0 (0.0)	1 (0.8)	1 (0.4)
Carbamazepine	0 (0.0)	1 (0.8)	1 (0.4)
Digitalis Glycosides	0 (0.0)	2 (1.6)	2 (0.7)
Deslanoside	0 (0.0)	2 (1.6)	2 (0.7)
Diphenylpropylamine Derivatives	0 (0.0)	1 (0.8)	1 (0.4)
Methadone Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Drugs Used In Erectile Dysfunction	0 (0.0)	1 (0.8)	1 (0.4)
Sildenafil Citrate	0 (0.0)	1 (0.8)	1 (0.4)
Drugs Used In Nicotine Dependence	0 (0.0)	2 (1.6)	2 (0.7)
Nicotine	0 (0.0)	1 (0.8)	1 (0.4)
Varenicline	0 (0.0)	1 (0.8)	1 (0.4)
Fenamates	0 (0.0)	1 (0.8)	1 (0.4)
Mefenamic Acid	0 (0.0)	1 (0.8)	1 (0.4)
Heparins Or Heparinoids For Topical Use	0 (0.0)	1 (0.8)	1 (0.4)
Mucopolysaccharide Polysulfuric Acid Ester	0 (0.0)	1 (0.8)	1 (0.4)
Hypnotics And Sedatives	0 (0.0)	1 (0.8)	1 (0.4)
Promethazine Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
I.V. Solution Additives	0 (0.0)	1 (0.8)	1 (0.4)
Calcium Chloride Dihydrate;glucose;potassium Chloride;sodium Acetate;sodium Chloride	0 (0.0)	1 (0.8)	1 (0.4)
Iodine Products	0 (0.0)	1 (0.8)	1 (0.4)
Iodine	0 (0.0)	1 (0.8)	1 (0.4)
Iodine Therapy	0 (0.0)	1 (0.8)	1 (0.4)
Potassium Iodide	0 (0.0)	1 (0.8)	1 (0.4)
Local Hemostatics	0 (0.0)	1 (0.8)	1 (0.4)
Epinephrine Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Low-Ceiling Diuretics And Potassium-Sparing Agents	0 (0.0)	1 (0.8)	1 (0.4)
Amiloride Hydrochloride;hydrochlorothiazide	0 (0.0)	1 (0.8)	1 (0.4)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Melatonin Receptor Agonists	0 (0.0)	1 (0.8)	1 (0.4)
Ramelteon	0 (0.0)	1 (0.8)	1 (0.4)
Multivitamins, Other Combinations	0 (0.0)	1 (0.8)	1 (0.4)
Biotin;cyanocobalamin;ergocalciferol;folic Acid;glycine;nicotinamide;pantothenate Sodium;phytomenadione;pyridoxine Hydrochloride;retinol;riboflavin Sodium Phosphate;sodium Ascorbate;thiamine Mononitrate;vitamin E Nos	0 (0.0)	1 (0.8)	1 (0.4)
Nitroferricyanide Derivatives	0 (0.0)	1 (0.8)	1 (0.4)
Nitroprusside Sodium	0 (0.0)	1 (0.8)	1 (0.4)
Non-Selective Monoamine Reuptake Inhibitors	0 (0.0)	3 (2.3)	3 (1.1)
Amitriptyline	0 (0.0)	1 (0.8)	1 (0.4)
Amitriptyline Hydrochloride	0 (0.0)	2 (1.6)	2 (0.7)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Oripavine Derivatives	0 (0.0)	1 (0.8)	1 (0.4)
Buprenorphine Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Other Antineoplastic Agents	0 (0.0)	1 (0.8)	1 (0.4)
Disodium Cantharidinate;pyridoxine Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Other Antipsychotics	0 (0.0)	1 (0.8)	1 (0.4)
Prothipendyl Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Other Antithrombotic Agents	0 (0.0)	1 (0.8)	1 (0.4)
Fondaparinux	0 (0.0)	1 (0.8)	1 (0.4)
Other Anxiolytics	0 (0.0)	2 (1.6)	2 (0.7)
Paroxetine Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Pregabalin	0 (0.0)	1 (0.8)	1 (0.4)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Other Cicatrizants	0 (0.0)	1 (0.8)	1 (0.4)
Trafermin	0 (0.0)	1 (0.8)	1 (0.4)
Other Protein Kinase Inhibitors	0 (0.0)	1 (0.8)	1 (0.4)
Catequentinib Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Other Therapeutic Products	0 (0.0)	1 (0.8)	1 (0.4)
Inosine	0 (0.0)	1 (0.8)	1 (0.4)
Other Throat Preparations	0 (0.0)	1 (0.8)	1 (0.4)
Other Throat Preparations	0 (0.0)	1 (0.8)	1 (0.4)
Perchlorates	0 (0.0)	1 (0.8)	1 (0.4)
Sodium Perchlorate	0 (0.0)	1 (0.8)	1 (0.4)

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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Phenylalkylamine Derivatives	0 (0.0)	1 (0.8)	1 (0.4)
Verapamil Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Preparations With No Effect On Uric Acid Metabolism	0 (0.0)	1 (0.8)	1 (0.4)
Colchicine	0 (0.0)	1 (0.8)	1 (0.4)
Preparations With Salicylic Acid Derivatives	0 (0.0)	1 (0.8)	1 (0.4)
Aconitum Carmichaelii Root Tuber;aconitum Kusnezoffii Root Tuber;angelica Dahurica Root;angelica Sinensis Root;atractylodes Lancea Rhizome;borneol;camphor;chondroitin Sulfate;diphenhydramine Hydrochloride;ephedra Spp. Stem;illicium Verum Fruit;kaempferia Galanga Rhizome;menthol;methyl Salicylate;musk;zingiber Officinale Rhizome	0 (0.0)	1 (0.8)	1 (0.4)
Prostaglandin Analogues	0 (0.0)	1 (0.8)	1 (0.4)
Latanoprost	0 (0.0)	1 (0.8)	1 (0.4)

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Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Prostaglandins	0 (0.0)	1 (0.8)	1 (0.4)
Misoprostol	0 (0.0)	1 (0.8)	1 (0.4)
Sulfur-Containing Imidazole Derivatives	0 (0.0)	3 (2.3)	3 (1.1)
Carbimazole	0 (0.0)	1 (0.8)	1 (0.4)
Thiamazole	0 (0.0)	2 (1.6)	2 (0.7)
Sympathomimetics In Glaucoma Therapy	0 (0.0)	1 (0.8)	1 (0.4)
Brimonidine Tartrate	0 (0.0)	1 (0.8)	1 (0.4)
Sympathomimetics Used As Decongestants	0 (0.0)	1 (0.8)	1 (0.4)
Chlorphenamine Maleate;chondroitin Sulfate Sodium;neostigmine Metilsulfate;potassium Aspartate;pyridoxine Hydrochloride;retinol Palmitate;taurine;tetryzoline Hydrochloride;tocopheryl Acetate	0 (0.0)	1 (0.8)	1 (0.4)

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Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Thiazolidinediones	0 (0.0)	1 (0.8)	1 (0.4)
Pioglitazone Hydrochloride	0 (0.0)	1 (0.8)	1 (0.4)
Topical Products For Joint And Muscular Pain	0 (0.0)	1 (0.8)	1 (0.4)
Achyranthes Bidentata Root;aconitum Carmichaelii Root;aconitum Kusnezoffii Root;angelica Pubescens Root;angelica Sinensis;aralia Chinensis Stem Bark;aucklandia Costus;biancaea Sappan Heartwood;borneol;boswellia Spp. Resin;carthamus Tinctorius Flower;cinnamomum Camphora;cinnamomum Cassia Essential Oil;clematis Spp. Root;commiphora Myrrha Resin;corydalis Yanhusuo Tuber;daemonorops Draco Fruit Resin;ephedra Spp.;eucalyptus Globulus Essential Oil;lindera Aggregata Root;menthol;methyl Salicylate;musk;ocimum Gratissimum Oil;periploca Sepium Root Bark;piper Kadsura Stem;rehmannia Glutinosa Root Tuber	0 (0.0)	1 (0.8)	1 (0.4)
Vasopressin And Analogues	0 (0.0)	1 (0.8)	1 (0.4)
Vasopressin	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.7.1.b:
Concomitant Medication
Safety Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)	Total (N = 268) n (%)
Vitamins, Other Combinations	0 (0.0)	2 (1.6)	2 (0.7)
Herbal Nos;minerals Nos;vitamins Nos	0 (0.0)	1 (0.8)	1 (0.4)
Vitamins, Other Combinations	0 (0.0)	1 (0.8)	1 (0.4)

Source: Listing: 16.2.4.8. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Concomitant medications include medications that either
(1) started before the first dose of study drug and were continuing at the time of the first dose of study drug, or
(2) started on or after the day of the first dose of study drug up to 30 days after the last dose of study drug.
Concomitant systemically administered corticosteroids/immunosuppressive medications are summarized up to 90 days after last dose of study treatment.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.1.8.1:
Summary of Follow-up Time by Efficacy-related Endpoint
ITT Analysis Set

Endpoint (Months)	Tislelizumab (N = 256)	ICC (N = 256)	Total (N = 512)
Overall Survival [a]			
n	256	256	512
Mean (SD)	12.75 (12.28)	8.79 (9.24)	10.77 (11.03)
Median	8.49	5.68	6.87
Q1, Q3	3.93, 17.07	2.81, 10.97	3.43, 13.21
Min, Max	0.2, 53.2	0.0, 50.7	0.0, 53.2
Progression-Free Survival [b]			
n	256	256	512
Mean (SD)	4.89 (7.70)	2.37 (2.78)	3.63 (5.92)
Median	1.64	1.45	1.48
Q1, Q3	1.31, 4.22	0.92, 2.81	1.22, 3.58
Min, Max	0.0, 49.2	0.0, 24.1	0.0, 49.2

Source: ADSL, ADQS, ADEFPRE. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

[a] Time from randomization to death or censoring date.

[b] Time from randomization to the last progression-free survival event or censoring date.

[c] Time from randomization to the last tumor assessment by investigator per RECIST 1.1. For patients without post-baseline tumor assessment, their last tumor assessment is considered as on date of randomization. Post-baseline tumor assessment after the initiation of new anti-cancer therapy were not considered.

[d] Time from randomization to the last adequate PRO assessment. For patients without baseline or post-baseline PRO assessment, their last PRO assessment is considered as on date of randomization.

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Table 14.1.8.1:
Summary of Follow-up Time by Efficacy-related Endpoint
ITT Analysis Set

Endpoint (Months)	Tislelizumab (N = 256)	ICC (N = 256)	Total (N = 512)
Investigator Tumor Assessment [c]			
n	256	256	512
Mean (SD)	5.68 (8.12)	2.26 (2.93)	3.97 (6.34)
Median	2.73	1.41	1.64
Q1, Q3	1.38, 5.80	0.66, 2.79	1.18, 4.11
Min, Max	0.0, 49.2	0.0, 24.1	0.0, 49.2
EORTC-QLQ-C30 [d]			
n	256	256	512
Mean (SD)	5.13 (8.06)	2.21 (2.70)	3.67 (6.18)
Median	2.79	1.54	1.87
Q1, Q3	1.41, 4.42	0.72, 2.83	0.79, 3.52
Min, Max	0.0, 49.7	0.0, 24.1	0.0, 49.7

Source: ADSL, ADQS, ADEFPRE. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

[a] Time from randomization to death or censoring date.

[b] Time from randomization to the last progression-free survival event or censoring date.

[c] Time from randomization to the last tumor assessment by investigator per RECIST 1.1. For patients without post-baseline tumor assessment, their last tumor assessment is considered as on date of randomization. Post-baseline tumor assessment after the initiation of new anti-cancer therapy were not considered.

[d] Time from randomization to the last adequate PRO assessment. For patients without baseline or post-baseline PRO assessment, their last PRO assessment is considered as on date of randomization.

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Table 14.1.8.1:
Summary of Follow-up Time by Efficacy-related Endpoint
ITT Analysis Set

Endpoint (Months)	Tislelizumab (N = 256)	ICC (N = 256)	Total (N = 512)
EORTC-QLQ-OES18 [d]			
n	256	256	512
Mean (SD)	5.00 (7.86)	2.20 (2.70)	3.60 (6.04)
Median	2.79	1.54	1.87
Q1, Q3	1.41, 4.35	0.72, 2.83	0.76, 3.52
Min, Max	0.0, 49.7	0.0, 24.1	0.0, 49.7
EQ-5D-VAS [d]			
n	256	256	512
Mean (SD)	5.00 (7.86)	2.17 (2.70)	3.59 (6.04)
Median	2.79	1.54	1.87
Q1, Q3	1.41, 4.35	0.57, 2.83	0.76, 3.52
Min, Max	0.0, 49.7	0.0, 24.1	0.0, 49.7

Source: ADSL, ADQS, ADEFPRE. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
[a] Time from randomization to death or censoring date.
[b] Time from randomization to the last progression-free survival event or censoring date.
[c] Time from randomization to the last tumor assessment by investigator per RECIST 1.1. For patients without post-baseline tumor assessment, their last tumor assessment is considered as on date of randomization. Post-baseline tumor assessment after the initiation of new anti-cancer therapy were not considered.
[d] Time from randomization to the last adequate PRO assessment. For patients without baseline or post-baseline PRO assessment, their last PRO assessment is considered as on date of randomization.
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Table 14.1.8.1.b:
Summary of Follow-up Time by Efficacy-related Endpoint
ITT Analysis Set - Subpopulation without Irinotecan

Endpoint (Months)	Tislelizumab (N = 139)	ICC (N = 138)	Total (N = 277)
Overall Survival [a]			
n	139	138	277
Mean (SD)	12.60 (11.88)	9.64 (9.81)	11.13 (10.98)
Median	8.61	6.54	7.39
Q1, Q3	3.91, 16.59	3.29, 12.25	3.68, 14.03
Min, Max	0.4, 49.8	0.0, 46.8	0.0, 49.8
Progression-Free Survival [b]			
n	139	138	277
Mean (SD)	5.45 (8.58)	2.81 (3.11)	4.13 (6.59)
Median	1.87	1.53	1.64
Q1, Q3	1.35, 5.52	1.18, 3.61	1.31, 4.07
Min, Max	0.0, 49.2	0.0, 24.1	0.0, 49.2

Source: ADSL, ADQS, ADEFPRE. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

[a] Time from randomization to death or censoring date.

[b] Time from randomization to the last progression-free survival event or censoring date.

[c] Time from randomization to the last tumor assessment by investigator per RECIST 1.1. For patients without post-baseline tumor assessment, their last tumor assessment is considered as on date of randomization. Post-baseline tumor assessment after the initiation of new anti-cancer therapy were not considered.

[d] Time from randomization to the last adequate PRO assessment. For patients without baseline or post-baseline PRO assessment, their last PRO assessment is considered as on date of randomization.

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Table 14.1.8.1.b:
Summary of Follow-up Time by Efficacy-related Endpoint
ITT Analysis Set - Subpopulation without Irinotecan

Endpoint (Months)	Tislelizumab (N = 139)	ICC (N = 138)	Total (N = 277)
Investigator Tumor Assessment [c]			
n	139	138	277
Mean (SD)	6.13 (8.90)	2.72 (3.15)	4.43 (6.89)
Median	2.73	1.51	2.30
Q1, Q3	1.38, 7.10	1.12, 3.29	1.35, 4.21
Min, Max	0.0, 49.2	0.0, 24.1	0.0, 49.2
EORTC-QLQ-C30 [d]			
n	139	138	277
Mean (SD)	5.43 (8.95)	2.73 (3.15)	4.08 (6.84)
Median	2.20	1.87	1.91
Q1, Q3	1.41, 4.40	0.89, 3.48	1.08, 3.78
Min, Max	0.0, 49.7	0.0, 24.1	0.0, 49.7

Source: ADSL, ADQS, ADEFPRE. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

[a] Time from randomization to death or censoring date.

[b] Time from randomization to the last progression-free survival event or censoring date.

[c] Time from randomization to the last tumor assessment by investigator per RECIST 1.1. For patients without post-baseline tumor assessment, their last tumor assessment is considered as on date of randomization. Post-baseline tumor assessment after the initiation of new anti-cancer therapy were not considered.

[d] Time from randomization to the last adequate PRO assessment. For patients without baseline or post-baseline PRO assessment, their last PRO assessment is considered as on date of randomization.

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Table 14.1.8.1.b:
Summary of Follow-up Time by Efficacy-related Endpoint
ITT Analysis Set - Subpopulation without Irinotecan

Endpoint (Months)	Tislelizumab (N = 139)	ICC (N = 138)	Total (N = 277)
EORTC-QLQ-OES18 [d]			
n	139	138	277
Mean (SD)	5.42 (8.95)	2.73 (3.15)	4.08 (6.84)
Median	2.20	1.87	1.91
Q1, Q3	1.41, 4.40	0.85, 3.48	1.08, 3.78
Min, Max	0.0, 49.7	0.0, 24.1	0.0, 49.7
EQ-5D-VAS [d]			
n	139	138	277
Mean (SD)	5.43 (8.95)	2.72 (3.16)	4.08 (6.84)
Median	2.20	1.87	1.91
Q1, Q3	1.41, 4.40	0.82, 3.48	1.05, 3.78
Min, Max	0.0, 49.7	0.0, 24.1	0.0, 49.7

Source: ADSL, ADQS, ADEFPRE. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

[a] Time from randomization to death or censoring date.

[b] Time from randomization to the last progression-free survival event or censoring date.

[c] Time from randomization to the last tumor assessment by investigator per RECIST 1.1. For patients without post-baseline tumor assessment, their last tumor assessment is considered as on date of randomization. Post-baseline tumor assessment after the initiation of new anti-cancer therapy were not considered.

[d] Time from randomization to the last adequate PRO assessment. For patients without baseline or post-baseline PRO assessment, their last PRO assessment is considered as on date of randomization.

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Table 14.1.8.2:
Summary of Follow-up Time by Safety-related Endpoint
Safety Analysis Set

Endpoint (Months)	Tislelizumab (N = 255)	ICC (N = 240)	Total (N = 495)
Safety for TEAEs except imAE [a]			
n	255	240	495
Mean (SD)	6.05 (8.07)	2.90 (2.68)	4.52 (6.28)
Median	3.02	1.94	2.43
Q1, Q3	1.71, 6.57	1.38, 3.37	1.61, 4.50
Min, Max	0.2, 49.8	0.2, 24.0	0.2, 49.8
Safety for imAEs [b]			
n	255	240	495
Mean (SD)	7.59 (8.08)	4.46 (2.93)	6.07 (6.34)
Median	5.06	3.81	4.17
Q1, Q3	3.65, 7.95	2.99, 5.29	3.15, 6.44
Min, Max	0.2, 49.8	0.2, 26.3	0.2, 49.8

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; imAE = immune-mediated adverse event.

[a] The time from the first dose date to the earliest date among the date of death, study discontinuation date, cut-off date, last date of study treatment + 30 days, and the date of the initiation of new anticancer therapy.

[b] The time from the first dose date to the earliest date among the date of death, study discontinuation date, cut-off date, last date of study treatment + 90 days.

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Table 14.1.8.2.b:
Summary of Follow-up Time by Safety-related Endpoint
Safety Analysis Set - Subpopulation without Irinotecan

Endpoint (Months)	Tislelizumab (N = 139)	ICC (N = 129)	Total (N = 268)
Safety for TEAEs except imAE [a]			
n	139	129	268
Mean (SD)	6.49 (8.89)	3.41 (3.10)	5.01 (6.91)
Median	3.02	2.40	2.71
Q1, Q3	1.71, 7.75	1.71, 4.21	1.71, 4.94
Min, Max	0.3, 49.8	0.2, 24.0	0.2, 49.8
Safety for imAEs [b]			
n	139	129	268
Mean (SD)	8.02 (8.78)	4.95 (3.35)	6.54 (6.90)
Median	4.99	4.11	4.37
Q1, Q3	3.65, 9.43	3.19, 5.78	3.45, 6.83
Min, Max	0.3, 49.8	0.2, 26.3	0.2, 49.8

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; imAE = immune-mediated adverse event.
[a] The time from the first dose date to the earliest date among the date of death, study discontinuation date, cut-off date, last date of study treatment + 30 days, and the date of the initiation of new anticancer therapy.
[b] The time from the first dose date to the earliest date among the date of death, study discontinuation date, cut-off date, last date of study treatment + 90 days.
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Table 14.2.1.1:
Overall Survival (OS)
ITT Analysis Set

	Tislelizumab (N = 256)	ICC (N = 256)
Number of Patients		
Death, n (%)	233 (91.0)	233 (91.0)
Censored, n (%)	23 (9.0)	23 (9.0)
Lost to Follow-up	1 (0.4)	3 (1.2)
Withdrew Consent	5 (2.0)	14 (5.5)
Study Discontinuation Due to Other Reasons	17 (6.6)	6 (2.3)
Two-Sided Stratified Log-Rank Test P-value [a]	0.0003	--
Stratified Hazard Ratio (95% CI) [b]	0.714 (0.593, 0.859)	--
Unstratified Hazard Ratio (95% CI) [c]	0.713 (0.594, 0.856)	--
Overall Survival (months)		
Median (95% CI)	8.6 (7.5, 10.4)	6.3 (5.3, 7.0)
1st Quartile (95% CI)	4.0 (3.5, 4.6)	3.3 (2.6, 4.0)
3rd Quartile (95% CI)	17.3 (14.7, 19.2)	11.4 (10.6, 13.1)

Source: Listing 16.2.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE=Not Evaluable.

Percentages were based on N.

In absence of death on or before data cut-off, patients will be censored either at the date that the patient was last known to be alive or the date of data cut-off, whichever comes earlier.

Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley.

Overall Survival rates (cumulative probability of OS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula.

Median follow-up time was estimated by the reverse Kaplan-Meier method.

[a] Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.

[b] Hazard ratio (Tislelizumab vs. ICC) was based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] Hazard ratio (Tislelizumab vs. ICC) was based on unstratified Cox regression model only including treatment arm as a factor.

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Table 14.2.1.1:
Overall Survival (OS)
ITT Analysis Set

	Tislelizumab (N = 256)	ICC (N = 256)
Overall Survival Rate at, % (95% CI)		
3 Months (95% CI)	84.0 (78.8, 87.9)	78.0 (72.3, 82.7)
6 Months (95% CI)	62.3 (56.0, 67.9)	51.8 (45.3, 57.9)
9 Months (95% CI)	48.7 (42.4, 54.7)	35.0 (29.0, 41.1)
12 Months (95% CI)	37.5 (31.6, 43.5)	24.1 (18.8, 29.6)
15 Months (95% CI)	29.1 (23.6, 34.8)	16.5 (12.1, 21.4)
18 Months (95% CI)	23.4 (18.4, 28.8)	12.2 (8.5, 16.8)
21 Months (95% CI)	18.6 (14.0, 23.6)	8.9 (5.7, 12.9)
24 Months (95% CI)	16.6 (12.3, 21.4)	8.0 (5.0, 11.9)
27 Months (95% CI)	15.4 (11.2, 20.1)	7.2 (4.4, 10.9)
30 Months (95% CI)	12.9 (9.1, 17.4)	6.7 (4.0, 10.4)
33 Months (95% CI)	10.4 (7.0, 14.6)	4.5 (2.3, 7.7)
36 Months (95% CI)	9.5 (6.2, 13.6)	3.6 (1.7, 6.6)

Source: Listing 16.2.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE=Not Evaluable.

Percentages were based on N.

In absence of death on or before data cut-off, patients will be censored either at the date that the patient was last known to be alive or the date of data cut-off, whichever comes earlier.

Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley.

Overall Survival rates (cumulative probability of OS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula.

Median follow-up time was estimated by the reverse Kaplan-Meier method.

[a] Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.

[b] Hazard ratio (Tislelizumab vs. ICC) was based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] Hazard ratio (Tislelizumab vs. ICC) was based on unstratified Cox regression model only including treatment arm as a factor.

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Table 14.2.1.1:
Overall Survival (OS)
ITT Analysis Set

	Tislelizumab (N = 256)	ICC (N = 256)
Follow-up Time (months)		
Median (95% CI)	44.7 (41.7, 48.4)	44.0 (36.6, NE)

Source: Listing 16.2.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE=Not Evaluable.

Percentages were based on N.

In absence of death on or before data cut-off, patients will be censored either at the date that the patient was last known to be alive or the date of data cut-off, whichever comes earlier.

Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley.

Overall Survival rates (cumulative probability of OS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula.

Median follow-up time was estimated by the reverse Kaplan-Meier method.

[a] Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.

[b] Hazard ratio (Tislelizumab vs. ICC) was based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] Hazard ratio (Tislelizumab vs. ICC) was based on unstratified Cox regression model only including treatment arm as a factor.

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Table 14.2.1.1.b:
Overall Survival (OS)
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)	ICC (N = 138)
Number of Patients		
Death, n (%)	127 (91.4)	125 (90.6)
Censored, n (%)	12 (8.6)	13 (9.4)
Lost to Follow-up	0 (0.0)	2 (1.4)
Withdrew Consent	4 (2.9)	7 (5.1)
Study Discontinuation Due to Other Reasons	8 (5.8)	4 (2.9)
Two-Sided Stratified Log-Rank Test P-value [a]	0.0828	--
Stratified Hazard Ratio (95% CI) [b]	0.801 (0.623, 1.030)	--
Unstratified Hazard Ratio (95% CI) [c]	0.787 (0.614, 1.008)	--
Overall Survival (months)		
Median (95% CI)	9.7 (7.0, 11.6)	7.0 (5.8, 8.6)
1st Quartile (95% CI)	4.0 (3.5, 5.2)	3.7 (2.7, 4.6)
3rd Quartile (95% CI)	17.0 (13.2, 22.9)	12.6 (10.6, 17.1)

Source: Listing 16.2.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE=Not Evaluable.

Percentages were based on N.

In absence of death on or before data cut-off, patients will be censored either at the date that the patient was last known to be alive or the date of data cut-off, whichever comes earlier.

Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley.

Overall Survival rates (cumulative probability of OS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula.

Median follow-up time was estimated by the reverse Kaplan-Meier method.

[a] Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.

[b] Hazard ratio (Tislelizumab vs. ICC) was based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] Hazard ratio (Tislelizumab vs. ICC) was based on unstratified Cox regression model only including treatment arm as a factor.

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Table 14.2.1.1.b:
Overall Survival (OS)
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)	ICC (N = 138)
Overall Survival Rate at, % (95% CI)		
3 Months (95% CI)	85.5 (78.5, 90.4)	82.0 (74.4, 87.6)
6 Months (95% CI)	63.6 (55.0, 71.0)	57.3 (48.4, 65.3)
9 Months (95% CI)	50.3 (41.6, 58.3)	38.6 (30.2, 46.9)
12 Months (95% CI)	38.5 (30.3, 46.5)	27.6 (20.2, 35.5)
15 Months (95% CI)	28.0 (20.7, 35.7)	20.5 (14.0, 27.9)
18 Months (95% CI)	21.2 (14.7, 28.4)	15.0 (9.4, 21.7)
21 Months (95% CI)	18.2 (12.2, 25.1)	10.2 (5.8, 16.2)
24 Months (95% CI)	15.9 (10.3, 22.6)	9.5 (5.2, 15.3)
27 Months (95% CI)	15.1 (9.7, 21.7)	7.9 (4.0, 13.4)
30 Months (95% CI)	12.9 (7.9, 19.1)	7.1 (3.5, 12.4)
33 Months (95% CI)	9.8 (5.5, 15.6)	4.7 (1.9, 9.4)
36 Months (95% CI)	9.8 (5.5, 15.6)	4.7 (1.9, 9.4)

Source: Listing 16.2.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE=Not Evaluable.

Percentages were based on N.

In absence of death on or before data cut-off, patients will be censored either at the date that the patient was last known to be alive or the date of data cut-off, whichever comes earlier.

Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley.

Overall Survival rates (cumulative probability of OS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula.

Median follow-up time was estimated by the reverse Kaplan-Meier method.

[a] Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.

[b] Hazard ratio (Tislelizumab vs. ICC) was based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] Hazard ratio (Tislelizumab vs. ICC) was based on unstratified Cox regression model only including treatment arm as a factor.

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Table 14.2.1.1.b:
Overall Survival (OS)
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)	ICC (N = 138)
Follow-up Time (months)		
Median (95% CI)	44.7 (41.7, 46.3)	44.0 (36.6, NE)

Source: Listing 16.2.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE=Not Evaluable.

Percentages were based on N.

In absence of death on or before data cut-off, patients will be censored either at the date that the patient was last known to be alive or the date of data cut-off, whichever comes earlier.

Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley.

Overall Survival rates (cumulative probability of OS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula.

Median follow-up time was estimated by the reverse Kaplan-Meier method.

[a] Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.

[b] Hazard ratio (Tislelizumab vs. ICC) was based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] Hazard ratio (Tislelizumab vs. ICC) was based on unstratified Cox regression model only including treatment arm as a factor.

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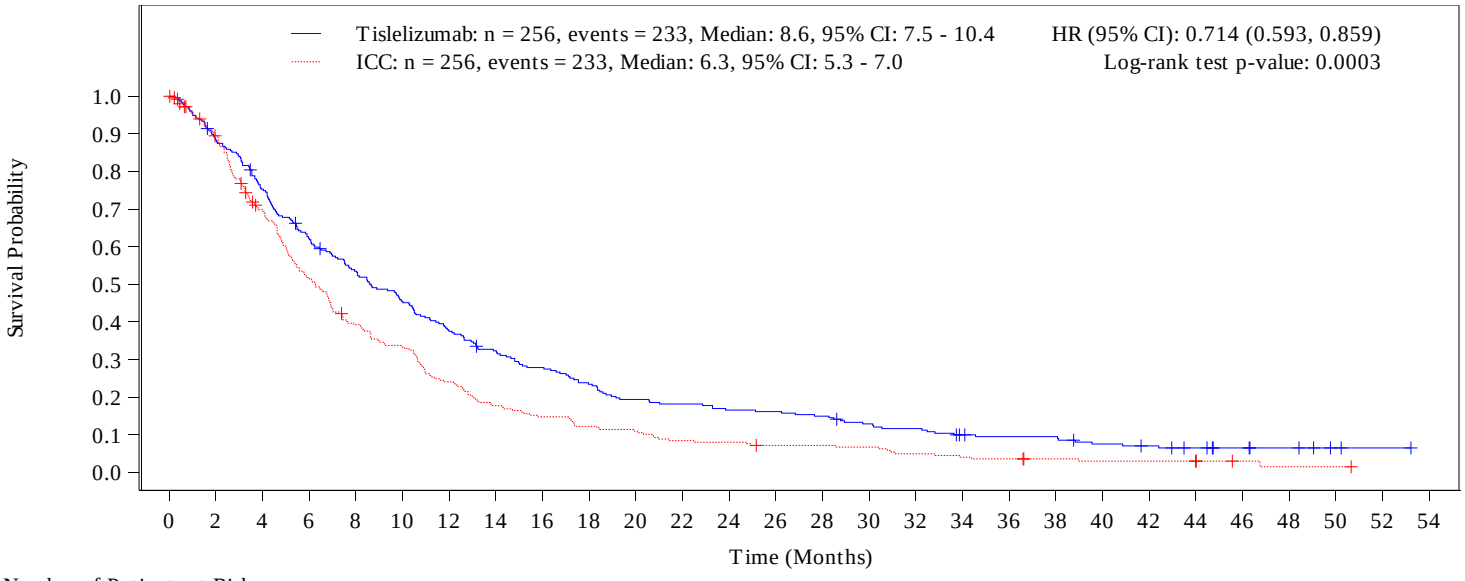
Figure 14.2.1.1:
Kaplan-Meier Plot of Overall Survival (OS)
ITT Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52	54
Tislelizumab	256	226	191	157	134	114	94	80	69	58	48	45	41	40	37	31	28	22	20	20	15	13	10	7	5	2	1	0
ICC	256	219	167	124	93	79	57	42	35	29	26	20	19	16	16	15	11	9	8	6	5	5	4	2	1	1	0	0

Source: Listing 16.2.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
Hazard ratio was based on Cox regression model including treatment as covariate stratified by ECOG status and ICC option.
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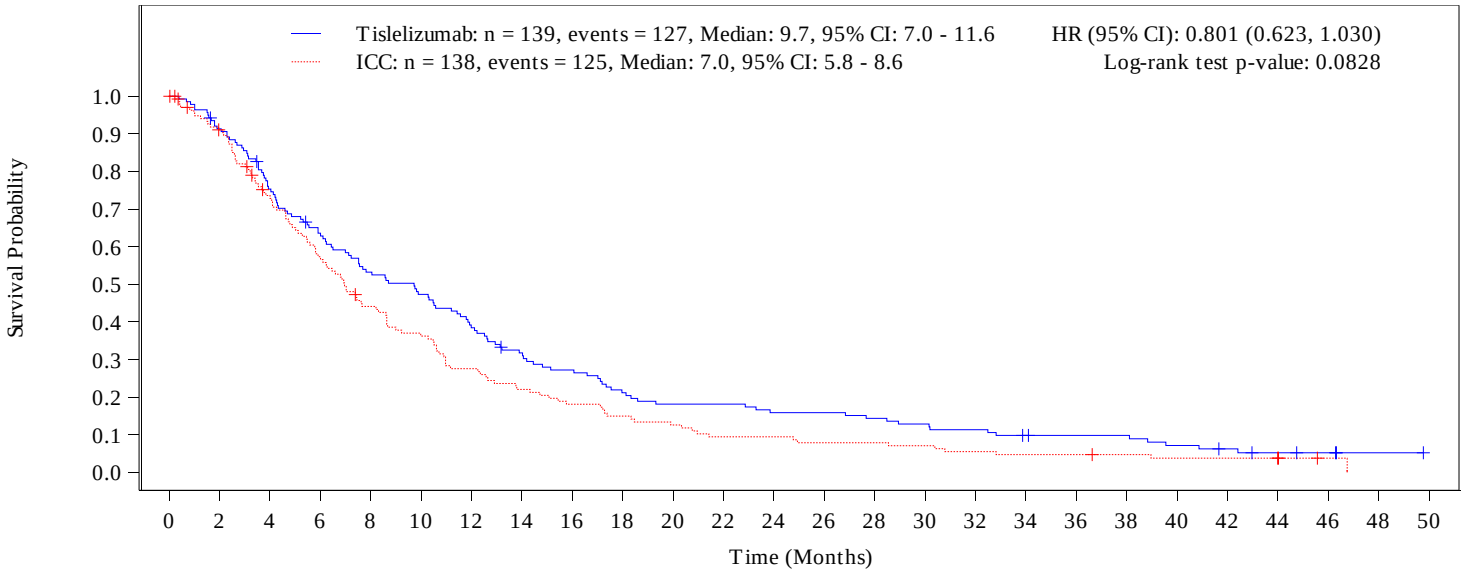
Figure 14.2.1.1.b:
Kaplan-Meier Plot of Overall Survival (OS)
ITT Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	126	103	86	72	64	52	42	36	28	24	24	21	21	19	17	15	12	11	11	8	6	4	3	1	0
ICC	138	121	95	74	56	46	35	28	23	19	16	12	12	10	10	9	7	6	6	5	4	4	3	1	0	0

Source: Listing 16.2.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
Hazard ratio was based on Cox regression model including treatment as covariate stratified by ECOG status and ICC option.
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Table 14.2.1.1.s:
Overall Survival (OS) - Subgroup Analysis
ITT Analysis Set

Subgroup	Tislelizumab (N = 256) Total No. of Patients	Tislelizumab (N = 256) Patients with events n (%)	Tislelizumab (N = 256) Median time to event (95% CI) [a]	ICC (N = 256) Total No. of Patients	ICC (N = 256) Patients with events n (%)	ICC (N = 256) Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	152	143 (94.1)	8.1 (6.0, 10.0)	158	142 (89.9)	5.4 (4.7, 6.7)	0.770 (0.610, 0.973)	0.0279
>= 65 Years	104	90 (86.5)	9.9 (7.7, 12.5)	98	91 (92.9)	7.0 (6.1, 10.0)	0.635 (0.472, 0.855)	0.0025
Interaction								0.4779
Gender								
Male	217	197 (90.8)	8.5 (6.9, 10.3)	215	196 (91.2)	6.3 (5.4, 7.0)	0.740 (0.606, 0.902)	0.0028
Female	39	36 (92.3)	11.2 (5.5, 17.2)	41	37 (90.2)	5.5 (3.7, 9.0)	0.600 (0.374, 0.962)	0.0321
Interaction								0.3894
Smoking Status								
Former/Current Smoker	188	169 (89.9)	7.8 (6.4, 10.0)	192	177 (92.2)	6.1 (5.1, 6.9)	0.670 (0.541, 0.831)	0.0002
Non-Smoker	68	64 (94.1)	10.5 (8.1, 12.2)	63	56 (88.9)	6.9 (4.9, 10.5)	0.838 (0.582, 1.206)	0.3387
Interaction								0.2375

Source: ADSL, ADTTE. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.1.1.s:
Overall Survival (OS) - Subgroup Analysis
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	73 (88.0)	8.7 (6.0, 11.9)	85	76 (89.4)	7.6 (5.9, 10.3)	0.723 (0.521, 1.003)	0.0505
Docetaxel	56	54 (96.4)	9.8 (6.2, 12.1)	53	49 (92.5)	6.2 (4.7, 8.6)	0.903 (0.611, 1.335)	0.6085
Irinotecan	117	106 (90.6)	8.5 (6.1, 10.4)	118	108 (91.5)	5.2 (4.6, 6.8)	0.641 (0.488, 0.841)	0.0012
Interaction								0.3173
ECOG Performance Score								
0	64	54 (84.4)	12.0 (8.0, 14.5)	63	51 (81.0)	8.2 (5.9, 10.8)	0.742 (0.505, 1.090)	0.1267
1	192	179 (93.2)	8.1 (6.2, 9.9)	193	182 (94.3)	5.5 (4.8, 6.8)	0.706 (0.574, 0.870)	0.0010
Interaction								0.7423

Source: ADSL, ADTTE. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.1.1.s:
Overall Survival (OS) - Subgroup Analysis
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #1								
Asia	201	184 (91.5)	8.5 (7.1, 10.3)	203	185 (91.1)	6.3 (5.3, 7.4)	0.727 (0.592, 0.893)	0.0023
Europe/North America	55	49 (89.1)	11.2 (5.9, 14.5)	53	48 (90.6)	6.3 (4.6, 7.7)	0.645 (0.431, 0.966)	0.0315
Interaction								0.7115
Region #2								
Asia (excluding Japan)	176	162 (92.0)	8.1 (6.2, 10.3)	178	163 (91.6)	6.0 (5.1, 7.0)	0.760 (0.611, 0.946)	0.0136
Japan	25	22 (88.0)	9.8 (7.5, 17.3)	25	22 (88.0)	7.6 (4.1, 10.5)	0.526 (0.282, 0.981)	0.0401
Europe/North America	55	49 (89.1)	11.2 (5.9, 14.5)	53	48 (90.6)	6.3 (4.6, 7.7)	0.645 (0.431, 0.966)	0.0315
Interaction								0.5962

Source: ADSL, ADTTE. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.1.1.s:
Overall Survival (OS) - Subgroup Analysis
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	186 (91.6)	8.5 (7.0, 10.0)	212	194 (91.5)	6.1 (5.2, 7.0)	0.721 (0.588, 0.883)	0.0015
White	53	47 (88.7)	11.8 (6.4, 14.5)	44	39 (88.6)	6.5 (4.7, 9.2)	0.668 (0.435, 1.027)	0.0640
Interaction								0.9165
Baseline PD-L1 Status								
vCPS >= 10%	80	71 (88.8)	10.2 (8.5, 14.5)	62	57 (91.9)	5.1 (3.8, 8.2)	0.571 (0.401, 0.813)	0.0017
vCPS < 10%	100	91 (91.0)	7.5 (5.5, 8.9)	122	115 (94.3)	5.8 (4.8, 6.9)	0.850 (0.645, 1.120)	0.2459
Missing	76	71 (93.4)	8.5 (6.2, 12.1)	72	61 (84.7)	7.0 (5.8, 8.6)	0.716 (0.505, 1.015)	0.0586
Interaction								0.2157

Source: ADSL, ADTTE. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-os-subgrp.sas 05JUN2024 17:42 t-14-02-01-01-s-eff-os-subgrp-itt-cl.rtf

Table 14.2.1.1.b.s:
Overall Survival (OS) - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	71 (93.4)	7.5 (5.3, 10.6)	76	67 (88.2)	6.9 (5.1, 9.0)	0.908 (0.649, 1.271)	0.5754
>= 65 Years	63	56 (88.9)	11.2 (7.6, 13.2)	62	58 (93.5)	7.0 (5.5, 8.6)	0.669 (0.462, 0.970)	0.0325
Interaction								0.2635
Gender								
Male	118	108 (91.5)	8.6 (6.2, 11.2)	111	102 (91.9)	7.0 (5.8, 8.6)	0.827 (0.630, 1.085)	0.1686
Female	21	19 (90.5)	11.9 (5.5, 17.3)	27	23 (85.2)	6.9 (3.2, 10.6)	0.652 (0.352, 1.210)	0.1710
Interaction								0.3936
Smoking Status								
Former/Current Smoker	104	95 (91.3)	7.6 (6.1, 10.6)	105	97 (92.4)	6.8 (5.8, 8.6)	0.739 (0.555, 0.985)	0.0382
Non-Smoker	35	32 (91.4)	11.8 (8.6, 12.6)	33	28 (84.8)	7.7 (4.6, 10.9)	0.942 (0.562, 1.577)	0.8195
Interaction								0.3622

Source: ADSL, ADTTE. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.1.1.b.s:
Overall Survival (OS) - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	73 (88.0)	8.7 (6.0, 11.9)	85	76 (89.4)	7.6 (5.9, 10.3)	0.723 (0.521, 1.003)	0.0505
Docetaxel	56	54 (96.4)	9.8 (6.2, 12.1)	53	49 (92.5)	6.2 (4.7, 8.6)	0.903 (0.611, 1.335)	0.6085
Interaction								0.3814
ECOG Performance Score								
0	43	37 (86.0)	12.0 (8.0, 14.8)	42	34 (81.0)	9.2 (5.9, 10.9)	0.689 (0.430, 1.102)	0.1175
1	96	90 (93.8)	7.2 (5.2, 10.3)	96	91 (94.8)	6.3 (5.0, 7.4)	0.836 (0.624, 1.120)	0.2294
Interaction								0.6862
Region #1								
Asia	103	94 (91.3)	8.7 (6.2, 11.4)	105	95 (90.5)	6.9 (5.6, 8.6)	0.800 (0.601, 1.065)	0.1250
Europe/North America	36	33 (91.7)	10.5 (4.0, 13.1)	33	30 (90.9)	7.0 (5.1, 10.0)	0.705 (0.427, 1.165)	0.1695
Interaction								0.8220

Source: ADSL, ADTTE. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.1.1.b.s:
Overall Survival (OS) - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	72 (92.3)	7.7 (5.9, 11.4)	80	73 (91.3)	6.9 (5.0, 8.6)	0.903 (0.652, 1.251)	0.5382
Japan	25	22 (88.0)	9.8 (7.5, 17.3)	25	22 (88.0)	7.6 (4.1, 10.5)	0.526 (0.282, 0.981)	0.0401
Europe/North America	36	33 (91.7)	10.5 (4.0, 13.1)	33	30 (90.9)	7.0 (5.1, 10.0)	0.705 (0.427, 1.165)	0.1695
Interaction								0.3282
Race								
Asian and other	105	96 (91.4)	8.6 (6.2, 10.6)	114	104 (91.2)	6.9 (5.5, 8.6)	0.783 (0.592, 1.034)	0.0835
White	34	31 (91.2)	11.5 (5.9, 14.5)	24	21 (87.5)	7.7 (6.2, 11.2)	0.773 (0.441, 1.353)	0.3658
Interaction								0.8169

Source: ADSL, ADTTE. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.1.1.b.s:
Overall Survival (OS) - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	41 (91.1)	9.9 (4.6, 14.5)	34	31 (91.2)	6.8 (3.5, 11.0)	0.803 (0.503, 1.282)	0.3554
vCPS < 10%	53	47 (88.7)	8.0 (5.9, 11.9)	56	53 (94.6)	6.2 (5.1, 8.6)	0.769 (0.518, 1.142)	0.1914
Missing	41	39 (95.1)	9.8 (6.1, 12.1)	48	41 (85.4)	7.6 (6.0, 10.5)	0.822 (0.526, 1.286)	0.3888
Interaction								0.9691

Source: ADSL, ADTTE. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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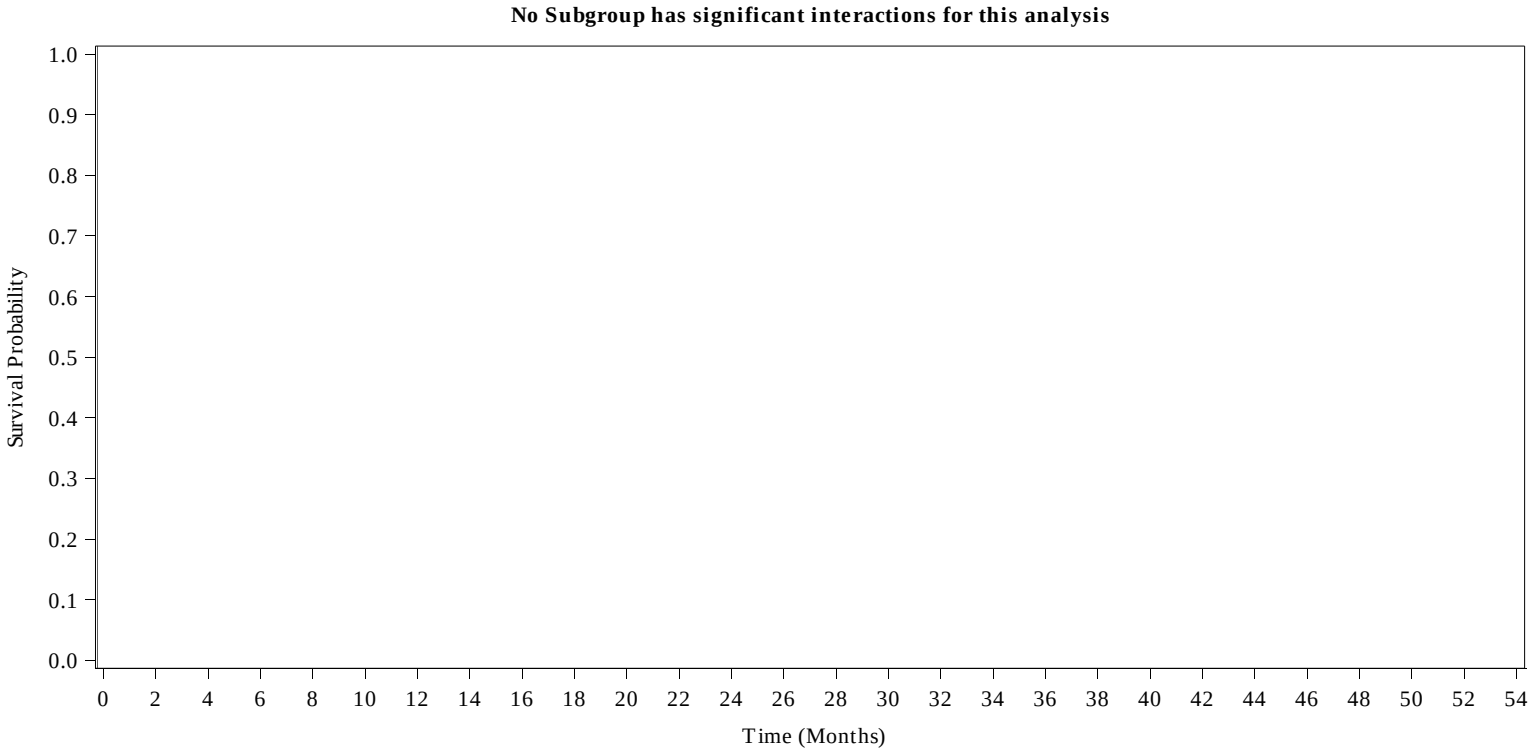
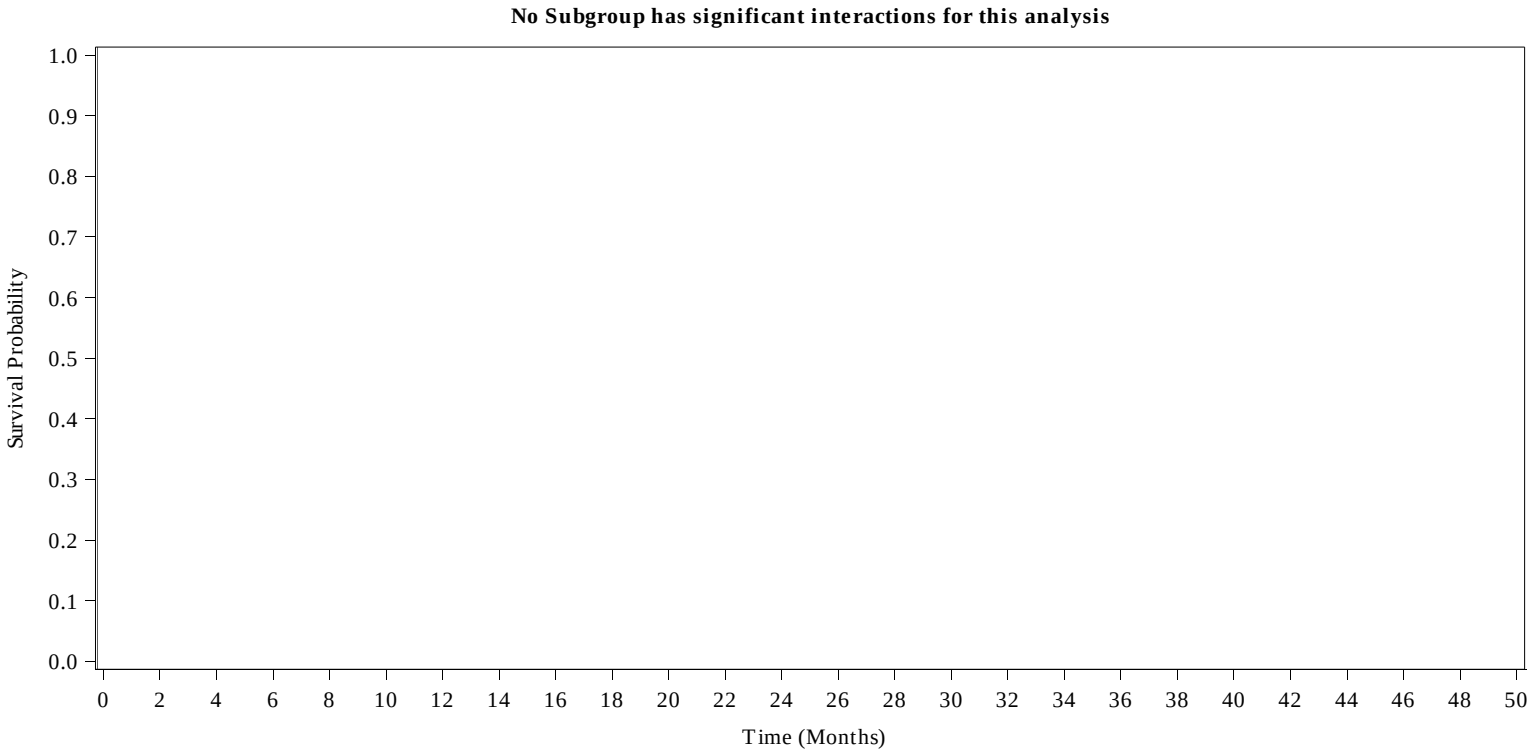
Figure 14.2.1.1.s:
Kaplan-Meier Plot of Overall Survival (OS) - Subgroup Analysis
ITT Analysis Set



Source: ADSL, ADTTE. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-subgrp.sas 05JUN2024 17:46 f-14-02-01-01-s-km-subgrp-os-itt-cl.rtf

Figure 14.2.1.1.b.s:
Kaplan-Meier Plot of Overall Survival (OS) - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTE. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
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Table 14.2.3.1:
Progression Free Survival (PFS)
ITT Analysis Set

	Tislelizumab (N = 256)	ICC (N = 256)
Progression-Free Survival		
Events, n (%)	229 (89.5)	181 (70.7)
Progressive Disease	197 (77.0)	146 (57.0)
Death	32 (12.5)	35 (13.7)
Censored, n (%)	27 (10.5)	75 (29.3)
No Post-Baseline	3 (1.2)	40 (15.6)
New Anti-Cancer Therapy	14 (5.5)	30 (11.7)
Missed >= 2 Assessments	4 (1.6)	4 (1.6)
No PD/Death [a]	6 (2.3)	1 (0.4)
Withdrew Consent	1 (0.4)	1 (0.4)
Study Terminated by Sponsor	5 (2.0)	0 (0.0)

Source: Listing 16.2.6.3. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; PD: Progressive Disease.
Percentages were based on N.
Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley.
Progression free survival rates (cumulative probability of PFS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula.
[a] Patients at study end without PD events are counted in 'No PD/Death Study Terminated by Sponsor' category.
[b] Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
[c] Hazard ratio (Tislelizumab vs. ICC) was based on Cox regression model including treatment arm as a factor and stratified by ICC and ECOG performance status.
[d] Hazard ratio (Tislelizumab vs. ICC) was based on unstratified Cox regression model only including treatment arm as a factor.
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Table 14.2.3.1:
Progression Free Survival (PFS)
ITT Analysis Set

	Tislelizumab (N = 256)	ICC (N = 256)
Two-Sided Stratified Log-Rank Test P-value [b]	0.0569	--
Stratified Hazard Ratio (95% CI) [c]	0.824 (0.674, 1.008)	--
Unstratified Hazard Ratio (95% CI) [d]	0.822 (0.673, 1.004)	--
Progression Free Survival (months)		
Median (95% CI)	1.6 (1.4, 2.7)	2.1 (1.5, 2.7)
1st Quartile (95% CI)	1.3 (1.2, 1.4)	1.2 (1.2, 1.4)
3rd Quartile (95% CI)	5.5 (4.1, 7.4)	4.1 (3.0, 5.5)

Source: Listing 16.2.6.3. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; PD: Progressive Disease.
Percentages were based on N.
Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley.
Progression free survival rates (cumulative probability of PFS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula.
[a] Patients at study end without PD events are counted in 'No PD/Death Study Terminated by Sponsor' category.
[b] Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
[c] Hazard ratio (Tislelizumab vs. ICC) was based on Cox regression model including treatment arm as a factor and stratified by ICC and ECOG performance status.
[d] Hazard ratio (Tislelizumab vs. ICC) was based on unstratified Cox regression model only including treatment arm as a factor.
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Table 14.2.3.1:
Progression Free Survival (PFS)
ITT Analysis Set

	Tislelizumab (N = 256)	ICC (N = 256)
Progression Free Survival Rate at, % (95% CI)		
3 Months (95% CI)	36.3 (30.3, 42.2)	33.1 (26.6, 39.7)
6 Months (95% CI)	21.7 (16.7, 27.2)	14.9 (9.9, 20.9)
9 Months (95% CI)	15.8 (11.4, 20.8)	9.6 (5.5, 15.0)
12 Months (95% CI)	13.0 (9.0, 17.7)	1.9 (0.4, 5.8)
15 Months (95% CI)	10.5 (6.9, 15.0)	1.9 (0.4, 5.8)
18 Months (95% CI)	8.0 (4.9, 12.1)	1.9 (0.4, 5.8)
21 Months (95% CI)	7.0 (4.1, 10.9)	1.9 (0.4, 5.8)
24 Months (95% CI)	6.4 (3.6, 10.3)	1.9 (0.4, 5.8)

Source: Listing 16.2.6.3. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; PD: Progressive Disease.
Percentages were based on N.
Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley.
Progression free survival rates (cumulative probability of PFS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula.
[a] Patients at study end without PD events are counted in 'No PD/Death Study Terminated by Sponsor' category.
[b] Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
[c] Hazard ratio (Tislelizumab vs. ICC) was based on Cox regression model including treatment arm as a factor and stratified by ICC and ECOG performance status.
[d] Hazard ratio (Tislelizumab vs. ICC) was based on unstratified Cox regression model only including treatment arm as a factor.
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Table 14.2.3.1.b:
Progression Free Survival (PFS)
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)	ICC (N = 138)
Progression-Free Survival		
Events, n (%)	124 (89.2)	105 (76.1)
Progressive Disease	108 (77.7)	88 (63.8)
Death	16 (11.5)	17 (12.3)
Censored, n (%)	15 (10.8)	33 (23.9)
No Post-Baseline	1 (0.7)	14 (10.1)
New Anti-Cancer Therapy	5 (3.6)	16 (11.6)
Missed >= 2 Assessments	4 (2.9)	3 (2.2)
No PD/Death [a]	5 (3.6)	0 (0.0)
Withdrew Consent	1 (0.7)	0 (0.0)
Study Terminated by Sponsor	4 (2.9)	0 (0.0)

Source: Listing 16.2.6.3. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; PD: Progressive Disease.
Percentages were based on N.
Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley.
Progression free survival rates (cumulative probability of PFS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula.
[a] Patients at study end without PD events are counted in 'No PD/Death Study Terminated by Sponsor' category.
[b] Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
[c] Hazard ratio (Tislelizumab vs. ICC) was based on Cox regression model including treatment arm as a factor and stratified by ICC and ECOG performance status.
[d] Hazard ratio (Tislelizumab vs. ICC) was based on unstratified Cox regression model only including treatment arm as a factor.
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Table 14.2.3.1.b:
Progression Free Survival (PFS)
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)	ICC (N = 138)
Two-Sided Stratified Log-Rank Test P-value [b]	0.2133	--
Stratified Hazard Ratio (95% CI) [c]	0.845 (0.646, 1.105)	--
Unstratified Hazard Ratio (95% CI) [d]	0.828 (0.634, 1.082)	--
Progression Free Survival (months)		
Median (95% CI)	2.0 (1.5, 2.8)	2.6 (1.5, 2.9)
1st Quartile (95% CI)	1.4 (1.3, 1.4)	1.4 (1.2, 1.4)
3rd Quartile (95% CI)	5.7 (4.1, 7.9)	4.3 (3.6, 6.2)

Source: Listing 16.2.6.3. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; PD: Progressive Disease.
Percentages were based on N.
Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley.
Progression free survival rates (cumulative probability of PFS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula.
[a] Patients at study end without PD events are counted in 'No PD/Death Study Terminated by Sponsor' category.
[b] Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
[c] Hazard ratio (Tislelizumab vs. ICC) was based on Cox regression model including treatment arm as a factor and stratified by ICC and ECOG performance status.
[d] Hazard ratio (Tislelizumab vs. ICC) was based on unstratified Cox regression model only including treatment arm as a factor.
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Table 14.2.3.1.b:
Progression Free Survival (PFS)
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)	ICC (N = 138)
Progression Free Survival Rate at, % (95% CI)		
3 Months (95% CI)	38.7 (30.5, 46.8)	37.4 (28.6, 46.2)
6 Months (95% CI)	24.3 (17.3, 31.9)	18.1 (11.3, 26.1)
9 Months (95% CI)	17.0 (11.1, 24.0)	10.6 (5.3, 18.0)
12 Months (95% CI)	13.6 (8.3, 20.2)	1.6 (0.1, 7.3)
15 Months (95% CI)	11.8 (6.9, 18.2)	1.6 (0.1, 7.3)
18 Months (95% CI)	8.2 (4.1, 14.0)	1.6 (0.1, 7.3)
21 Months (95% CI)	8.2 (4.1, 14.0)	1.6 (0.1, 7.3)
24 Months (95% CI)	8.2 (4.1, 14.0)	1.6 (0.1, 7.3)

Source: Listing 16.2.6.3. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; PD: Progressive Disease.
Percentages were based on N.
Medians and other quartiles were estimated by Kaplan-Meier method with 95% CIs estimated using the method of Brookmeyer and Crowley.
Progression free survival rates (cumulative probability of PFS) were estimated by Kaplan-Meier method with 95% CIs estimated using the Greenwood's formula.
[a] Patients at study end without PD events are counted in 'No PD/Death Study Terminated by Sponsor' category.
[b] Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
[c] Hazard ratio (Tislelizumab vs. ICC) was based on Cox regression model including treatment arm as a factor and stratified by ICC and ECOG performance status.
[d] Hazard ratio (Tislelizumab vs. ICC) was based on unstratified Cox regression model only including treatment arm as a factor.
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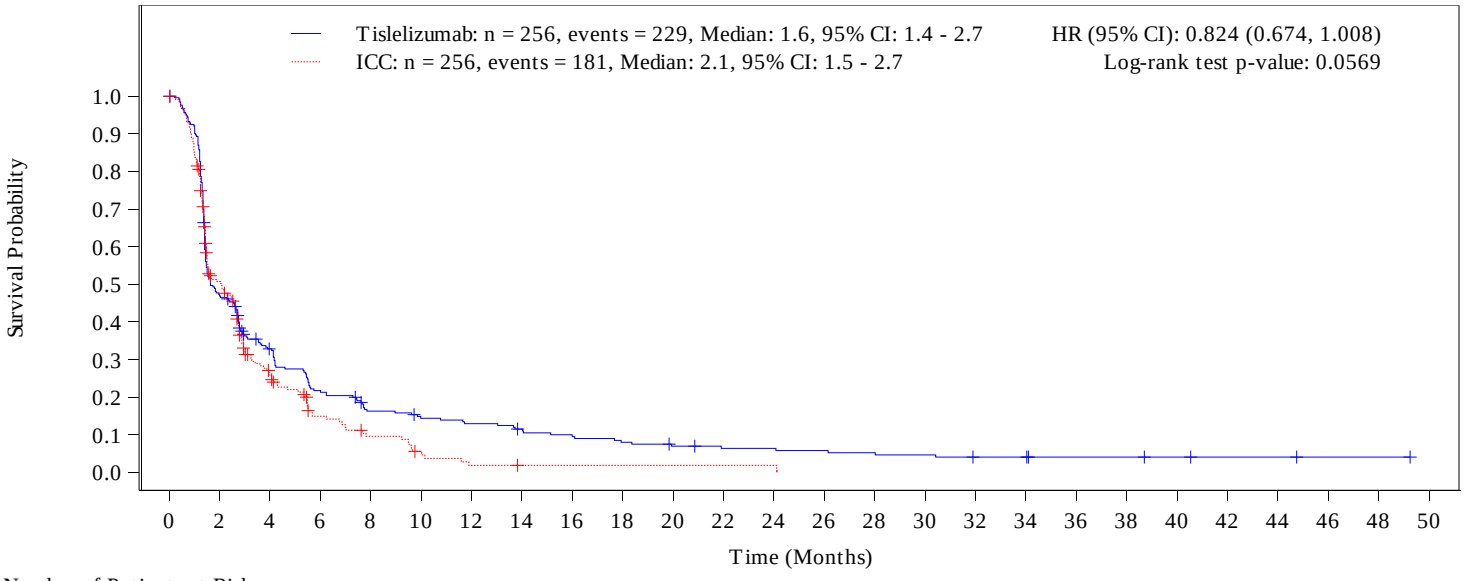
Figure 14.2.4.1:
Kaplan-Meier Plot of Progression Free Survival (PFS)
ITT Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	256	119	74	49	35	30	27	23	20	16	13	11	11	10	9	8	6	6	4	4	3	2	2	1	1	0
ICC	256	98	42	20	12	6	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: Listing 16.2.6.3. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
Hazard ratio was based on Cox regression model including treatment as covariate stratified by ECOG status and ICC option.
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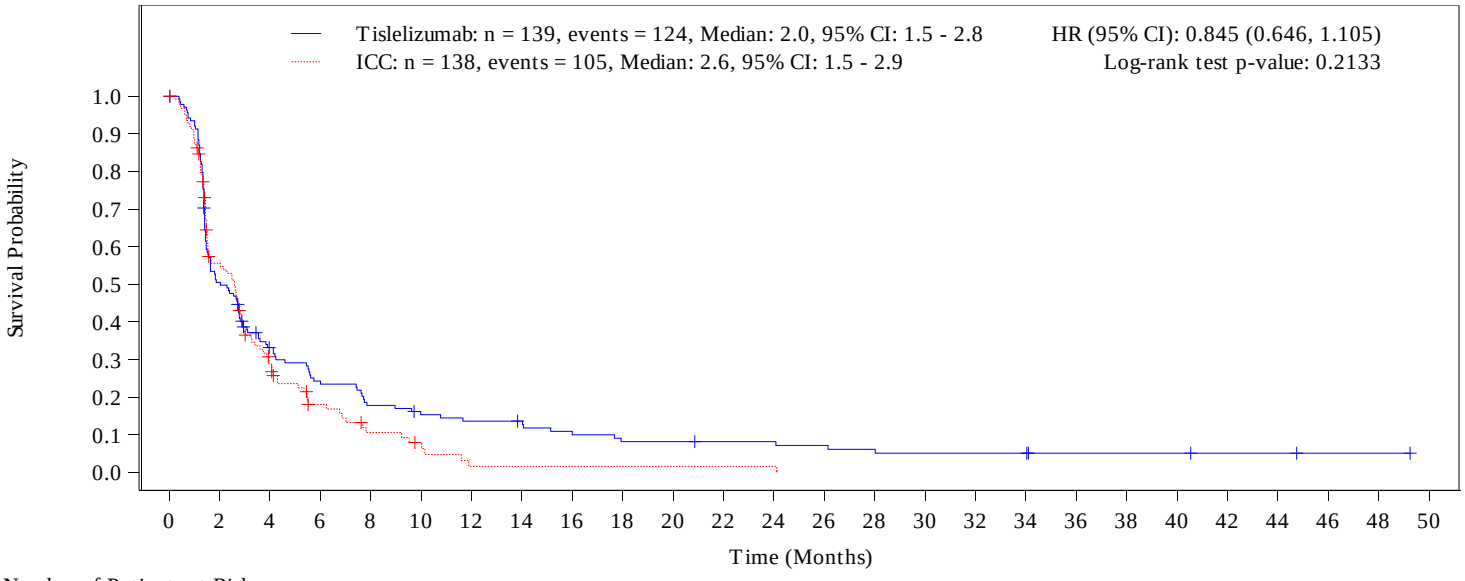
Figure 14.2.4.1.b:
Kaplan-Meier Plot of Progression Free Survival (PFS)
ITT Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	69	41	30	22	18	16	15	12	9	9	8	8	7	6	5	5	5	3	3	3	2	2	1	1	0
ICC	138	62	29	15	8	5	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: Listing 16.2.6.3. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
Hazard ratio was based on Cox regression model including treatment as covariate stratified by ECOG status and ICC option.
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Table 14.2.3.1.s:
Progression Free Survival (PFS) - Subgroup Analysis
ITT Analysis Set

Subgroup	Tislelizumab (N = 256) Total No. of Patients	Tislelizumab (N = 256) Patients with events n (%)	Tislelizumab (N = 256) Median time to event (95% CI) [a]	ICC (N = 256) Total No. of Patients	ICC (N = 256) Patients with events n (%)	ICC (N = 256) Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	152	137 (90.1)	1.5 (1.4, 2.4)	158	116 (73.4)	1.5 (1.4, 2.1)	0.816 (0.635, 1.049)	0.1074
>= 65 Years	104	92 (88.5)	2.6 (1.5, 3.0)	98	65 (66.3)	2.9 (2.2, 3.9)	0.825 (0.591, 1.150)	0.2502
Interaction								0.7069
Gender								
Male	217	192 (88.5)	1.6 (1.4, 2.6)	215	151 (70.2)	2.0 (1.5, 2.7)	0.814 (0.653, 1.013)	0.0619
Female	39	37 (94.9)	2.3 (1.3, 2.9)	41	30 (73.2)	2.5 (1.4, 2.7)	0.878 (0.539, 1.430)	0.5972
Interaction								0.8425
Smoking Status								
Former/Current Smoker	188	169 (89.9)	1.8 (1.4, 2.7)	192	140 (72.9)	2.1 (1.5, 2.7)	0.814 (0.646, 1.025)	0.0764
Non-Smoker	68	60 (88.2)	1.5 (1.4, 2.9)	63	41 (65.1)	1.6 (1.4, 2.7)	0.884 (0.590, 1.323)	0.5442
Interaction								0.9504

Source: ADSL, ADTTE. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.3.1.s:
Progression Free Survival (PFS) - Subgroup Analysis
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	75 (90.4)	2.5 (1.6, 3.5)	85	64 (75.3)	2.6 (1.5, 3.3)	0.800 (0.566, 1.132)	0.2034
Docetaxel	56	49 (87.5)	1.5 (1.4, 2.8)	53	41 (77.4)	1.7 (1.4, 2.9)	0.882 (0.580, 1.342)	0.5534
Irinotecan	117	105 (89.7)	1.4 (1.4, 2.6)	118	76 (64.4)	1.5 (1.4, 2.2)	0.802 (0.593, 1.087)	0.1478
Interaction								0.9044
ECOG Performance Score								
0	64	59 (92.2)	2.9 (1.7, 4.2)	63	43 (68.3)	2.8 (1.7, 3.3)	0.787 (0.522, 1.186)	0.2483
1	192	170 (88.5)	1.5 (1.4, 2.0)	193	138 (71.5)	1.5 (1.4, 2.5)	0.832 (0.661, 1.047)	0.1108
Interaction								0.7563

Source: ADSL, ADTTE. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.3.1.s:
Progression Free Survival (PFS) - Subgroup Analysis
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #1								
Asia	201	177 (88.1)	1.5 (1.4, 2.6)	203	141 (69.5)	1.7 (1.5, 2.6)	0.802 (0.639, 1.007)	0.0544
Europe/North America	55	52 (94.5)	2.3 (1.5, 2.8)	53	40 (75.5)	2.7 (1.4, 3.9)	0.942 (0.619, 1.433)	0.7794
Interaction								0.4965
Region #2								
Asia (excluding Japan)	176	154 (87.5)	1.5 (1.4, 1.8)	178	120 (67.4)	1.9 (1.5, 2.6)	0.859 (0.673, 1.096)	0.2144
Japan	25	23 (92.0)	3.6 (2.0, 7.4)	25	21 (84.0)	1.7 (1.4, 2.8)	0.504 (0.266, 0.954)	0.0317
Europe/North America	55	52 (94.5)	2.3 (1.5, 2.8)	53	40 (75.5)	2.7 (1.4, 3.9)	0.942 (0.619, 1.433)	0.7794
Interaction								0.3929

Source: ADSL, ADTTE. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.3.1.s:
Progression Free Survival (PFS) - Subgroup Analysis
ITT Analysis Set

Subgroup	Tislelizumab (N = 256) Total No. of Patients	Tislelizumab (N = 256) Patients with events n (%)	Tislelizumab (N = 256) Median time to event (95% CI) [a]	ICC (N = 256) Total No. of Patients	ICC (N = 256) Patients with events n (%)	ICC (N = 256) Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	203	178 (87.7)	1.5 (1.4, 2.6)	212	147 (69.3)	1.7 (1.5, 2.6)	0.802 (0.641, 1.004)	0.0512
White	53	51 (96.2)	2.4 (1.5, 2.8)	44	34 (77.3)	2.7 (1.4, 4.3)	0.979 (0.630, 1.521)	0.9236
Interaction								0.4336
Baseline PD-L1 Status								
vCPS >= 10%	80	70 (87.5)	2.7 (1.5, 4.2)	62	42 (67.7)	2.3 (1.4, 3.0)	0.740 (0.500, 1.095)	0.1273
vCPS < 10%	100	89 (89.0)	1.5 (1.4, 2.6)	122	94 (77.0)	1.7 (1.4, 2.7)	0.880 (0.654, 1.185)	0.3935
Missing	76	70 (92.1)	1.5 (1.4, 2.8)	72	45 (62.5)	2.1 (1.4, 2.8)	0.908 (0.620, 1.331)	0.6168
Interaction								0.8111

Source: ADSL, ADTTE. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.3.1.b.s:
Progression Free Survival (PFS) - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	67 (88.2)	1.6 (1.4, 2.8)	76	57 (75.0)	1.7 (1.4, 2.7)	0.894 (0.625, 1.279)	0.5344
>= 65 Years	63	57 (90.5)	2.6 (1.5, 4.2)	62	48 (77.4)	2.8 (1.7, 3.9)	0.723 (0.482, 1.085)	0.1137
Interaction								0.6561
Gender								
Male	118	105 (89.0)	2.0 (1.5, 2.8)	111	85 (76.6)	2.6 (1.5, 3.0)	0.830 (0.618, 1.116)	0.2134
Female	21	19 (90.5)	2.3 (1.3, 4.6)	27	20 (74.1)	2.5 (1.4, 3.0)	0.836 (0.443, 1.577)	0.5783
Interaction								0.8779
Smoking Status								
Former/Current Smoker	104	95 (91.3)	2.4 (1.6, 2.8)	105	82 (78.1)	2.7 (1.5, 2.9)	0.820 (0.604, 1.113)	0.1985
Non-Smoker	35	29 (82.9)	1.5 (1.4, 3.8)	33	23 (69.7)	2.5 (1.4, 3.7)	0.865 (0.497, 1.506)	0.6046
Interaction								0.9282

Source: ADSL, ADTTE. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.3.1.b.s:
Progression Free Survival (PFS) - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	75 (90.4)	2.5 (1.6, 3.5)	85	64 (75.3)	2.6 (1.5, 3.3)	0.800 (0.566, 1.132)	0.2034
Docetaxel	56	49 (87.5)	1.5 (1.4, 2.8)	53	41 (77.4)	1.7 (1.4, 2.9)	0.882 (0.580, 1.342)	0.5534
Interaction								0.8058
ECOG Performance Score								
0	43	39 (90.7)	2.9 (1.6, 4.2)	42	31 (73.8)	2.9 (2.0, 5.1)	0.783 (0.477, 1.286)	0.3305
1	96	85 (88.5)	1.6 (1.4, 2.7)	96	74 (77.1)	2.2 (1.4, 2.8)	0.855 (0.622, 1.174)	0.3266
Interaction								0.9114
Region #1								
Asia	103	90 (87.4)	1.8 (1.4, 2.9)	105	81 (77.1)	2.5 (1.5, 2.8)	0.772 (0.566, 1.053)	0.0975
Europe/North America	36	34 (94.4)	2.7 (1.5, 2.9)	33	24 (72.7)	3.0 (1.5, 4.3)	1.094 (0.645, 1.854)	0.7382
Interaction								0.2268

Source: ADSL, ADTTE. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.3.1.b.s:
Progression Free Survival (PFS) - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	67 (85.9)	1.5 (1.4, 2.8)	80	60 (75.0)	2.6 (1.5, 3.0)	0.884 (0.619, 1.263)	0.4930
Japan	25	23 (92.0)	3.6 (2.0, 7.4)	25	21 (84.0)	1.7 (1.4, 2.8)	0.504 (0.266, 0.954)	0.0317
Europe/North America	36	34 (94.4)	2.7 (1.5, 2.9)	33	24 (72.7)	3.0 (1.5, 4.3)	1.094 (0.645, 1.854)	0.7382
Interaction								0.2239
Race								
Asian and other	105	91 (86.7)	1.6 (1.4, 2.9)	114	87 (76.3)	2.5 (1.5, 2.8)	0.770 (0.568, 1.044)	0.0881
White	34	33 (97.1)	2.7 (1.5, 3.1)	24	18 (75.0)	3.3 (1.5, 6.2)	1.226 (0.687, 2.186)	0.4883
Interaction								0.1574

Source: ADSL, ADTTE. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.3.1.b.s:
Progression Free Survival (PFS) - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	42 (93.3)	2.6 (1.5, 4.1)	34	27 (79.4)	2.6 (1.5, 3.6)	0.933 (0.573, 1.518)	0.7784
vCPS < 10%	53	44 (83.0)	2.7 (1.5, 3.9)	56	47 (83.9)	2.7 (1.4, 3.4)	0.697 (0.455, 1.069)	0.0933
Missing	41	38 (92.7)	1.4 (1.4, 2.8)	48	31 (64.6)	2.5 (1.5, 2.9)	1.018 (0.621, 1.668)	0.9440
Interaction								0.5064

Source: ADSL, ADTTE. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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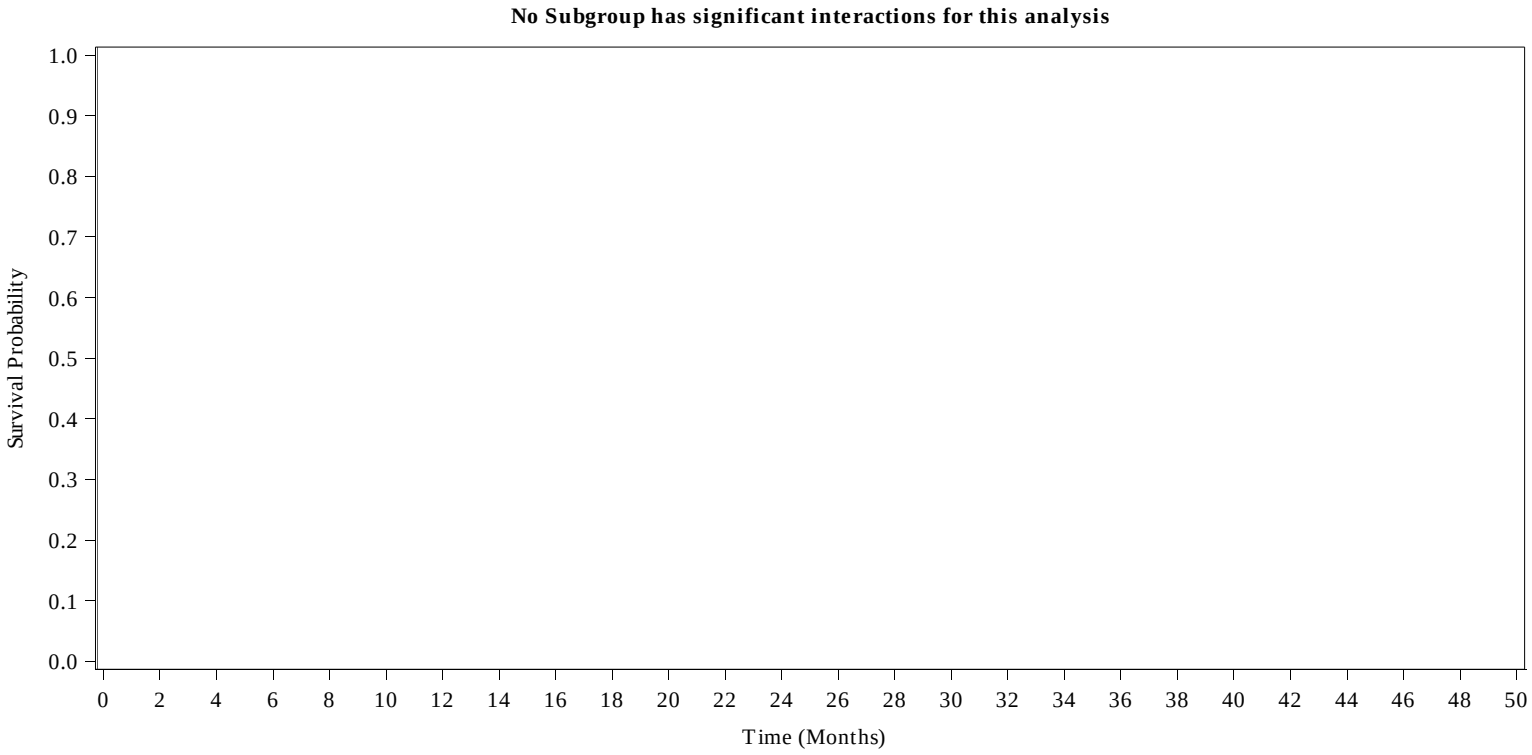
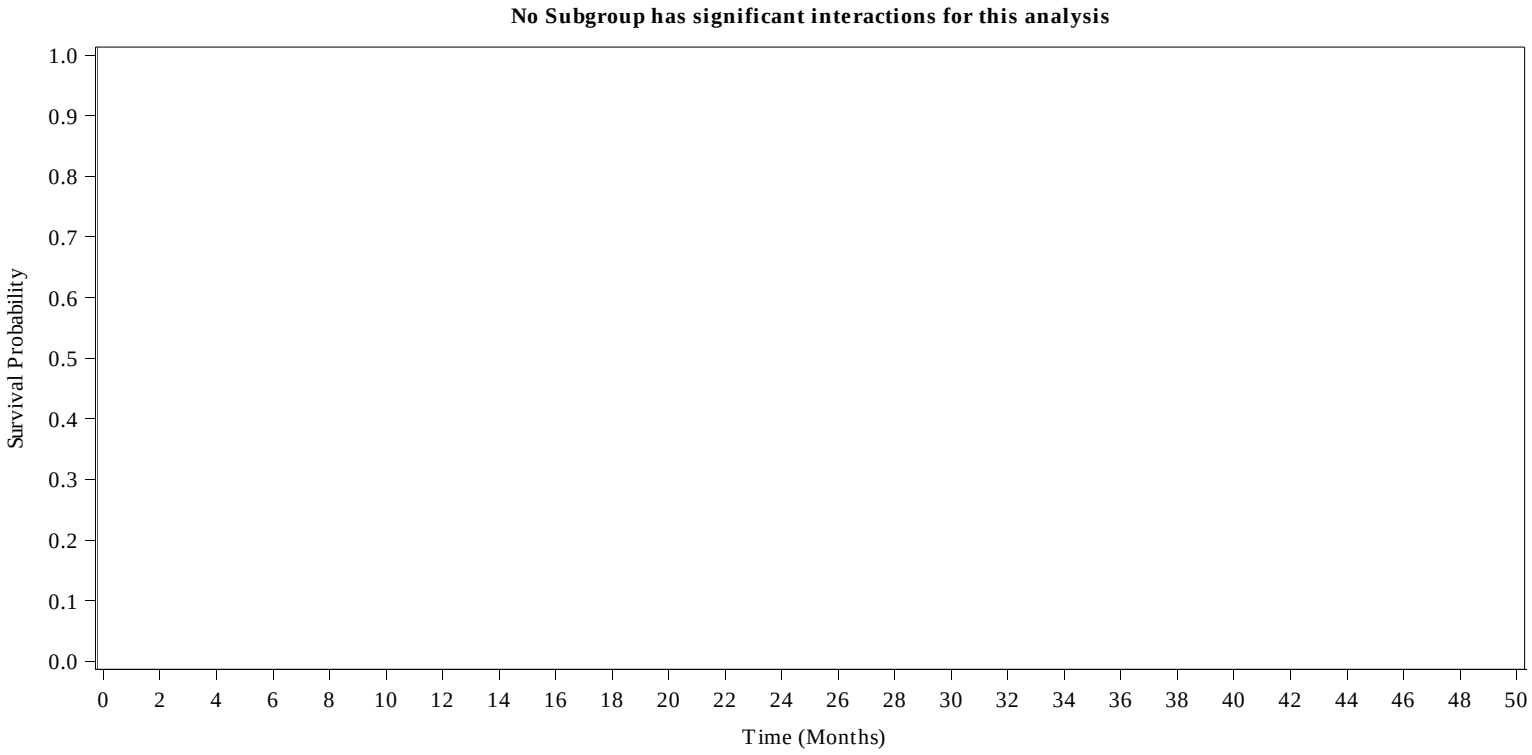
Figure 14.2.4.1.s:
Kaplan-Meier Plot of Progression Free Survival (PFS) - Subgroup Analysis
ITT Analysis Set



Source: ADSL, ADTTE. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-subgrp.sas 05JUN2024 17:46 f-14-02-04-01-s-km-subgrp-pfs-itt-cl.rtf

Figure 14.2.4.1.b.s:
Kaplan-Meier Plot of Progression Free Survival (PFS) - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTE. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-subgrp.sas 05JUN2024 17:46 f-14-02-04-01-b-s-km-subgrp-pfs-itts-cl.rtf

Table 14.2.4.1:
Objective Response
ITT Analysis Set

	Tislelizumab (N = 256)	ICC (N = 256)	Odds Ratio (95% CI) [a]	Relative Risk (95% CI) [a]	Risk Difference (95% CI) [a]	2-sided p-value [b]
Objective Response Rate (ORR), n	52	25				
%	20.3	9.8	2.389 (1.422, 4.015)	2.088 (1.341, 3.251)	10.590 (4.500, 16.680)	0.0008
Best Overall Response (BOR), n (%)						
Complete Response (CR)	6 (2.3)	1 (0.4)				
Partial Response (PR)	46 (18.0)	24 (9.4)				
Stable Disease (SD)	68 (26.6)	82 (32.0)				
Progressive Disease (PD)	116 (45.3)	86 (33.6)				
Not Evaluable (NE) [c]	1 (0.4)	3 (1.2)				
Not Assessable [d]	19 (7.4)	60 (23.4)				
Disease Control Rate (DCR), n	120	107				
%	46.9	41.8	1.236 (0.867, 1.763)	1.121 (0.926, 1.358)	5.067 (-3.397, 13.530)	0.2434

Source: ADSL, ADRS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Percentages were based on N.

ORR is unconfirmed and defined as proportion of number of patients with a PR or CR per RECIST v1.1 (i.e. ORR = CR+PR); DCR is defined as proportion of number of patients with a PR or CR or a SD per RECIST v1.1 (i.e. DCR = CR+PR+SD).

[a] Odds ratio and relative risk were assumed to be log normally distributed. Mantel-Haenszel common risk difference was estimated. 95% CI was constructed by a normal approximation and Sato's variance estimator, stratified by randomization stratification factors.

[b] P-value was calculated using the Cochran-Mantel-Haenszel Chi-square test, stratified by ECOG performance status and ICC option.

[c] Not evaluable is based on RECIST v1.1.

[d] Patients with no post-baseline tumor assessment by the data cutoff, including those who discontinued study (any reason) or died without having any post-baseline tumor assessment.

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Table 14.2.4.1.b:
Objective Response
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)	ICC (N = 138)	Odds Ratio (95% CI) [a]	Relative Risk (95% CI) [a]	Risk Difference (95% CI) [a]	2-sided p-value [b]
Objective Response Rate (ORR), n	31	19				
%	22.3	13.8	1.822 (0.968, 3.430)	1.634 (0.971, 2.748)	8.668 (-0.298, 17.635)	0.0606
Best Overall Response (BOR), n (%)						
Complete Response (CR)	4 (2.9)	1 (0.7)				
Partial Response (PR)	27 (19.4)	18 (13.0)				
Stable Disease (SD)	40 (28.8)	49 (35.5)				
Progressive Disease (PD)	62 (44.6)	45 (32.6)				
Not Evaluable (NE) [c]	0 (0.0)	2 (1.4)				
Not Assessable [d]	6 (4.3)	23 (16.7)				
Disease Control Rate (DCR), n	71	68				
%	51.1	49.3	1.080 (0.671, 1.737)	1.038 (0.823, 1.311)	1.893 (-9.783, 13.568)	0.7521

Source: ADSL, ADRS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
ORR is unconfirmed and defined as proportion of number of patients with a PR or CR per RECIST v1.1 (i.e. ORR = CR+PR); DCR is defined as proportion of number of patients with a PR or CR or a SD per RECIST v1.1 (i.e. DCR = CR+PR+SD).
[a] Odds ratio and relative risk were assumed to be log normally distributed. Mantel-Haenszel common risk difference was estimated. 95% CI was constructed by a normal approximation and Sato's variance estimator, stratified by randomization stratification factors.
[b] P-value was calculated using the Cochran-Mantel-Haenszel Chi-square test, stratified by ECOG performance status and ICC option.
[c] Not evaluable is based on RECIST v1.1.
[d] Patients with no post-baseline tumor assessment by the data cutoff, including those who discontinued study (any reason) or died without having any post-baseline tumor assessment.
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Table 14.2.4.1.s:
Analysis of Objective Response Rate - Subgroup Analysis
ITT Analysis Set

Subgroup	Tislelizumab (N = 256) Total No. of Patients	Tislelizumab (N = 256) Responders n (%)	ICC (N = 256) Total No. of Patients	ICC (N = 256) Responders n (%)	Odds Ratio (95% CI) [a]	Relative Risk (95% CI) [a]	Risk Difference (95% CI) [a]	2-sided p-value [b]
Age								
< 65 Years	152	27 (17.8)	158	16 (10.1)	1.917 (0.987, 3.722)	1.754 (0.985, 3.123)	7.637 (-0.048, 15.321)	0.0522
>= 65 Years	104	25 (24.0)	98	9 (9.2)	3.129 (1.378, 7.105)	2.618 (1.287, 5.325)	14.855 (4.848, 24.862)	0.0049
Interaction								0.3613
Gender								
Male	217	41 (18.9)	215	21 (9.8)	2.152 (1.224, 3.783)	1.934 (1.184, 3.161)	9.127 (2.579, 15.674)	0.0069
Female	39	11 (28.2)	41	4 (9.8)	3.634 (1.046, 12.623)	2.891 (1.005, 8.320)	18.449 (1.658, 35.240)	0.0357
Interaction								0.4507

Source: ADSL, ADRS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Percentages were based on N.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 responders, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of responders are displayed.

ORR is unconfirmed and defined as proportion of number of patients with a PR or CR per RECIST v1.1 (i.e. ORR = CR+PR).

[a] Odds ratio and relative risk were assumed to be log normally distributed. Mantel-Haenszel common risk difference was estimated. 95% CI was constructed by a normal approximation and Sato's variance estimator.

[b] P-value was based on unstratified chi-squared test. P-value for the interaction was based on Breslow-Day test testing for differences in treatment effect across subgroups.

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Table 14.2.4.1.s:
Analysis of Objective Response Rate - Subgroup Analysis
ITT Analysis Set

Subgroup	Tislelizumab (N = 256) Total No. of Patients	Tislelizumab (N = 256) Responders n (%)	ICC (N = 256) Total No. of Patients	ICC (N = 256) Responders n (%)	Odds Ratio (95% CI) [a]	Relative Risk (95% CI) [a]	Risk Difference (95% CI) [a]	2-sided p-value [b]
Smoking Status								
Former/Current Smoker	188	37 (19.7)	192	18 (9.4)	2.369 (1.295, 4.333)	2.099 (1.240, 3.553)	10.306 (3.285, 17.327)	0.0044
Non-Smoker	68	15 (22.1)	63	7 (11.1)	2.264 (0.856, 5.988)	1.985 (0.866, 4.549)	10.948 (-1.596, 23.492)	0.0952
Interaction								0.9384
ICC Options								
Paclitaxel	83	20 (24.1)	85	16 (18.8)	1.369 (0.653, 2.872)	1.280 (0.714, 2.295)	5.273 (-7.125, 17.671)	0.4064
Docetaxel	56	11 (19.6)	53	3 (5.7)	4.074 (1.068, 15.538)	3.470 (1.024, 11.755)	13.982 (1.859, 26.106)	0.0300
Irinotecan	117	21 (17.9)	118	6 (5.1)	4.083 (1.583, 10.530)	3.530 (1.478, 8.430)	12.864 (4.860, 20.868)	0.0020
Interaction								0.1301

Source: ADSL, ADRS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Percentages were based on N.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 responders, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of responders are displayed.

ORR is unconfirmed and defined as proportion of number of patients with a PR or CR per RECIST v1.1 (i.e. ORR = CR+PR).

[a] Odds ratio and relative risk were assumed to be log normally distributed. Mantel-Haenszel common risk difference was estimated. 95% CI was constructed by a normal approximation and Sato's variance estimator.

[b] P-value was based on unstratified chi-squared test. P-value for the interaction was based on Breslow-Day test testing for differences in treatment effect across subgroups.

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Table 14.2.4.1.s:
Analysis of Objective Response Rate - Subgroup Analysis
ITT Analysis Set

Subgroup	Tislelizumab (N = 256) Total No. of Patients	Tislelizumab (N = 256) Responders n (%)	ICC (N = 256) Total No. of Patients	ICC (N = 256) Responders n (%)	Odds Ratio (95% CI) [a]	Relative Risk (95% CI) [a]	Risk Difference (95% CI) [a]	2-sided p-value [b]
ECOG Performance Score								
0	64	15 (23.4)	63	10 (15.9)	1.622 (0.667, 3.949)	1.477 (0.718, 3.035)	7.564 (-6.188, 21.317)	0.2856
1	192	37 (19.3)	193	15 (7.8)	2.833 (1.498, 5.358)	2.480 (1.408, 4.366)	11.499 (4.761, 18.236)	0.0010
Interaction								0.3168
Region #1								
Asia	201	41 (20.4)	203	19 (9.4)	2.482 (1.384, 4.449)	2.179 (1.312, 3.621)	11.038 (4.176, 17.900)	0.0018
Europe/North America	55	11 (20.0)	53	6 (11.3)	1.958 (0.667, 5.746)	1.767 (0.704, 4.435)	8.679 (-4.904, 22.263)	0.2178
Interaction								0.7044

Source: ADSL, ADRS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Percentages were based on N.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 responders, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of responders are displayed.

ORR is unconfirmed and defined as proportion of number of patients with a PR or CR per RECIST v1.1 (i.e. ORR = CR+PR).

[a] Odds ratio and relative risk were assumed to be log normally distributed. Mantel-Haenszel common risk difference was estimated. 95% CI was constructed by a normal approximation and Sato's variance estimator.

[b] P-value was based on unstratified chi-squared test. P-value for the interaction was based on Breslow-Day test testing for differences in treatment effect across subgroups.

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Table 14.2.4.1.s:
Analysis of Objective Response Rate - Subgroup Analysis
ITT Analysis Set

Subgroup	Tislelizumab (N = 256) Total No. of Patients	Tislelizumab (N = 256) Responders n (%)	ICC (N = 256) Total No. of Patients	ICC (N = 256) Responders n (%)	Odds Ratio (95% CI) [a]	Relative Risk (95% CI) [a]	Risk Difference (95% CI) [a]	2-sided p-value [b]
Region #2								
Asia (excluding Japan)	176	33 (18.8)	178	14 (7.9)	2.703 (1.391, 5.252)	2.384 (1.322, 4.298)	10.885 (3.893, 17.877)	0.0026
Japan	25	8 (32.0)	25	5 (20.0)	1.882 (0.518, 6.845)	1.600 (0.606, 4.221)	12.000 (-12.088, 36.088)	0.3383
Europe/North America	55	11 (20.0)	53	6 (11.3)	1.958 (0.667, 5.746)	1.767 (0.704, 4.435)	8.679 (-4.904, 22.263)	0.2178
Interaction								0.8209
Race								
Asian and other	203	41 (20.2)	212	19 (9.0)	2.571 (1.436, 4.604)	2.254 (1.355, 3.748)	11.235 (4.505, 17.964)	0.0012
White	53	11 (20.8)	44	6 (13.6)	1.659 (0.559, 4.920)	1.522 (0.612, 3.784)	7.118 (-7.782, 22.019)	0.3611
Interaction								0.4852

Source: ADSL, ADRS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Percentages were based on N.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 responders, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of responders are displayed.

ORR is unconfirmed and defined as proportion of number of patients with a PR or CR per RECIST v1.1 (i.e. ORR = CR+PR).

[a] Odds ratio and relative risk were assumed to be log normally distributed. Mantel-Haenszel common risk difference was estimated. 95% CI was constructed by a normal approximation and Sato's variance estimator.

[b] P-value was based on unstratified chi-squared test. P-value for the interaction was based on Breslow-Day test testing for differences in treatment effect across subgroups.

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Table 14.2.4.1.s:
Analysis of Objective Response Rate - Subgroup Analysis
ITT Analysis Set

	Tislelizumab (N = 256)		ICC (N = 256)					
Subgroup	**Total No. of Patients**	**Responders n (%)**	**Total No. of Patients**	**Responders n (%)**	**Odds Ratio (95% CI) [a]**	**Relative Risk (95% CI) [a]**	**Risk Difference (95% CI) [a]**	**2-sided p-value [b]**
Baseline PD-L1 Status								
vCPS >= 10%	80	21 (26.3)	62	7 (11.3)	2.797 (1.102, 7.095)	2.325 (1.057, 5.115)	14.960 (2.509, 27.410)	0.0268
vCPS < 10%	100	16 (16.0)	122	11 (9.0)	1.922 (0.848, 4.357)	1.775 (0.863, 3.648)	6.984 (-1.818, 15.785)	0.1140
Missing	76	15 (19.7)	72	7 (9.7)	2.283 (0.872, 5.980)	2.030 (0.879, 4.689)	10.015 (-1.250, 21.280)	0.0880
Interaction								0.8382

Source: ADSL, ADRS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Percentages were based on N.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 responders, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of responders are displayed.

ORR is unconfirmed and defined as proportion of number of patients with a PR or CR per RECIST v1.1 (i.e. ORR = CR+PR).

[a] Odds ratio and relative risk were assumed to be log normally distributed. Mantel-Haenszel common risk difference was estimated. 95% CI was constructed by a normal approximation and Sato's variance estimator.

[b] P-value was based on unstratified chi-squared test. P-value for the interaction was based on Breslow-Day test testing for differences in treatment effect across subgroups.

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Table 14.2.4.1.b.s:
Analysis of Objective Response Rate - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)		ICC (N = 138)					
Subgroup	Total No. of Patients	Responders n (%)	Total No. of Patients	Responders n (%)	Odds Ratio (95% CI) [a]	Relative Risk (95% CI) [a]	Risk Difference (95% CI) [a]	2-sided p-value [b]
Age								
< 65 Years	76	15 (19.7)	76	12 (15.8)	1.311 (0.568, 3.026)	1.250 (0.627, 2.490)	3.947 (-8.188, 16.083)	0.5257
>= 65 Years	63	16 (25.4)	62	7 (11.3)	2.675 (1.014, 7.054)	2.249 (0.995, 5.087)	14.107 (0.780, 27.433)	0.0427
Interaction								0.2736
Gender								
Male	118	24 (20.3)	111	16 (14.4)	1.516 (0.757, 3.034)	1.411 (0.792, 2.513)	5.925 (-3.845, 15.694)	0.2390
Female	21	7 (33.3)	27	3 (11.1)	4.000 (0.888, 18.009)	3.000 (0.880, 10.227)	22.222 (-1.166, 45.611)	0.0628
Interaction								0.2456

Source: ADSL, ADRS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 responders, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of responders are displayed.
ORR is unconfirmed and defined as proportion of number of patients with a PR or CR per RECIST v1.1 (i.e. ORR = CR+PR).
[a] Odds ratio and relative risk were assumed to be log normally distributed. Mantel-Haenszel common risk difference was estimated. 95% CI was constructed by a normal approximation and Sato's variance estimator.
[b] P-value was based on unstratified chi-squared test. P-value for the interaction was based on Breslow-Day test testing for differences in treatment effect across subgroups.
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Table 14.2.4.1.b.s:
Analysis of Objective Response Rate - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Subgroup	Tislelizumab (N = 139) Total No. of Patients	Tislelizumab (N = 139) Responders n (%)	ICC (N = 138) Total No. of Patients	ICC (N = 138) Responders n (%)	Odds Ratio (95% CI) [a]	Relative Risk (95% CI) [a]	Risk Difference (95% CI) [a]	2-sided p-value [b]
Smoking Status								
Former/Current Smoker	104	23 (22.1)	105	14 (13.3)	1.846 (0.891, 3.825)	1.659 (0.904, 3.042)	8.782 (-1.509, 19.073)	0.0971
Non-Smoker	35	8 (22.9)	33	5 (15.2)	1.659 (0.482, 5.711)	1.509 (0.549, 4.146)	7.706 (-10.820, 26.231)	0.4228
Interaction								0.8844
ICC Options								
Paclitaxel	83	20 (24.1)	85	16 (18.8)	1.369 (0.653, 2.872)	1.280 (0.714, 2.295)	5.273 (-7.125, 17.671)	0.4064
Docetaxel	56	11 (19.6)	53	3 (5.7)	4.074 (1.068, 15.538)	3.470 (1.024, 11.755)	13.982 (1.859, 26.106)	0.0300
Interaction								0.1551

Source: ADSL, ADRS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

Percentages were based on N.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 responders, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of responders are displayed.

ORR is unconfirmed and defined as proportion of number of patients with a PR or CR per RECIST v1.1 (i.e. ORR = CR+PR).

[a] Odds ratio and relative risk were assumed to be log normally distributed. Mantel-Haenszel common risk difference was estimated. 95% CI was constructed by a normal approximation and Sato's variance estimator.

[b] P-value was based on unstratified chi-squared test. P-value for the interaction was based on Breslow-Day test testing for differences in treatment effect across subgroups.

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Table 14.2.4.1.b.s:
Analysis of Objective Response Rate - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)		ICC (N = 138)					
Subgroup	**Total No. of Patients**	**Responders n (%)**	**Total No. of Patients**	**Responders n (%)**	**Odds Ratio (95% CI) [a]**	**Relative Risk (95% CI) [a]**	**Risk Difference (95% CI) [a]**	**2-sided p-value [b]**
ECOG Performance Score								
0	43	9 (20.9)	42	9 (21.4)	0.971 (0.343, 2.748)	0.977 (0.430, 2.218)	-0.498 (-17.872, 16.875)	0.9554
1	96	22 (22.9)	96	10 (10.4)	2.557 (1.138, 5.745)	2.200 (1.101, 4.395)	12.500 (2.106, 22.894)	0.0205
Interaction								0.1473
Region #1								
Asia	103	25 (24.3)	105	13 (12.4)	2.268 (1.088, 4.730)	1.960 (1.062, 3.617)	11.891 (1.487, 22.295)	0.0269
Europe/North America	36	6 (16.7)	33	6 (18.2)	0.900 (0.259, 3.127)	0.917 (0.328, 2.563)	-1.515 (-19.442, 16.412)	0.8692
Interaction								0.2062

Source: ADSL, ADRS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 responders, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of responders are displayed.
ORR is unconfirmed and defined as proportion of number of patients with a PR or CR per RECIST v1.1 (i.e. ORR = CR+PR).
[a] Odds ratio and relative risk were assumed to be log normally distributed. Mantel-Haenszel common risk difference was estimated. 95% CI was constructed by a normal approximation and Sato's variance estimator.
[b] P-value was based on unstratified chi-squared test. P-value for the interaction was based on Breslow-Day test testing for differences in treatment effect across subgroups.
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Table 14.2.4.1.b.s:
Analysis of Objective Response Rate - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)		ICC (N = 138)					
Subgroup	**Total No. of Patients**	**Responders n (%)**	**Total No. of Patients**	**Responders n (%)**	**Odds Ratio (95% CI) [a]**	**Relative Risk (95% CI) [a]**	**Risk Difference (95% CI) [a]**	**2-sided p-value [b]**
Region #2								
Asia (excluding Japan)	78	17 (21.8)	80	8 (10.0)	2.508 (1.013, 6.212)	2.179 (0.999, 4.756)	11.795 (0.518, 23.071)	0.0429
Japan	25	8 (32.0)	25	5 (20.0)	1.882 (0.518, 6.845)	1.600 (0.606, 4.221)	12.000 (-12.088, 36.088)	0.3383
Europe/North America	36	6 (16.7)	33	6 (18.2)	0.900 (0.259, 3.127)	0.917 (0.328, 2.563)	-1.515 (-19.442, 16.412)	0.8692
Interaction								0.4190
Race								
Asian and other	105	25 (23.8)	114	13 (11.4)	2.428 (1.168, 5.046)	2.088 (1.128, 3.864)	12.406 (2.385, 22.427)	0.0157
White	34	6 (17.6)	24	6 (25.0)	0.643 (0.179, 2.306)	0.706 (0.259, 1.926)	-7.353 (-28.901, 14.195)	0.4997
Interaction								0.0717

Source: ADSL, ADRS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

Percentages were based on N.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 responders, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of responders are displayed.

ORR is unconfirmed and defined as proportion of number of patients with a PR or CR per RECIST v1.1 (i.e. ORR = CR+PR).

[a] Odds ratio and relative risk were assumed to be log normally distributed. Mantel-Haenszel common risk difference was estimated. 95% CI was constructed by a normal approximation and Sato's variance estimator.

[b] P-value was based on unstratified chi-squared test. P-value for the interaction was based on Breslow-Day test testing for differences in treatment effect across subgroups.

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Table 14.2.4.1.b.s:
Analysis of Objective Response Rate - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)		ICC (N = 138)					
Subgroup	**Total No. of Patients**	**Responders n (%)**	**Total No. of Patients**	**Responders n (%)**	**Odds Ratio (95% CI) [a]**	**Relative Risk (95% CI) [a]**	**Risk Difference (95% CI) [a]**	**2-sided p-value [b]**
Baseline PD-L1 Status								
vCPS >= 10%	45	12 (26.7)	34	4 (11.8)	2.727 (0.793, 9.376)	2.267 (0.801, 6.415)	14.902 (-1.957, 31.761)	0.1049
vCPS < 10%	53	12 (22.6)	56	10 (17.9)	1.346 (0.527, 3.443)	1.268 (0.599, 2.685)	4.784 (-10.301, 19.870)	0.5358
Missing	41	7 (17.1)	48	5 (10.4)	1.771 (0.516, 6.074)	1.639 (0.563, 4.775)	6.657 (-7.743, 21.056)	0.3621
Interaction								0.6694

Source: ADSL, ADRS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

Percentages were based on N.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 responders, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of responders are displayed.

ORR is unconfirmed and defined as proportion of number of patients with a PR or CR per RECIST v1.1 (i.e. ORR = CR+PR).

[a] Odds ratio and relative risk were assumed to be log normally distributed. Mantel-Haenszel common risk difference was estimated. 95% CI was constructed by a normal approximation and Sato's variance estimator.

[b] P-value was based on unstratified chi-squared test. P-value for the interaction was based on Breslow-Day test testing for differences in treatment effect across subgroups.

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Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set

Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab (N = 256)	ICC (N = 256)
Baseline		
Patients in study at visit, n	256	256
Patients complete questionnaire, n	242	247
Completion rate (%) [a]	94.5	96.5
Adjusted completion rate (%) [b]	94.5	96.5
Cycle 1		
Patients in study at visit, n	256	256
Patients complete questionnaire, n	140	134
Completion rate (%) [a]	54.7	52.3
Adjusted completion rate (%) [b]	54.7	52.3
Cycle 2		
Patients in study at visit, n	237	184
Patients complete questionnaire, n	222	174
Completion rate (%) [a]	86.7	68.0
Adjusted completion rate (%) [b]	93.7	94.6

Source: Listing 16.2.6.6.1, 16.2.6.6.2, 16.2.6.6.3. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients in study at relevant visits in relevant treatment arm.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-comp.sas 05JUN2024 17:45 t-14-02-06-01-01-qs-comp-itt-cl.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set

Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab (N = 256)	ICC (N = 256)
Cycle 3		
Patients in study at visit, n	188	99
Patients complete questionnaire, n	181	92
Completion rate (%) [a]	70.7	35.9
Adjusted completion rate (%) [b]	96.3	92.9
Cycle 4		
Patients in study at visit, n	157	83
Patients complete questionnaire, n	147	77
Completion rate (%) [a]	57.4	30.1
Adjusted completion rate (%) [b]	93.6	92.8
Cycle 5		
Patients in study at visit, n	116	48
Patients complete questionnaire, n	108	45
Completion rate (%) [a]	42.2	17.6
Adjusted completion rate (%) [b]	93.1	93.8

Source: Listing 16.2.6.6.1, 16.2.6.6.2, 16.2.6.6.3. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients in study at relevant visits in relevant treatment arm.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-comp.sas 05JUN2024 17:45 t-14-02-06-01-01-qs-comp-itt-cl.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set

Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab (N = 256)	ICC (N = 256)
Cycle 6		
Patients in study at visit, n	100	39
Patients complete questionnaire, n	99	38
Completion rate (%) [a]	38.7	14.8
Adjusted completion rate (%) [b]	99.0	97.4
End of Treatment		
Patients in study at visit, n	256	256
Patients complete questionnaire, n	79	83
Completion rate (%) [a]	30.9	32.4
Adjusted completion rate (%) [b]	30.9	32.4
Safety Follow-up		
Patients in study at visit, n	151	119
Patients complete questionnaire, n	118	97
Completion rate (%) [a]	46.1	37.9
Adjusted completion rate (%) [b]	78.1	81.5

Source: Listing 16.2.6.6.1, 16.2.6.6.2, 16.2.6.6.3. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients in study at relevant visits in relevant treatment arm.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-comp.sas 05JUN2024 17:45 t-14-02-06-01-01-qs-comp-itt-cl.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set

Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab (N = 256)	ICC (N = 256)
Baseline		
Patients in study at visit, n	256	256
Patients complete questionnaire, n	240	248
Completion rate (%) [a]	93.8	96.9
Adjusted completion rate (%) [b]	93.8	96.9
Cycle 1		
Patients in study at visit, n	256	256
Patients complete questionnaire, n	138	132
Completion rate (%) [a]	53.9	51.6
Adjusted completion rate (%) [b]	53.9	51.6
Cycle 2		
Patients in study at visit, n	237	184
Patients complete questionnaire, n	224	174
Completion rate (%) [a]	87.5	68.0
Adjusted completion rate (%) [b]	94.5	94.6

Source: Listing 16.2.6.6.1, 16.2.6.6.2, 16.2.6.6.3. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients in study at relevant visits in relevant treatment arm.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-comp.sas 05JUN2024 17:45 t-14-02-06-01-01-qs-comp-itt-cl.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set

Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab (N = 256)	ICC (N = 256)
Cycle 3		
Patients in study at visit, n	188	99
Patients complete questionnaire, n	181	91
Completion rate (%) [a]	70.7	35.5
Adjusted completion rate (%) [b]	96.3	91.9
Cycle 4		
Patients in study at visit, n	157	83
Patients complete questionnaire, n	146	76
Completion rate (%) [a]	57.0	29.7
Adjusted completion rate (%) [b]	93.0	91.6
Cycle 5		
Patients in study at visit, n	116	48
Patients complete questionnaire, n	110	45
Completion rate (%) [a]	43.0	17.6
Adjusted completion rate (%) [b]	94.8	93.8

Source: Listing 16.2.6.6.1, 16.2.6.6.2, 16.2.6.6.3. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients in study at relevant visits in relevant treatment arm.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-comp.sas 05JUN2024 17:45 t-14-02-06-01-01-qs-comp-itt-cl.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set

Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab (N = 256)	ICC (N = 256)
Cycle 6		
Patients in study at visit, n	100	39
Patients complete questionnaire, n	99	37
Completion rate (%) [a]	38.7	14.5
Adjusted completion rate (%) [b]	99.0	94.9
End of Treatment		
Patients in study at visit, n	256	256
Patients complete questionnaire, n	76	83
Completion rate (%) [a]	29.7	32.4
Adjusted completion rate (%) [b]	29.7	32.4
Safety Follow-up		
Patients in study at visit, n	151	119
Patients complete questionnaire, n	117	97
Completion rate (%) [a]	45.7	37.9
Adjusted completion rate (%) [b]	77.5	81.5

Source: Listing 16.2.6.6.1, 16.2.6.6.2, 16.2.6.6.3. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients in study at relevant visits in relevant treatment arm.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-comp.sas 05JUN2024 17:45 t-14-02-06-01-01-qs-comp-itt-cl.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set

Questionnaire: EQ-5D VAS

Visit	Tislelizumab (N = 256)	ICC (N = 256)
Baseline		
Patients in study at visit, n	256	256
Patients complete questionnaire, n	242	247
Completion rate (%) [a]	94.5	96.5
Adjusted completion rate (%) [b]	94.5	96.5
Cycle 1		
Patients in study at visit, n	256	256
Patients complete questionnaire, n	140	134
Completion rate (%) [a]	54.7	52.3
Adjusted completion rate (%) [b]	54.7	52.3
Cycle 2		
Patients in study at visit, n	237	184
Patients complete questionnaire, n	223	173
Completion rate (%) [a]	87.1	67.6
Adjusted completion rate (%) [b]	94.1	94.0

Source: Listing 16.2.6.6.1, 16.2.6.6.2, 16.2.6.6.3. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.

[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients in study at relevant visits in relevant treatment arm.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-comp.sas 05JUN2024 17:45 t-14-02-06-01-01-qs-comp-itt-cl.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set

Questionnaire: EQ-5D VAS

Visit	Tislelizumab (N = 256)	ICC (N = 256)
Cycle 3		
Patients in study at visit, n	188	99
Patients complete questionnaire, n	180	90
Completion rate (%) [a]	70.3	35.2
Adjusted completion rate (%) [b]	95.7	90.9
Cycle 4		
Patients in study at visit, n	157	83
Patients complete questionnaire, n	147	77
Completion rate (%) [a]	57.4	30.1
Adjusted completion rate (%) [b]	93.6	92.8
Cycle 5		
Patients in study at visit, n	116	48
Patients complete questionnaire, n	109	45
Completion rate (%) [a]	42.6	17.6
Adjusted completion rate (%) [b]	94.0	93.8

Source: Listing 16.2.6.6.1, 16.2.6.6.2, 16.2.6.6.3. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients in study at relevant visits in relevant treatment arm.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-comp.sas 05JUN2024 17:45 t-14-02-06-01-01-qs-comp-itt-cl.rtf

Table 14.2.6.1.1:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set

Questionnaire: EQ-5D VAS

Visit	Tislelizumab (N = 256)	ICC (N = 256)
Cycle 6		
Patients in study at visit, n	100	39
Patients complete questionnaire, n	99	36
Completion rate (%) [a]	38.7	14.1
Adjusted completion rate (%) [b]	99.0	92.3
End of Treatment		
Patients in study at visit, n	256	256
Patients complete questionnaire, n	78	83
Completion rate (%) [a]	30.5	32.4
Adjusted completion rate (%) [b]	30.5	32.4
Safety Follow-up		
Patients in study at visit, n	151	119
Patients complete questionnaire, n	117	97
Completion rate (%) [a]	45.7	37.9
Adjusted completion rate (%) [b]	77.5	81.5

Source: Listing 16.2.6.6.1, 16.2.6.6.2, 16.2.6.6.3. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients in study at relevant visits in relevant treatment arm.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-comp.sas 05JUN2024 17:45 t-14-02-06-01-01-qs-comp-itt-cl.rtf

Table 14.2.6.1.1.b:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation without Irinotecan

Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab (N = 139)	ICC (N = 138)
Baseline		
Patients in study at visit, n	139	138
Patients complete questionnaire, n	128	133
Completion rate (%) [a]	92.1	96.4
Adjusted completion rate (%) [b]	92.1	96.4
Cycle 1		
Patients in study at visit, n	139	138
Patients complete questionnaire, n	83	83
Completion rate (%) [a]	59.7	60.1
Adjusted completion rate (%) [b]	59.7	60.1
Cycle 2		
Patients in study at visit, n	132	105
Patients complete questionnaire, n	123	97
Completion rate (%) [a]	88.5	70.3
Adjusted completion rate (%) [b]	93.2	92.4

Source: Listing 16.2.6.6.1, 16.2.6.6.2, 16.2.6.6.3. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients in study at relevant visits in relevant treatment arm.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-comp.sas 05JUN2024 17:45 t-14-02-06-01-01-b-qs-comp-itts-cl.rtf

Table 14.2.6.1.1.b:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation without Irinotecan

Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab (N = 139)	ICC (N = 138)
Cycle 3		
Patients in study at visit, n	103	65
Patients complete questionnaire, n	98	58
Completion rate (%) [a]	70.5	42.0
Adjusted completion rate (%) [b]	95.1	89.2
Cycle 4		
Patients in study at visit, n	82	56
Patients complete questionnaire, n	77	52
Completion rate (%) [a]	55.4	37.7
Adjusted completion rate (%) [b]	93.9	92.9
Cycle 5		
Patients in study at visit, n	62	33
Patients complete questionnaire, n	56	32
Completion rate (%) [a]	40.3	23.2
Adjusted completion rate (%) [b]	90.3	97.0

Source: Listing 16.2.6.6.1, 16.2.6.6.2, 16.2.6.6.3. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients in study at relevant visits in relevant treatment arm.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-comp.sas 05JUN2024 17:45 t-14-02-06-01-01-b-qs-comp-itts-cl.rtf

Table 14.2.6.1.1.b:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation without Irinotecan

Questionnaire: EORTC QLQ-C30

Visit	Tislelizumab (N = 139)	ICC (N = 138)
Cycle 6		
Patients in study at visit, n	55	27
Patients complete questionnaire, n	55	26
Completion rate (%) [a]	39.6	18.8
Adjusted completion rate (%) [b]	100.0	96.3
End of Treatment		
Patients in study at visit, n	139	138
Patients complete questionnaire, n	43	46
Completion rate (%) [a]	30.9	33.3
Adjusted completion rate (%) [b]	30.9	33.3
Safety Follow-up		
Patients in study at visit, n	93	78
Patients complete questionnaire, n	71	62
Completion rate (%) [a]	51.1	44.9
Adjusted completion rate (%) [b]	76.3	79.5

Source: Listing 16.2.6.6.1, 16.2.6.6.2, 16.2.6.6.3. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients in study at relevant visits in relevant treatment arm.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-comp.sas 05JUN2024 17:45 t-14-02-06-01-01-b-qs-comp-itts-cl.rtf

Table 14.2.6.1.1.b:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation without Irinotecan

Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab (N = 139)	ICC (N = 138)
Baseline		
Patients in study at visit, n	139	138
Patients complete questionnaire, n	128	134
Completion rate (%) [a]	92.1	97.1
Adjusted completion rate (%) [b]	92.1	97.1
Cycle 1		
Patients in study at visit, n	139	138
Patients complete questionnaire, n	82	82
Completion rate (%) [a]	59.0	59.4
Adjusted completion rate (%) [b]	59.0	59.4
Cycle 2		
Patients in study at visit, n	132	105
Patients complete questionnaire, n	124	97
Completion rate (%) [a]	89.2	70.3
Adjusted completion rate (%) [b]	93.9	92.4

Source: Listing 16.2.6.6.1, 16.2.6.6.2, 16.2.6.6.3. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients in study at relevant visits in relevant treatment arm.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-comp.sas 05JUN2024 17:45 t-14-02-06-01-01-b-qs-comp-itts-cl.rtf

Table 14.2.6.1.1.b:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation without Irinotecan

Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab (N = 139)	ICC (N = 138)
Cycle 3		
Patients in study at visit, n	103	65
Patients complete questionnaire, n	98	57
Completion rate (%) [a]	70.5	41.3
Adjusted completion rate (%) [b]	95.1	87.7
Cycle 4		
Patients in study at visit, n	82	56
Patients complete questionnaire, n	76	52
Completion rate (%) [a]	54.7	37.7
Adjusted completion rate (%) [b]	92.7	92.9
Cycle 5		
Patients in study at visit, n	62	33
Patients complete questionnaire, n	57	32
Completion rate (%) [a]	41.0	23.2
Adjusted completion rate (%) [b]	91.9	97.0

Source: Listing 16.2.6.6.1, 16.2.6.6.2, 16.2.6.6.3. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients in study at relevant visits in relevant treatment arm.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-comp.sas 05JUN2024 17:45 t-14-02-06-01-01-b-qs-comp-itts-cl.rtf

Table 14.2.6.1.1.b:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation without Irinotecan

Questionnaire: EORTC QLQ-OES18

Visit	Tislelizumab (N = 139)	ICC (N = 138)
Cycle 6		
Patients in study at visit, n	55	27
Patients complete questionnaire, n	54	26
Completion rate (%) [a]	38.8	18.8
Adjusted completion rate (%) [b]	98.2	96.3
End of Treatment		
Patients in study at visit, n	139	138
Patients complete questionnaire, n	41	46
Completion rate (%) [a]	29.5	33.3
Adjusted completion rate (%) [b]	29.5	33.3
Safety Follow-up		
Patients in study at visit, n	93	78
Patients complete questionnaire, n	71	62
Completion rate (%) [a]	51.1	44.9
Adjusted completion rate (%) [b]	76.3	79.5

Source: Listing 16.2.6.6.1, 16.2.6.6.2, 16.2.6.6.3. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients in study at relevant visits in relevant treatment arm.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-comp.sas 05JUN2024 17:45 t-14-02-06-01-01-b-qs-comp-itts-cl.rtf

Table 14.2.6.1.1.b:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation without Irinotecan

Questionnaire: EQ-5D VAS

Visit	Tislelizumab (N = 139)	ICC (N = 138)
Baseline		
Patients in study at visit, n	139	138
Patients complete questionnaire, n	128	134
Completion rate (%) [a]	92.1	97.1
Adjusted completion rate (%) [b]	92.1	97.1
Cycle 1		
Patients in study at visit, n	139	138
Patients complete questionnaire, n	83	83
Completion rate (%) [a]	59.7	60.1
Adjusted completion rate (%) [b]	59.7	60.1
Cycle 2		
Patients in study at visit, n	132	105
Patients complete questionnaire, n	124	96
Completion rate (%) [a]	89.2	69.6
Adjusted completion rate (%) [b]	93.9	91.4

Source: Listing 16.2.6.6.1, 16.2.6.6.2, 16.2.6.6.3. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.

[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients in study at relevant visits in relevant treatment arm.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-comp.sas 05JUN2024 17:45 t-14-02-06-01-01-b-qs-comp-itts-cl.rtf

Table 14.2.6.1.1.b:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation without Irinotecan

Questionnaire: EQ-5D VAS

Visit	Tislelizumab (N = 139)	ICC (N = 138)
Cycle 3		
Patients in study at visit, n	103	65
Patients complete questionnaire, n	98	57
Completion rate (%) [a]	70.5	41.3
Adjusted completion rate (%) [b]	95.1	87.7
Cycle 4		
Patients in study at visit, n	82	56
Patients complete questionnaire, n	77	52
Completion rate (%) [a]	55.4	37.7
Adjusted completion rate (%) [b]	93.9	92.9
Cycle 5		
Patients in study at visit, n	62	33
Patients complete questionnaire, n	57	32
Completion rate (%) [a]	41.0	23.2
Adjusted completion rate (%) [b]	91.9	97.0

Source: Listing 16.2.6.6.1, 16.2.6.6.2, 16.2.6.6.3. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.
[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients in study at relevant visits in relevant treatment arm.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-comp.sas 05JUN2024 17:45 t-14-02-06-01-01-b-qs-comp-itts-cl.rtf

Table 14.2.6.1.1.b:
Summary of EORTC QLQ-C30/EORTC QLQ-OES18/EQ-5D VAS - Completion Rate by Visit
ITT Analysis Set - Subpopulation without Irinotecan

Questionnaire: EQ-5D VAS

Visit	Tislelizumab (N = 139)	ICC (N = 138)
Cycle 6		
Patients in study at visit, n	55	27
Patients complete questionnaire, n	55	25
Completion rate (%) [a]	39.6	18.1
Adjusted completion rate (%) [b]	100.0	92.6
End of Treatment		
Patients in study at visit, n	139	138
Patients complete questionnaire, n	42	46
Completion rate (%) [a]	30.2	33.3
Adjusted completion rate (%) [b]	30.2	33.3
Safety Follow-up		
Patients in study at visit, n	93	78
Patients complete questionnaire, n	71	62
Completion rate (%) [a]	51.1	44.9
Adjusted completion rate (%) [b]	76.3	79.5

Source: Listing 16.2.6.6.1, 16.2.6.6.2, 16.2.6.6.3. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

[a] Completion rate = number of patients complete questionnaire / total number of patients in relevant treatment arm.

[b] Adjusted completion rate = number of patients complete questionnaire / total number of patients in study at relevant visits in relevant treatment arm.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-comp.sas 05JUN2024 17:45 t-14-02-06-01-01-b-qs-comp-itts-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: QLQ-C30 index-score

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	239		246	
	Mean (SD)	16.2 (12.28)		18.3 (13.86)	
	Median	13.8		14.8	
	Min, Max	0, 88		0, 74	
Cycle 1	n	139	131	133	129
	Mean (SD)	17.1 (13.34)	0.6 (6.07)	19.7 (13.94)	1.5 (7.71)
	Median	13.7	0.4	15.9	1.6
	Min, Max	0, 89	-23, 23	0, 65	-25, 20
Cycle 2	n	220	208	174	171
	Mean (SD)	17.5 (14.80)	2.1 (9.66)	21.0 (15.06)	4.0 (10.32)
	Median	13.1	0.7	17.0	2.7
	Min, Max	0, 93	-28, 50	0, 70	-28, 46
Cycle 3	n	180	170	92	89
	Mean (SD)	16.7 (13.40)	2.2 (9.33)	18.0 (14.12)	1.8 (9.33)
	Median	13.1	0.5	15.1	1.1
	Min, Max	0, 67	-19, 45	0, 65	-34, 24

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: QLQ-C30 index-score

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	147	138	77	74
	Mean (SD)	14.9 (12.81)	1.0 (10.06)	19.7 (14.22)	4.1 (11.17)
	Median	11.4	0.0	16.3	2.5
	Min, Max	0, 63	-26, 41	0, 60	-21, 44
Cycle 5	n	107	102	45	43
	Mean (SD)	12.5 (9.55)	-0.6 (7.96)	15.6 (11.62)	2.5 (11.25)
	Median	10.5	-0.4	13.7	1.2
	Min, Max	0, 39	-26, 30	2, 41	-38, 28
Cycle 6	n	98	93	38	36
	Mean (SD)	13.2 (10.54)	0.2 (8.28)	16.9 (12.18)	4.8 (9.38)
	Median	10.8	-0.8	14.3	3.1
	Min, Max	0, 49	-20, 28	1, 51	-15, 28
End of Treatment	n	76	74	83	81
	Mean (SD)	25.4 (19.74)	10.3 (15.29)	26.2 (17.28)	10.9 (11.56)
	Median	19.2	7.5	25.6	8.9
	Min, Max	1, 71	-14, 59	0, 75	-8, 37

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: QLQ-C30 index-score

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	115	111	97	96
	Mean (SD)	24.3 (18.42)	8.7 (14.49)	26.3 (17.68)	9.7 (12.79)
	Median	19.6	5.7	22.2	8.0
	Min, Max	1, 89	-21, 62	0, 79	-23, 50
Worst Post-Baseline Value	n	245	229	227	220
	Mean (SD)	26.3 (17.90)	10.6 (13.39)	29.3 (17.34)	11.3 (12.38)
	Median	22.1	7.3	26.7	9.6
	Min, Max	1, 93	-23, 62	0, 79	-28, 50

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Global health status / QoL

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	241		247	
	Mean (SD)	66.7 (19.34)		67.3 (19.12)	
	Median	66.7		66.7	
	Min, Max	8, 100		0, 100	
Cycle 1	n	140	133	133	130
	Mean (SD)	66.4 (18.95)	-1.1 (13.66)	65.1 (18.18)	-2.4 (15.30)
	Median	66.7	0.0	66.7	0.0
	Min, Max	17, 100	-58, 33	17, 100	-58, 33
Cycle 2	n	222	211	174	171
	Mean (SD)	66.0 (19.78)	-1.9 (16.03)	62.2 (20.29)	-5.6 (17.78)
	Median	66.7	0.0	66.7	0.0
	Min, Max	0, 100	-67, 50	0, 100	-67, 42
Cycle 3	n	181	172	92	90
	Mean (SD)	67.0 (18.89)	-1.7 (14.45)	69.2 (16.28)	1.3 (17.88)
	Median	66.7	0.0	66.7	0.0
	Min, Max	0, 100	-42, 33	17, 100	-33, 83

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Global health status / QoL

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	147	139	77	75
	Mean (SD)	70.2 (17.03)	0.5 (16.14)	64.3 (18.33)	-3.8 (17.13)
	Median	66.7	0.0	66.7	0.0
	Min, Max	25, 100	-42, 33	0, 100	-67, 33
Cycle 5	n	108	103	45	43
	Mean (SD)	73.1 (15.35)	2.1 (15.86)	69.6 (16.01)	-1.4 (17.15)
	Median	66.7	0.0	66.7	0.0
	Min, Max	33, 100	-50, 50	33, 100	-33, 50
Cycle 6	n	99	94	38	36
	Mean (SD)	72.6 (17.17)	1.9 (16.45)	66.0 (14.55)	-6.3 (14.82)
	Median	75.0	0.0	66.7	-8.3
	Min, Max	25, 100	-33, 42	42, 100	-42, 25
End of Treatment	n	79	77	83	81
	Mean (SD)	54.5 (23.90)	-11.9 (20.87)	54.9 (21.86)	-14.2 (18.18)
	Median	50.0	-16.7	50.0	-16.7
	Min, Max	0, 100	-83, 33	0, 100	-67, 25

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Global health status / QoL

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	116	112	97	96
	Mean (SD)	58.0 (22.07)	-9.4 (18.97)	56.3 (22.21)	-11.7 (21.68)
	Median	58.3	-8.3	58.3	-8.3
	Min, Max	0, 100	-75, 33	0, 100	-75, 33
Worst Post-Baseline Value	n	245	231	227	221
	Mean (SD)	53.1 (21.86)	-14.3 (18.01)	51.5 (20.63)	-16.1 (19.60)
	Median	50.0	-16.7	50.0	-16.7
	Min, Max	0, 100	-83, 33	0, 100	-75, 42

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Physical functioning

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	242		247	
	Mean (SD)	87.4 (13.88)		84.4 (16.59)	
	Median	93.3		86.7	
	Min, Max	33, 100		0, 100	
Cycle 1	n	140	133	134	131
	Mean (SD)	87.4 (15.46)	-0.5 (9.22)	83.1 (16.40)	-2.3 (10.18)
	Median	93.3	0.0	86.7	0.0
	Min, Max	20, 100	-53, 27	20, 100	-33, 27
Cycle 2	n	222	211	174	171
	Mean (SD)	84.5 (18.07)	-4.0 (13.24)	79.8 (20.31)	-6.5 (15.62)
	Median	86.7	0.0	86.7	0.0
	Min, Max	0, 100	-60, 27	0, 100	-80, 33
Cycle 3	n	181	172	92	90
	Mean (SD)	85.4 (17.11)	-4.5 (13.67)	81.4 (19.34)	-5.4 (15.77)
	Median	86.7	0.0	86.7	0.0
	Min, Max	0, 100	-67, 20	27, 100	-60, 47

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Physical functioning

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	147	139	77	75
	Mean (SD)	87.6 (14.63)	-3.4 (11.75)	81.5 (19.24)	-5.9 (14.70)
	Median	93.3	0.0	86.7	0.0
	Min, Max	33, 100	-60, 20	20, 100	-60, 27
Cycle 5	n	108	103	45	43
	Mean (SD)	89.9 (13.84)	-1.6 (10.93)	86.4 (13.48)	-2.9 (13.36)
	Median	93.3	0.0	86.7	0.0
	Min, Max	33, 100	-47, 20	47, 100	-33, 40
Cycle 6	n	99	94	38	36
	Mean (SD)	89.8 (13.45)	-1.9 (10.33)	84.0 (14.08)	-5.7 (12.05)
	Median	93.3	0.0	86.7	0.0
	Min, Max	40, 100	-40, 20	47, 100	-33, 20
End of Treatment	n	79	77	83	81
	Mean (SD)	74.3 (26.90)	-14.1 (22.84)	71.0 (26.59)	-17.2 (21.91)
	Median	86.7	-6.7	80.0	-13.3
	Min, Max	7, 100	-80, 13	0, 100	-80, 13

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Physical functioning

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	118	114	97	96
	Mean (SD)	77.5 (23.51)	-10.9 (20.27)	72.7 (24.40)	-13.8 (19.83)
	Median	86.7	-6.7	80.0	-6.7
	Min, Max	0, 100	-93, 20	0, 100	-67, 20
Worst Post-Baseline Value	n	246	232	228	222
	Mean (SD)	73.6 (23.95)	-14.8 (19.92)	68.2 (24.73)	-16.8 (20.00)
	Median	80.0	-6.7	80.0	-13.3
	Min, Max	0, 100	-93, 20	0, 100	-80, 27

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Role functioning

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	242		247	
	Mean (SD)	88.8 (18.13)		84.7 (23.39)	
	Median	100.0		100.0	
	Min, Max	0, 100		0, 100	
Cycle 1	n	140	133	134	131
	Mean (SD)	85.4 (21.01)	-5.4 (15.96)	83.1 (23.66)	-2.2 (18.07)
	Median	100.0	0.0	100.0	0.0
	Min, Max	0, 100	-100, 33	0, 100	-67, 67
Cycle 2	n	222	211	174	171
	Mean (SD)	83.9 (24.35)	-6.2 (19.08)	81.0 (26.78)	-6.4 (20.95)
	Median	100.0	0.0	100.0	0.0
	Min, Max	0, 100	-100, 33	0, 100	-100, 67
Cycle 3	n	181	172	92	90
	Mean (SD)	86.3 (21.88)	-4.7 (19.93)	79.9 (27.13)	-7.6 (23.46)
	Median	100.0	0.0	100.0	0.0
	Min, Max	0, 100	-100, 50	0, 100	-83, 83

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Role functioning

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	147	139	77	75
	Mean (SD)	86.8 (20.57)	-5.6 (19.51)	77.7 (27.92)	-10.2 (25.54)
	Median	100.0	0.0	83.3	0.0
	Min, Max	0, 100	-100, 33	0, 100	-100, 33
Cycle 5	n	108	103	45	43
	Mean (SD)	89.0 (15.81)	-2.6 (14.15)	86.3 (18.22)	-4.3 (23.60)
	Median	100.0	0.0	100.0	0.0
	Min, Max	33, 100	-33, 33	33, 100	-67, 83
Cycle 6	n	99	94	38	36
	Mean (SD)	88.0 (16.84)	-3.9 (14.75)	84.2 (16.87)	-6.0 (16.97)
	Median	100.0	0.0	83.3	0.0
	Min, Max	33, 100	-33, 50	50, 100	-33, 33
End of Treatment	n	79	77	83	81
	Mean (SD)	69.2 (32.80)	-20.6 (29.11)	68.9 (31.10)	-20.2 (26.97)
	Median	66.7	-16.7	66.7	-16.7
	Min, Max	0, 100	-100, 33	0, 100	-100, 33

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Role functioning

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	118	114	97	96
	Mean (SD)	74.3 (29.04)	-16.1 (25.47)	69.8 (28.90)	-18.2 (24.55)
	Median	83.3	0.0	66.7	-16.7
	Min, Max	0, 100	-100, 33	0, 100	-100, 33
Worst Post-Baseline Value	n	246	232	228	222
	Mean (SD)	68.8 (30.23)	-21.0 (25.87)	65.3 (31.32)	-20.4 (27.30)
	Median	66.7	-16.7	66.7	-16.7
	Min, Max	0, 100	-100, 33	0, 100	-100, 67

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Emotional functioning

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	242		247	
	Mean (SD)	85.8 (15.70)		85.0 (17.62)	
	Median	91.7		91.7	
	Min, Max	0, 100		17, 100	
Cycle 1	n	140	133	133	130
	Mean (SD)	86.0 (15.17)	-0.8 (10.50)	83.1 (17.71)	-0.8 (13.98)
	Median	91.7	0.0	83.3	0.0
	Min, Max	0, 100	-42, 33	17, 100	-42, 50
Cycle 2	n	222	211	174	171
	Mean (SD)	86.6 (17.38)	-0.6 (12.09)	84.8 (17.11)	-1.2 (15.02)
	Median	91.7	0.0	91.7	0.0
	Min, Max	0, 100	-42, 42	8, 100	-75, 58
Cycle 3	n	181	172	92	90
	Mean (SD)	86.1 (16.53)	-2.0 (14.30)	85.5 (19.53)	-0.8 (14.84)
	Median	91.7	0.0	91.7	0.0
	Min, Max	17, 100	-58, 58	17, 100	-58, 58

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Emotional functioning

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	147	139	77	75
	Mean (SD)	88.5 (14.99)	0.0 (13.42)	85.7 (19.54)	-0.8 (14.45)
	Median	91.7	0.0	91.7	0.0
	Min, Max	33, 100	-42, 50	17, 100	-67, 25
Cycle 5	n	108	103	45	43
	Mean (SD)	90.1 (13.39)	0.3 (12.88)	90.2 (14.13)	1.2 (18.60)
	Median	100.0	0.0	100.0	0.0
	Min, Max	50, 100	-42, 42	58, 100	-42, 75
Cycle 6	n	99	94	38	36
	Mean (SD)	89.1 (14.27)	-0.7 (13.31)	88.4 (17.17)	-2.5 (17.46)
	Median	91.7	0.0	100.0	0.0
	Min, Max	33, 100	-42, 42	33, 100	-67, 33
End of Treatment	n	79	77	83	81
	Mean (SD)	78.0 (21.89)	-6.1 (17.81)	76.4 (24.69)	-8.2 (18.56)
	Median	83.3	0.0	83.3	0.0
	Min, Max	17, 100	-58, 33	0, 100	-83, 25

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Emotional functioning

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	116	112	97	96
	Mean (SD)	78.8 (22.13)	-7.4 (20.42)	78.6 (23.32)	-8.1 (20.39)
	Median	83.3	0.0	83.3	0.0
	Min, Max	8, 100	-92, 58	0, 100	-92, 25
Worst Post-Baseline Value	n	245	231	227	221
	Mean (SD)	75.3 (22.00)	-11.6 (17.78)	74.4 (22.58)	-10.6 (19.18)
	Median	75.0	-8.3	75.0	-8.3
	Min, Max	0, 100	-92, 33	0, 100	-92, 50

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Cognitive functioning

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	242		247	
	Mean (SD)	90.3 (14.20)		88.5 (17.04)	
	Median	100.0		100.0	
	Min, Max	0, 100		0, 100	
Cycle 1	n	140	133	133	130
	Mean (SD)	88.3 (14.24)	-1.1 (11.27)	87.1 (16.99)	-2.4 (14.84)
	Median	83.3	0.0	83.3	0.0
	Min, Max	17, 100	-33, 33	17, 100	-50, 50
Cycle 2	n	222	211	174	171
	Mean (SD)	88.4 (16.73)	-2.1 (12.95)	87.5 (16.15)	-1.6 (14.15)
	Median	100.0	0.0	100.0	0.0
	Min, Max	0, 100	-50, 50	33, 100	-33, 33
Cycle 3	n	181	172	92	90
	Mean (SD)	89.0 (16.04)	-2.9 (14.57)	88.0 (19.19)	-0.9 (16.45)
	Median	100.0	0.0	100.0	0.0
	Min, Max	0, 100	-67, 50	0, 100	-67, 50

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Cognitive functioning

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	147	139	77	75
	Mean (SD)	89.5 (13.80)	-1.8 (12.80)	85.5 (20.48)	-4.2 (18.40)
	Median	100.0	0.0	100.0	0.0
	Min, Max	50, 100	-50, 33	0, 100	-67, 33
Cycle 5	n	108	103	45	43
	Mean (SD)	89.7 (15.07)	-2.9 (14.84)	91.1 (12.10)	-0.4 (11.78)
	Median	100.0	0.0	100.0	0.0
	Min, Max	17, 100	-67, 33	50, 100	-33, 33
Cycle 6	n	99	94	38	36
	Mean (SD)	88.7 (15.21)	-4.3 (15.05)	89.9 (14.26)	-2.3 (13.31)
	Median	100.0	0.0	100.0	0.0
	Min, Max	17, 100	-67, 33	50, 100	-33, 33
End of Treatment	n	79	77	83	81
	Mean (SD)	79.5 (21.34)	-9.7 (18.41)	81.3 (21.21)	-8.2 (16.06)
	Median	83.3	0.0	83.3	0.0
	Min, Max	33, 100	-67, 33	0, 100	-50, 33

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Cognitive functioning

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	116	112	97	96
	Mean (SD)	80.9 (21.34)	-7.3 (19.98)	83.0 (17.84)	-5.9 (17.60)
	Median	83.3	0.0	83.3	0.0
	Min, Max	17, 100	-67, 50	33, 100	-50, 50
Worst Post-Baseline Value	n	245	231	227	221
	Mean (SD)	77.9 (21.55)	-12.9 (18.07)	78.3 (20.79)	-10.3 (17.71)
	Median	83.3	0.0	83.3	0.0
	Min, Max	0, 100	-67, 33	0, 100	-67, 33

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Social functioning

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	242		247	
	Mean (SD)	81.7 (20.11)		79.4 (24.10)	
	Median	83.3		83.3	
	Min, Max	0, 100		0, 100	
Cycle 1	n	139	132	133	130
	Mean (SD)	81.1 (21.44)	-0.9 (17.87)	74.4 (28.10)	-3.1 (22.33)
	Median	83.3	0.0	83.3	0.0
	Min, Max	0, 100	-50, 67	0, 100	-83, 67
Cycle 2	n	222	211	174	171
	Mean (SD)	79.1 (25.46)	-3.6 (20.36)	76.2 (27.66)	-3.1 (24.25)
	Median	83.3	0.0	83.3	0.0
	Min, Max	0, 100	-67, 50	0, 100	-100, 67
Cycle 3	n	181	172	92	90
	Mean (SD)	83.4 (19.36)	-0.9 (18.84)	80.4 (24.78)	-0.4 (23.43)
	Median	83.3	0.0	83.3	0.0
	Min, Max	0, 100	-67, 67	0, 100	-83, 50

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Social functioning

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	147	139	77	75
	Mean (SD)	83.2 (20.41)	-1.7 (20.19)	76.6 (25.97)	-5.6 (24.71)
	Median	83.3	0.0	83.3	0.0
	Min, Max	0, 100	-83, 67	0, 100	-100, 33
Cycle 5	n	108	103	45	43
	Mean (SD)	86.1 (16.51)	0.5 (17.06)	81.5 (23.36)	-1.9 (26.03)
	Median	100.0	0.0	83.3	0.0
	Min, Max	17, 100	-50, 50	0, 100	-67, 83
Cycle 6	n	99	94	38	36
	Mean (SD)	86.7 (16.32)	-0.0 (15.84)	79.4 (22.07)	-5.1 (22.82)
	Median	100.0	0.0	83.3	0.0
	Min, Max	50, 100	-50, 33	33, 100	-50, 50
End of Treatment	n	79	77	83	81
	Mean (SD)	70.9 (29.89)	-10.2 (27.19)	73.1 (28.73)	-11.3 (27.11)
	Median	66.7	0.0	66.7	0.0
	Min, Max	0, 100	-100, 33	0, 100	-100, 33

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Social functioning

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	116	112	97	96
	Mean (SD)	73.3 (29.15)	-10.3 (29.87)	66.2 (31.22)	-16.3 (27.46)
	Median	83.3	0.0	66.7	-16.7
	Min, Max	0, 100	-100, 67	0, 100	-100, 50
Worst Post-Baseline Value	n	245	231	227	221
	Mean (SD)	65.9 (28.14)	-16.3 (25.27)	60.8 (29.99)	-18.9 (24.95)
	Median	66.7	-16.7	66.7	-16.7
	Min, Max	0, 100	-100, 50	0, 100	-100, 50

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Fatigue

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	242		247	
	Mean (SD)	23.3 (20.18)		27.0 (22.39)	
	Median	22.2		22.2	
	Min, Max	0, 100		0, 100	
Cycle 1	n	140	133	134	131
	Mean (SD)	26.0 (20.64)	3.7 (14.16)	29.1 (22.50)	1.5 (14.44)
	Median	22.2	0.0	33.3	0.0
	Min, Max	0, 100	-33, 61	0, 100	-44, 33
Cycle 2	n	222	211	174	171
	Mean (SD)	26.2 (23.26)	4.5 (17.34)	31.7 (22.78)	7.1 (17.61)
	Median	22.2	0.0	33.3	0.0
	Min, Max	0, 100	-33, 89	0, 100	-56, 56
Cycle 3	n	181	172	92	90
	Mean (SD)	24.7 (22.02)	4.1 (17.45)	29.5 (24.23)	6.9 (21.17)
	Median	22.2	0.0	33.3	0.0
	Min, Max	0, 100	-33, 78	0, 100	-100, 89

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Fatigue

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	147	139	77	75
	Mean (SD)	21.9 (22.03)	3.0 (17.89)	33.8 (25.90)	12.3 (21.11)
	Median	22.2	0.0	33.3	11.1
	Min, Max	0, 100	-33, 67	0, 100	-33, 67
Cycle 5	n	108	103	45	43
	Mean (SD)	17.5 (18.49)	0.3 (15.59)	22.7 (19.95)	3.9 (23.24)
	Median	11.1	0.0	22.2	0.0
	Min, Max	0, 100	-33, 44	0, 78	-89, 44
Cycle 6	n	99	94	38	36
	Mean (SD)	18.5 (16.95)	1.4 (14.78)	25.0 (18.16)	9.4 (16.31)
	Median	22.2	0.0	33.3	11.1
	Min, Max	0, 67	-33, 33	0, 67	-33, 33
End of Treatment	n	79	77	83	81
	Mean (SD)	38.7 (30.86)	14.9 (23.89)	41.8 (27.03)	19.5 (22.81)
	Median	33.3	11.1	33.3	22.2
	Min, Max	0, 100	-33, 89	0, 100	-33, 89

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Fatigue

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	118	114	97	96
	Mean (SD)	35.4 (28.17)	13.3 (23.55)	40.3 (26.66)	17.5 (22.56)
	Median	33.3	11.1	33.3	22.2
	Min, Max	0, 100	-44, 100	0, 100	-44, 78
Worst Post-Baseline Value	n	246	232	228	222
	Mean (SD)	40.4 (26.87)	18.6 (21.30)	45.9 (26.71)	19.4 (22.81)
	Median	33.3	11.1	33.3	22.2
	Min, Max	0, 100	-33, 100	0, 100	-33, 89

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Nausea and vomiting

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	242		247	
	Mean (SD)	7.2 (13.97)		8.4 (17.13)	
	Median	0.0		0.0	
	Min, Max	0, 100		0, 100	
Cycle 1	n	140	133	134	131
	Mean (SD)	8.9 (19.01)	1.6 (13.74)	7.7 (16.05)	-1.4 (13.56)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-50, 83	0, 100	-33, 67
Cycle 2	n	221	210	174	171
	Mean (SD)	10.1 (20.56)	3.3 (18.84)	11.4 (17.26)	4.4 (16.63)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-50, 100	0, 83	-67, 67
Cycle 3	n	180	171	92	90
	Mean (SD)	9.7 (19.53)	4.1 (18.86)	8.0 (15.91)	2.2 (14.18)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 83	-33, 67

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Nausea and vomiting

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	147	139	77	75
	Mean (SD)	7.0 (15.96)	1.6 (14.73)	7.8 (13.68)	2.7 (14.25)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-50, 67	0, 50	-33, 33
Cycle 5	n	108	103	45	43
	Mean (SD)	3.5 (8.84)	-1.0 (10.90)	10.7 (15.14)	6.2 (16.68)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 33	-67, 33	0, 67	-33, 33
Cycle 6	n	99	94	38	36
	Mean (SD)	4.2 (10.47)	0.5 (11.84)	9.2 (17.20)	5.6 (18.69)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 50	-67, 33	0, 67	-33, 67
End of Treatment	n	78	76	83	81
	Mean (SD)	15.4 (26.69)	7.9 (22.69)	12.9 (21.98)	6.2 (19.27)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-50, 83	0, 100	-50, 67

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Nausea and vomiting

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	118	114	97	96
	Mean (SD)	14.3 (24.19)	6.9 (22.81)	10.5 (18.68)	3.5 (21.89)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 83	-100, 83
Worst Post-Baseline Value	n	246	232	228	222
	Mean (SD)	18.5 (26.68)	12.1 (23.77)	18.2 (22.70)	9.5 (21.40)
	Median	0.0	0.0	16.7	0.0
	Min, Max	0, 100	-50, 100	0, 100	-100, 83

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Pain

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	242		247	
	Mean (SD)	21.1 (22.51)		23.3 (26.74)	
	Median	16.7		16.7	
	Min, Max	0, 100		0, 100	
Cycle 1	n	140	133	134	131
	Mean (SD)	23.9 (23.16)	2.5 (15.28)	24.1 (25.08)	1.4 (15.75)
	Median	16.7	0.0	16.7	0.0
	Min, Max	0, 100	-33, 67	0, 100	-50, 50
Cycle 2	n	222	211	174	171
	Mean (SD)	21.5 (23.18)	2.0 (16.90)	24.0 (25.69)	4.0 (22.48)
	Median	16.7	0.0	16.7	0.0
	Min, Max	0, 100	-33, 83	0, 100	-67, 83
Cycle 3	n	181	172	92	90
	Mean (SD)	20.8 (20.85)	2.3 (18.41)	19.0 (24.53)	2.4 (20.07)
	Median	16.7	0.0	16.7	0.0
	Min, Max	0, 100	-67, 67	0, 100	-67, 67

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Pain

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	147	139	77	75
	Mean (SD)	17.3 (19.69)	-0.4 (19.08)	22.1 (25.71)	6.9 (23.74)
	Median	16.7	0.0	16.7	0.0
	Min, Max	0, 67	-67, 67	0, 100	-33, 83
Cycle 5	n	108	103	45	43
	Mean (SD)	14.7 (17.90)	-2.1 (18.03)	14.1 (17.39)	2.3 (18.40)
	Median	8.3	0.0	0.0	0.0
	Min, Max	0, 67	-67, 50	0, 67	-33, 50
Cycle 6	n	99	94	38	36
	Mean (SD)	15.2 (19.65)	-2.0 (20.43)	16.7 (19.76)	6.0 (18.32)
	Median	0.0	0.0	16.7	0.0
	Min, Max	0, 83	-67, 83	0, 67	-33, 50
End of Treatment	n	79	77	83	81
	Mean (SD)	33.8 (31.80)	14.9 (28.17)	27.3 (26.75)	10.1 (22.31)
	Median	33.3	0.0	16.7	0.0
	Min, Max	0, 100	-33, 100	0, 100	-83, 67

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Pain

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	118	114	97	96
	Mean (SD)	29.1 (26.35)	10.7 (23.58)	29.9 (28.86)	10.6 (24.32)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-50, 100
Worst Post-Baseline Value	n	246	232	228	222
	Mean (SD)	36.4 (26.83)	16.2 (23.87)	37.9 (29.55)	15.5 (24.05)
	Median	33.3	16.7	33.3	16.7
	Min, Max	0, 100	-33, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Dyspnoea

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	241		247	
	Mean (SD)	13.6 (19.97)		14.8 (21.57)	
	Median	0.0		0.0	
	Min, Max	0, 100		0, 100	
Cycle 1	n	140	132	134	131
	Mean (SD)	14.8 (20.10)	1.8 (16.12)	15.9 (21.52)	0.0 (18.95)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 67	0, 100	-67, 67
Cycle 2	n	222	210	174	171
	Mean (SD)	17.1 (23.24)	4.6 (18.30)	17.8 (21.70)	4.7 (21.18)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 67	0, 100	-33, 67
Cycle 3	n	181	172	92	90
	Mean (SD)	15.5 (22.36)	3.7 (20.85)	13.8 (18.59)	4.1 (18.58)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 67	-33, 67

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Dyspnoea

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	147	139	77	75
	Mean (SD)	14.3 (20.27)	2.9 (20.65)	14.7 (20.59)	4.4 (19.25)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-33, 67	0, 67	-33, 33
Cycle 5	n	108	103	45	43
	Mean (SD)	11.1 (18.23)	-0.3 (16.50)	15.6 (24.20)	4.7 (23.66)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-33, 33	0, 100	-33, 67
Cycle 6	n	99	94	38	36
	Mean (SD)	11.4 (19.73)	-0.4 (18.61)	18.4 (22.86)	8.3 (20.12)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 33	0, 67	-33, 33
End of Treatment	n	79	77	83	81
	Mean (SD)	23.6 (28.32)	12.6 (27.59)	25.3 (28.79)	15.2 (27.41)
	Median	0.0	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-33, 100

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Dyspnoea

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	118	114	97	96
	Mean (SD)	22.9 (25.30)	8.8 (25.11)	27.1 (29.00)	13.9 (28.88)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-67, 100	0, 100	-33, 100
Worst Post-Baseline Value	n	246	231	228	222
	Mean (SD)	28.9 (27.65)	16.3 (24.45)	31.1 (27.99)	16.1 (27.77)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-33, 100

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Insomnia

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	241		247	
	Mean (SD)	17.6 (25.10)		22.9 (26.29)	
	Median	0.0		33.3	
	Min, Max	0, 100		0, 100	
Cycle 1	n	140	132	134	131
	Mean (SD)	15.2 (22.04)	-1.0 (18.85)	23.1 (25.93)	2.0 (20.15)
	Median	0.0	0.0	33.3	0.0
	Min, Max	0, 100	-67, 33	0, 100	-67, 67
Cycle 2	n	222	210	174	171
	Mean (SD)	16.2 (23.67)	1.4 (23.13)	21.1 (27.11)	-0.0 (23.43)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 67
Cycle 3	n	181	172	92	90
	Mean (SD)	17.1 (24.75)	2.7 (23.48)	16.7 (24.46)	-2.6 (21.91)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 33

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Insomnia

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	147	139	77	75
	Mean (SD)	14.1 (21.34)	-0.0 (24.08)	18.6 (24.48)	-0.9 (23.87)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 67	0, 100	-67, 67
Cycle 5	n	108	103	45	43
	Mean (SD)	12.0 (19.04)	-1.6 (24.87)	12.6 (19.19)	-1.6 (20.51)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-67, 67	0, 67	-67, 33
Cycle 6	n	99	94	38	36
	Mean (SD)	14.5 (22.42)	0.4 (25.63)	14.0 (22.77)	1.9 (19.43)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 67	0, 67	-33, 67
End of Treatment	n	79	77	83	81
	Mean (SD)	24.9 (31.34)	11.3 (27.36)	27.3 (30.42)	7.8 (31.74)
	Median	0.0	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Insomnia

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	118	114	97	96
	Mean (SD)	26.3 (31.98)	12.0 (28.44)	27.8 (31.06)	5.2 (30.33)
	Median	0.0	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100
Worst Post-Baseline Value	n	246	231	228	222
	Mean (SD)	31.8 (29.85)	16.3 (27.78)	34.1 (30.57)	11.9 (29.14)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Appetite loss

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	241		246	
	Mean (SD)	19.2 (24.80)		19.4 (26.24)	
	Median	0.0		0.0	
	Min, Max	0, 100		0, 100	
Cycle 1	n	140	133	134	130
	Mean (SD)	18.6 (24.74)	-1.5 (21.66)	21.6 (27.50)	4.9 (22.39)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 100	0, 100	-67, 100
Cycle 2	n	220	209	174	171
	Mean (SD)	18.8 (27.60)	1.3 (25.50)	26.2 (29.02)	8.4 (24.28)
	Median	0.0	0.0	33.3	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 100
Cycle 3	n	181	171	92	89
	Mean (SD)	20.6 (26.84)	3.5 (25.32)	17.4 (25.90)	0.4 (28.20)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-100, 100

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Appetite loss

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	147	138	77	74
	Mean (SD)	13.8 (20.95)	-0.5 (25.15)	21.2 (27.52)	6.3 (26.27)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 67	0, 100	-67, 100
Cycle 5	n	107	102	45	43
	Mean (SD)	9.7 (17.74)	-4.2 (23.77)	15.6 (24.20)	4.7 (31.36)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 100	0, 100	-100, 100
Cycle 6	n	98	93	38	36
	Mean (SD)	10.2 (16.86)	-5.0 (25.03)	14.9 (24.13)	7.4 (27.73)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-100, 67	0, 100	-67, 100
End of Treatment	n	77	75	83	81
	Mean (SD)	31.6 (33.72)	15.1 (33.01)	30.5 (29.08)	16.5 (29.40)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Appetite loss

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	117	113	97	96
	Mean (SD)	29.9 (30.76)	12.7 (31.28)	28.5 (33.33)	13.2 (27.98)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-67, 100	0, 100	-33, 100
Worst Post-Baseline Value	n	246	231	228	221
	Mean (SD)	37.1 (32.07)	19.0 (30.82)	38.6 (30.52)	20.8 (26.19)
	Median	33.3	0.0	33.3	33.3
	Min, Max	0, 100	-100, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Constipation

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	242		247	
	Mean (SD)	13.1 (22.90)		13.8 (22.48)	
	Median	0.0		0.0	
	Min, Max	0, 100		0, 100	
Cycle 1	n	140	133	134	131
	Mean (SD)	14.3 (24.04)	0.3 (18.58)	12.4 (20.71)	0.3 (17.29)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 67	0, 100	-67, 67
Cycle 2	n	222	211	174	171
	Mean (SD)	14.0 (23.73)	1.6 (22.48)	12.1 (20.93)	1.4 (20.88)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 67	0, 100	-67, 100
Cycle 3	n	181	172	92	90
	Mean (SD)	13.6 (23.27)	1.9 (24.90)	13.0 (21.52)	2.6 (18.17)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-33, 67

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Constipation

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	147	139	77	75
	Mean (SD)	12.0 (22.05)	0.7 (23.90)	12.1 (22.24)	0.9 (22.58)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 100
Cycle 5	n	108	103	45	43
	Mean (SD)	9.0 (17.42)	0.6 (17.45)	11.1 (21.32)	1.6 (16.19)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 33	0, 67	-33, 67
Cycle 6	n	99	94	38	36
	Mean (SD)	10.1 (18.72)	1.4 (20.69)	11.4 (26.02)	2.8 (20.12)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-33, 67
End of Treatment	n	78	76	83	81
	Mean (SD)	15.8 (23.25)	2.2 (24.55)	16.1 (22.91)	5.3 (26.59)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-100, 67

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Constipation

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	118	114	97	96
	Mean (SD)	19.5 (28.02)	5.6 (27.66)	14.8 (21.50)	1.7 (23.38)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 67
Worst Post-Baseline Value	n	246	232	228	222
	Mean (SD)	27.2 (30.77)	14.9 (27.34)	23.4 (26.52)	10.1 (25.05)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-67, 100	0, 100	-100, 100

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Diarrhea

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	242		247	
	Mean (SD)	6.5 (15.16)		5.9 (14.44)	
	Median	0.0		0.0	
	Min, Max	0, 100		0, 67	
Cycle 1	n	140	133	133	130
	Mean (SD)	4.5 (12.13)	-2.0 (12.14)	6.3 (14.30)	0.8 (12.77)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-33, 33	0, 67	-67, 33
Cycle 2	n	222	211	174	171
	Mean (SD)	5.7 (15.45)	-0.8 (17.35)	13.0 (21.72)	6.6 (23.04)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 100
Cycle 3	n	181	172	92	90
	Mean (SD)	5.3 (13.23)	-1.2 (16.08)	10.9 (17.89)	4.4 (18.83)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-67, 67	0, 67	-33, 67

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Diarrhea

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	147	139	77	75
	Mean (SD)	5.2 (13.35)	-1.2 (16.74)	10.4 (18.93)	3.1 (18.32)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-67, 67	0, 100	-33, 100
Cycle 5	n	108	103	45	43
	Mean (SD)	4.9 (13.53)	-1.3 (15.43)	10.4 (17.15)	6.2 (16.68)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-33, 67	0, 67	-33, 33
Cycle 6	n	99	94	38	36
	Mean (SD)	8.1 (17.23)	2.1 (19.44)	12.3 (18.04)	8.3 (16.67)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-33, 67	0, 67	-33, 33
End of Treatment	n	78	76	83	81
	Mean (SD)	7.7 (16.05)	-0.0 (19.63)	10.0 (19.29)	2.9 (23.69)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-67, 67	0, 100	-67, 100

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Diarrhea

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	116	112	97	96
	Mean (SD)	6.6 (17.15)	-0.6 (17.89)	10.3 (20.62)	4.9 (22.15)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 67	0, 100	-67, 67
Worst Post-Baseline Value	n	245	231	227	221
	Mean (SD)	12.7 (21.73)	6.2 (20.97)	18.4 (24.71)	12.1 (24.72)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Financial difficulties

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	242		247	
	Mean (SD)	26.9 (30.36)		30.2 (31.87)	
	Median	33.3		33.3	
	Min, Max	0, 100		0, 100	
Cycle 1	n	139	132	133	130
	Mean (SD)	27.1 (28.82)	-1.8 (21.92)	30.3 (30.56)	0.5 (23.10)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-67, 67	0, 100	-67, 67
Cycle 2	n	222	211	174	171
	Mean (SD)	24.8 (28.92)	-1.6 (22.95)	29.7 (30.30)	-0.6 (26.68)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-100, 67	0, 100	-67, 67
Cycle 3	n	181	172	92	90
	Mean (SD)	23.8 (26.88)	-1.9 (23.83)	26.1 (28.31)	-3.7 (20.87)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-100, 100	0, 100	-67, 33

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Financial difficulties

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	147	139	77	75
	Mean (SD)	23.1 (28.30)	-3.1 (26.89)	26.0 (28.42)	-4.4 (27.58)
	Median	0.0	0.0	33.3	0.0
	Min, Max	0, 100	-67, 100	0, 100	-100, 67
Cycle 5	n	108	103	45	43
	Mean (SD)	21.0 (27.57)	-4.2 (26.68)	26.7 (26.21)	-0.8 (27.69)
	Median	0.0	0.0	33.3	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 33
Cycle 6	n	99	94	38	36
	Mean (SD)	19.2 (26.12)	-4.3 (26.88)	22.8 (26.96)	-5.6 (29.28)
	Median	0.0	0.0	33.3	0.0
	Min, Max	0, 100	-100, 100	0, 100	-100, 33
End of Treatment	n	79	77	83	81
	Mean (SD)	27.8 (28.96)	6.1 (25.21)	28.1 (33.12)	0.8 (28.86)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-100, 67

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Financial difficulties

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	116	112	97	96
	Mean (SD)	28.2 (30.96)	0.3 (30.18)	31.3 (30.74)	1.4 (31.31)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-100, 100	0, 100	-100, 100
Worst Post-Baseline Value	n	245	231	227	221
	Mean (SD)	37.8 (31.69)	10.4 (25.78)	39.1 (32.61)	9.2 (25.24)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-qs-chg-c30-itt-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: QLQ-C30 index-score

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	127		132	
	Mean (SD)	16.1 (11.38)		17.8 (14.06)	
	Median	13.8		13.9	
	Min, Max	0, 50		0, 74	
Cycle 1	n	82	76	82	80
	Mean (SD)	16.8 (12.53)	1.1 (5.38)	19.9 (14.72)	2.0 (7.19)
	Median	14.2	0.4	15.4	1.6
	Min, Max	0, 52	-17, 23	0, 62	-14, 20
Cycle 2	n	123	112	97	96
	Mean (SD)	17.7 (15.15)	2.4 (10.16)	20.0 (15.21)	3.3 (9.15)
	Median	13.3	0.6	15.0	3.5
	Min, Max	0, 93	-19, 50	0, 69	-28, 33
Cycle 3	n	97	88	58	56
	Mean (SD)	17.5 (14.90)	2.6 (10.45)	17.1 (13.85)	1.2 (9.66)
	Median	13.1	0.0	11.4	0.9
	Min, Max	0, 67	-19, 45	0, 65	-34, 24

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: QLQ-C30 index-score

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	77	69	52	50
	Mean (SD)	15.5 (14.36)	1.4 (11.08)	20.9 (14.63)	5.3 (10.15)
	Median	10.5	0.0	17.2	3.3
	Min, Max	0, 63	-19, 41	0, 56	-12, 36
Cycle 5	n	55	50	32	31
	Mean (SD)	12.8 (10.35)	-0.6 (7.60)	15.9 (12.46)	2.1 (12.43)
	Median	10.6	-1.3	13.0	1.2
	Min, Max	0, 39	-22, 30	2, 41	-38, 28
Cycle 6	n	54	49	26	25
	Mean (SD)	13.5 (10.89)	0.3 (8.25)	16.5 (11.14)	4.3 (8.30)
	Median	12.1	-1.5	13.2	2.5
	Min, Max	0, 49	-16, 28	2, 38	-14, 18
End of Treatment	n	43	41	46	45
	Mean (SD)	28.9 (20.45)	13.2 (15.43)	26.1 (18.79)	12.1 (11.88)
	Median	29.6	8.9	23.7	11.8
	Min, Max	1, 71	-14, 59	0, 75	-8, 37

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: QLQ-C30 index-score

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	71	67	62	61
	Mean (SD)	28.2 (19.16)	10.9 (15.34)	24.5 (17.85)	9.4 (11.83)
	Median	27.3	7.8	20.3	8.1
	Min, Max	1, 89	-18, 62	0, 79	-19, 43
Worst Post-Baseline Value	n	136	124	128	124
	Mean (SD)	28.2 (18.59)	12.6 (13.99)	29.2 (17.67)	11.3 (12.07)
	Median	24.4	8.4	24.6	10.3
	Min, Max	1, 93	-13, 62	0, 79	-28, 43

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Global health status / QoL

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		133	
	Mean (SD)	67.1 (17.87)		66.9 (19.37)	
	Median	66.7		66.7	
	Min, Max	25, 100		0, 100	
Cycle 1	n	83	78	82	81
	Mean (SD)	66.6 (19.89)	-2.5 (13.50)	63.9 (18.93)	-3.0 (16.68)
	Median	66.7	0.0	66.7	0.0
	Min, Max	17, 100	-58, 25	17, 100	-58, 33
Cycle 2	n	123	113	97	96
	Mean (SD)	65.0 (20.05)	-3.1 (14.95)	62.8 (20.38)	-4.7 (17.18)
	Median	66.7	0.0	66.7	0.0
	Min, Max	0, 100	-33, 33	0, 100	-67, 42
Cycle 3	n	98	89	58	57
	Mean (SD)	65.7 (19.36)	-2.4 (14.55)	69.5 (17.14)	2.9 (20.01)
	Median	66.7	0.0	66.7	0.0
	Min, Max	0, 100	-42, 25	17, 100	-33, 83

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Global health status / QoL

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	77	69	52	51
	Mean (SD)	69.4 (17.75)	1.3 (15.03)	62.5 (17.19)	-3.6 (15.57)
	Median	66.7	0.0	66.7	0.0
	Min, Max	25, 100	-42, 33	25, 100	-42, 25
Cycle 5	n	56	51	32	31
	Mean (SD)	72.3 (16.06)	1.8 (15.57)	68.0 (16.27)	0.0 (18.63)
	Median	66.7	0.0	66.7	0.0
	Min, Max	33, 100	-50, 33	33, 100	-33, 50
Cycle 6	n	55	50	26	25
	Mean (SD)	72.9 (17.58)	2.3 (15.34)	66.3 (14.43)	-4.3 (15.24)
	Median	75.0	0.0	66.7	0.0
	Min, Max	25, 100	-33, 42	50, 100	-42, 25
End of Treatment	n	43	41	46	45
	Mean (SD)	49.2 (23.42)	-16.9 (22.55)	54.9 (23.28)	-13.7 (16.59)
	Median	50.0	-16.7	50.0	-16.7
	Min, Max	0, 100	-83, 33	0, 100	-42, 25

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Global health status / QoL

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	71	67	62	61
	Mean (SD)	53.8 (22.79)	-11.3 (20.24)	55.9 (23.25)	-13.0 (20.72)
	Median	58.3	-8.3	66.7	-8.3
	Min, Max	0, 100	-75, 25	0, 100	-67, 25
Worst Post-Baseline Value	n	136	125	128	125
	Mean (SD)	50.8 (22.22)	-17.0 (18.07)	51.6 (21.15)	-15.9 (19.11)
	Median	50.0	-16.7	50.0	-16.7
	Min, Max	0, 100	-83, 17	0, 100	-67, 42

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Physical functioning

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		133	
	Mean (SD)	87.8 (13.75)		83.7 (17.01)	
	Median	93.3		86.7	
	Min, Max	33, 100		0, 100	
Cycle 1	n	83	78	83	82
	Mean (SD)	87.5 (15.80)	-0.8 (10.42)	81.6 (16.93)	-2.7 (10.46)
	Median	93.3	0.0	86.7	0.0
	Min, Max	40, 100	-53, 20	20, 100	-33, 27
Cycle 2	n	123	113	97	96
	Mean (SD)	84.0 (18.48)	-4.7 (13.82)	79.2 (20.78)	-6.3 (13.54)
	Median	86.7	0.0	86.7	0.0
	Min, Max	0, 100	-60, 27	0, 100	-60, 13
Cycle 3	n	98	89	58	57
	Mean (SD)	83.2 (20.36)	-6.4 (16.01)	80.0 (19.94)	-6.4 (16.47)
	Median	86.7	0.0	86.7	0.0
	Min, Max	0, 100	-67, 13	27, 100	-60, 47

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Physical functioning

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	77	69	52	51
	Mean (SD)	87.0 (16.11)	-3.8 (13.31)	78.7 (20.33)	-8.0 (15.95)
	Median	93.3	0.0	86.7	-6.7
	Min, Max	33, 100	-60, 20	20, 100	-60, 27
Cycle 5	n	56	51	32	31
	Mean (SD)	89.4 (14.70)	-2.1 (10.11)	84.6 (14.80)	-3.4 (14.49)
	Median	93.3	0.0	86.7	0.0
	Min, Max	33, 100	-47, 13	47, 100	-33, 40
Cycle 6	n	55	50	26	25
	Mean (SD)	89.1 (13.66)	-2.0 (9.64)	83.8 (14.87)	-5.3 (12.62)
	Median	93.3	0.0	86.7	0.0
	Min, Max	47, 100	-33, 13	47, 100	-33, 20
End of Treatment	n	43	41	46	45
	Mean (SD)	71.2 (27.82)	-19.0 (23.74)	68.7 (28.90)	-19.7 (23.57)
	Median	80.0	-13.3	80.0	-13.3
	Min, Max	7, 100	-80, 13	0, 100	-80, 13

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Physical functioning

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	71	67	62	61
	Mean (SD)	73.6 (24.36)	-13.8 (21.25)	73.1 (24.26)	-13.6 (18.70)
	Median	80.0	-6.7	80.0	-6.7
	Min, Max	0, 100	-87, 20	0, 100	-67, 13
Worst Post-Baseline Value	n	136	125	129	126
	Mean (SD)	71.5 (25.13)	-17.2 (21.30)	66.1 (25.04)	-17.6 (19.72)
	Median	80.0	-13.3	73.3	-13.3
	Min, Max	0, 100	-87, 20	0, 100	-80, 27

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Role functioning

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		133	
	Mean (SD)	89.3 (16.30)		83.6 (25.12)	
	Median	100.0		100.0	
	Min, Max	33, 100		0, 100	
Cycle 1	n	83	78	83	82
	Mean (SD)	83.9 (22.00)	-6.0 (17.61)	80.9 (24.71)	-3.0 (17.20)
	Median	100.0	0.0	83.3	0.0
	Min, Max	0, 100	-100, 33	0, 100	-50, 67
Cycle 2	n	123	113	97	96
	Mean (SD)	83.3 (24.24)	-6.9 (20.62)	80.4 (26.68)	-6.1 (19.21)
	Median	100.0	0.0	100.0	0.0
	Min, Max	0, 100	-100, 33	0, 100	-67, 67
Cycle 3	n	98	89	58	57
	Mean (SD)	83.2 (25.94)	-7.7 (22.90)	80.7 (24.94)	-7.6 (24.61)
	Median	100.0	0.0	100.0	0.0
	Min, Max	0, 100	-100, 33	0, 100	-83, 83

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Role functioning

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	77	69	52	51
	Mean (SD)	85.3 (21.63)	-7.5 (22.42)	74.7 (28.29)	-13.1 (23.41)
	Median	100.0	0.0	83.3	-16.7
	Min, Max	0, 100	-100, 33	0, 100	-100, 33
Cycle 5	n	56	51	32	31
	Mean (SD)	89.0 (15.33)	-2.3 (12.92)	85.4 (19.74)	-2.7 (26.21)
	Median	100.0	0.0	100.0	0.0
	Min, Max	50, 100	-33, 33	33, 100	-67, 83
Cycle 6	n	55	50	26	25
	Mean (SD)	87.9 (15.86)	-4.0 (11.93)	84.0 (17.31)	-5.3 (16.47)
	Median	100.0	0.0	83.3	0.0
	Min, Max	67, 100	-33, 17	50, 100	-33, 33
End of Treatment	n	43	41	46	45
	Mean (SD)	68.6 (33.18)	-24.4 (30.75)	66.7 (32.01)	-22.2 (28.65)
	Median	66.7	-16.7	66.7	-16.7
	Min, Max	0, 100	-100, 17	0, 100	-100, 33

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Role functioning

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	71	67	62	61
	Mean (SD)	71.1 (29.94)	-18.9 (28.26)	69.4 (27.69)	-20.5 (23.05)
	Median	66.7	0.0	66.7	-16.7
	Min, Max	0, 100	-100, 33	0, 100	-100, 33
Worst Post-Baseline Value	n	136	125	129	126
	Mean (SD)	65.9 (30.96)	-23.9 (28.19)	62.7 (30.25)	-21.4 (27.80)
	Median	66.7	-16.7	66.7	-16.7
	Min, Max	0, 100	-100, 33	0, 100	-100, 67

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Emotional functioning

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		133	
	Mean (SD)	85.7 (13.92)		85.0 (18.71)	
	Median	91.7		91.7	
	Min, Max	33, 100		17, 100	
Cycle 1	n	83	78	82	81
	Mean (SD)	85.8 (13.63)	-1.6 (10.32)	82.6 (18.30)	-1.3 (15.28)
	Median	91.7	0.0	83.3	0.0
	Min, Max	50, 100	-33, 33	17, 100	-42, 50
Cycle 2	n	123	113	97	96
	Mean (SD)	86.5 (16.51)	-0.4 (13.22)	85.2 (17.70)	-1.0 (16.85)
	Median	91.7	0.0	91.7	0.0
	Min, Max	0, 100	-42, 42	8, 100	-75, 58
Cycle 3	n	98	89	58	57
	Mean (SD)	85.0 (17.67)	-2.4 (16.68)	86.6 (17.45)	-0.1 (14.39)
	Median	91.7	0.0	91.7	0.0
	Min, Max	17, 100	-58, 58	25, 100	-33, 58

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Emotional functioning

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	77	69	52	51
	Mean (SD)	86.3 (16.54)	-2.2 (13.83)	85.1 (19.96)	-2.1 (12.89)
	Median	91.7	0.0	91.7	0.0
	Min, Max	42, 100	-42, 25	17, 100	-42, 25
Cycle 5	n	56	51	32	31
	Mean (SD)	88.5 (14.95)	-1.1 (12.47)	89.8 (14.93)	1.3 (21.31)
	Median	100.0	0.0	100.0	0.0
	Min, Max	50, 100	-42, 25	58, 100	-42, 75
Cycle 6	n	55	50	26	25
	Mean (SD)	87.4 (14.86)	-2.2 (11.76)	90.1 (16.50)	-1.3 (18.43)
	Median	91.7	0.0	100.0	0.0
	Min, Max	33, 100	-42, 25	33, 100	-67, 33
End of Treatment	n	43	41	46	45
	Mean (SD)	74.2 (22.03)	-8.9 (16.71)	75.9 (25.89)	-9.4 (20.92)
	Median	75.0	0.0	83.3	-8.3
	Min, Max	25, 100	-58, 25	0, 100	-83, 25

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Emotional functioning

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	71	67	62	61
	Mean (SD)	75.5 (22.04)	-9.5 (21.36)	82.0 (21.08)	-6.1 (20.46)
	Median	75.0	-8.3	83.3	0.0
	Min, Max	8, 100	-92, 58	0, 100	-92, 25
Worst Post-Baseline Value	n	136	125	128	125
	Mean (SD)	72.5 (22.11)	-14.2 (18.39)	74.1 (23.18)	-11.1 (19.68)
	Median	75.0	-8.3	75.0	-8.3
	Min, Max	0, 100	-92, 33	0, 100	-92, 50

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Cognitive functioning

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		133	
	Mean (SD)	90.1 (13.46)		88.8 (17.85)	
	Median	100.0		100.0	
	Min, Max	50, 100		0, 100	
Cycle 1	n	83	78	82	81
	Mean (SD)	88.4 (13.46)	-1.1 (10.86)	86.0 (19.33)	-2.9 (15.32)
	Median	83.3	0.0	91.7	0.0
	Min, Max	33, 100	-33, 33	17, 100	-50, 33
Cycle 2	n	123	113	97	96
	Mean (SD)	87.5 (17.02)	-2.5 (13.22)	87.3 (15.73)	-1.4 (13.39)
	Median	100.0	0.0	83.3	0.0
	Min, Max	0, 100	-50, 50	33, 100	-33, 33
Cycle 3	n	98	89	58	57
	Mean (SD)	87.8 (17.35)	-3.6 (15.98)	86.5 (20.82)	-1.8 (16.57)
	Median	100.0	0.0	100.0	0.0
	Min, Max	0, 100	-67, 50	0, 100	-67, 33

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Cognitive functioning

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	77	69	52	51
	Mean (SD)	88.1 (14.52)	-2.4 (12.87)	83.7 (22.01)	-5.2 (18.41)
	Median	100.0	0.0	83.3	0.0
	Min, Max	50, 100	-50, 17	0, 100	-67, 33
Cycle 5	n	56	51	32	31
	Mean (SD)	88.7 (15.93)	-3.6 (15.39)	91.7 (12.70)	-0.0 (12.91)
	Median	100.0	0.0	100.0	0.0
	Min, Max	17, 100	-67, 33	50, 100	-33, 33
Cycle 6	n	55	50	26	25
	Mean (SD)	88.8 (16.68)	-4.3 (16.77)	89.1 (14.10)	-3.3 (13.61)
	Median	100.0	0.0	100.0	0.0
	Min, Max	17, 100	-67, 17	50, 100	-33, 33
End of Treatment	n	43	41	46	45
	Mean (SD)	76.7 (21.25)	-11.0 (19.22)	79.0 (23.68)	-11.1 (17.77)
	Median	83.3	0.0	83.3	-16.7
	Min, Max	33, 100	-67, 33	0, 100	-50, 33

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Cognitive functioning

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	71	67	62	61
	Mean (SD)	77.2 (22.23)	-9.0 (21.19)	83.6 (17.20)	-7.7 (15.69)
	Median	83.3	0.0	83.3	0.0
	Min, Max	17, 100	-67, 50	33, 100	-50, 17
Worst Post-Baseline Value	n	136	125	128	125
	Mean (SD)	75.9 (22.57)	-14.5 (18.08)	76.3 (22.29)	-12.1 (17.50)
	Median	83.3	-16.7	83.3	-16.7
	Min, Max	0, 100	-67, 17	0, 100	-67, 33

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Social functioning

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		133	
	Mean (SD)	81.5 (20.62)		82.5 (23.06)	
	Median	83.3		100.0	
	Min, Max	17, 100		0, 100	
Cycle 1	n	82	77	82	81
	Mean (SD)	81.3 (21.82)	-0.4 (16.88)	74.4 (28.59)	-6.2 (21.96)
	Median	83.3	0.0	83.3	0.0
	Min, Max	17, 100	-50, 50	0, 100	-83, 50
Cycle 2	n	123	113	97	96
	Mean (SD)	81.8 (23.95)	-0.9 (20.02)	77.1 (27.88)	-4.3 (23.97)
	Median	100.0	0.0	83.3	0.0
	Min, Max	0, 100	-67, 50	0, 100	-67, 50
Cycle 3	n	98	89	58	57
	Mean (SD)	85.5 (19.97)	1.9 (20.17)	81.3 (25.95)	-2.6 (25.35)
	Median	100.0	0.0	100.0	0.0
	Min, Max	0, 100	-67, 67	0, 100	-83, 50

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Social functioning

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	77	69	52	51
	Mean (SD)	85.7 (18.68)	0.5 (21.76)	75.6 (27.31)	-7.8 (23.89)
	Median	100.0	0.0	83.3	0.0
	Min, Max	17, 100	-83, 67	0, 100	-67, 33
Cycle 5	n	56	51	32	31
	Mean (SD)	88.1 (14.46)	3.3 (16.34)	81.8 (24.81)	-2.7 (27.59)
	Median	100.0	0.0	100.0	0.0
	Min, Max	67, 100	-17, 50	0, 100	-67, 83
Cycle 6	n	55	50	26	25
	Mean (SD)	87.9 (16.18)	1.0 (15.58)	80.8 (20.92)	-4.7 (21.26)
	Median	100.0	0.0	83.3	0.0
	Min, Max	50, 100	-33, 33	33, 100	-50, 33
End of Treatment	n	43	41	46	45
	Mean (SD)	69.4 (29.75)	-11.8 (26.15)	73.6 (29.31)	-16.3 (27.64)
	Median	66.7	0.0	83.3	0.0
	Min, Max	0, 100	-100, 33	0, 100	-100, 33

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Social functioning

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	71	67	62	61
	Mean (SD)	71.1 (29.94)	-11.7 (33.08)	71.2 (30.20)	-14.2 (27.69)
	Median	66.7	0.0	66.7	0.0
	Min, Max	0, 100	-100, 67	0, 100	-100, 50
Worst Post-Baseline Value	n	136	125	128	125
	Mean (SD)	65.8 (28.35)	-15.6 (27.50)	61.1 (30.47)	-21.2 (25.96)
	Median	66.7	0.0	66.7	-16.7
	Min, Max	0, 100	-100, 50	0, 100	-100, 50

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Fatigue

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		133	
	Mean (SD)	21.8 (18.55)		27.7 (23.36)	
	Median	22.2		22.2	
	Min, Max	0, 67		0, 100	
Cycle 1	n	83	78	83	82
	Mean (SD)	26.0 (21.62)	5.5 (14.67)	29.5 (23.57)	0.8 (14.89)
	Median	22.2	0.0	33.3	0.0
	Min, Max	0, 78	-33, 61	0, 100	-44, 33
Cycle 2	n	123	113	97	96
	Mean (SD)	25.8 (22.92)	5.1 (17.53)	31.0 (24.42)	5.2 (16.90)
	Median	22.2	0.0	33.3	0.0
	Min, Max	0, 100	-33, 78	0, 100	-56, 44
Cycle 3	n	98	89	58	57
	Mean (SD)	26.9 (24.30)	6.4 (19.09)	29.1 (24.87)	6.2 (24.22)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-22, 78	0, 100	-100, 89

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Fatigue

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	77	69	52	51
	Mean (SD)	21.6 (21.62)	2.4 (17.96)	35.7 (27.60)	13.5 (21.92)
	Median	11.1	0.0	33.3	11.1
	Min, Max	0, 67	-33, 44	0, 100	-33, 67
Cycle 5	n	56	51	32	31
	Mean (SD)	16.7 (17.34)	-0.7 (15.14)	23.3 (21.37)	3.6 (25.56)
	Median	11.1	0.0	22.2	0.0
	Min, Max	0, 78	-33, 44	0, 78	-89, 44
Cycle 6	n	55	50	26	25
	Mean (SD)	18.2 (16.75)	-0.4 (15.71)	25.9 (18.79)	9.1 (16.73)
	Median	22.2	0.0	33.3	11.1
	Min, Max	0, 67	-33, 33	0, 67	-33, 33
End of Treatment	n	43	41	46	45
	Mean (SD)	42.9 (31.11)	20.1 (24.37)	42.8 (28.78)	21.0 (24.53)
	Median	33.3	11.1	33.3	22.2
	Min, Max	0, 100	-33, 89	0, 100	-33, 89

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Fatigue

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	71	67	62	61
	Mean (SD)	40.4 (28.00)	16.7 (24.34)	37.1 (26.76)	14.6 (21.71)
	Median	33.3	11.1	33.3	11.1
	Min, Max	0, 100	-33, 89	0, 100	-44, 78
Worst Post-Baseline Value	n	136	125	129	126
	Mean (SD)	42.9 (27.29)	22.2 (21.08)	46.6 (27.21)	19.2 (24.07)
	Median	33.3	22.2	33.3	19.4
	Min, Max	0, 100	-11, 89	0, 100	-33, 89

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Nausea and vomiting

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		133	
	Mean (SD)	6.9 (13.48)		9.1 (19.30)	
	Median	0.0		0.0	
	Min, Max	0, 67		0, 100	
Cycle 1	n	83	78	83	82
	Mean (SD)	7.8 (16.94)	0.6 (12.14)	7.4 (17.89)	-1.0 (13.19)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-50, 67	0, 100	-33, 67
Cycle 2	n	123	113	97	96
	Mean (SD)	11.1 (23.15)	4.4 (21.94)	8.9 (17.52)	2.1 (16.97)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-50, 100	0, 83	-67, 67
Cycle 3	n	97	88	58	57
	Mean (SD)	10.8 (20.13)	4.9 (19.44)	5.5 (12.25)	0.3 (10.20)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 50	-33, 33

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Nausea and vomiting

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	77	69	52	51
	Mean (SD)	7.4 (16.56)	1.4 (14.50)	5.1 (11.21)	0.7 (11.04)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-50, 50	0, 50	-33, 33
Cycle 5	n	56	51	32	31
	Mean (SD)	4.5 (9.26)	0.3 (13.54)	9.4 (15.23)	5.4 (14.52)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 33	-67, 33	0, 67	-33, 33
Cycle 6	n	55	50	26	25
	Mean (SD)	4.2 (9.74)	0.7 (13.02)	7.7 (16.49)	4.7 (17.02)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 33	-67, 33	0, 67	-33, 67
End of Treatment	n	43	41	46	45
	Mean (SD)	17.1 (28.98)	8.9 (23.60)	8.0 (19.16)	1.5 (17.34)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-50, 83	0, 100	-50, 67

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Nausea and vomiting

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	71	67	62	61
	Mean (SD)	17.1 (26.57)	8.5 (24.85)	8.9 (18.78)	1.9 (22.79)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 83	-100, 83
Worst Post-Baseline Value	n	136	125	129	126
	Mean (SD)	19.6 (27.66)	13.5 (25.37)	16.4 (23.20)	7.1 (21.85)
	Median	8.3	0.0	0.0	0.0
	Min, Max	0, 100	-50, 100	0, 100	-100, 83

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Pain

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		133	
	Mean (SD)	20.3 (20.91)		22.4 (26.75)	
	Median	16.7		16.7	
	Min, Max	0, 83		0, 100	
Cycle 1	n	83	78	83	82
	Mean (SD)	23.1 (23.55)	4.5 (14.88)	23.7 (25.39)	1.2 (13.55)
	Median	16.7	0.0	16.7	0.0
	Min, Max	0, 83	-33, 67	0, 100	-50, 33
Cycle 2	n	123	113	97	96
	Mean (SD)	20.2 (21.26)	1.3 (14.80)	22.9 (25.50)	2.8 (21.99)
	Median	16.7	0.0	16.7	0.0
	Min, Max	0, 100	-33, 50	0, 100	-67, 67
Cycle 3	n	98	89	58	57
	Mean (SD)	21.3 (22.55)	2.2 (19.49)	18.1 (21.92)	1.2 (22.02)
	Median	16.7	0.0	16.7	0.0
	Min, Max	0, 100	-67, 67	0, 67	-67, 67

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Pain

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	77	69	52	51
	Mean (SD)	19.3 (19.70)	1.4 (20.36)	24.0 (26.28)	7.5 (23.41)
	Median	16.7	0.0	16.7	0.0
	Min, Max	0, 67	-50, 67	0, 100	-33, 83
Cycle 5	n	56	51	32	31
	Mean (SD)	15.8 (18.10)	-1.0 (16.47)	15.1 (19.10)	0.5 (18.50)
	Median	16.7	0.0	0.0	0.0
	Min, Max	0, 67	-33, 50	0, 67	-33, 50
Cycle 6	n	55	50	26	25
	Mean (SD)	15.5 (19.99)	-1.3 (20.44)	16.0 (20.81)	3.3 (19.25)
	Median	0.0	0.0	8.3	0.0
	Min, Max	0, 83	-50, 83	0, 67	-33, 50
End of Treatment	n	43	41	46	45
	Mean (SD)	37.2 (32.50)	21.5 (31.68)	27.5 (28.16)	11.1 (18.80)
	Median	33.3	16.7	16.7	0.0
	Min, Max	0, 100	-33, 100	0, 100	-50, 67

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Pain

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	71	67	62	61
	Mean (SD)	32.4 (26.26)	12.2 (25.39)	28.2 (28.72)	9.0 (20.09)
	Median	33.3	0.0	25.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-33, 67
Worst Post-Baseline Value	n	136	125	129	126
	Mean (SD)	37.9 (25.94)	18.0 (25.19)	37.5 (29.02)	14.9 (24.66)
	Median	33.3	16.7	33.3	16.7
	Min, Max	0, 100	-33, 100	0, 100	-67, 83

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Dyspnoea

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	127		133	
	Mean (SD)	13.9 (18.99)		15.0 (21.50)	
	Median	0.0		0.0	
	Min, Max	0, 100		0, 100	
Cycle 1	n	83	77	83	82
	Mean (SD)	15.3 (20.36)	1.3 (15.71)	15.3 (21.02)	0.4 (19.24)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 67	0, 67	-67, 67
Cycle 2	n	123	112	97	96
	Mean (SD)	17.9 (24.99)	4.5 (20.74)	18.2 (20.98)	6.3 (20.12)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 67	0, 100	-33, 67
Cycle 3	n	98	89	58	57
	Mean (SD)	17.7 (25.42)	4.5 (23.67)	16.7 (18.99)	5.3 (18.68)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 67	-33, 33

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Dyspnoea

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	77	69	52	51
	Mean (SD)	14.3 (21.24)	1.0 (22.12)	17.3 (22.38)	5.9 (21.81)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-33, 67	0, 67	-33, 33
Cycle 5	n	56	51	32	31
	Mean (SD)	13.1 (19.78)	-0.7 (15.62)	17.7 (26.75)	5.4 (27.35)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-33, 33	0, 100	-33, 67
Cycle 6	n	55	50	26	25
	Mean (SD)	14.5 (21.05)	-0.0 (20.20)	19.2 (23.42)	8.0 (22.11)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 33	0, 67	-33, 33
End of Treatment	n	43	41	46	45
	Mean (SD)	28.7 (30.50)	18.7 (31.67)	27.5 (30.88)	18.5 (27.11)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-33, 100

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Dyspnoea

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	71	67	62	61
	Mean (SD)	28.2 (28.53)	12.4 (28.33)	28.5 (29.47)	15.8 (29.57)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-67, 100	0, 100	-33, 100
Worst Post-Baseline Value	n	136	124	129	126
	Mean (SD)	32.4 (30.07)	19.6 (27.22)	33.6 (28.72)	19.0 (28.10)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-33, 100

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Insomnia

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	127		133	
	Mean (SD)	16.3 (22.56)		21.3 (24.73)	
	Median	0.0		33.3	
	Min, Max	0, 100		0, 100	
Cycle 1	n	83	77	83	82
	Mean (SD)	12.9 (19.36)	0.4 (16.66)	23.3 (28.39)	2.0 (22.44)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-33, 33	0, 100	-67, 67
Cycle 2	n	123	112	97	96
	Mean (SD)	15.4 (23.49)	1.5 (22.98)	20.6 (27.40)	1.7 (21.29)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-33, 67
Cycle 3	n	98	89	58	57
	Mean (SD)	18.4 (25.83)	3.7 (24.33)	19.0 (25.83)	1.2 (20.86)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-33, 33

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Insomnia

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	77	69	52	51
	Mean (SD)	14.3 (21.92)	0.5 (21.76)	23.1 (26.02)	3.3 (22.37)
	Median	0.0	0.0	33.3	0.0
	Min, Max	0, 100	-67, 67	0, 100	-33, 67
Cycle 5	n	56	51	32	31
	Mean (SD)	13.7 (19.88)	-0.0 (23.09)	14.6 (20.63)	1.1 (16.06)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-33, 67	0, 67	-33, 33
Cycle 6	n	55	50	26	25
	Mean (SD)	12.7 (20.78)	-1.3 (22.29)	11.5 (20.96)	-1.3 (15.15)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 67	0, 67	-33, 33
End of Treatment	n	43	41	46	45
	Mean (SD)	27.1 (33.54)	15.4 (26.97)	27.5 (32.44)	11.9 (31.10)
	Median	0.0	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-33, 100

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Insomnia

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	71	67	62	61
	Mean (SD)	30.5 (33.69)	14.9 (29.75)	27.4 (31.08)	7.1 (26.61)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-33, 67
Worst Post-Baseline Value	n	136	124	129	126
	Mean (SD)	33.6 (31.03)	19.4 (27.58)	35.7 (30.67)	14.6 (26.83)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Appetite loss

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		132	
	Mean (SD)	19.8 (24.90)		17.9 (26.18)	
	Median	0.0		0.0	
	Min, Max	0, 100		0, 100	
Cycle 1	n	83	78	83	81
	Mean (SD)	19.3 (25.57)	-1.7 (19.29)	20.5 (27.46)	4.9 (22.43)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 67	0, 100	-67, 100
Cycle 2	n	123	113	97	96
	Mean (SD)	19.2 (28.31)	2.1 (24.10)	22.3 (29.55)	4.5 (24.48)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 100
Cycle 3	n	98	89	58	56
	Mean (SD)	24.1 (29.81)	6.0 (27.32)	12.6 (23.22)	-3.0 (30.67)
	Median	16.7	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-100, 100

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Appetite loss

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	77	69	52	50
	Mean (SD)	16.5 (23.34)	2.4 (25.77)	23.1 (27.64)	9.3 (25.23)
	Median	0.0	0.0	33.3	0.0
	Min, Max	0, 100	-67, 67	0, 100	-33, 100
Cycle 5	n	55	50	32	31
	Mean (SD)	9.1 (14.98)	-4.7 (23.34)	13.5 (25.20)	3.2 (30.25)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 33	-100, 33	0, 100	-100, 100
Cycle 6	n	54	49	26	25
	Mean (SD)	11.7 (17.32)	-4.1 (27.75)	15.4 (25.35)	9.3 (24.57)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-100, 33	0, 100	-33, 100
End of Treatment	n	43	41	46	45
	Mean (SD)	34.1 (32.92)	17.1 (31.73)	29.7 (33.13)	16.3 (33.05)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Appetite loss

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	71	67	62	61
	Mean (SD)	34.7 (30.57)	15.4 (30.88)	27.4 (34.95)	13.7 (28.14)
	Median	33.3	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-33, 100
Worst Post-Baseline Value	n	136	125	129	125
	Mean (SD)	40.2 (31.72)	22.1 (30.22)	37.5 (32.01)	20.0 (27.44)
	Median	33.3	33.3	33.3	33.3
	Min, Max	0, 100	-100, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Constipation

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		133	
	Mean (SD)	14.1 (23.14)		14.8 (22.63)	
	Median	0.0		0.0	
	Min, Max	0, 100		0, 100	
Cycle 1	n	83	78	83	82
	Mean (SD)	17.3 (25.69)	4.3 (16.43)	12.0 (19.88)	-1.2 (16.93)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 67	0, 67	-67, 33
Cycle 2	n	123	113	97	96
	Mean (SD)	16.0 (25.01)	3.5 (22.43)	13.1 (21.28)	1.4 (19.89)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 67	0, 100	-67, 67
Cycle 3	n	98	89	58	57
	Mean (SD)	14.6 (23.96)	1.9 (23.76)	10.9 (20.12)	-0.6 (16.05)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-33, 33

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Constipation

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	77	69	52	51
	Mean (SD)	17.3 (25.71)	5.3 (27.19)	12.2 (21.92)	-1.3 (18.81)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 33
Cycle 5	n	56	51	32	31
	Mean (SD)	9.5 (18.76)	-0.0 (20.00)	11.5 (21.77)	-1.1 (13.56)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 33	0, 67	-33, 33
Cycle 6	n	55	50	26	25
	Mean (SD)	12.1 (21.62)	2.0 (23.72)	14.1 (28.55)	1.3 (20.37)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-33, 33
End of Treatment	n	43	41	46	45
	Mean (SD)	17.8 (23.40)	4.1 (18.55)	15.9 (19.55)	7.4 (22.35)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 33	0, 67	-67, 67

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Constipation

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	71	67	62	61
	Mean (SD)	26.8 (29.61)	10.0 (29.60)	15.1 (19.72)	1.6 (23.90)
	Median	33.3	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 67	-67, 67
Worst Post-Baseline Value	n	136	125	129	126
	Mean (SD)	30.4 (32.58)	17.3 (29.21)	23.3 (25.21)	8.5 (23.07)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 67

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Diarrhea

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		133	
	Mean (SD)	7.8 (16.98)		6.3 (15.43)	
	Median	0.0		0.0	
	Min, Max	0, 100		0, 67	
Cycle 1	n	83	78	82	81
	Mean (SD)	4.4 (11.37)	-2.1 (12.41)	7.7 (15.97)	1.6 (11.67)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 33	-33, 33	0, 67	-33, 33
Cycle 2	n	123	113	97	96
	Mean (SD)	7.6 (16.43)	-0.3 (16.96)	7.6 (17.01)	0.7 (15.28)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 67	-33, 67
Cycle 3	n	98	89	58	57
	Mean (SD)	5.8 (13.56)	-3.7 (17.00)	8.0 (14.39)	0.6 (13.35)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-67, 33	0, 33	-33, 33

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Diarrhea

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	77	69	52	51
	Mean (SD)	6.5 (14.35)	-3.9 (18.56)	7.7 (14.18)	0.7 (14.13)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-67, 33	0, 33	-33, 33
Cycle 5	n	56	51	32	31
	Mean (SD)	7.1 (15.19)	-2.0 (15.51)	10.4 (17.84)	5.4 (15.15)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-33, 33	0, 67	-33, 33
Cycle 6	n	55	50	26	25
	Mean (SD)	11.5 (20.51)	3.3 (22.59)	12.8 (19.04)	8.0 (14.53)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-33, 67	0, 67	0, 33
End of Treatment	n	43	41	46	45
	Mean (SD)	9.3 (16.79)	-2.4 (20.26)	5.8 (12.77)	-3.0 (15.61)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-67, 67	0, 33	-33, 33

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Diarrhea

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	71	67	62	61
	Mean (SD)	8.9 (19.48)	-1.5 (19.62)	5.9 (14.19)	1.6 (16.58)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 67	0, 67	-33, 67
Worst Post-Baseline Value	n	136	125	128	125
	Mean (SD)	15.0 (22.89)	7.5 (20.68)	12.8 (20.11)	6.1 (17.65)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 67	-33, 67

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Financial difficulties

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		133	
	Mean (SD)	23.7 (30.21)		26.3 (29.03)	
	Median	0.0		33.3	
	Min, Max	0, 100		0, 100	
Cycle 1	n	82	77	82	81
	Mean (SD)	22.4 (27.24)	-2.6 (21.47)	27.6 (30.90)	1.2 (18.59)
	Median	0.0	0.0	33.3	0.0
	Min, Max	0, 100	-67, 33	0, 100	-33, 33
Cycle 2	n	123	113	97	96
	Mean (SD)	20.1 (26.56)	-2.1 (24.91)	26.8 (29.91)	0.7 (26.92)
	Median	0.0	0.0	33.3	0.0
	Min, Max	0, 100	-100, 67	0, 100	-67, 67
Cycle 3	n	98	89	58	57
	Mean (SD)	18.4 (22.00)	-3.4 (26.61)	21.3 (26.27)	-3.5 (19.60)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-100, 67	0, 100	-67, 33

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Financial difficulties

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	77	69	52	51
	Mean (SD)	17.7 (25.70)	-3.9 (29.45)	25.0 (27.91)	-0.0 (25.82)
	Median	0.0	0.0	33.3	0.0
	Min, Max	0, 100	-67, 100	0, 100	-100, 67
Cycle 5	n	56	51	32	31
	Mean (SD)	15.5 (22.89)	-4.6 (29.07)	25.0 (28.08)	1.1 (25.07)
	Median	0.0	0.0	33.3	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 33
Cycle 6	n	55	50	26	25
	Mean (SD)	12.7 (22.67)	-4.7 (33.00)	19.2 (23.42)	-2.7 (23.41)
	Median	0.0	0.0	16.7	0.0
	Min, Max	0, 100	-100, 100	0, 100	-67, 33
End of Treatment	n	43	41	46	45
	Mean (SD)	27.9 (27.15)	3.3 (20.82)	26.1 (34.36)	4.4 (29.81)
	Median	33.3	0.0	0.0	0.0
	Min, Max	0, 100	-33, 33	0, 100	-100, 67

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.b:
Summary of EORTC QLQ-C30 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Financial difficulties

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	71	67	62	61
	Mean (SD)	25.8 (28.28)	0.0 (32.31)	24.2 (27.77)	1.1 (27.87)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-100, 100	0, 100	-100, 67
Worst Post-Baseline Value	n	136	125	128	125
	Mean (SD)	33.1 (29.67)	8.5 (25.72)	36.2 (31.31)	10.4 (24.47)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 67

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-02-01-b-qs-chg-c30-itts-cl.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Global health status / QoL									
Cycle 4	139		0.46 (1.23)	75		-4.35 (1.57)	4.81 (0.98, 8.64)	0.32 (0.06, 0.58)	0.0140
Cycle 6	94		-0.58 (1.35)	36		-8.02 (1.98)	7.44 (2.81, 12.06)	0.51 (0.19, 0.83)	0.0018
Overall Treatment Effect	229	66.67 (19.34)	-0.48 (0.87)	208	67.31 (19.12)	-3.27 (1.03)	2.78 (0.29, 5.28)	0.25 (0.03, 0.48)	0.0289

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Only patients with baseline and postbaseline value are included in analysis.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-02-01-01-eff-mmrmqs-c30-itt-cl.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Physical functioning									
Cycle 4	139		-3.61 (1.11)	75		-6.55 (1.38)	2.94 (-0.45, 6.32)	0.21 (-0.03, 0.45)	0.0886
Cycle 6	94		-4.02 (1.20)	36		-8.60 (1.68)	4.59 (0.59, 8.58)	0.33 (0.04, 0.62)	0.0248
Overall Treatment Effect	229	87.38 (13.88)	-2.98 (0.86)	209	84.40 (16.59)	-5.89 (1.02)	2.91 (0.41, 5.41)	0.26 (0.04, 0.49)	0.0225

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Only patients with baseline and postbaseline value are included in analysis.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-02-01-01-eff-mmrmqs-c30-itt-cl.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Role functioning									
Cycle 4	139		-6.31 (1.85)	75		-9.96 (2.37)	3.65 (-2.13, 9.44)	0.16 (-0.09, 0.41)	0.2147
Cycle 6	94		-6.37 (1.67)	36		-7.90 (2.41)	1.53 (-4.14, 7.20)	0.08 (-0.22, 0.39)	0.5951
Overall Treatment Effect	229	88.77 (18.13)	-5.22 (1.25)	209	84.68 (23.39)	-6.58 (1.49)	1.37 (-2.26, 4.99)	0.09 (-0.14, 0.31)	0.4588

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Only patients with baseline and postbaseline value are included in analysis.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-02-01-01-eff-mmrmqs-c30-itt-cl.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Emotional functioning									
Cycle 4	139		0.58 (1.15)	75		-1.46 (1.52)	2.04 (-1.63, 5.72)	0.15 (-0.12, 0.42)	0.2748
Cycle 6	94		-0.58 (1.38)	36		-2.79 (2.06)	2.21 (-2.62, 7.04)	0.15 (-0.18, 0.48)	0.3677
Overall Treatment Effect	229	85.85 (15.70)	-0.30 (0.80)	208	85.02 (17.62)	-1.26 (0.99)	0.96 (-1.41, 3.33)	0.10 (-0.14, 0.34)	0.4251

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-02-01-01-eff-mmrmqs-c30-itt-cl.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Cognitive functioning									
Cycle 4	139		-1.65 (1.16)	75		-4.99 (1.49)	3.34 (-0.28, 6.96)	0.23 (-0.02, 0.49)	0.0705
Cycle 6	94		-4.40 (1.34)	36		-2.03 (2.00)	-2.36 (-7.05, 2.32)	-0.16 (-0.48, 0.16)	0.3206
Overall Treatment Effect	229	90.29 (14.20)	-2.51 (0.84)	208	88.53 (17.04)	-1.99 (1.01)	-0.51 (-2.96, 1.93)	-0.05 (-0.28, 0.18)	0.6795

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Only patients with baseline and postbaseline value are included in analysis.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-02-01-01-eff-mmrmqs-c30-itt-cl.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Social functioning									
Cycle 4	139		-0.08 (1.73)	75		-5.45 (2.20)	5.38 (0.01, 10.74)	0.26 (-0.00, 0.51)	0.0496
Cycle 6	94		-1.53 (1.88)	36		-7.19 (2.63)	5.66 (-0.60, 11.92)	0.26 (-0.03, 0.56)	0.0759
Overall Treatment Effect	229	81.75 (20.11)	-0.13 (1.27)	208	79.42 (24.10)	-3.75 (1.52)	3.62 (-0.06, 7.30)	0.23 (-0.00, 0.46)	0.0537

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-02-01-01-eff-mmrmqs-c30-itt-cl.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Fatigue									
Cycle 4	139		3.04 (1.58)	75		11.59 (2.02)	-8.55 (-13.48, -3.61)	-0.44 (-0.70, -0.18)	0.0008
Cycle 6	94		2.16 (1.52)	36		7.66 (2.22)	-5.50 (-10.70, -0.30)	-0.33 (-0.65, -0.02)	0.0384
Overall Treatment Effect	229	23.35 (20.18)	2.71 (1.08)	209	27.04 (22.39)	6.45 (1.29)	-3.74 (-6.88, -0.60)	-0.27 (-0.50, -0.04)	0.0199

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Only patients with baseline and postbaseline value are included in analysis.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-02-01-01-eff-mmrmqs-c30-itt-cl.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Nausea and vomiting									
Cycle 4	139		2.20 (1.19)	75		1.80 (1.52)	0.40 (-3.29, 4.09)	0.03 (-0.22, 0.28)	0.8309
Cycle 6	94		2.62 (1.41)	36		3.98 (2.02)	-1.36 (-6.13, 3.41)	-0.08 (-0.38, 0.21)	0.5738
Overall Treatment Effect	229	7.23 (13.97)	2.27 (0.96)	209	8.43 (17.13)	2.47 (1.13)	-0.20 (-2.94, 2.54)	-0.02 (-0.24, 0.21)	0.8866

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Only patients with baseline and postbaseline value are included in analysis.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-02-01-01-eff-mmrmqs-c30-itt-cl.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Pain									
Cycle 4	139		-0.45 (1.72)	75		7.26 (2.23)	-7.71 (-13.13, -2.28)	-0.37 (-0.62, -0.11)	0.0056
Cycle 6	94		-0.19 (1.85)	36		7.01 (2.77)	-7.19 (-13.66, -0.72)	-0.37 (-0.70, -0.04)	0.0295
Overall Treatment Effect	229	21.14 (22.51)	0.52 (1.17)	209	23.35 (26.74)	4.68 (1.42)	-4.17 (-7.59, -0.74)	-0.28 (-0.52, -0.05)	0.0172

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-02-01-01-eff-mmrmqs-c30-itt-cl.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Dyspnoea									
Cycle 4	139		3.00 (1.62)	75		2.80 (2.11)	0.19 (-4.94, 5.33)	0.01 (-0.25, 0.27)	0.9408
Cycle 6	94		0.83 (1.87)	36		6.84 (2.89)	-6.01 (-12.73, 0.71)	-0.32 (-0.67, 0.04)	0.0794
Overall Treatment Effect	228	13.55 (19.97)	2.04 (1.07)	209	14.84 (21.57)	3.48 (1.31)	-1.44 (-4.58, 1.70)	-0.11 (-0.35, 0.13)	0.3666

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Only patients with baseline and postbaseline value are included in analysis.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-02-01-01-eff-mmrmqs-c30-itt-cl.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Insomnia									
Cycle 4	139		-0.53 (1.75)	75		-1.22 (2.24)	0.69 (-4.77, 6.16)	0.03 (-0.23, 0.29)	0.8029
Cycle 6	94		1.37 (2.23)	36		-1.14 (3.40)	2.51 (-5.42, 10.45)	0.11 (-0.24, 0.46)	0.5329
Overall Treatment Effect	228	17.57 (25.10)	-0.14 (1.27)	209	22.94 (26.29)	-0.98 (1.54)	0.84 (-2.86, 4.54)	0.05 (-0.19, 0.29)	0.6554

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-02-01-01-eff-mmrmqs-c30-itt-cl.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Appetite loss									
Cycle 4	138		-1.86 (1.87)	74		6.52 (2.39)	-8.38 (-14.16, -2.60)	-0.37 (-0.63, -0.11)	0.0046
Cycle 6	93		-1.23 (2.26)	36		6.84 (3.29)	-8.08 (-15.79, -0.36)	-0.33 (-0.64, -0.01)	0.0403
Overall Treatment Effect	228	19.23 (24.80)	-1.05 (1.45)	208	19.38 (26.24)	4.74 (1.74)	-5.79 (-9.98, -1.61)	-0.32 (-0.55, -0.09)	0.0068

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-02-01-01-eff-mmrmqs-c30-itt-cl.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Constipation									
Cycle 4	139		-0.49 (1.72)	75		0.83 (2.30)	-1.32 (-6.90, 4.25)	-0.06 (-0.34, 0.21)	0.6410
Cycle 6	94		-0.19 (1.83)	36		1.38 (2.78)	-1.58 (-8.08, 4.92)	-0.08 (-0.42, 0.25)	0.6322
Overall Treatment Effect	229	13.09 (22.90)	0.14 (1.05)	209	13.77 (22.48)	0.53 (1.34)	-0.39 (-3.58, 2.81)	-0.03 (-0.29, 0.22)	0.8114

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Only patients with baseline and postbaseline value are included in analysis.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-02-01-01-eff-mmrmqs-c30-itt-cl.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Diarrhea									
Cycle 4	139		-1.39 (1.20)	75		3.96 (1.53)	-5.35 (-9.10, -1.60)	-0.36 (-0.62, -0.11)	0.0053
Cycle 6	94		1.44 (1.73)	36		6.13 (2.70)	-4.68 (-10.96, 1.59)	-0.27 (-0.63, 0.09)	0.1425
Overall Treatment Effect	229	6.47 (15.16)	-0.81 (0.86)	208	5.94 (14.44)	4.38 (1.08)	-5.18 (-7.78, -2.58)	-0.49 (-0.74, -0.24)	0.0001

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Only patients with baseline and postbaseline value are included in analysis.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-02-01-01-eff-mmrmqs-c30-itt-cl.rtf

Table 14.2.6.2.1.1:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Financial difficulties									
Cycle 4	139		-4.26 (1.86)	75		-3.05 (2.38)	-1.22 (-7.02, 4.59)	-0.05 (-0.31, 0.20)	0.6804
Cycle 6	94		-4.05 (2.18)	36		-4.31 (3.18)	0.26 (-7.23, 7.74)	0.01 (-0.30, 0.32)	0.9462
Overall Treatment Effect	229	26.86 (30.36)	-3.98 (1.36)	208	30.23 (31.87)	-2.05 (1.62)	-1.94 (-5.87, 1.99)	-0.11 (-0.34, 0.12)	0.3329

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Only patients with baseline and postbaseline value are included in analysis.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

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Table 14.2.6.2.1.1.b:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Global health status / QoL									
Cycle 4	69		0.36 (1.57)	51		-4.25 (1.78)	4.61 (0.04, 9.18)	0.33 (0.00, 0.66)	0.0482
Cycle 6	50		-0.19 (1.77)	25		-5.77 (2.34)	5.58 (-0.17, 11.33)	0.39 (-0.01, 0.79)	0.0570
Overall Treatment Effect	123	67.06 (17.87)	-1.00 (1.19)	119	66.85 (19.37)	-2.63 (1.33)	1.63 (-1.73, 4.99)	0.14 (-0.15, 0.44)	0.3394

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

Only patients with baseline and postbaseline value are included in analysis.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.

[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

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Table 14.2.6.2.1.1.b:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Physical functioning									
Cycle 4	69		-4.37 (1.69)	51		-8.28 (1.90)	3.91 (-1.04, 8.86)	0.25 (-0.07, 0.56)	0.1204
Cycle 6	50		-3.83 (1.54)	25		-7.46 (1.90)	3.63 (-1.14, 8.40)	0.26 (-0.08, 0.61)	0.1337
Overall Treatment Effect	123	87.81 (13.75)	-3.48 (1.21)	120	83.66 (17.01)	-6.16 (1.34)	2.69 (-0.77, 6.14)	0.23 (-0.07, 0.52)	0.1268

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-02-01-01-b-eff-mmrmqs-c30-itts-cl.rtf

Table 14.2.6.2.1.1.b:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Role functioning									
Cycle 4	69		-8.73 (2.71)	51		-10.49 (3.07)	1.76 (-6.24, 9.76)	0.07 (-0.25, 0.40)	0.6639
Cycle 6	50		-5.59 (2.06)	25		-6.60 (2.72)	1.00 (-5.71, 7.71)	0.06 (-0.34, 0.47)	0.7659
Overall Treatment Effect	123	89.32 (16.30)	-5.98 (1.71)	120	83.58 (25.12)	-6.22 (1.91)	0.24 (-4.67, 5.16)	0.01 (-0.28, 0.31)	0.9225

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-02-01-01-b-eff-mmrmqs-c30-itts-cl.rtf

Table 14.2.6.2.1.1.b:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Emotional functioning									
Cycle 4	69		-1.77 (1.67)	51		-2.52 (1.94)	0.75 (-4.25, 5.75)	0.05 (-0.30, 0.41)	0.7670
Cycle 6	50		-2.47 (1.91)	25		0.02 (2.57)	-2.49 (-8.80, 3.82)	-0.17 (-0.61, 0.26)	0.4346
Overall Treatment Effect	123	85.74 (13.92)	-1.42 (1.11)	119	85.03 (18.71)	-0.87 (1.29)	-0.55 (-3.80, 2.69)	-0.05 (-0.37, 0.26)	0.7372

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-02-01-01-b-eff-mmrmqs-c30-itts-cl.rtf

Table 14.2.6.2.1.1.b:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Cognitive functioning									
Cycle 4	69		-2.98 (1.68)	51		-5.82 (1.91)	2.85 (-2.11, 7.81)	0.19 (-0.14, 0.52)	0.2586
Cycle 6	50		-4.75 (1.95)	25		-2.58 (2.57)	-2.18 (-8.51, 4.16)	-0.14 (-0.54, 0.26)	0.4974
Overall Treatment Effect	123	90.10 (13.46)	-3.22 (1.14)	119	88.85 (17.85)	-2.55 (1.30)	-0.67 (-3.99, 2.65)	-0.06 (-0.37, 0.24)	0.6901

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-02-01-01-b-eff-mmrmqs-c30-itts-cl.rtf

Table 14.2.6.2.1.1.b:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Social functioning									
Cycle 4	69		1.51 (2.47)	51		-7.22 (2.86)	8.73 (1.36, 16.09)	0.40 (0.06, 0.73)	0.0206
Cycle 6	50		-1.16 (2.43)	25		-8.22 (2.98)	7.07 (-0.46, 14.59)	0.33 (-0.02, 0.69)	0.0653
Overall Treatment Effect	123	81.51 (20.62)	1.39 (1.72)	119	82.46 (23.06)	-5.20 (1.95)	6.59 (1.63, 11.55)	0.40 (0.10, 0.71)	0.0096

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-02-01-01-b-eff-mmrmqs-c30-itts-cl.rtf

Table 14.2.6.2.1.1.b:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Fatigue									
Cycle 4	69		3.44 (2.22)	51		11.69 (2.55)	-8.24 (-14.84, -1.65)	-0.42 (-0.76, -0.08)	0.0146
Cycle 6	50		0.84 (2.12)	25		6.70 (2.83)	-5.86 (-12.81, 1.09)	-0.35 (-0.77, 0.07)	0.0972
Overall Treatment Effect	123	21.83 (18.55)	3.13 (1.47)	120	27.65 (23.36)	5.38 (1.66)	-2.25 (-6.49, 1.98)	-0.16 (-0.47, 0.14)	0.2941

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-02-01-01-b-eff-mmrmqs-c30-itts-cl.rtf

Table 14.2.6.2.1.1.b:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Nausea and vomiting									
Cycle 4	69		3.07 (1.56)	51		-0.71 (1.82)	3.78 (-0.87, 8.43)	0.26 (-0.06, 0.59)	0.1105
Cycle 6	50		2.89 (1.92)	25		2.76 (2.51)	0.14 (-6.08, 6.35)	0.01 (-0.38, 0.40)	0.9656
Overall Treatment Effect	123	6.90 (13.48)	3.12 (1.29)	120	9.15 (19.30)	0.84 (1.47)	2.28 (-1.47, 6.02)	0.18 (-0.12, 0.48)	0.2310

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-02-01-01-b-eff-mmrmqs-c30-itts-cl.rtf

Table 14.2.6.2.1.1.b:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Pain									
Cycle 4	69		1.47 (2.54)	51		9.39 (2.94)	-7.92 (-15.54, -0.30)	-0.35 (-0.69, -0.01)	0.0419
Cycle 6	50		-1.10 (2.60)	25		7.40 (3.35)	-8.50 (-16.89, -0.12)	-0.39 (-0.77, -0.00)	0.0470
Overall Treatment Effect	123	20.31 (20.91)	0.67 (1.59)	120	22.43 (26.75)	4.67 (1.83)	-4.00 (-8.68, 0.68)	-0.26 (-0.57, 0.05)	0.0930

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-02-01-01-b-eff-mmrmqs-c30-itts-cl.rtf

Table 14.2.6.2.1.1.b:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Dyspnoea									
Cycle 4	69		1.92 (2.48)	51		4.30 (2.88)	-2.38 (-9.82, 5.06)	-0.11 (-0.46, 0.24)	0.5275
Cycle 6	50		3.45 (2.83)	25		7.11 (3.81)	-3.66 (-13.05, 5.72)	-0.17 (-0.60, 0.26)	0.4392
Overall Treatment Effect	122	13.91 (18.99)	2.57 (1.56)	120	15.04 (21.50)	4.33 (1.80)	-1.76 (-6.31, 2.79)	-0.12 (-0.44, 0.19)	0.4464

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-02-01-01-b-eff-mmrmqs-c30-itts-cl.rtf

Table 14.2.6.2.1.1.b:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Insomnia									
Cycle 4	69		-0.15 (2.36)	51		3.43 (2.74)	-3.58 (-10.63, 3.47)	-0.18 (-0.53, 0.17)	0.3172
Cycle 6	50		-0.23 (2.70)	25		-1.56 (3.63)	1.32 (-7.59, 10.24)	0.06 (-0.37, 0.49)	0.7682
Overall Treatment Effect	122	16.27 (22.56)	0.18 (1.57)	120	21.30 (24.73)	0.71 (1.76)	-0.53 (-4.99, 3.94)	-0.04 (-0.34, 0.27)	0.8154

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-02-01-01-b-eff-mmrmqs-c30-itts-cl.rtf

Table 14.2.6.2.1.1.b:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Appetite loss									
Cycle 4	69		0.86 (2.59)	50		8.23 (2.99)	-7.37 (-15.01, 0.28)	-0.32 (-0.65, 0.01)	0.0589
Cycle 6	49		-1.07 (3.15)	25		7.63 (4.17)	-8.71 (-18.96, 1.55)	-0.36 (-0.78, 0.06)	0.0951
Overall Treatment Effect	123	19.79 (24.90)	-0.15 (1.91)	119	17.93 (26.18)	3.45 (2.18)	-3.60 (-9.10, 1.90)	-0.20 (-0.50, 0.10)	0.1975

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-02-01-01-b-eff-mmrmqs-c30-itts-cl.rtf

Table 14.2.6.2.1.1.b:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Constipation									
Cycle 4	69		3.93 (2.53)	51		0.17 (2.93)	3.76 (-3.83, 11.35)	0.17 (-0.17, 0.51)	0.3290
Cycle 6	50		0.19 (2.65)	25		3.16 (3.52)	-2.97 (-11.64, 5.71)	-0.14 (-0.54, 0.26)	0.4989
Overall Treatment Effect	123	14.06 (23.14)	1.52 (1.44)	120	14.79 (22.63)	-0.39 (1.68)	1.91 (-2.32, 6.15)	0.14 (-0.17, 0.46)	0.3742

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-02-01-01-b-eff-mmrmqs-c30-itts-cl.rtf

Table 14.2.6.2.1.1.b:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Diarrhea									
Cycle 4	69		-2.15 (1.53)	51		0.33 (1.77)	-2.48 (-7.06, 2.11)	-0.19 (-0.54, 0.16)	0.2870
Cycle 6	50		2.92 (2.61)	25		5.72 (3.62)	-2.80 (-11.65, 6.05)	-0.15 (-0.61, 0.32)	0.5304
Overall Treatment Effect	123	7.81 (16.98)	-0.85 (1.05)	119	6.27 (15.43)	1.79 (1.26)	-2.64 (-5.81, 0.54)	-0.28 (-0.63, 0.06)	0.1027

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-02-01-01-b-eff-mmrmqs-c30-itts-cl.rtf

Table 14.2.6.2.1.1.b:
EORTC QLQ-C30: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Financial difficulties									
Cycle 4	69		-4.46 (2.60)	51		-1.18 (2.98)	-3.28 (-10.98, 4.41)	-0.14 (-0.47, 0.19)	0.4003
Cycle 6	50		-5.43 (3.00)	25		-2.29 (3.89)	-3.14 (-12.79, 6.50)	-0.13 (-0.52, 0.26)	0.5198
Overall Treatment Effect	123	23.70 (30.21)	-4.79 (1.84)	119	26.32 (29.03)	-0.71 (2.06)	-4.07 (-9.35, 1.21)	-0.23 (-0.53, 0.07)	0.1297

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. For global health status or functional scales, positive changes from baseline are favorable; for symptom scales, negative changes are favorable.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. For global health status or functional scales, positive differences favor tislelizumab arm; for symptom scales, negative differences favor tislelizumab arm.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-02-01-01-b-eff-mmrmqs-c30-itts-cl.rtf

Table 14.2.6.2.1.2:
Analyses of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Global Health Status/QOL	256	59 (23.0)	NR (NE, NE)	256	47 (18.4)	NR (NE, NE)	0.982 (0.666, 1.448)	0.9249
Physical Functioning	256	47 (18.4)	NR (NE, NE)	256	52 (20.3)	10.0 (4.5, NE)	0.669 (0.448, 0.998)	0.0460
Role Functioning	256	64 (25.0)	NR (NE, NE)	256	62 (24.2)	10.0 (3.3, NE)	0.787 (0.550, 1.124)	0.1811
Emotional Functioning	256	31 (12.1)	NR (NE, NE)	256	35 (13.7)	NR (NE, NE)	0.689 (0.422, 1.125)	0.1319
Cognitive Functioning	256	51 (19.9)	NR (NE, NE)	256	41 (16.0)	10.2 (10.0, NE)	0.976 (0.644, 1.479)	0.9075
Social Functioning	256	55 (21.5)	NR (NE, NE)	256	48 (18.8)	NR (4.7, NE)	0.919 (0.622, 1.358)	0.6691
Fatigue	256	88 (34.4)	9.1 (3.5, NE)	256	83 (32.4)	3.1 (2.1, 3.8)	0.770 (0.565, 1.050)	0.0912
Nausea and Vomiting	256	42 (16.4)	NR (NE, NE)	256	35 (13.7)	NR (NE, NE)	0.919 (0.583, 1.450)	0.7171

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-tte-qlq.sas 05JUN2024 19:37 t-14-02-06-02-01-02-eff-tte-qlq-c30-itt-cl.rtf

Table 14.2.6.2.1.2:
Analyses of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Pain	256	61 (23.8)	NR (NE, NE)	256	53 (20.7)	10.0 (3.8, NE)	0.900 (0.619, 1.308)	0.5754
Dyspnoea	256	41 (16.0)	NR (NE, NE)	256	38 (14.8)	NR (10.2, NE)	0.846 (0.541, 1.324)	0.4606
Insomnia	256	47 (18.4)	NR (NE, NE)	256	26 (10.2)	NR (NE, NE)	1.423 (0.876, 2.309)	0.1475
Appetite Loss	256	47 (18.4)	NR (26.3, NE)	256	40 (15.6)	NR (NE, NE)	0.888 (0.577, 1.367)	0.5870
Constipation	256	37 (14.5)	NR (NE, NE)	256	23 (9.0)	NR (NE, NE)	1.338 (0.788, 2.270)	0.2757
Diarrhea	256	14 (5.5)	NR (NE, NE)	256	23 (9.0)	NR (NE, NE)	0.397 (0.202, 0.782)	0.0055
Financial Difficulties	256	25 (9.8)	NR (NE, NE)	256	28 (10.9)	NR (NE, NE)	0.722 (0.417, 1.249)	0.2377

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-tte-qlq.sas 05JUN2024 19:37 t-14-02-06-02-01-02-eff-tte-qlq-c30-itt-cl.rtf

Table 14.2.6.2.1.2.b:
Analyses of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Global Health Status/QOL	139	32 (23.0)	NR (NE, NE)	138	30 (21.7)	NR (NE, NE)	0.956 (0.579, 1.578)	0.8592
Physical Functioning	139	26 (18.7)	NR (NE, NE)	138	34 (24.6)	10.0 (3.5, NE)	0.637 (0.381, 1.066)	0.0818
Role Functioning	139	36 (25.9)	NR (NE, NE)	138	42 (30.4)	4.9 (2.7, NE)	0.757 (0.482, 1.189)	0.2187
Emotional Functioning	139	20 (14.4)	NR (NE, NE)	138	23 (16.7)	NR (NE, NE)	0.760 (0.416, 1.389)	0.3678
Cognitive Functioning	139	31 (22.3)	NR (9.1, NE)	138	27 (19.6)	NR (10.0, NE)	0.973 (0.578, 1.637)	0.9170
Social Functioning	139	25 (18.0)	NR (NE, NE)	138	31 (22.5)	NR (4.7, NE)	0.714 (0.421, 1.211)	0.2049
Fatigue	139	54 (38.8)	3.7 (2.8, 26.3)	138	50 (36.2)	2.3 (1.7, 3.8)	0.904 (0.610, 1.341)	0.6113
Nausea and Vomiting	139	26 (18.7)	NR (NE, NE)	138	15 (10.9)	NR (NE, NE)	1.538 (0.810, 2.918)	0.1833

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-tte-qlq.sas 05JUN2024 19:37 t-14-02-06-02-01-02-b-eff-tte-qlq-c30-itts-cl.rtf

Table 14.2.6.2.1.2.b:
Analyses of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Pain	139	33 (23.7)	NR (11.8, NE)	138	30 (21.7)	10.0 (3.8, NE)	0.961 (0.583, 1.584)	0.8758
Dyspnoea	139	25 (18.0)	NR (NE, NE)	138	26 (18.8)	NR (3.8, NE)	0.826 (0.475, 1.437)	0.4961
Insomnia	139	26 (18.7)	NR (NE, NE)	138	18 (13.0)	NR (NE, NE)	1.296 (0.708, 2.373)	0.3912
Appetite Loss	139	28 (20.1)	NR (11.8, NE)	138	20 (14.5)	NR (NE, NE)	1.160 (0.646, 2.082)	0.6172
Constipation	139	21 (15.1)	NR (NE, NE)	138	11 (8.0)	NR (NE, NE)	1.999 (0.961, 4.157)	0.0570
Diarrhea	139	6 (4.3)	NR (NE, NE)	138	8 (5.8)	NR (NE, NE)	0.609 (0.210, 1.766)	0.3567
Financial Difficulties	139	16 (11.5)	NR (NE, NE)	138	14 (10.1)	NR (NE, NE)	1.080 (0.526, 2.215)	0.8329

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
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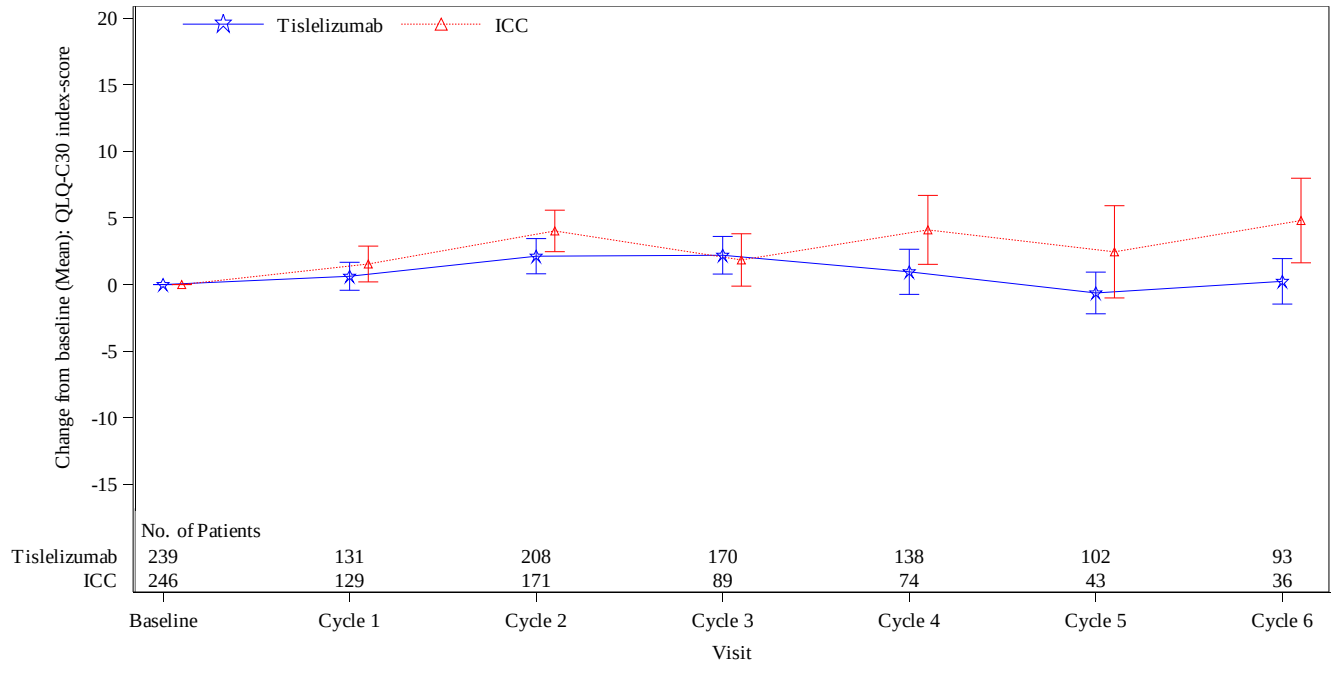
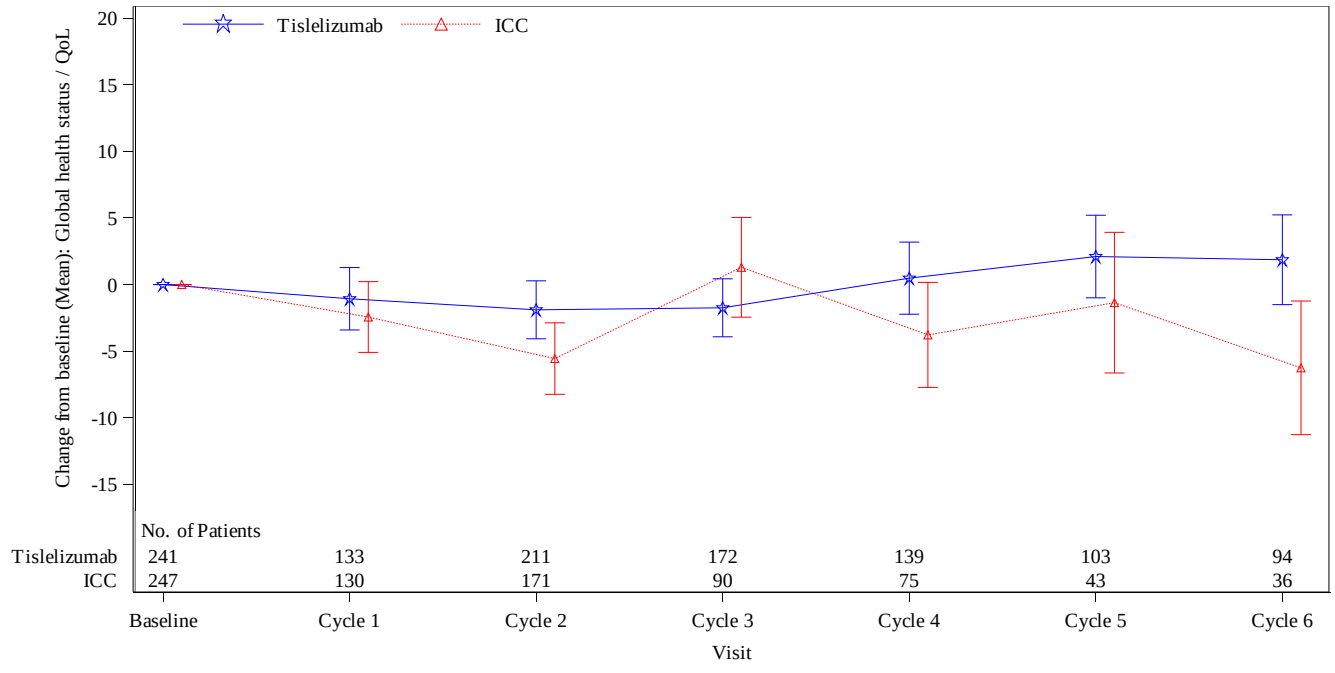
Figure 14.2.7.1:
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set



Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Datapoints represent means and 95% CI.
Increases in scores for global health status/QoL, physical functioning, role functioning, emotional functioning, cognitive functioning and social functioning are improvements, while increases in scores for index score, fatigue, nausea and vomiting, pain, dyspnoea, insomnia, appetite loss, constipation, diarrhea and financial difficulty are deteriorations for C30.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-series.sas 05JUN2024 17:48 f-14-02-07-01-series-c30-itt-cl.rtf

Figure 14.2.7.1:
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set



Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
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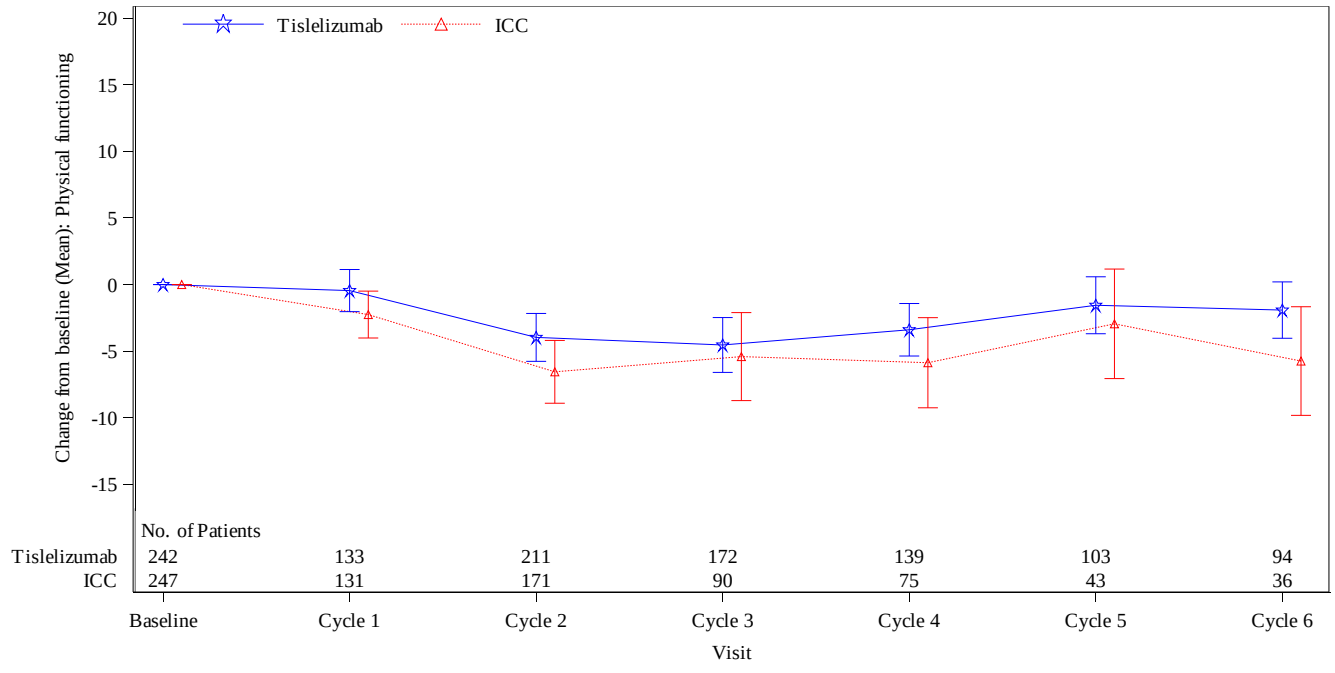
ITT Analysis Set



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Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
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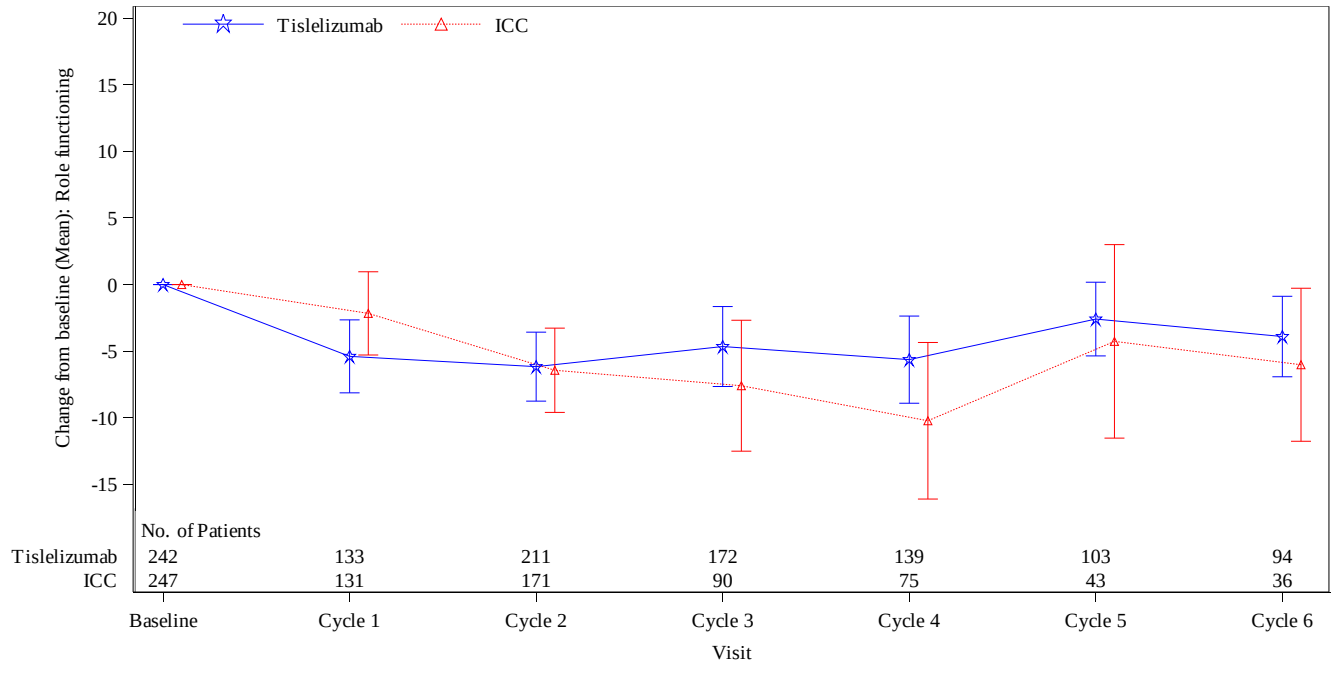
Figure 14.2.7.1:
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set



Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
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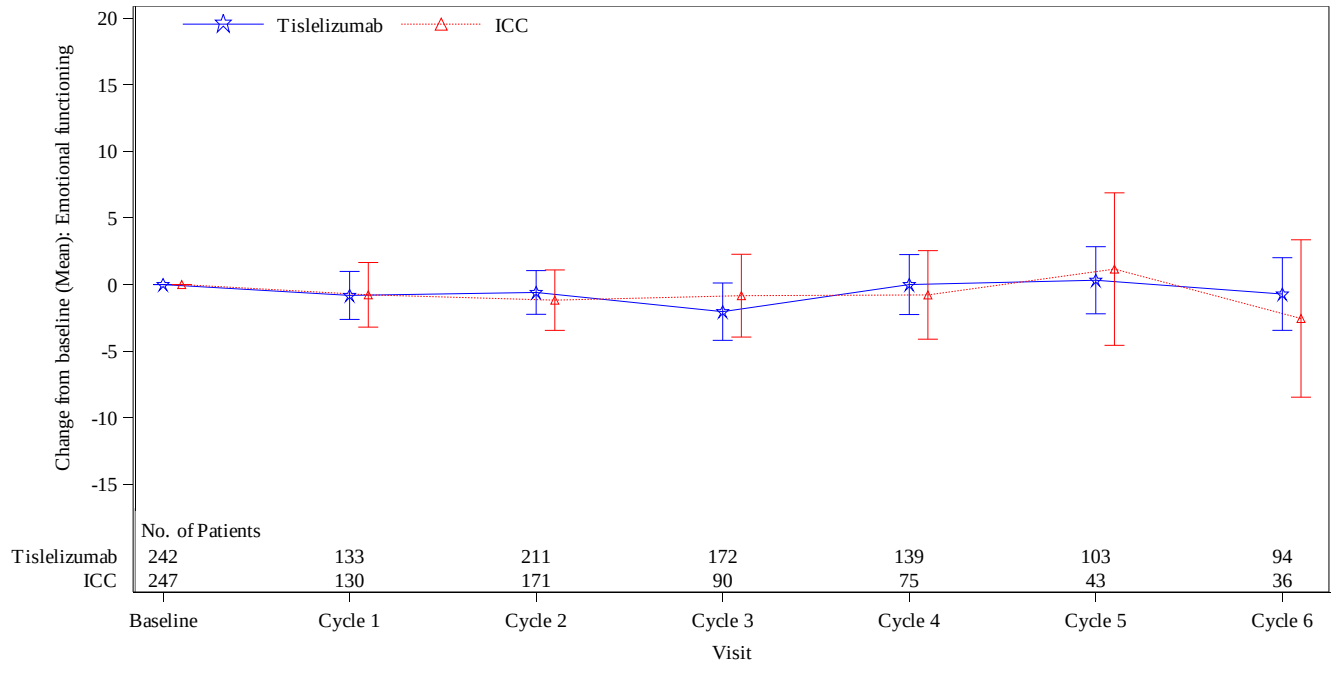
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set



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Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
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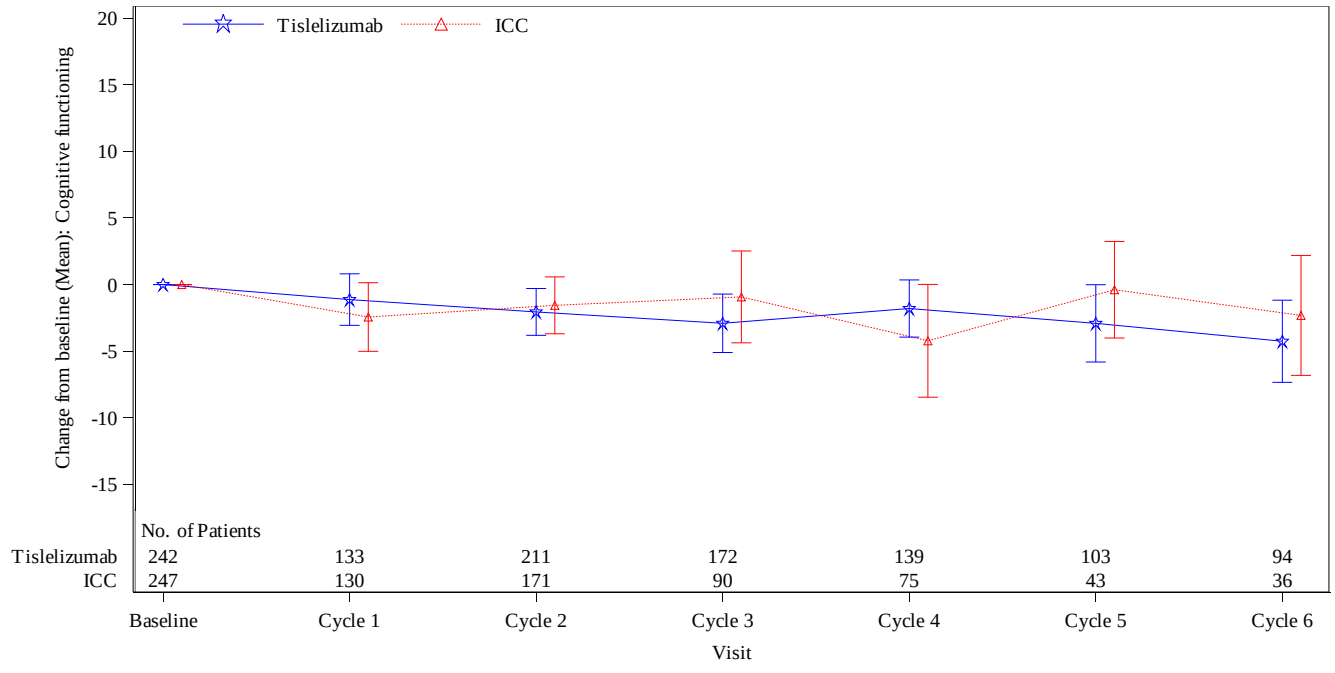

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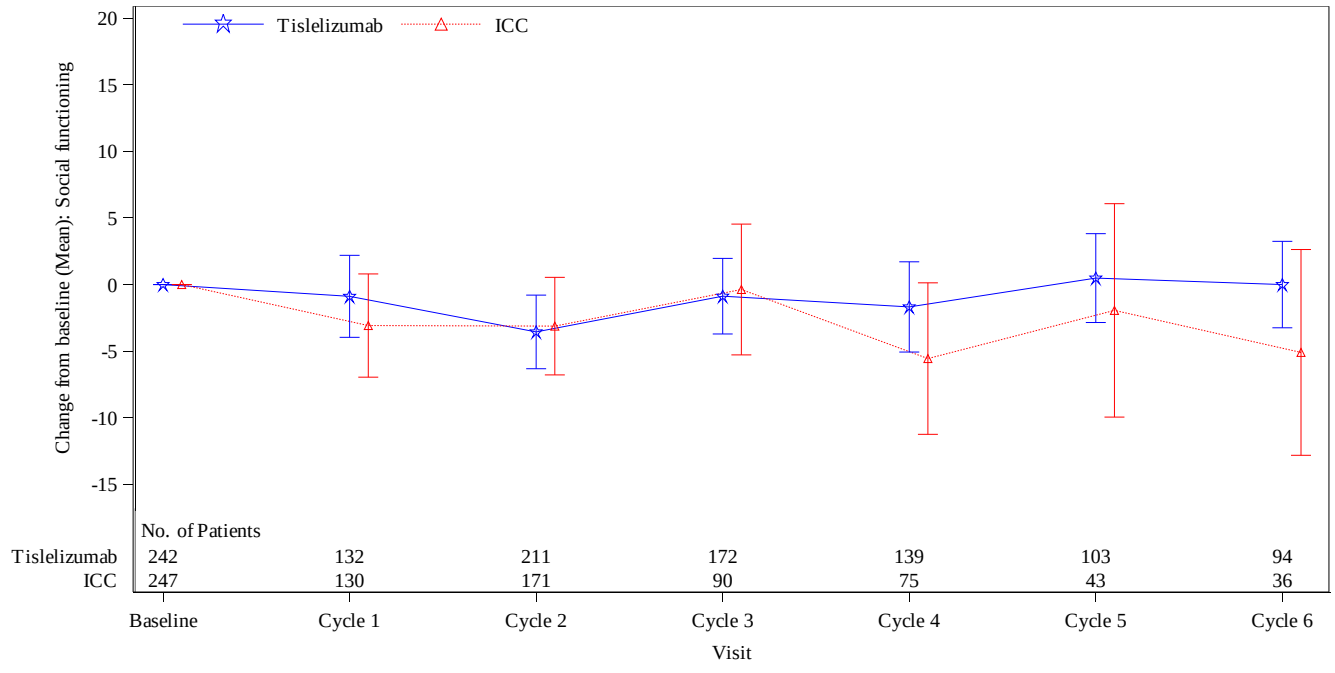

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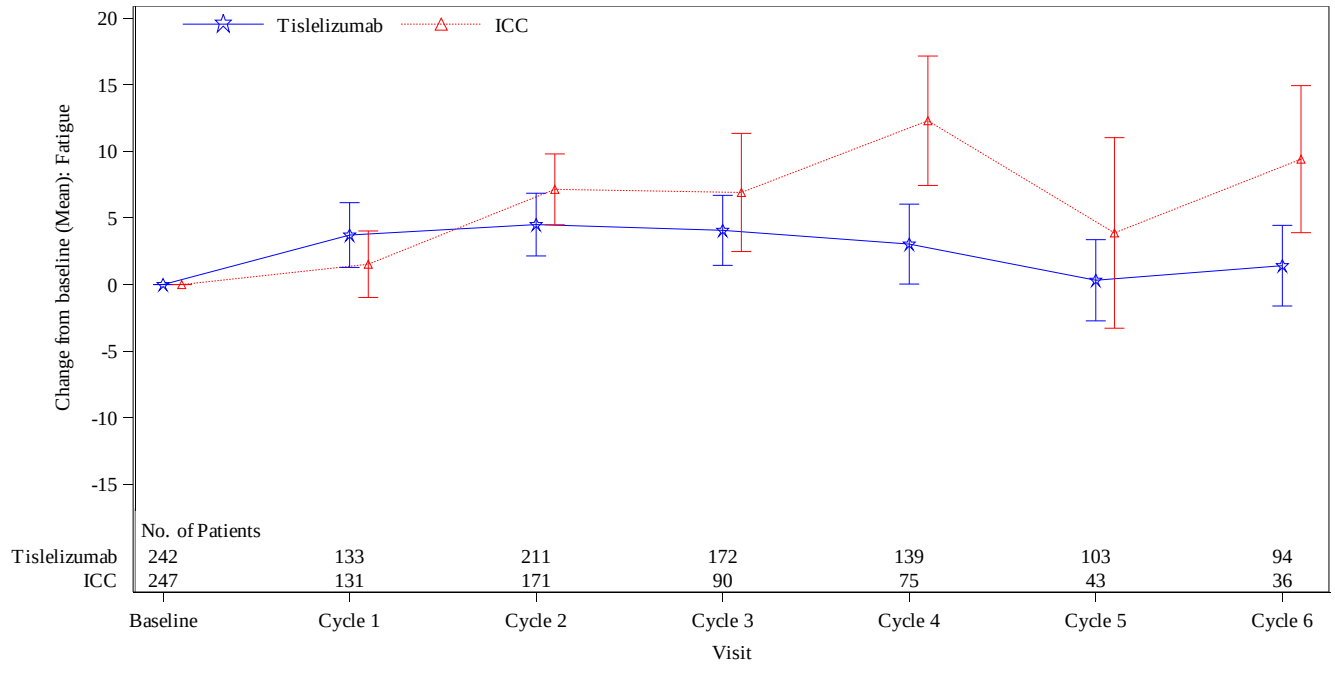

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ITT Analysis Set

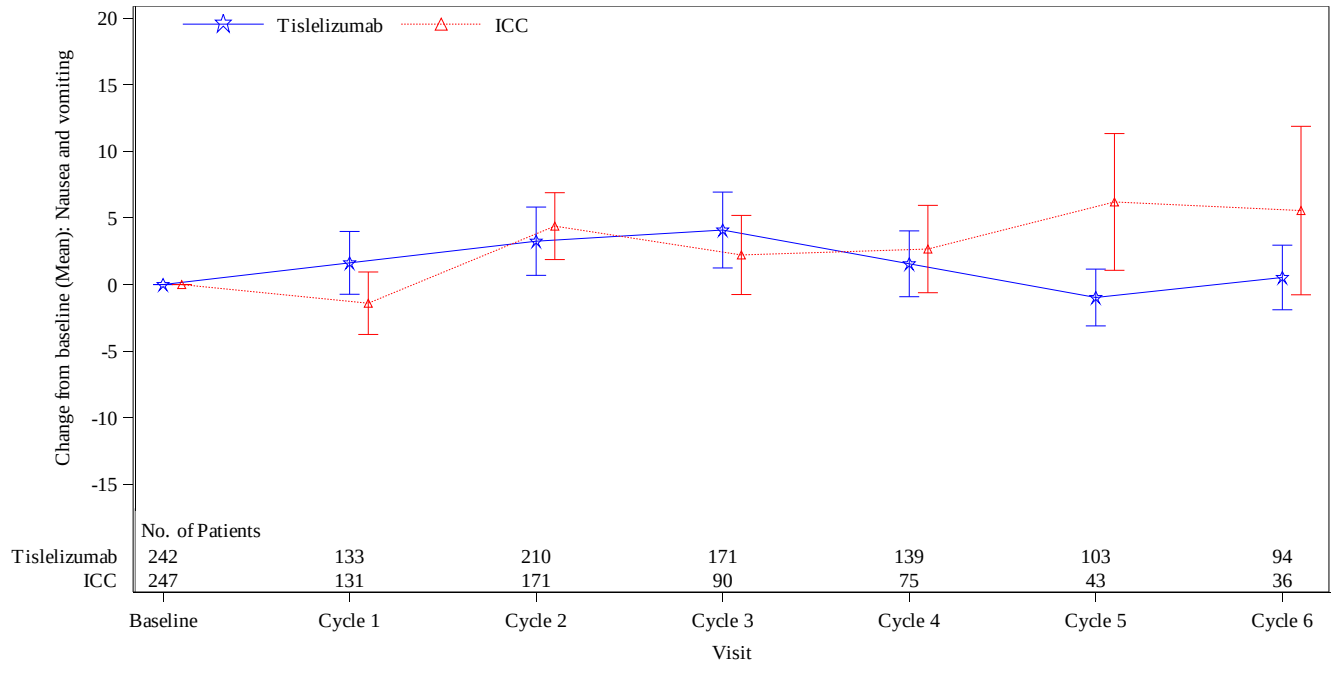

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Figure 14.2.7.1:
Summary of EORTC QLQ-C30 Scores by Visit
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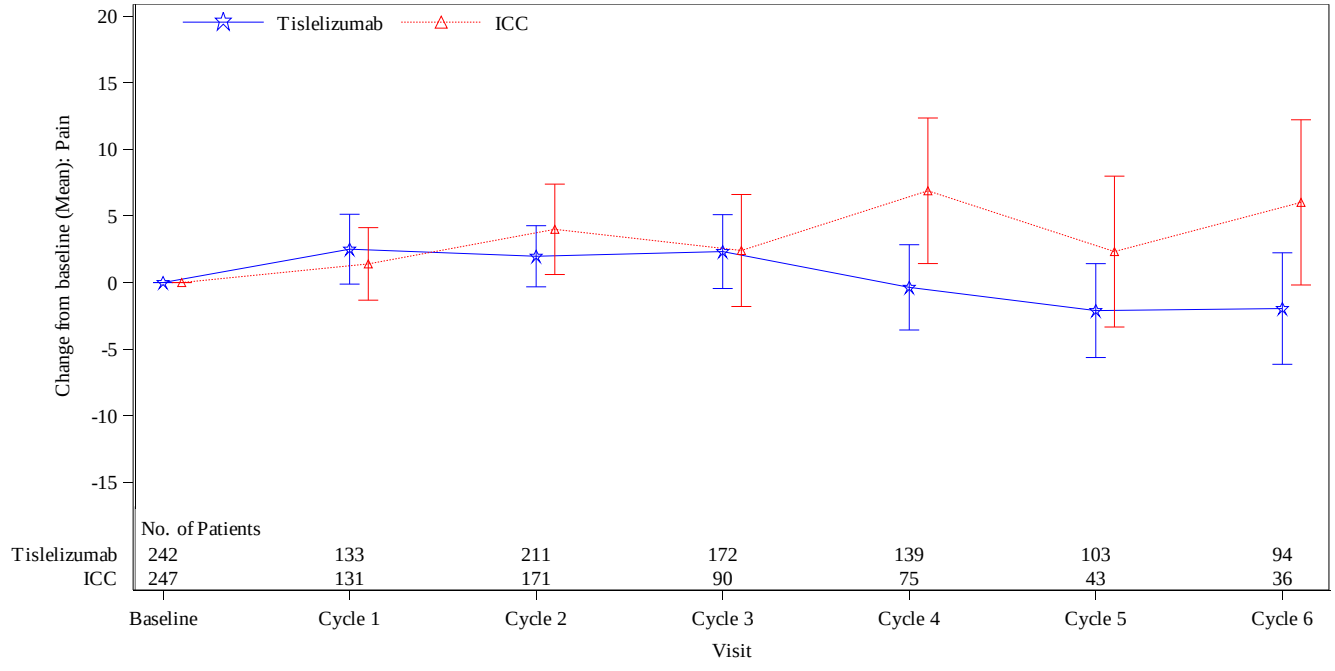

Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
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Summary of EORTC QLQ-C30 Scores by Visit
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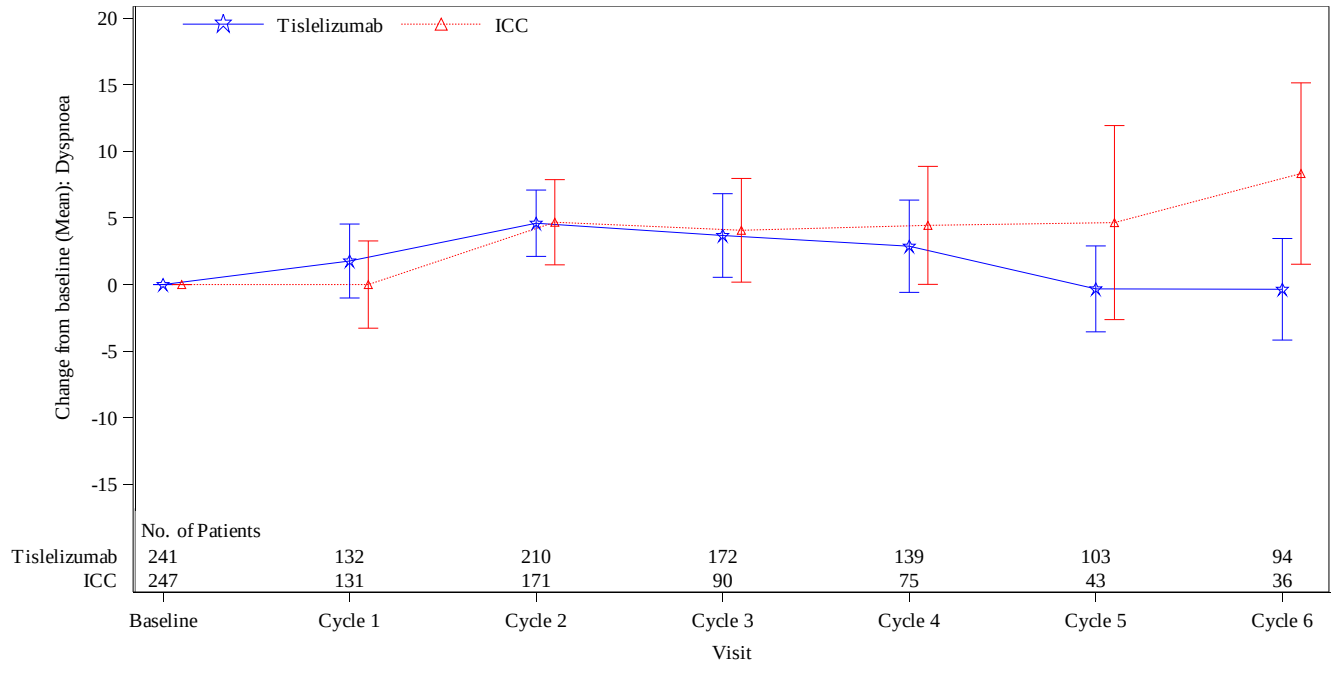

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Figure 14.2.7.1:
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set

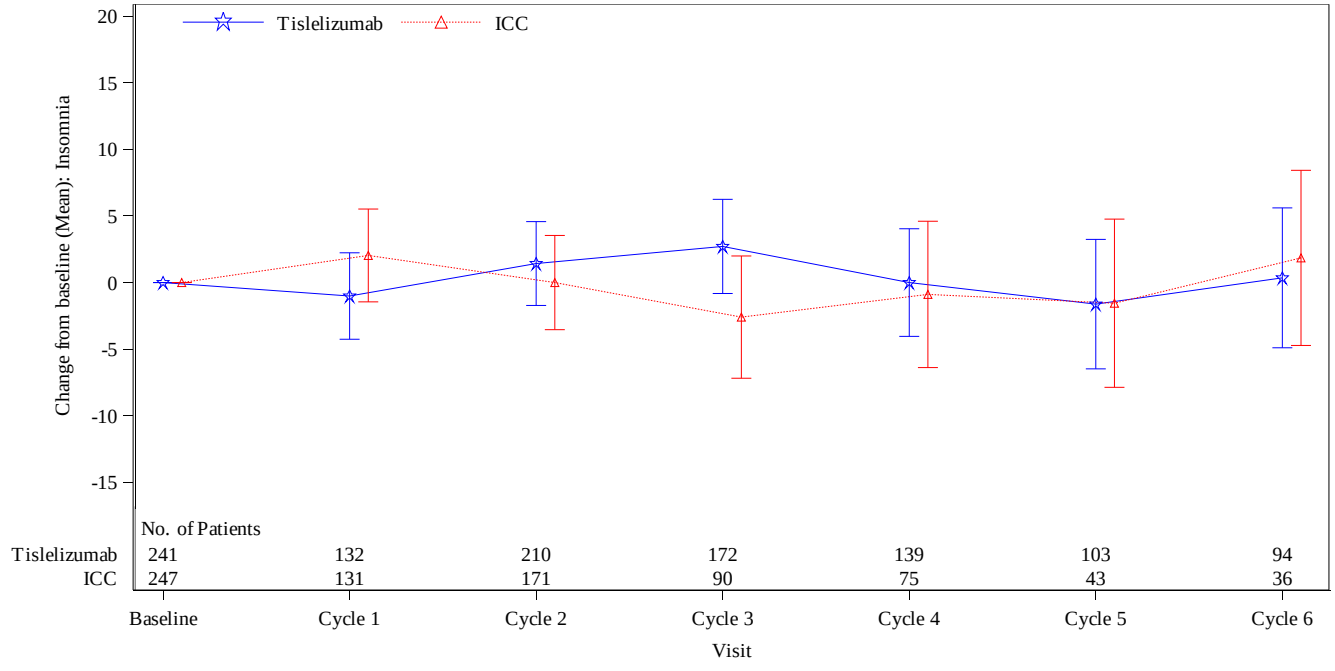

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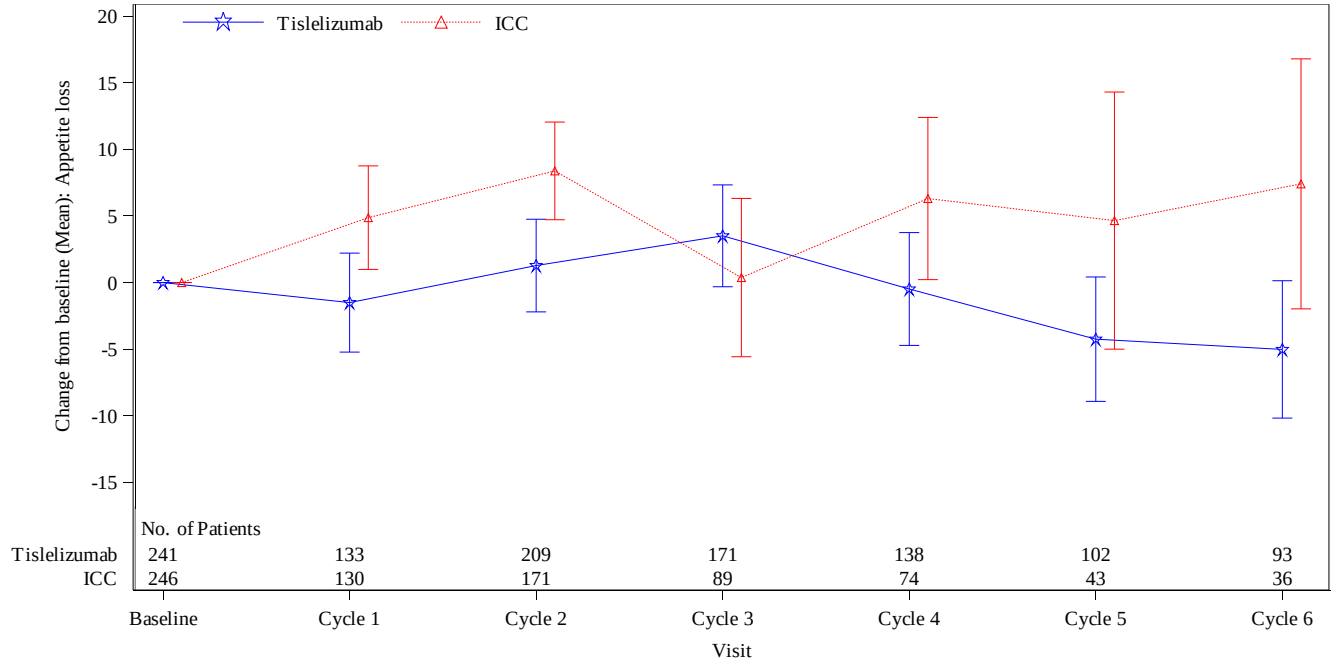
Figure 14.2.7.1:
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set



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Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
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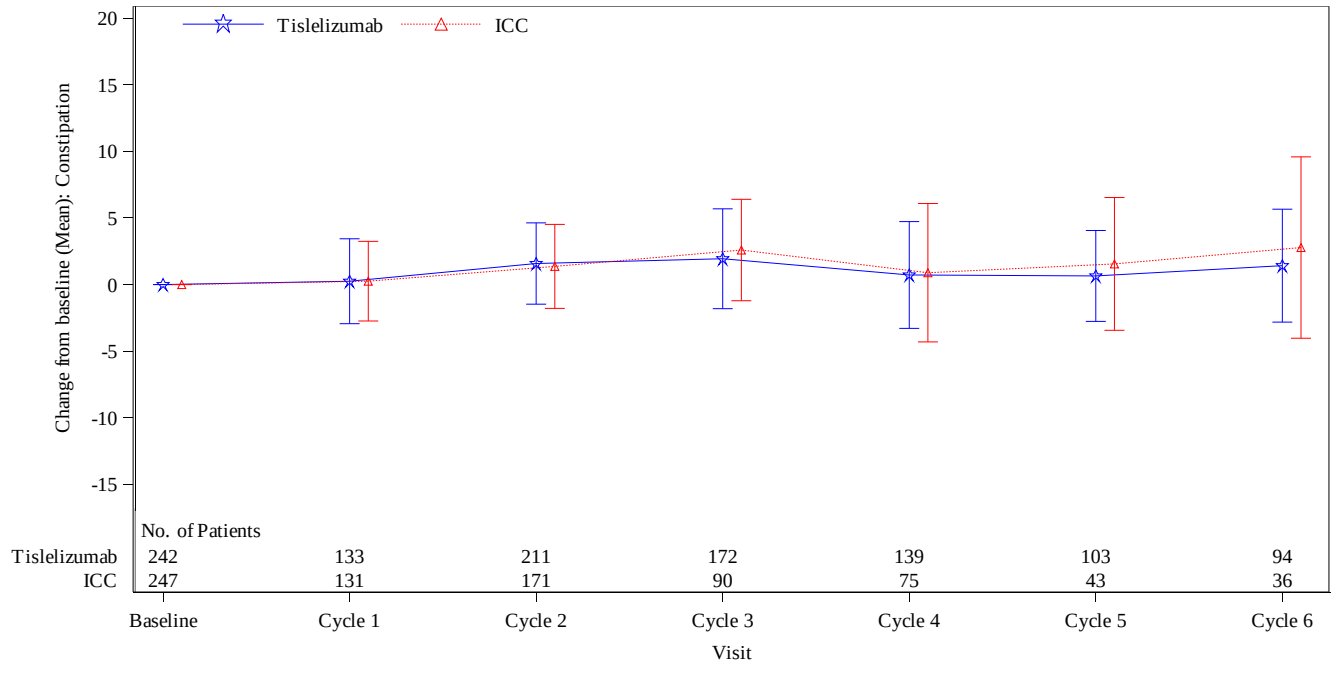
Figure 14.2.7.1:
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set



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Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
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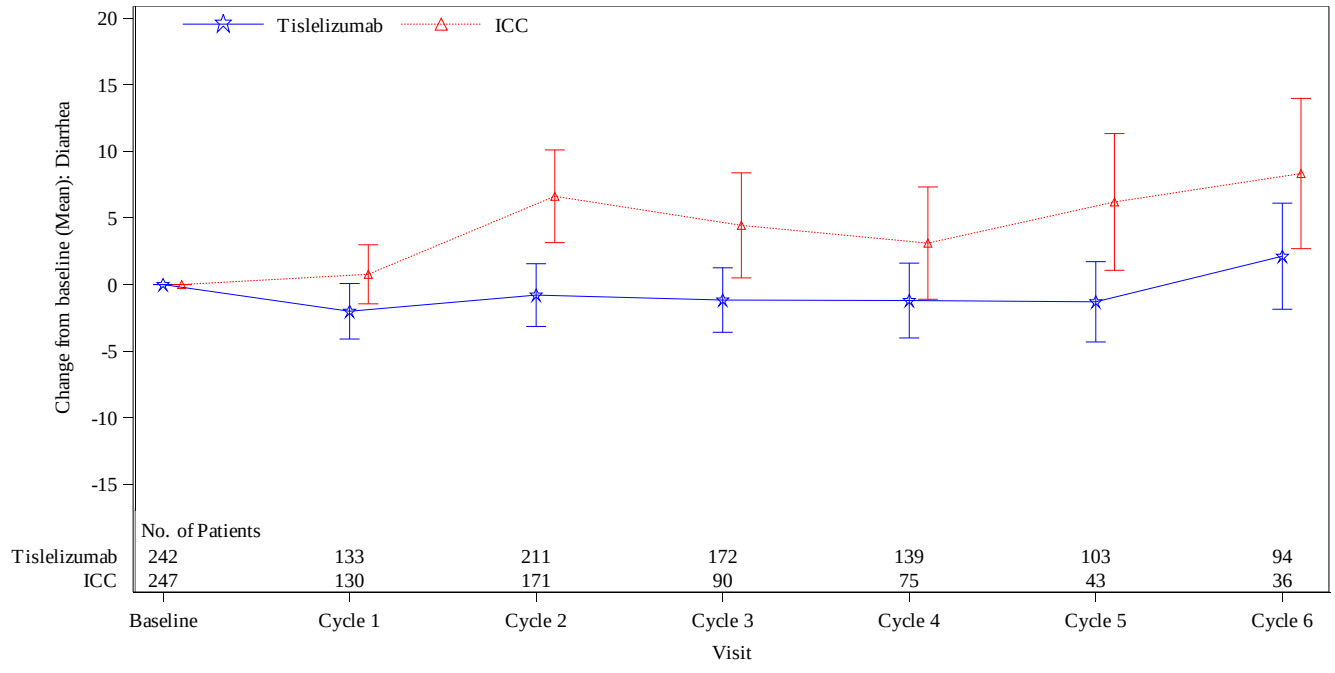
Figure 14.2.7.1:
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set



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Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
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Figure 14.2.7.1:
Summary of EORTC QLQ-C30 Scores by Visit
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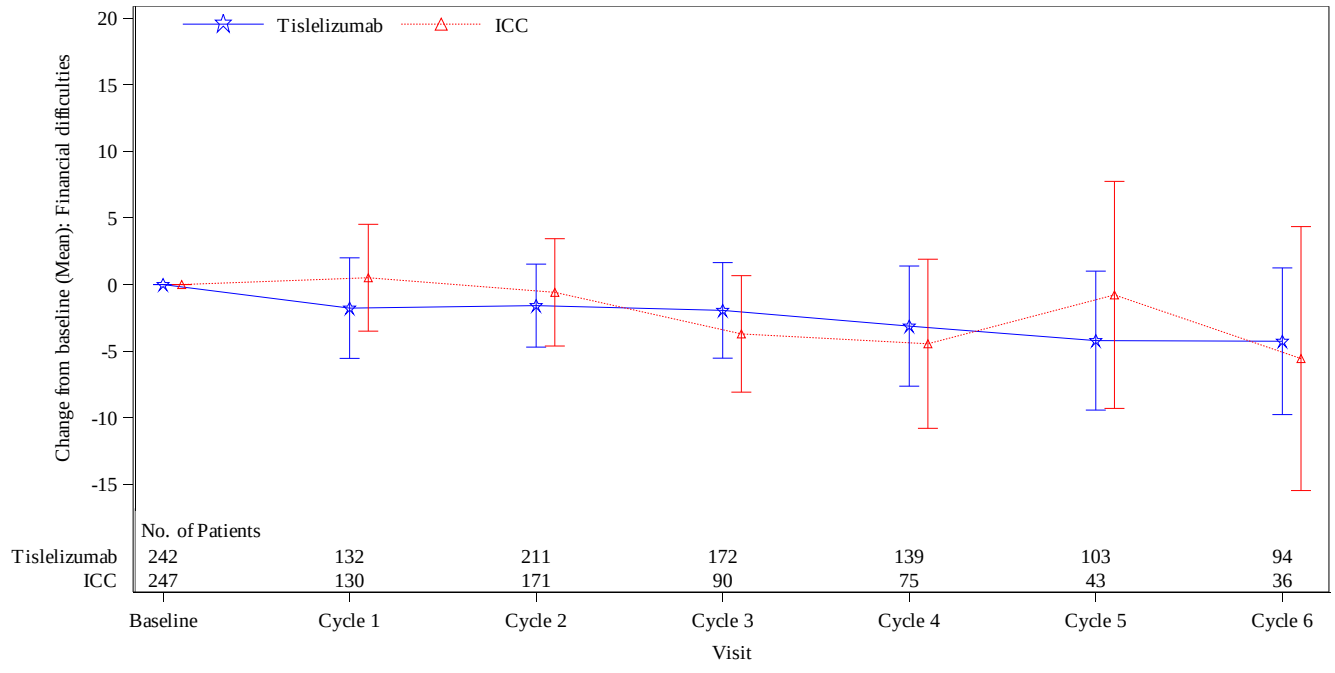

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Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
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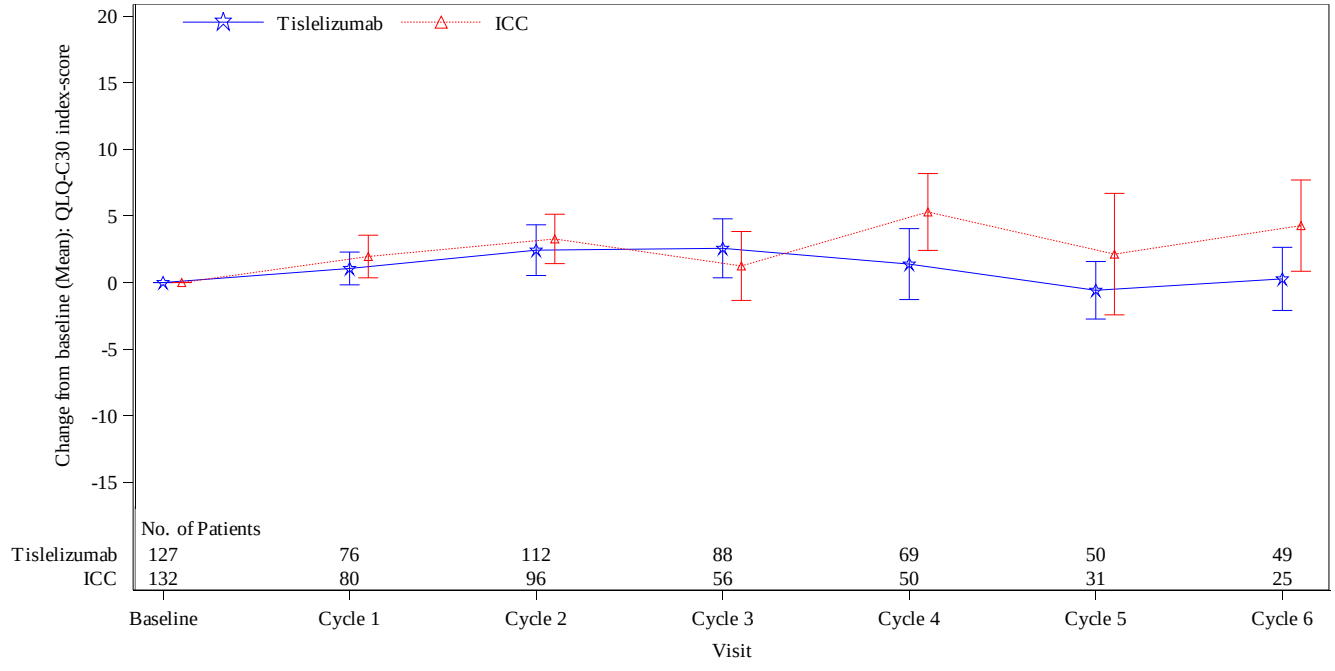
Figure 14.2.7.1.b:
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set - Subpopulation without Irinotecan



Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Datapoints represent means and 95% CI.
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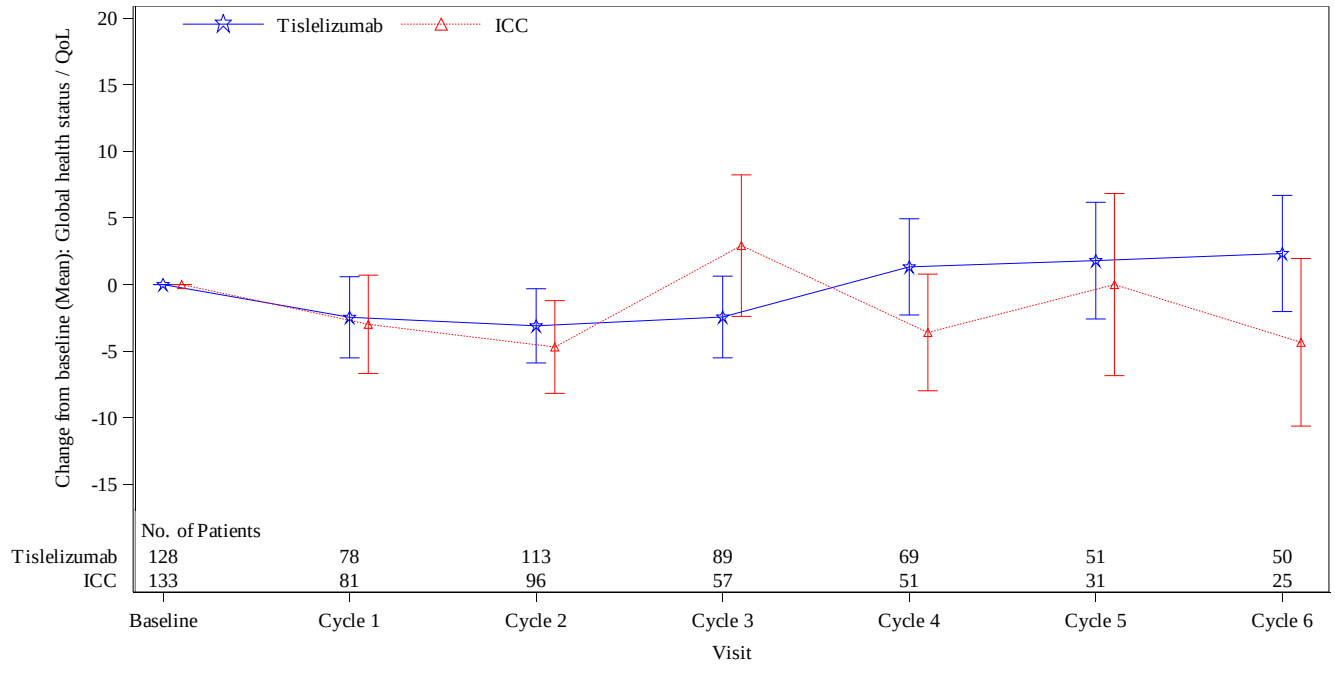
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-series.sas 05JUN2024 17:48 f-14-02-07-01-b-series-c30-itts-cl.rtf

Figure 14.2.7.1.b:
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set - Subpopulation without Irinotecan



Source: Listing 16.2.6.6.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Datapoints represent means and 95% CI.
Increases in scores for global health status/QoL, physical functioning, role functioning, emotional functioning, cognitive functioning and social functioning are improvements, while increases in scores for index score, fatigue, nausea and vomiting, pain, dyspnoea, insomnia, appetite loss, constipation, diarrhea and financial difficulty are deteriorations for C30.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-series.sas 05JUN2024 17:48 f-14-02-07-01-b-series-c30-itts-cl.rtf

Figure 14.2.7.1.b:
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set - Subpopulation without Irinotecan

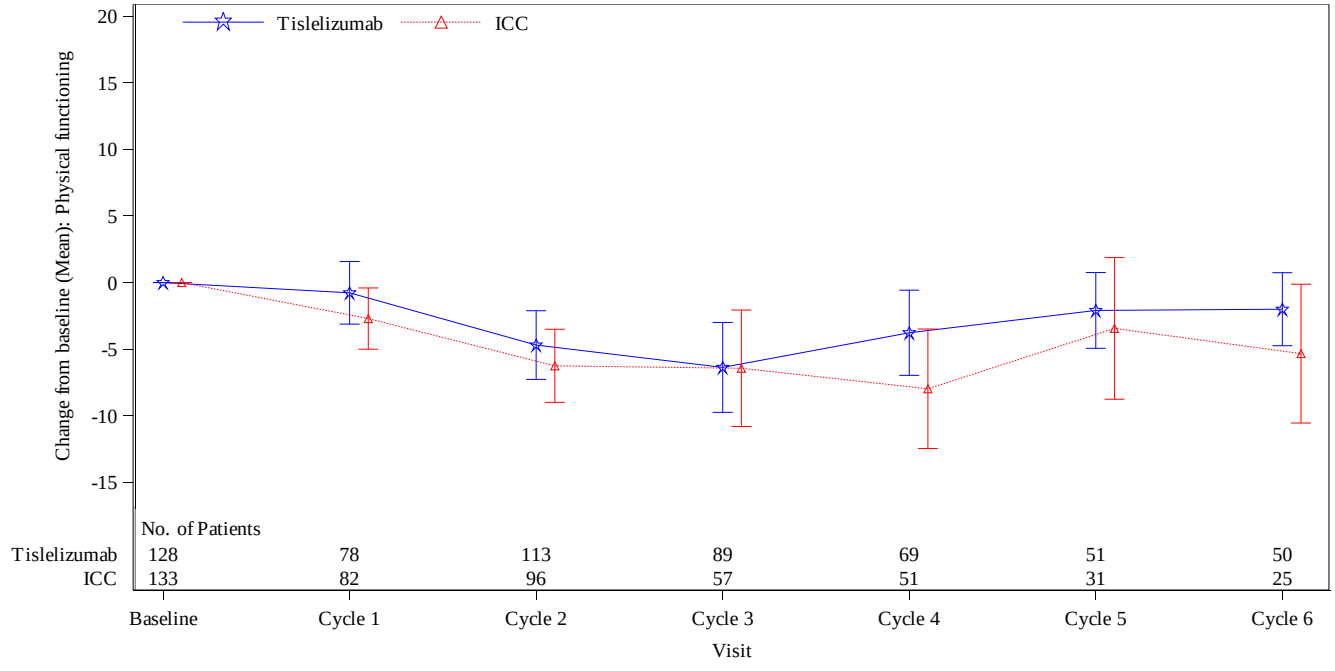


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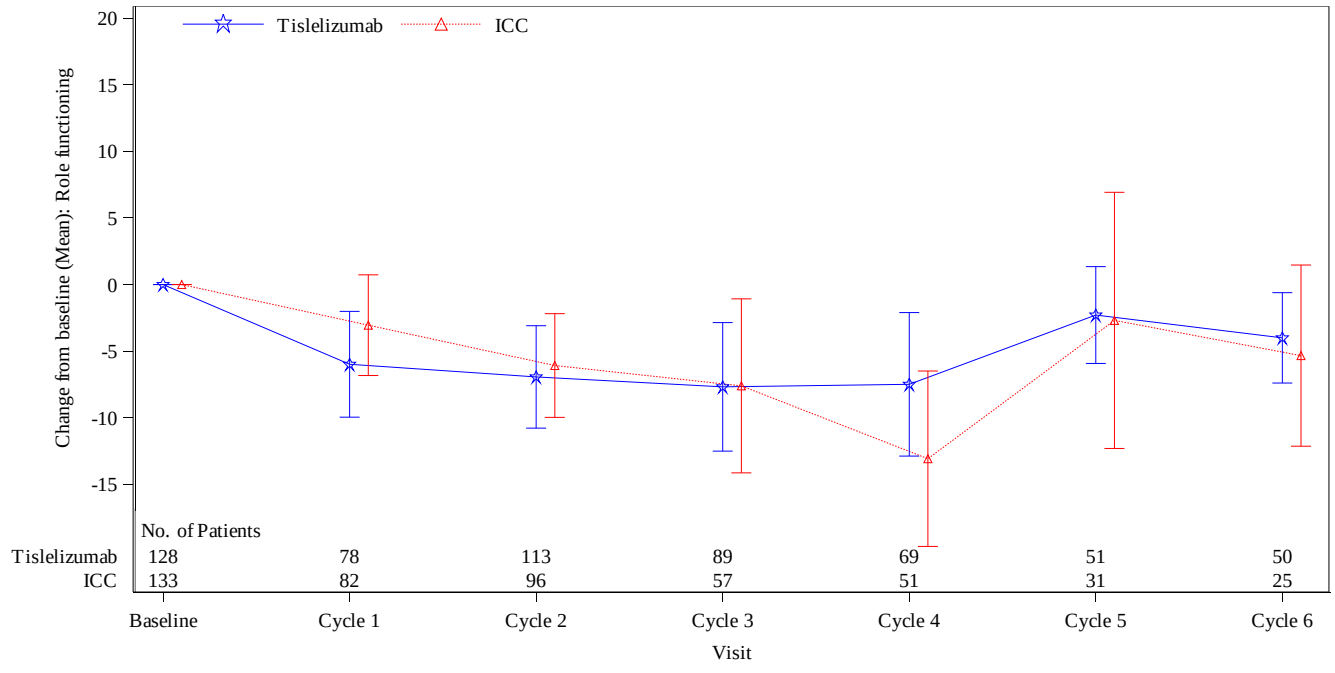
Figure 14.2.7.1.b:
Summary of EORTC QLQ-C30 Scores by Visit
ITT Analysis Set - Subpopulation without Irinotecan



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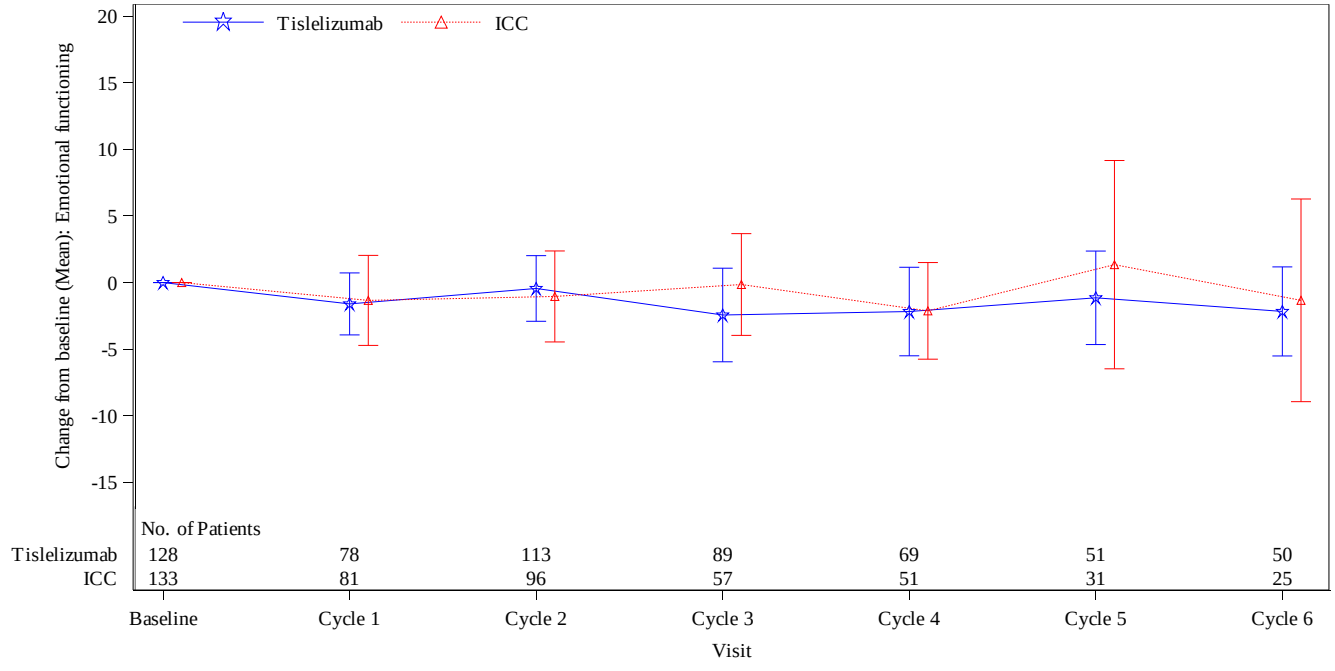

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Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
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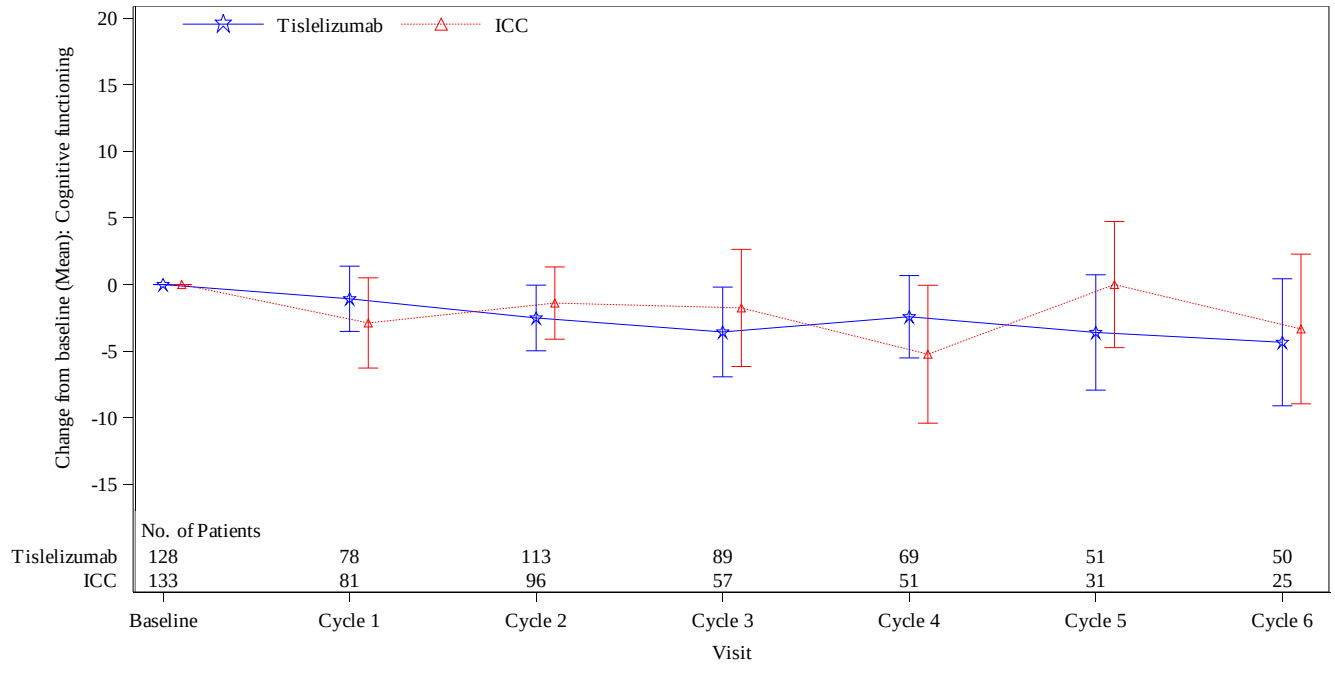
ITT Analysis Set - Subpopulation without Irinotecan



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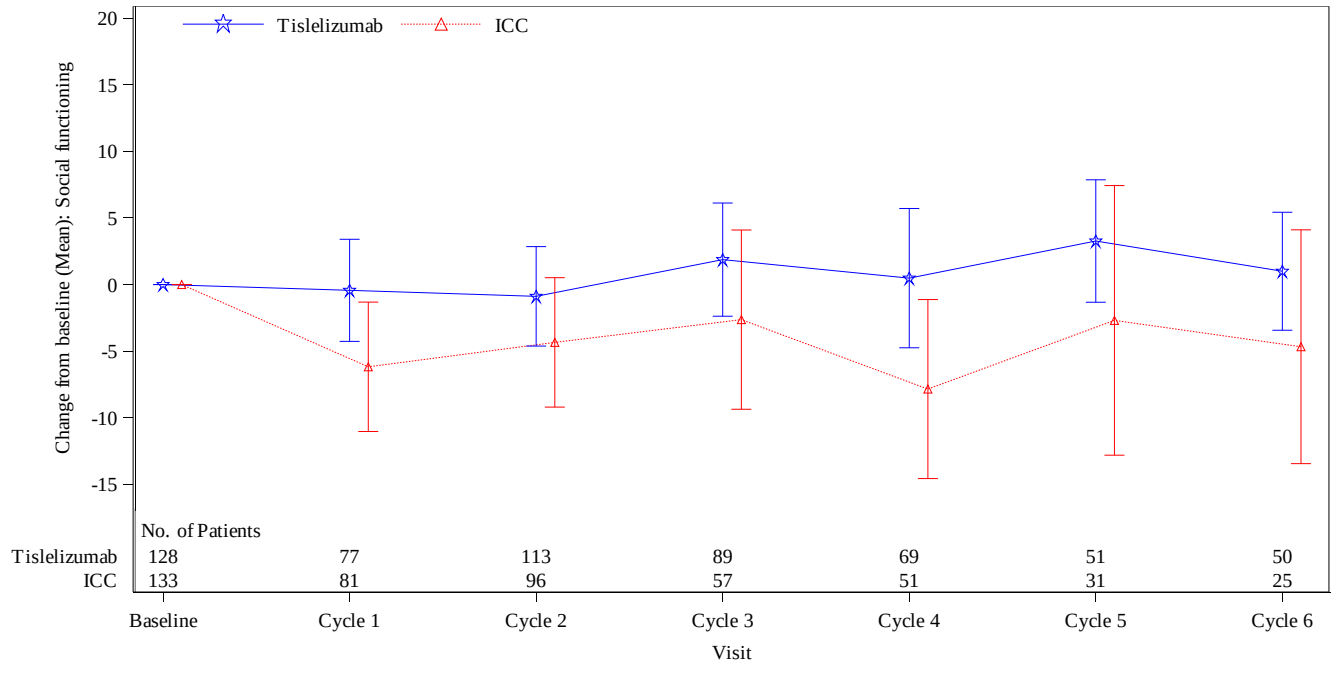

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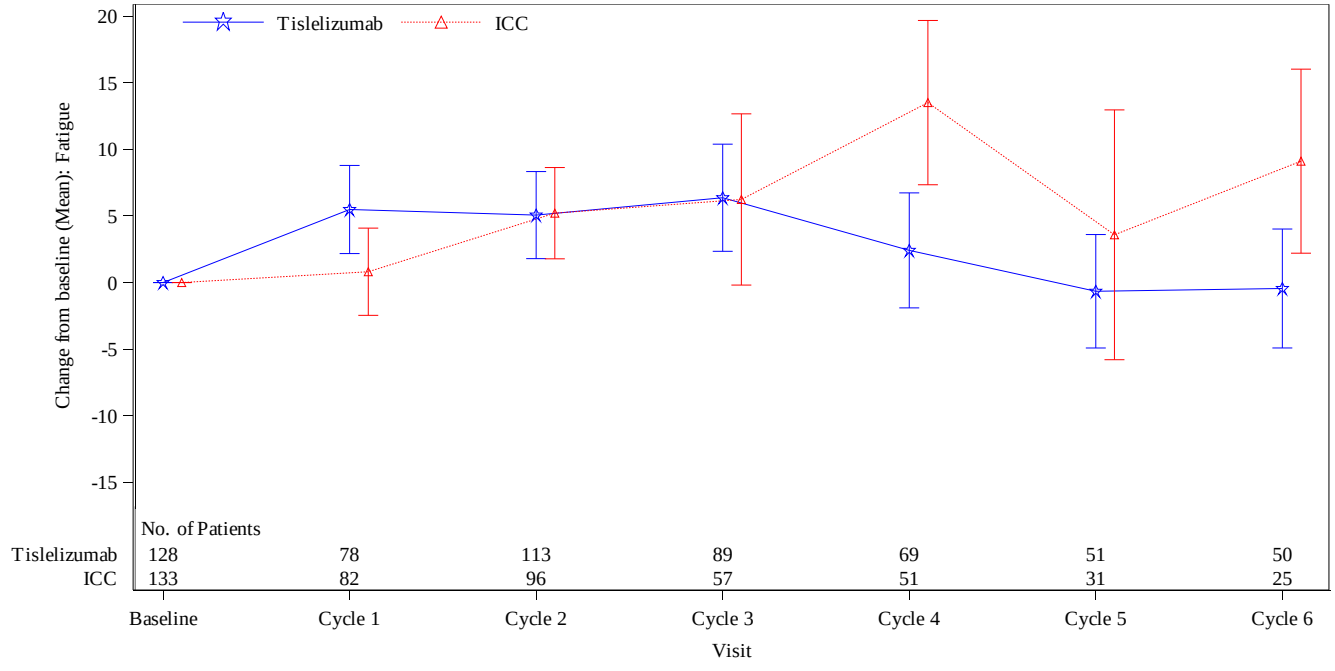

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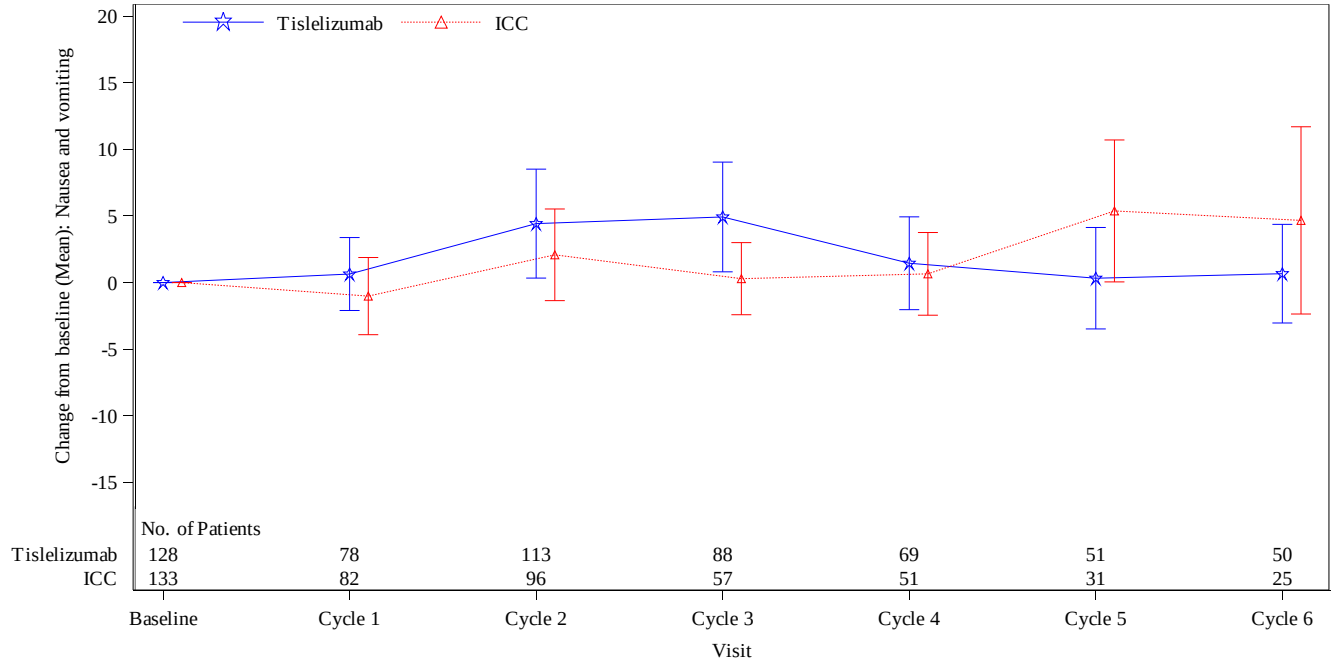

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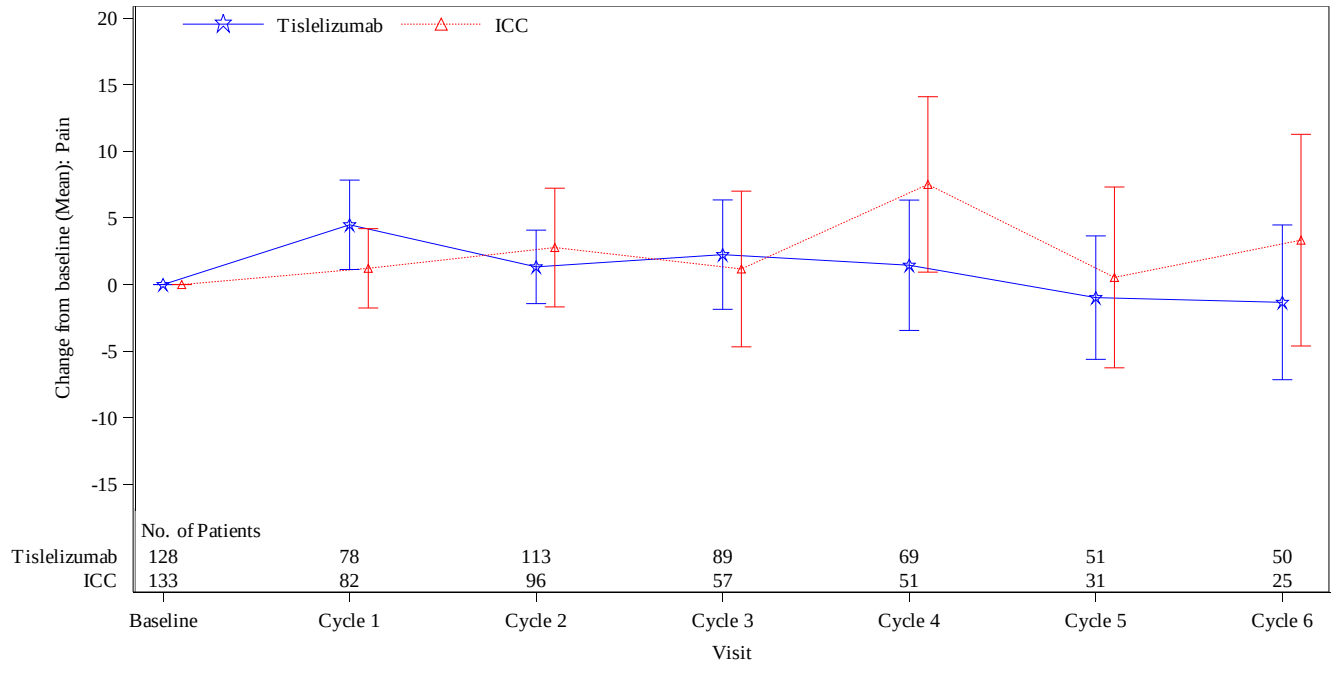

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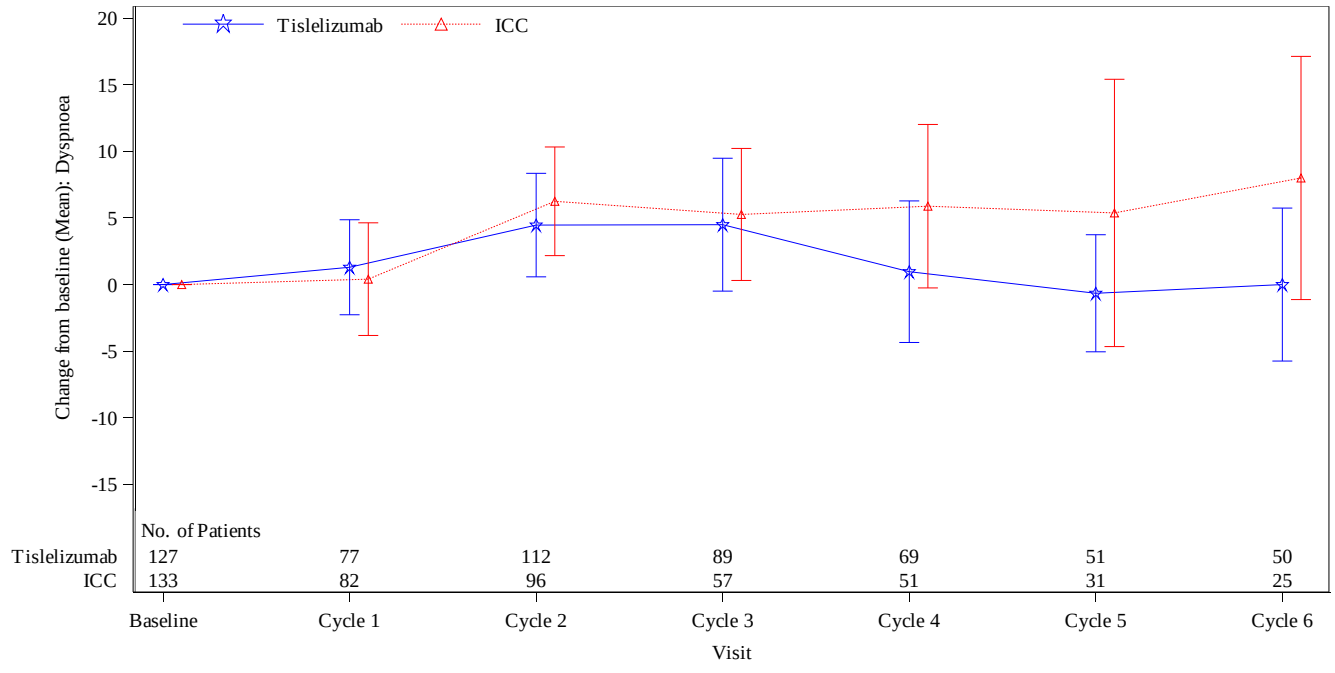

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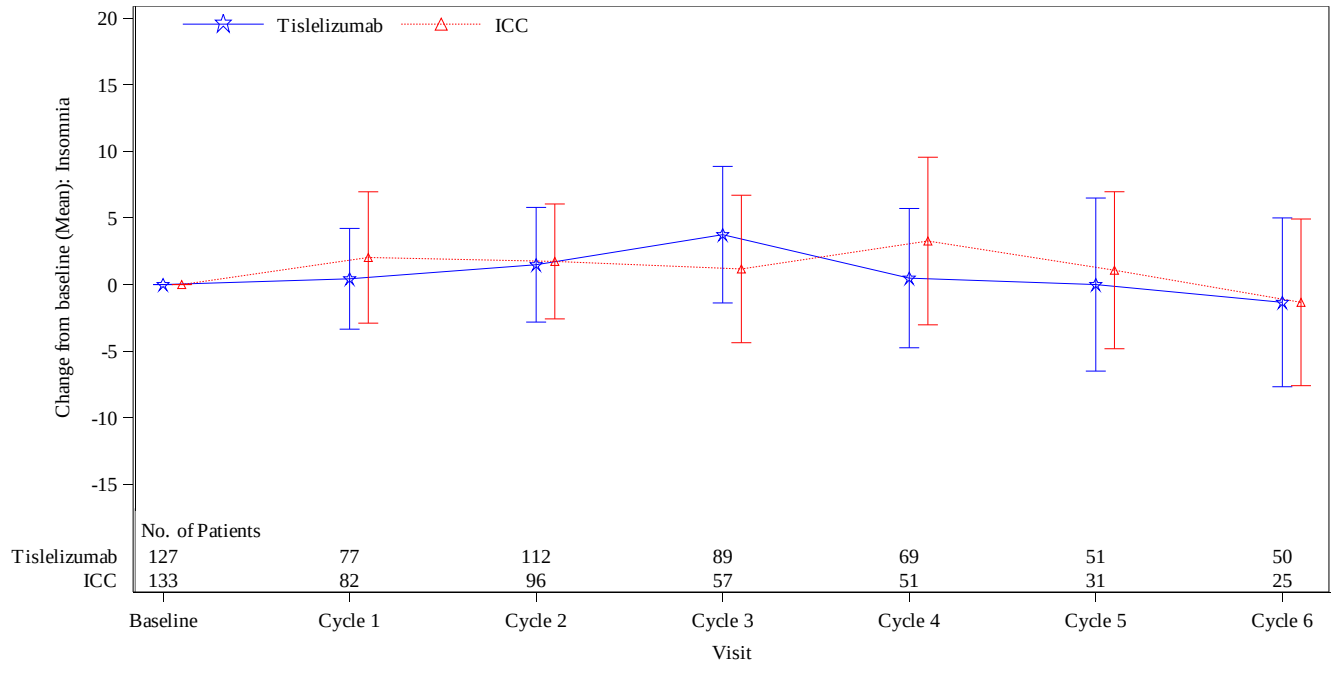

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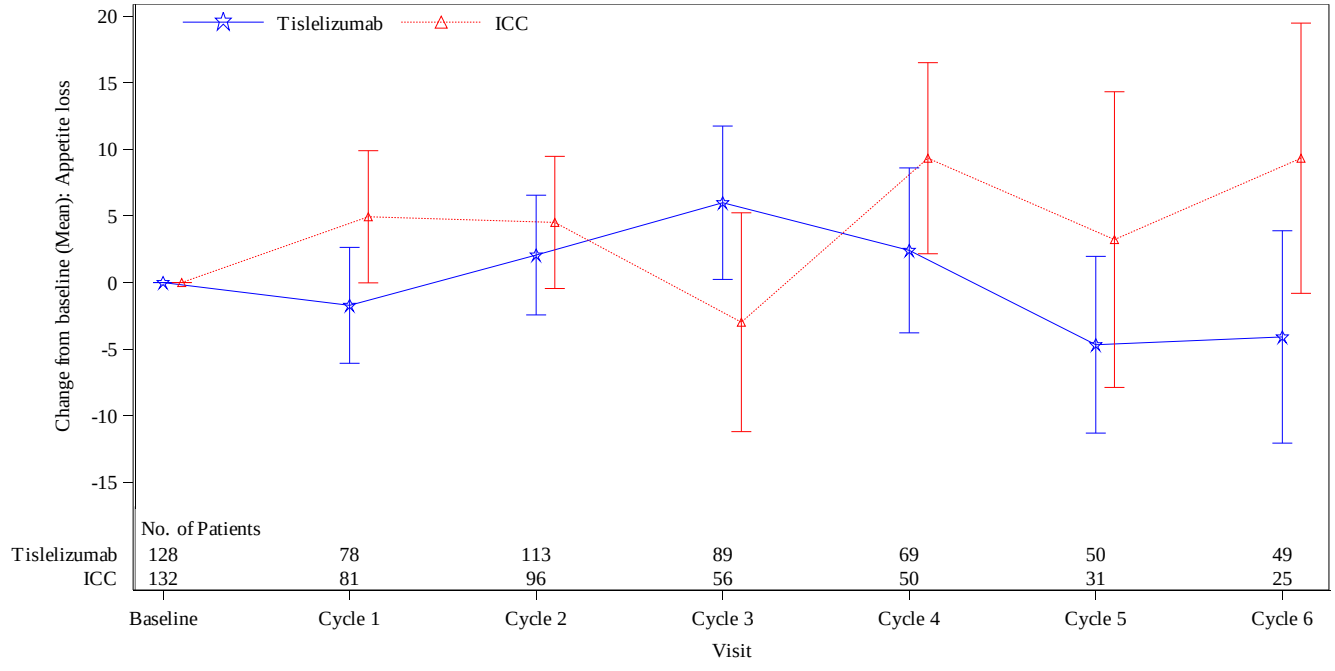

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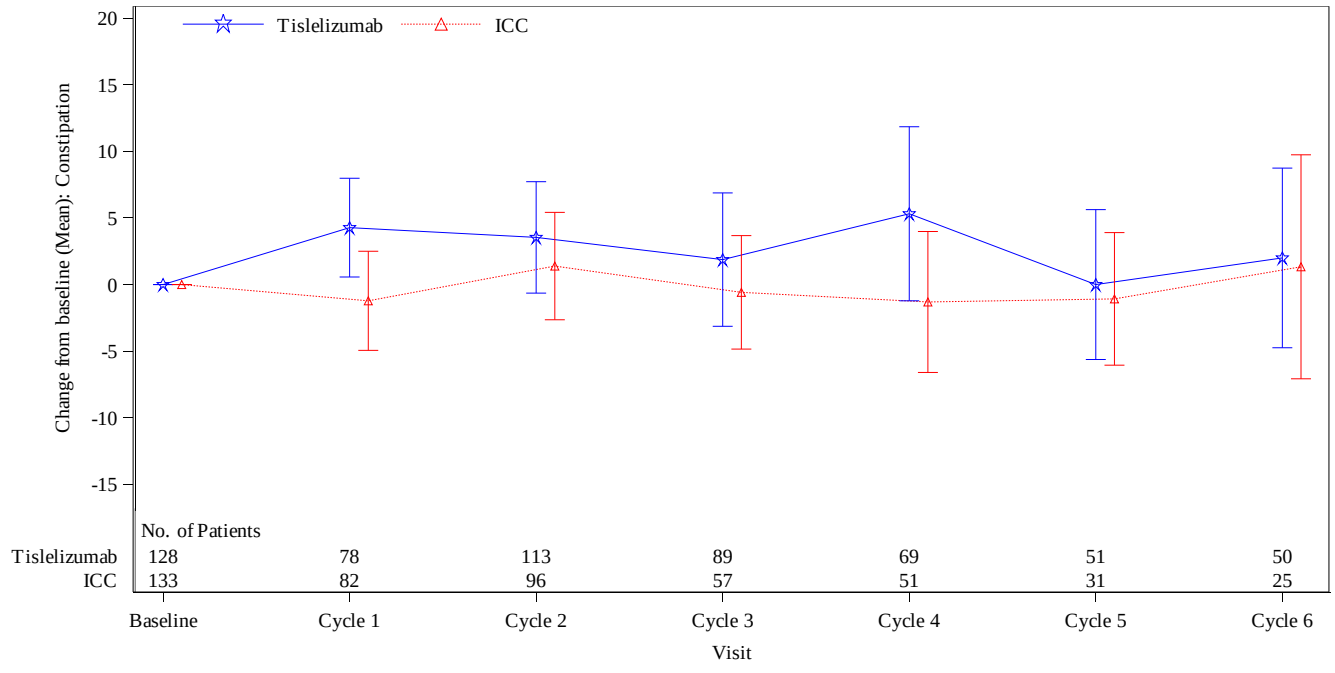

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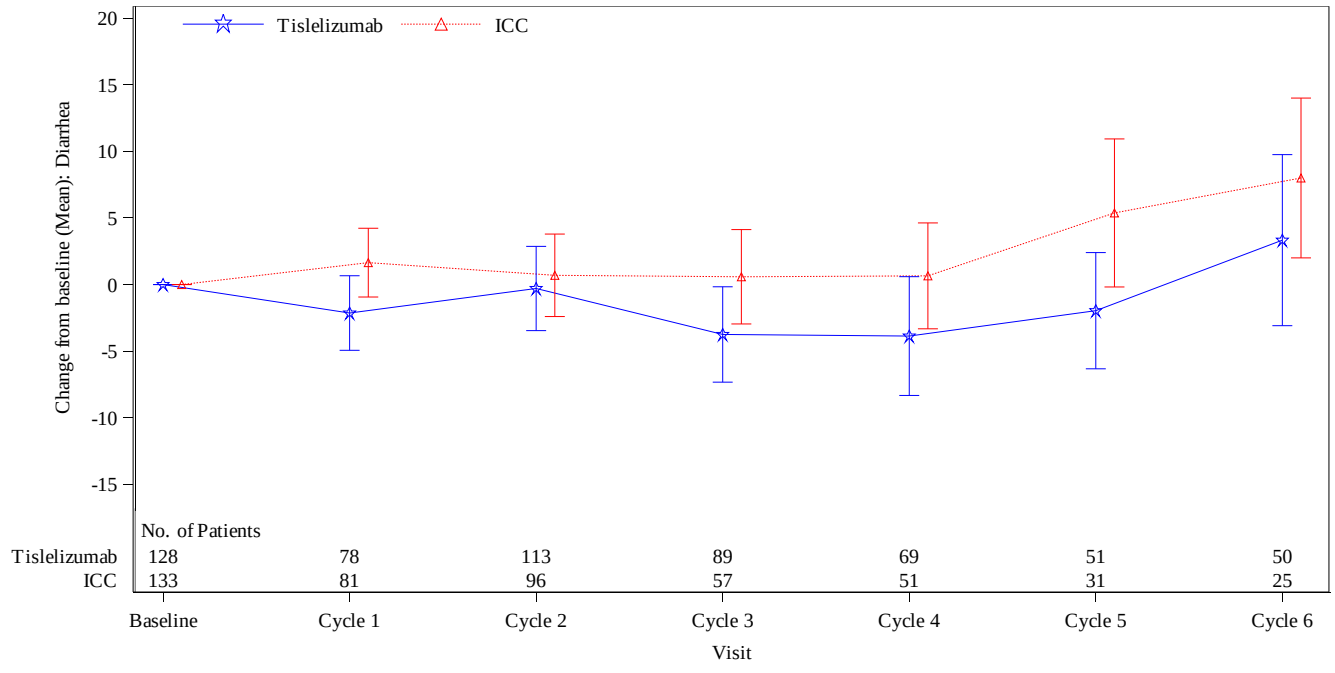

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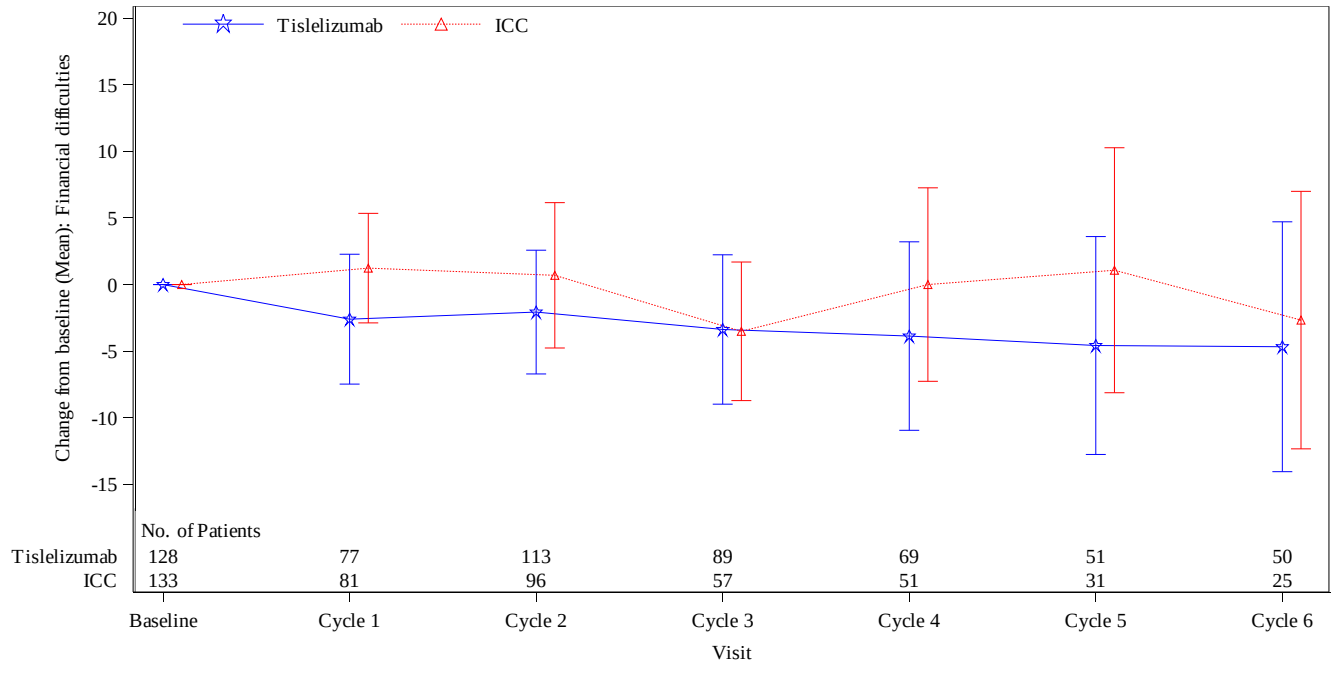

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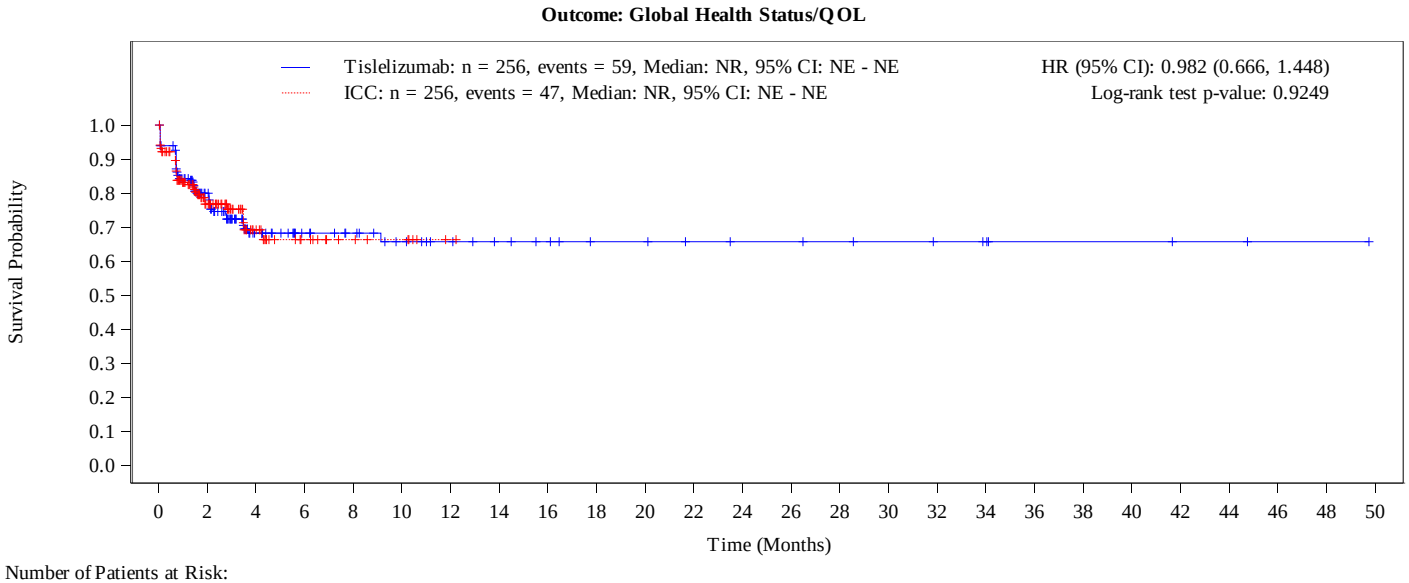
Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set

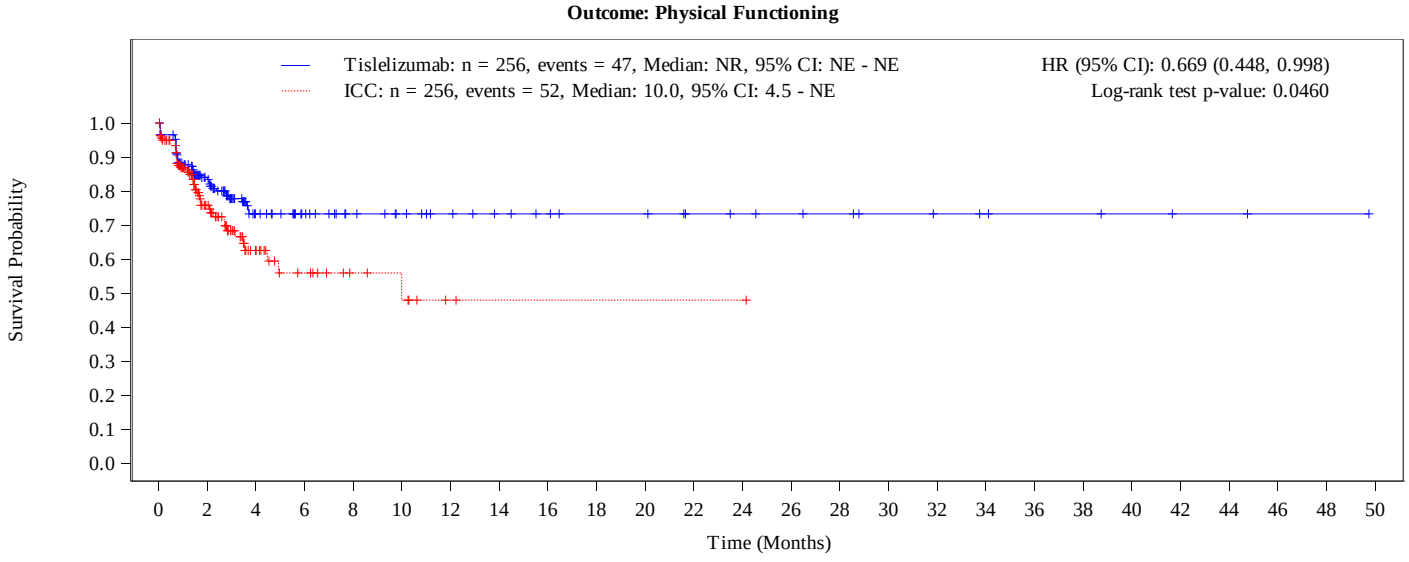


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	256	122	51	37	30	24	20	17	15	12	12	10	9	9	8	7	6	5	3	3	3	2	2	1	1	0
ICC	256	74	27	14	8	6	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-01-02-km-qs-c30-itt-cl.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	256	130	55	41	31	27	23	19	17	15	15	12	11	10	9	7	6	5	4	4	3	2	2	1	1	0
ICC	256	72	25	14	8	6	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
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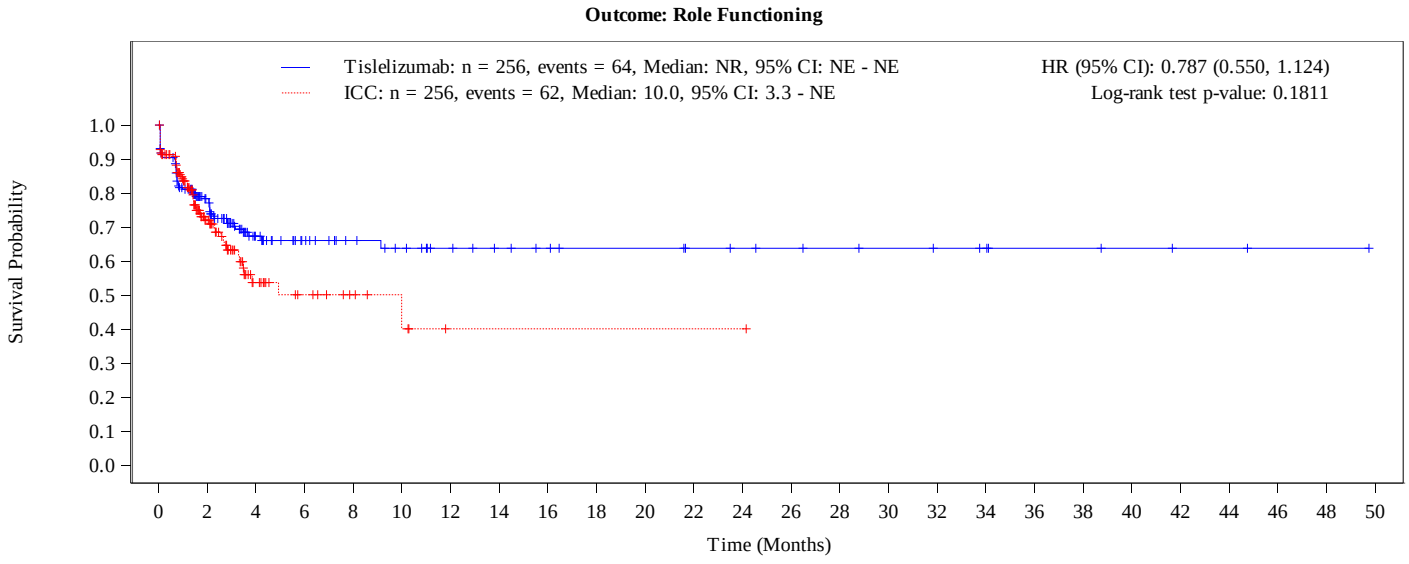

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	256	123	54	38	30	26	21	18	16	14	14	12	11	10	9	8	7	6	4	4	3	2	2	1	1	0
ICC	256	67	21	12	7	4	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

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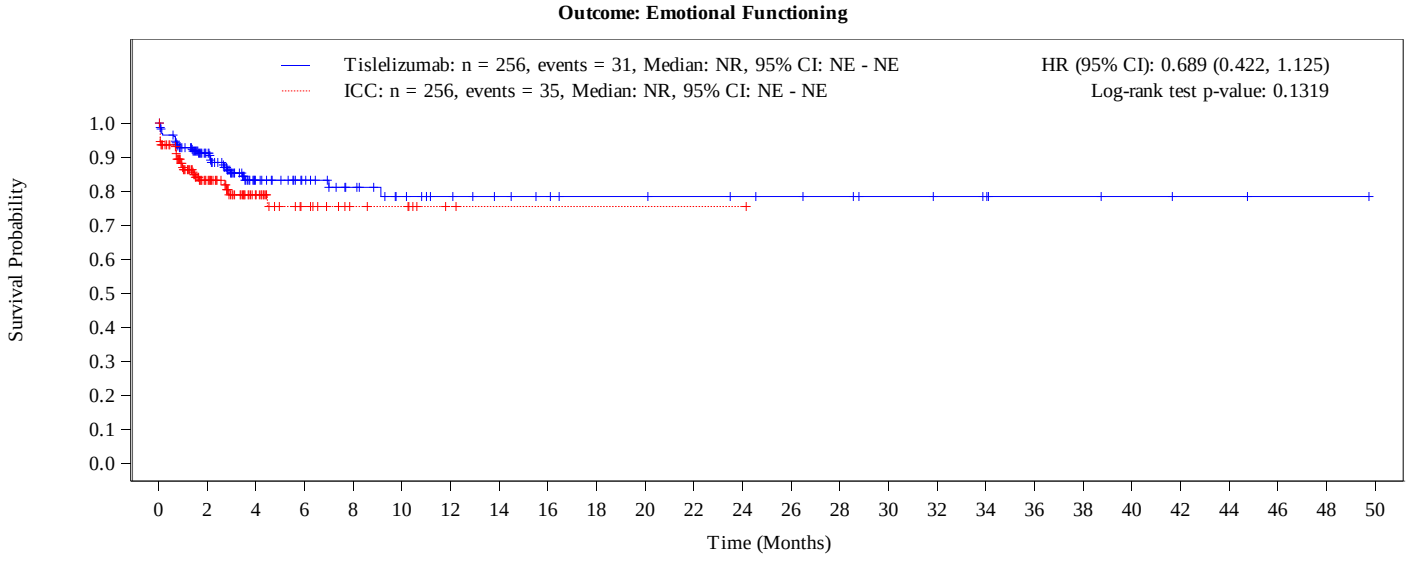

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	256	137	59	44	33	26	22	18	16	14	14	13	12	11	10	8	7	6	4	4	3	2	2	1	1	0
ICC	256	79	31	16	8	7	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
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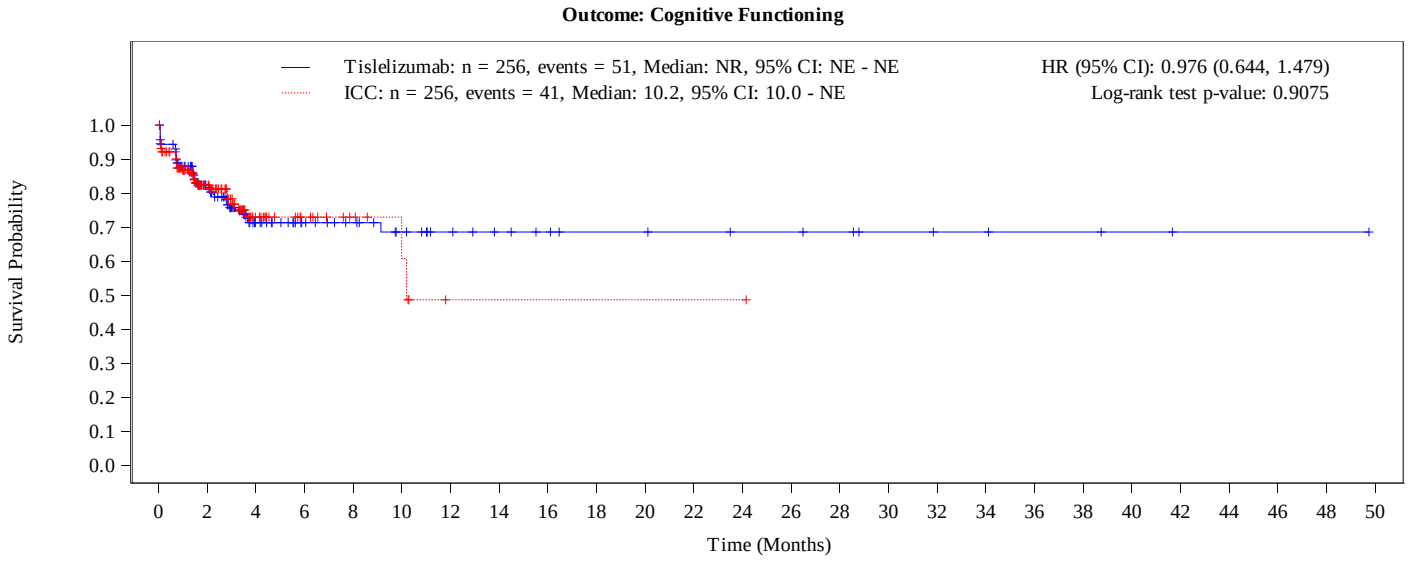
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-01-02-km-qs-c30-itt-cl.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set

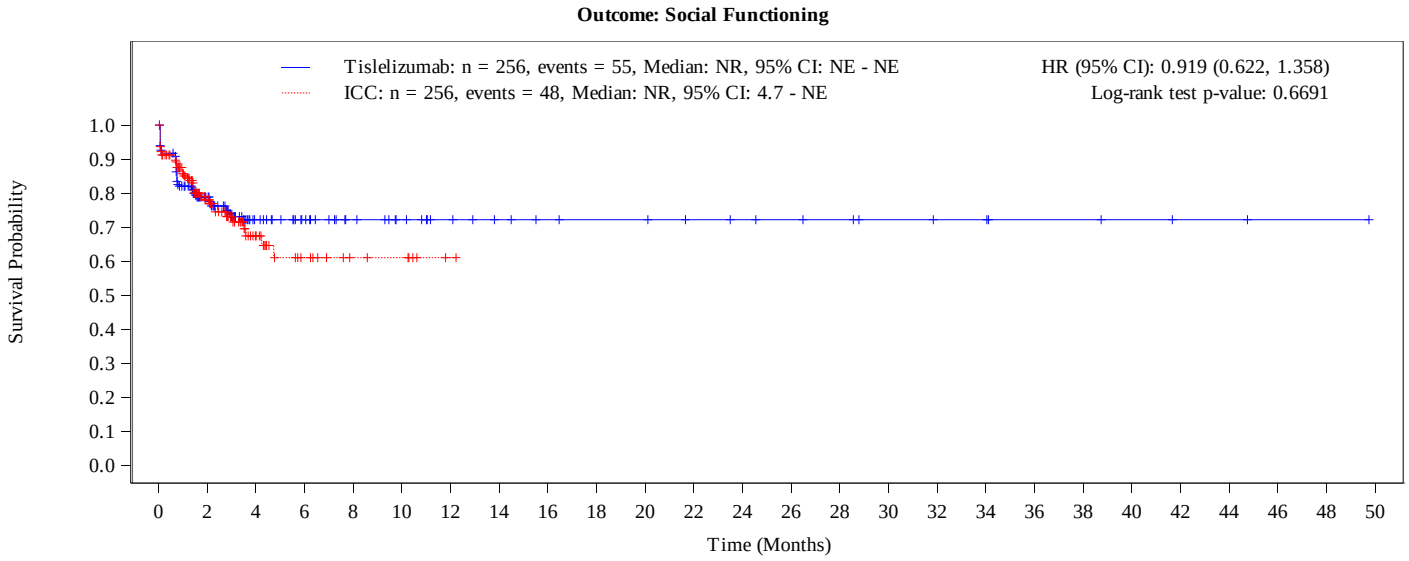


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	256	121	49	35	29	23	18	14	12	10	10	9	8	8	7	5	4	4	3	3	2	1	1	1	1	0
ICC	256	79	27	15	8	5	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-01-02-km-qs-c30-itt-cl.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set

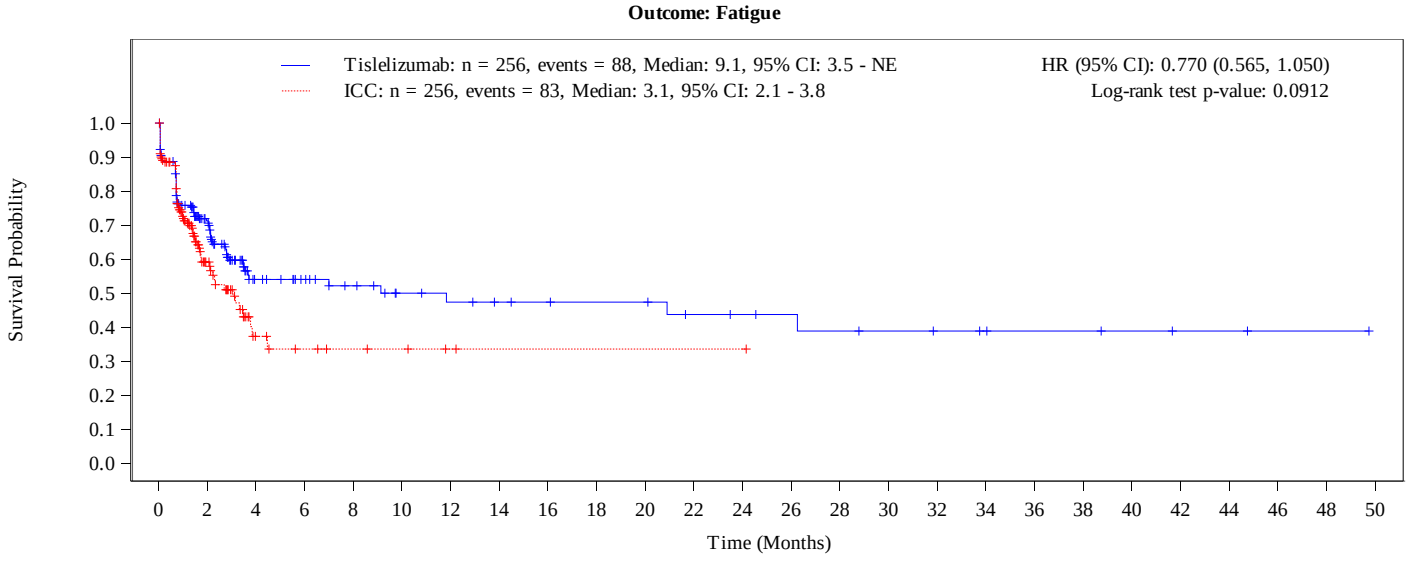


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	256	123	55	42	31	26	21	17	15	14	14	12	11	10	9	7	6	6	4	4	3	2	2	1	1	0
ICC	256	74	27	13	7	6	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-01-02-km-qs-c30-itt-cl.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set

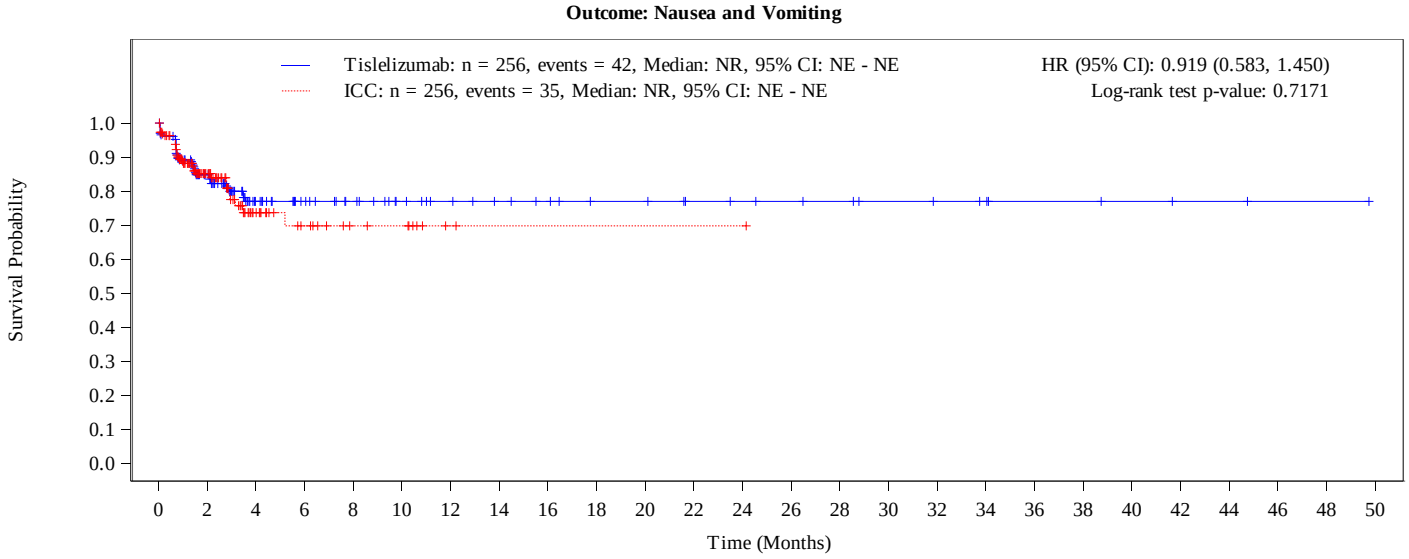


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	256	107	40	32	26	20	18	16	15	14	14	11	10	9	8	7	6	5	4	4	3	2	2	1	1	0
ICC	256	49	11	7	5	4	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-01-02-km-qs-c30-itt-cl.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set

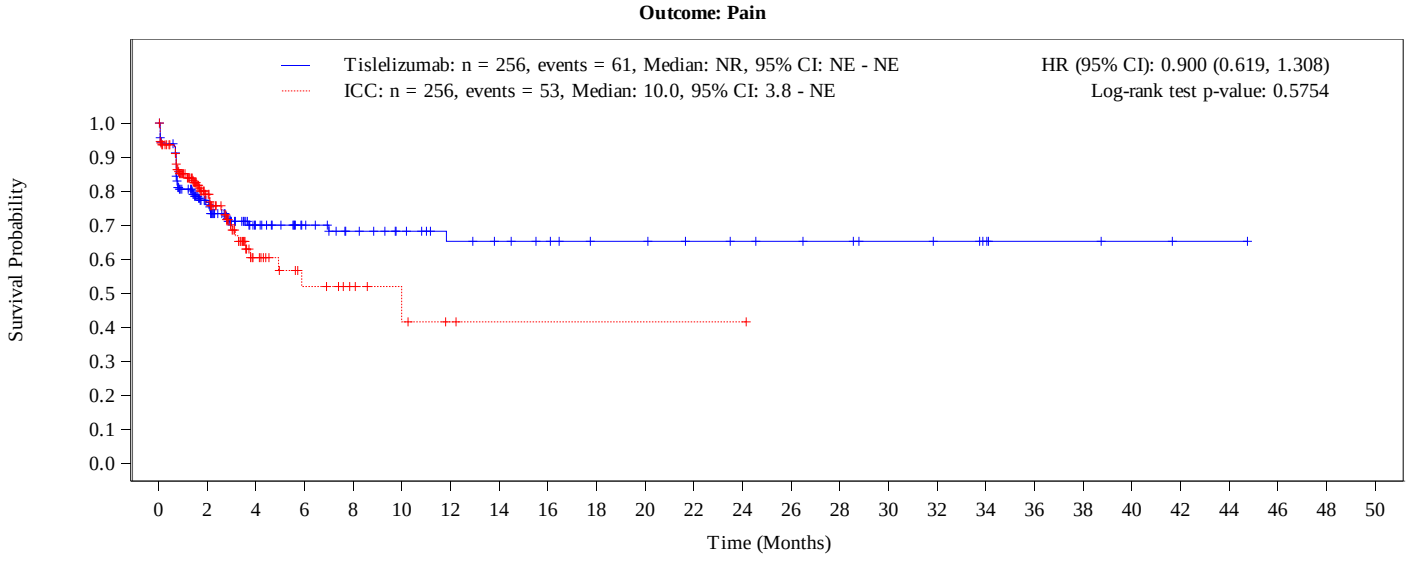


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	256	132	58	44	36	29	25	21	19	16	16	13	12	11	10	8	7	6	4	4	3	2	2	1	1	0
ICC	256	76	27	16	9	8	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-01-02-km-qs-c30-itt-cl.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set

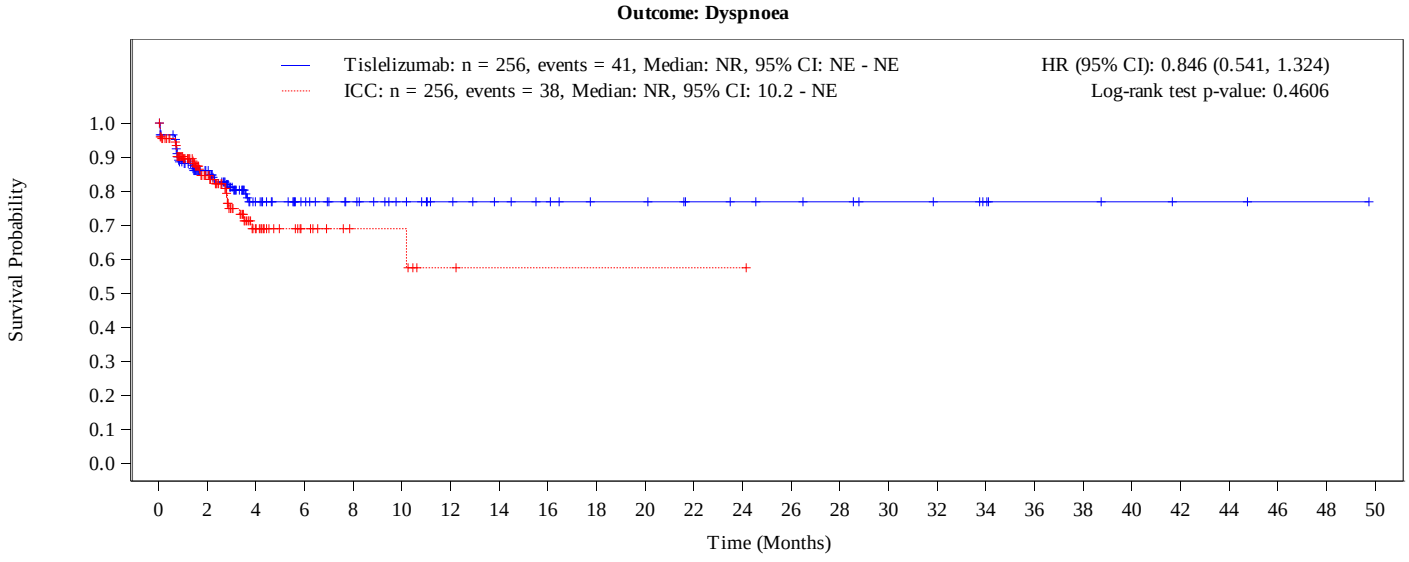


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	256	120	56	42	32	27	22	20	18	15	15	13	12	11	10	8	7	5	3	3	2	1	1	0	0	0
ICC	256	76	21	11	7	4	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-01-02-km-qs-c30-itt-cl.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set

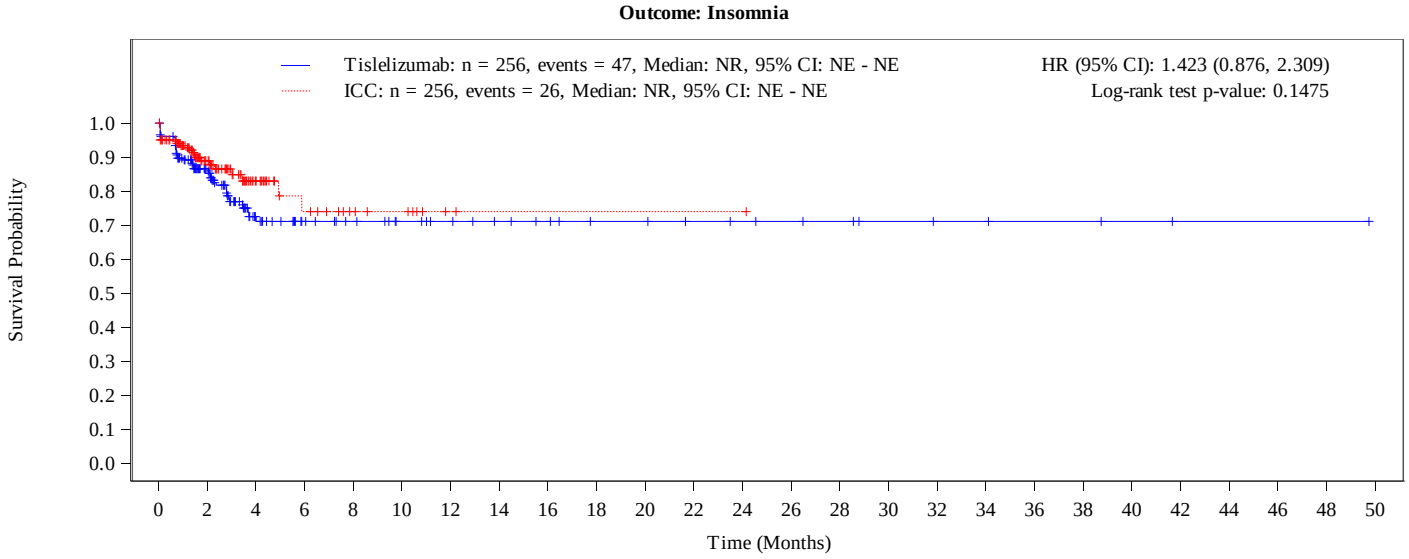


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	256	132	60	45	37	31	26	22	20	17	17	14	13	12	11	9	8	6	4	4	3	2	2	1	1	0
ICC	256	78	27	13	6	6	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-01-02-km-qs-c30-itt-cl.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set

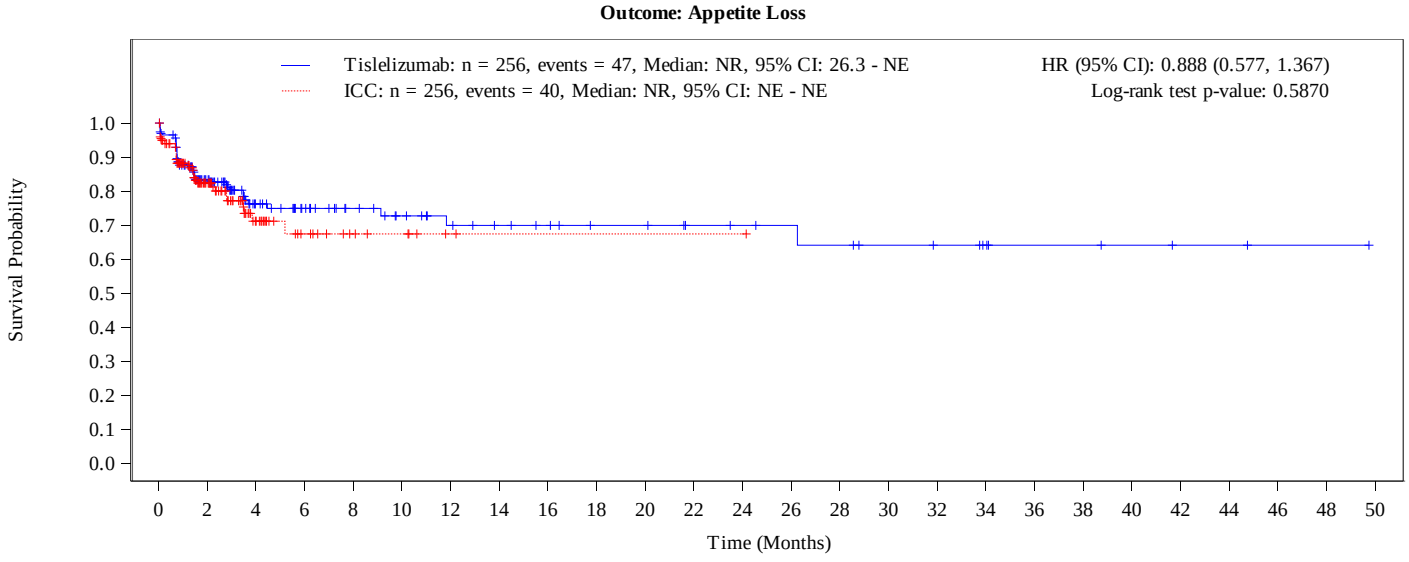


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	256	131	51	35	29	24	21	17	15	12	12	10	9	8	7	5	4	4	3	3	2	1	1	1	1	0
ICC	256	83	30	16	9	7	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-01-02-km-qs-c30-itt-cl.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set

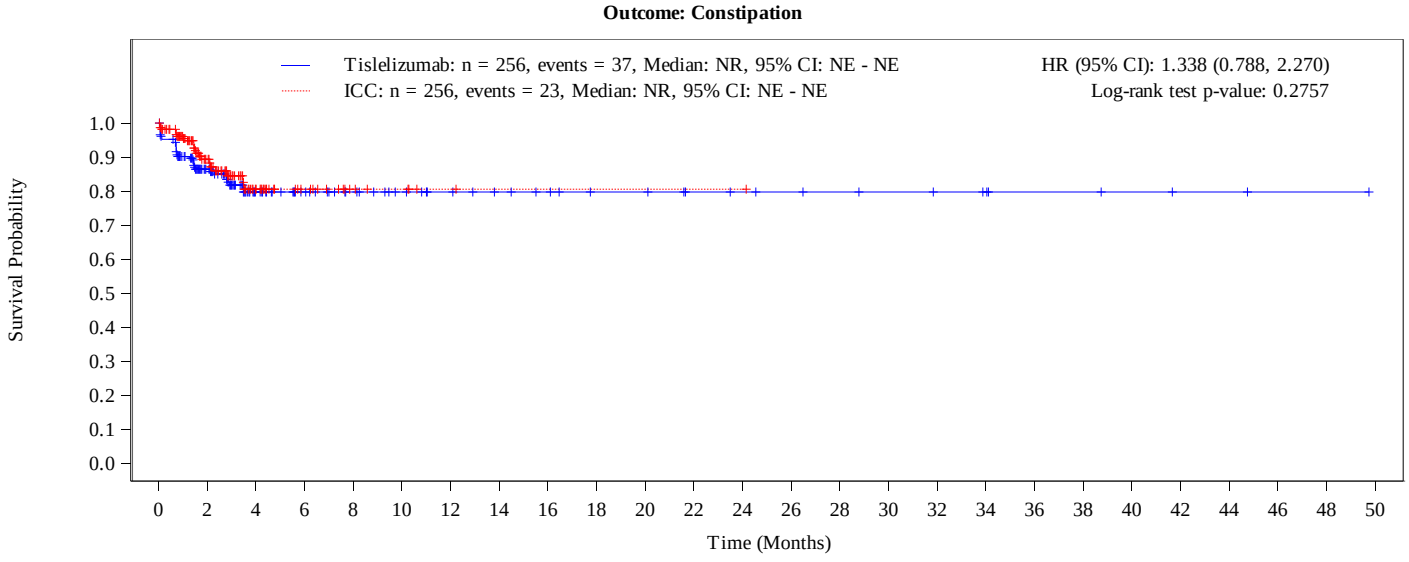


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	256	126	61	47	36	30	25	22	20	17	17	14	13	12	11	9	8	6	4	4	3	2	2	1	1	0
ICC	256	77	29	15	8	6	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-01-02-km-qs-c30-itt-cl.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set

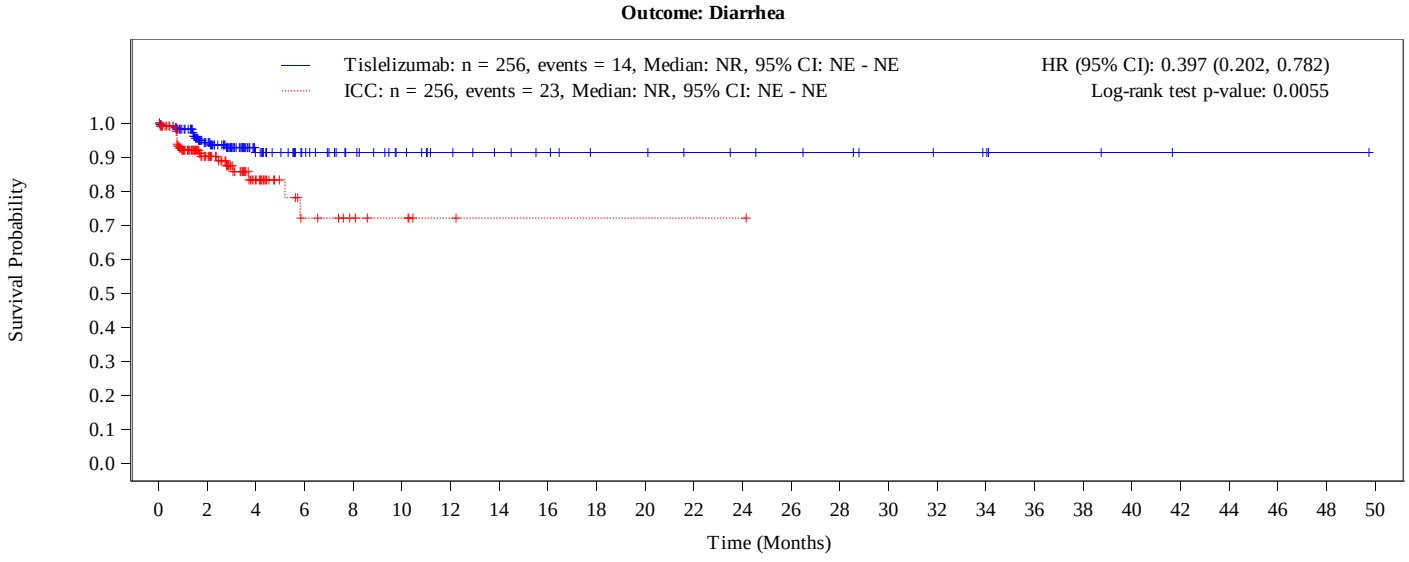


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	256	128	55	41	33	27	23	20	18	15	15	12	11	10	9	8	7	6	4	4	3	2	2	1	1	0
ICC	256	87	30	16	7	5	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-01-02-km-qs-c30-itt-cl.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set

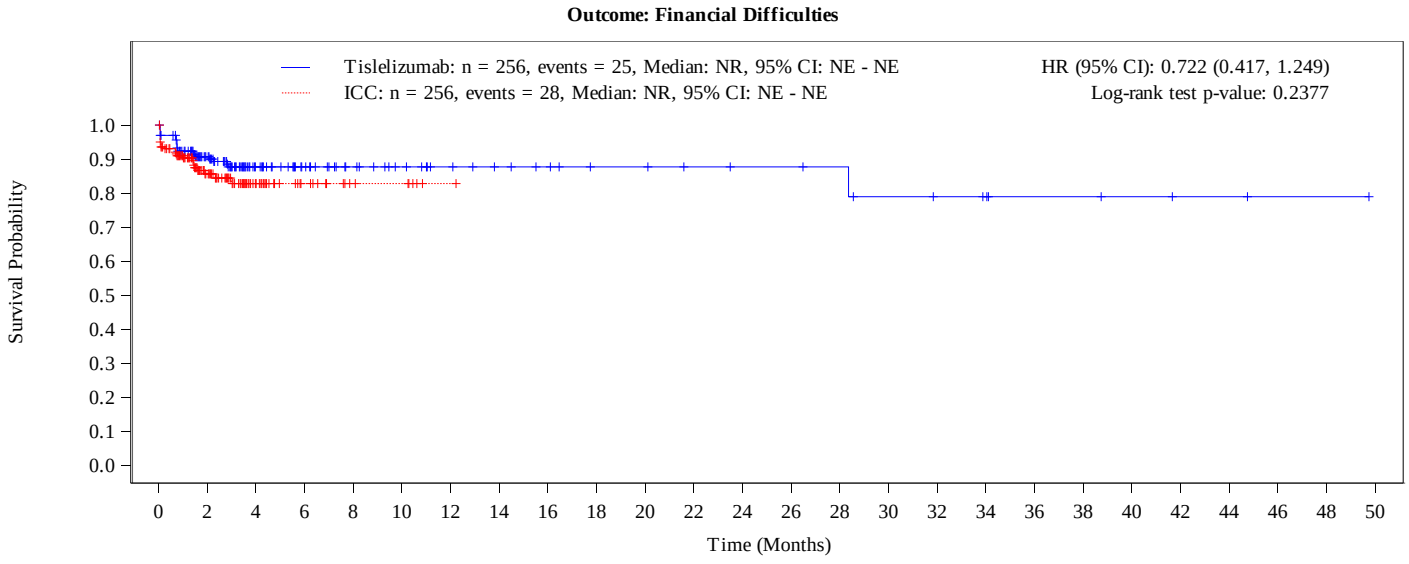


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	256	141	62	45	35	28	23	19	17	14	14	12	11	10	9	7	6	5	3	3	2	1	1	1	1	0
ICC	256	83	29	11	7	5	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-01-02-km-qs-c30-itt-cl.rtf

Figure 14.2.7.1.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set

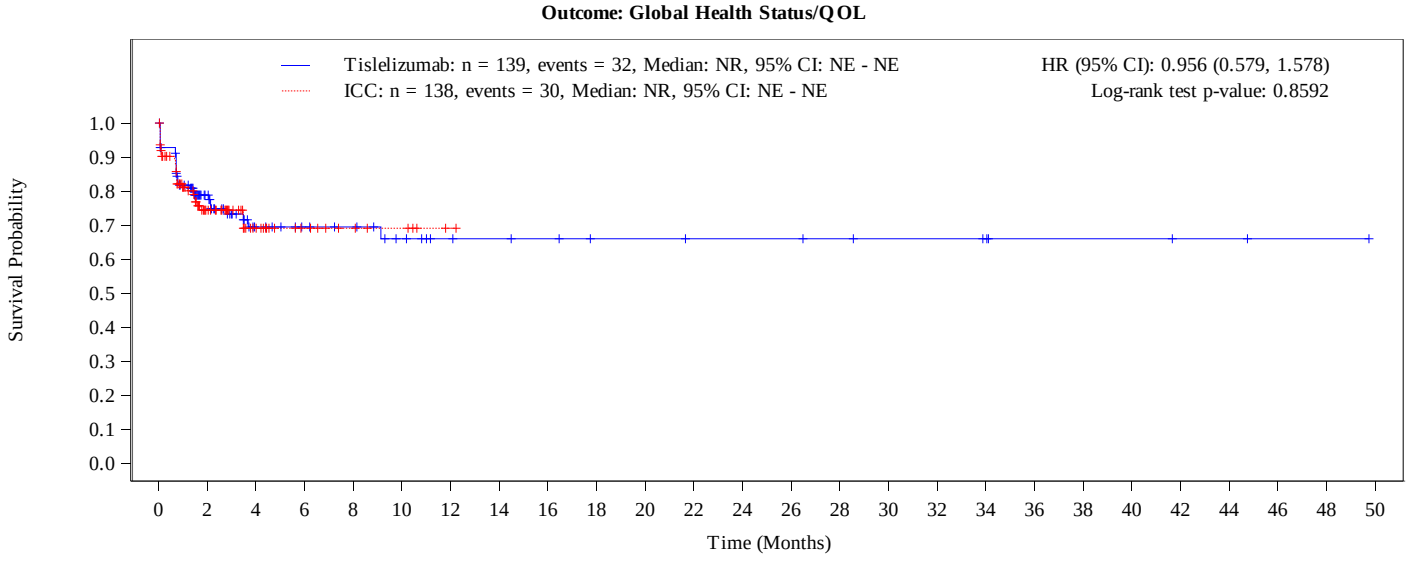


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	256	136	64	46	34	28	23	19	17	14	14	12	11	11	10	8	7	6	4	4	3	2	2	1	1	0
ICC	256	80	31	15	7	6	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-01-02-km-qs-c30-itt-cl.rtf

Figure 14.2.7.1.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation without Irinotecan

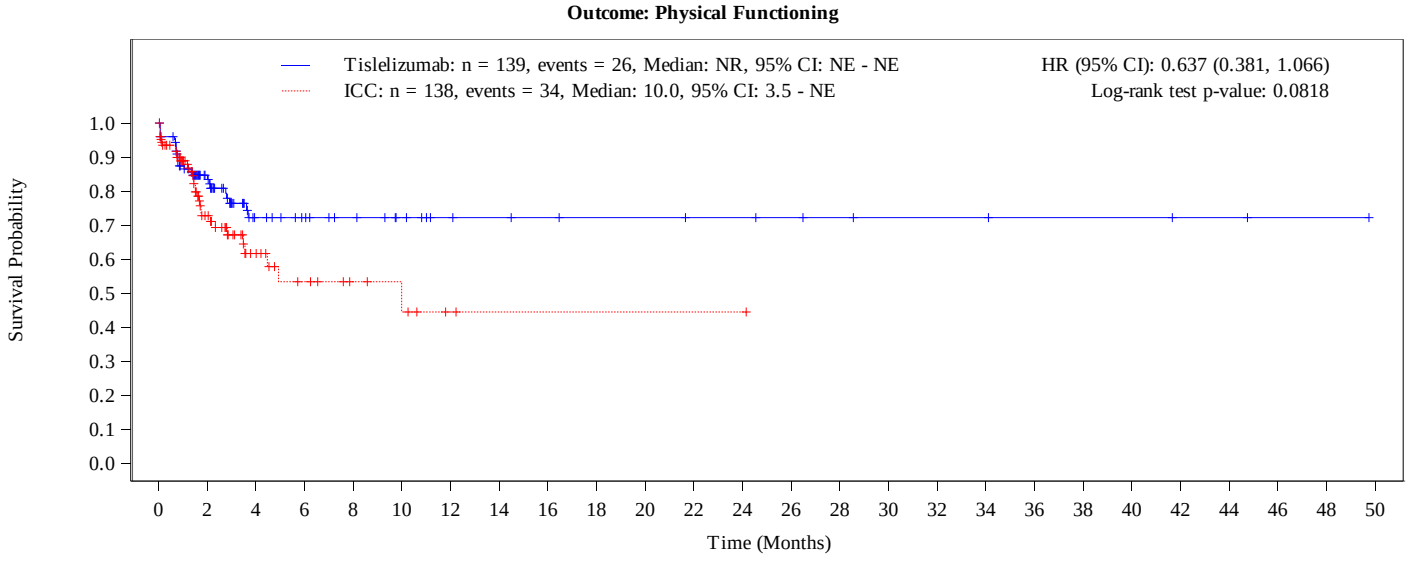


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	61	29	24	22	17	13	12	11	9	9	8	8	8	7	6	6	5	3	3	3	2	2	1	1	0
ICC	138	47	20	11	7	5	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-01-02-b-km-qs-c30-itts-cl.rtf

Figure 14.2.7.1.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation without Irinotecan

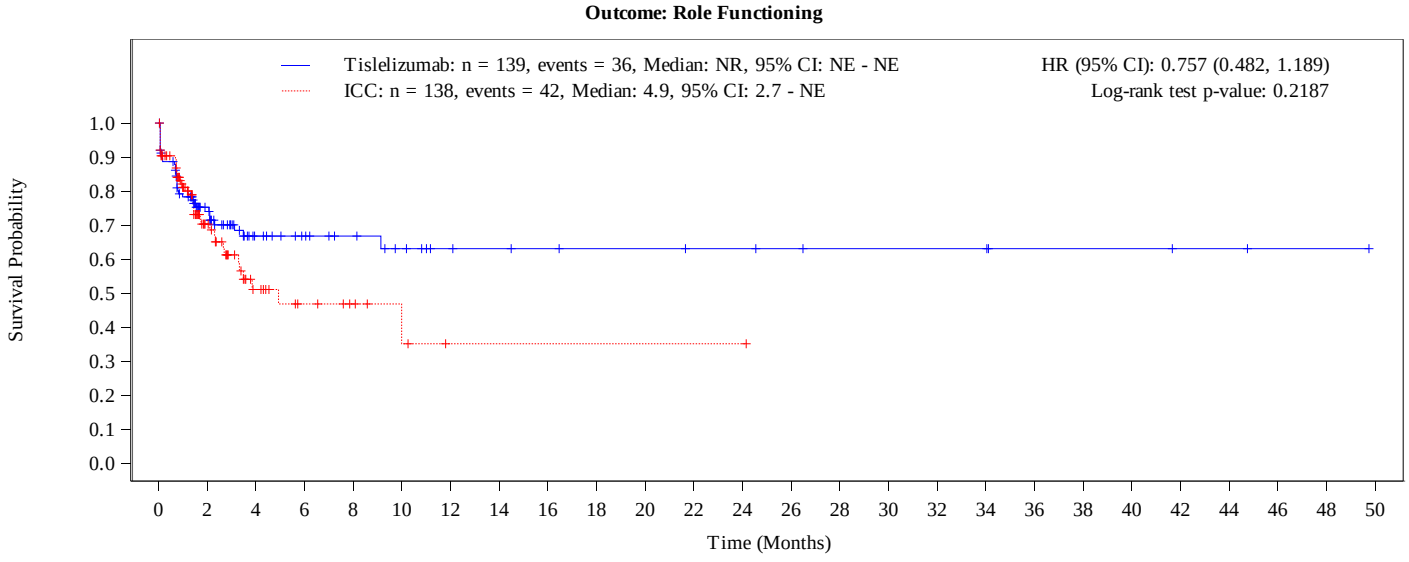


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	67	29	24	20	16	12	10	9	8	8	7	7	6	5	4	4	4	3	3	3	2	2	1	1	0
ICC	138	45	19	11	7	5	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-01-02-b-km-qs-c30-itts-cl.rtf

Figure 14.2.7.1.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation without Irinotecan

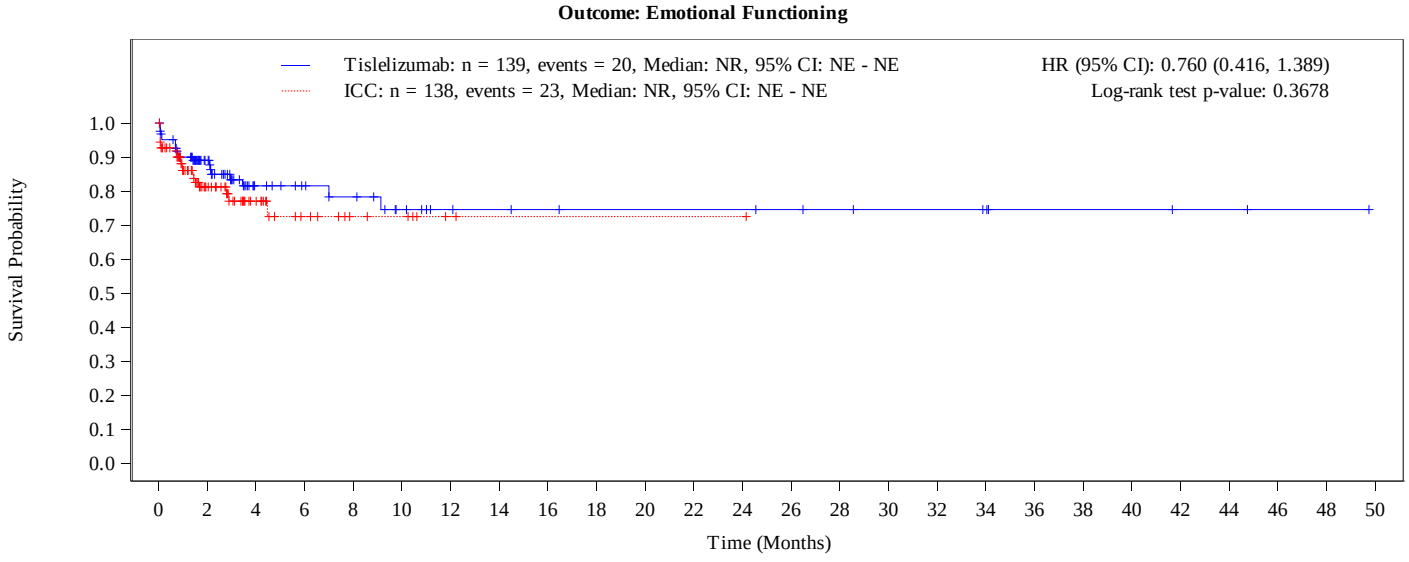


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	60	29	23	19	15	11	10	9	8	8	7	7	6	5	5	5	5	3	3	3	2	2	1	1	0
ICC	138	43	16	9	6	3	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-01-02-b-km-qs-c30-itts-cl.rtf

Figure 14.2.7.1.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	68	31	26	23	17	13	11	10	9	9	9	9	8	7	6	6	5	3	3	3	2	2	1	1	0
ICC	138	51	23	12	7	6	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
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unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-01-02-b-km-qs-c30-itts-cl.rtf

Figure 14.2.7.1.2.b:
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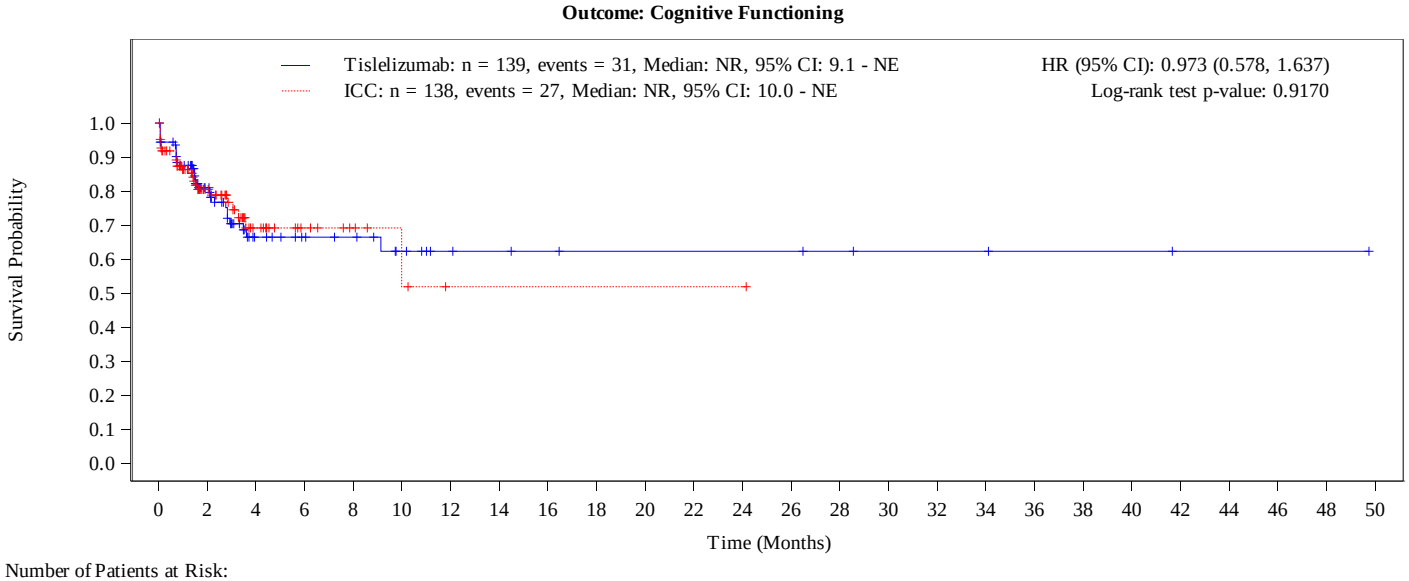
ITT Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	59	25	20	18	13	9	7	6	5	5	5	5	5	4	3	3	3	2	2	2	1	1	1	1	0
ICC	138	51	19	10	6	3	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
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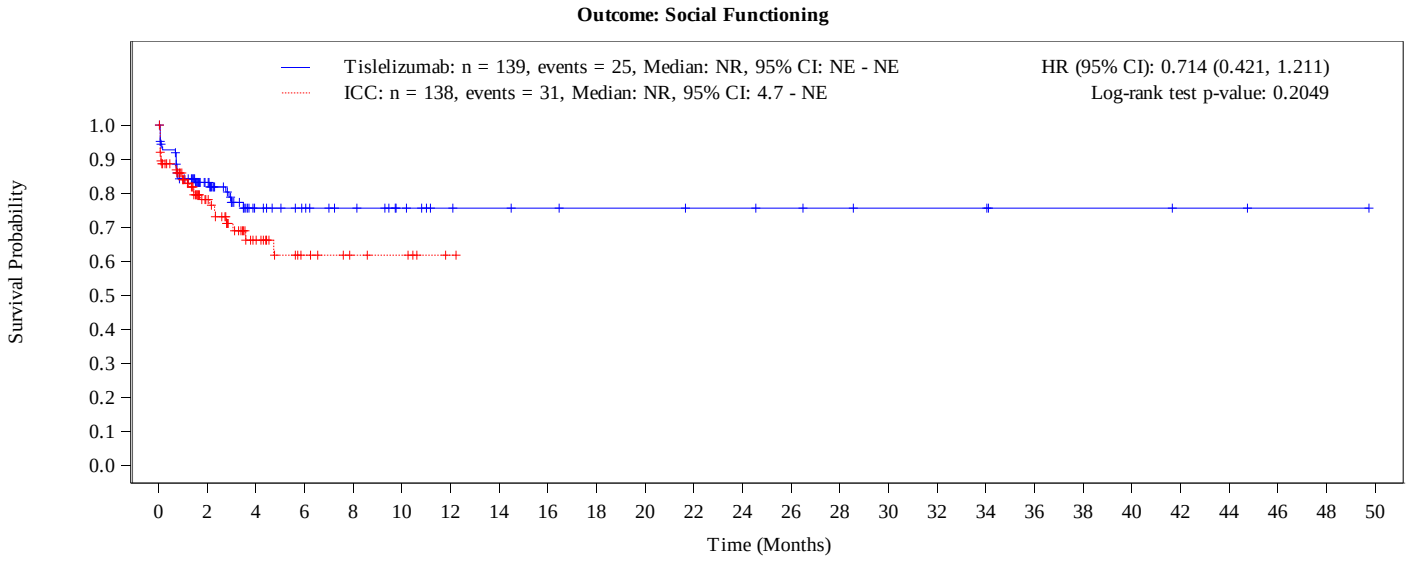
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-01-02-b-km-qs-c30-itts-cl.rtf

Figure 14.2.7.1.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	65	32	26	22	17	13	11	10	9	9	8	8	7	6	5	5	5	3	3	3	2	2	1	1	0
ICC	138	50	21	10	6	5	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
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The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-01-02-b-km-qs-c30-itts-cl.rtf

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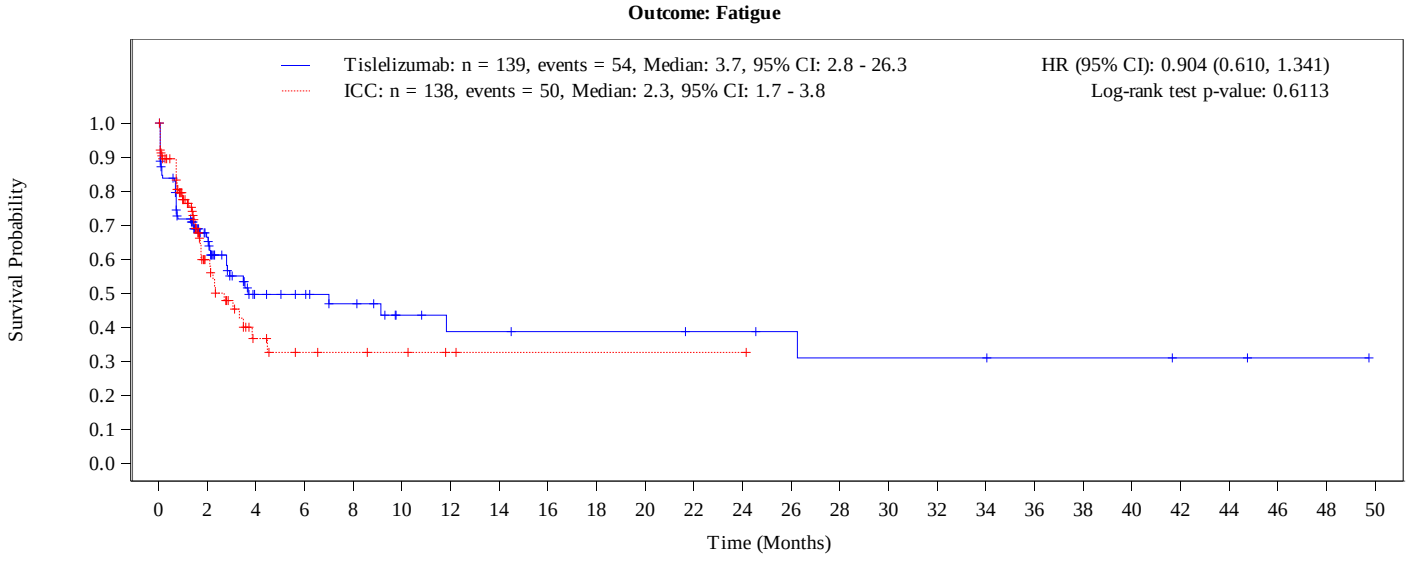
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	52	23	20	16	10	8	8	7	7	7	6	6	5	4	4	4	4	3	3	3	2	2	1	1	0
ICC	138	31	10	6	5	4	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
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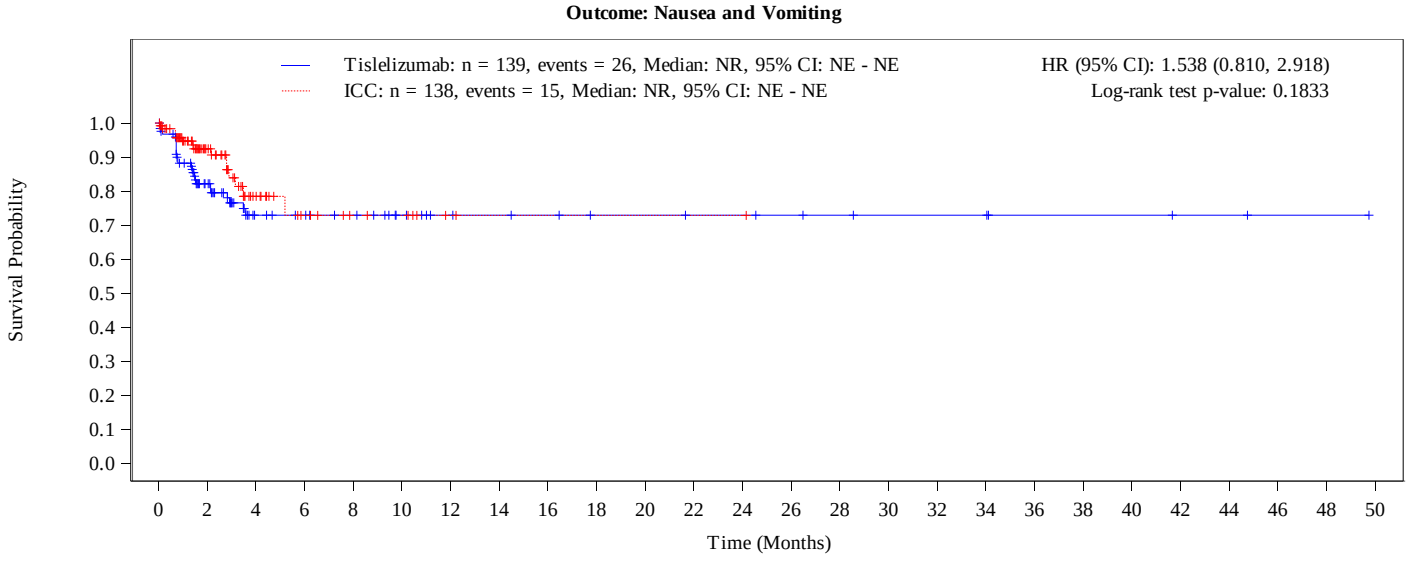
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-01-02-b-km-qs-c30-itts-cl.rtf

Figure 14.2.7.1.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	64	30	27	24	18	14	12	11	9	9	8	8	7	6	5	5	5	3	3	3	2	2	1	1	0
ICC	138	55	21	11	7	6	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
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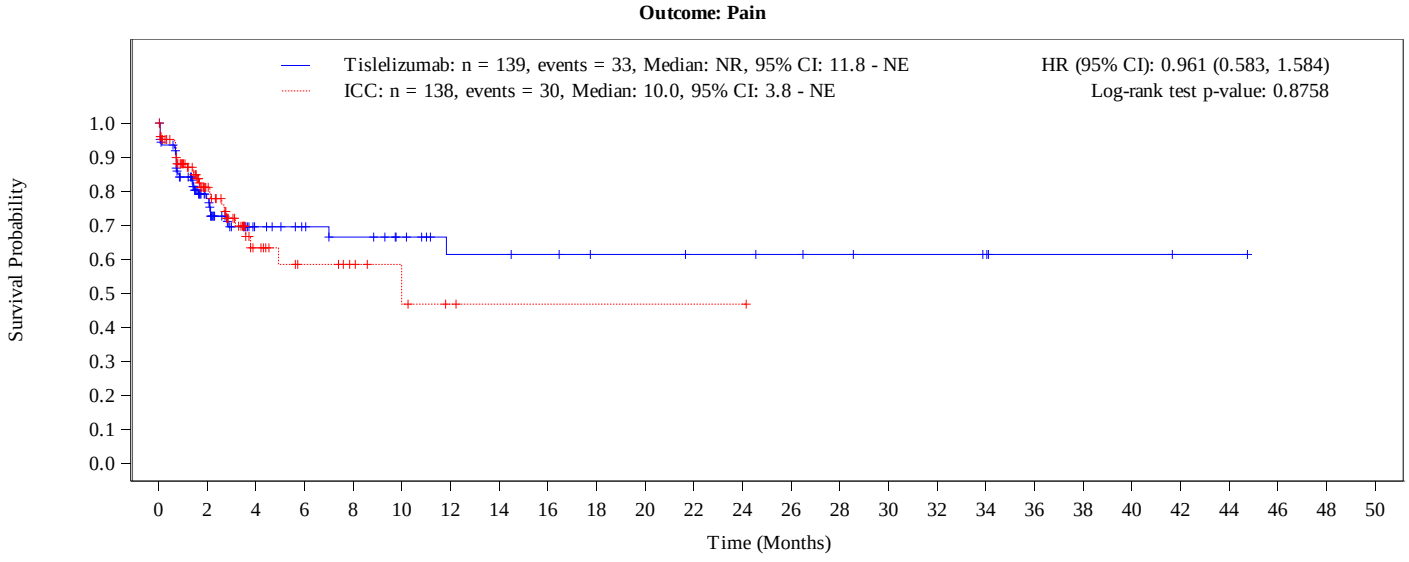
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-01-02-b-km-qs-c30-itts-cl.rtf

Figure 14.2.7.1.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	61	29	24	21	17	12	12	11	9	9	8	8	7	6	5	5	4	2	2	2	1	1	0	0	0
ICC	138	51	17	10	7	4	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
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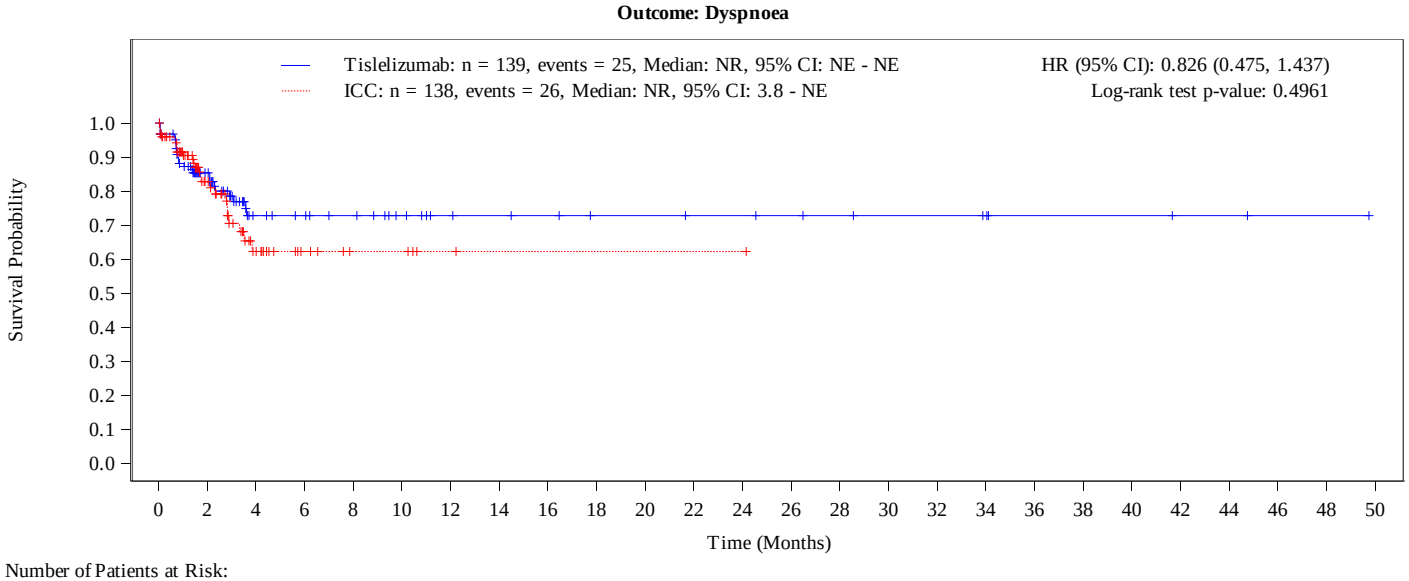
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-01-02-b-km-qs-c30-itts-cl.rtf

Figure 14.2.7.1.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation without Irinotecan

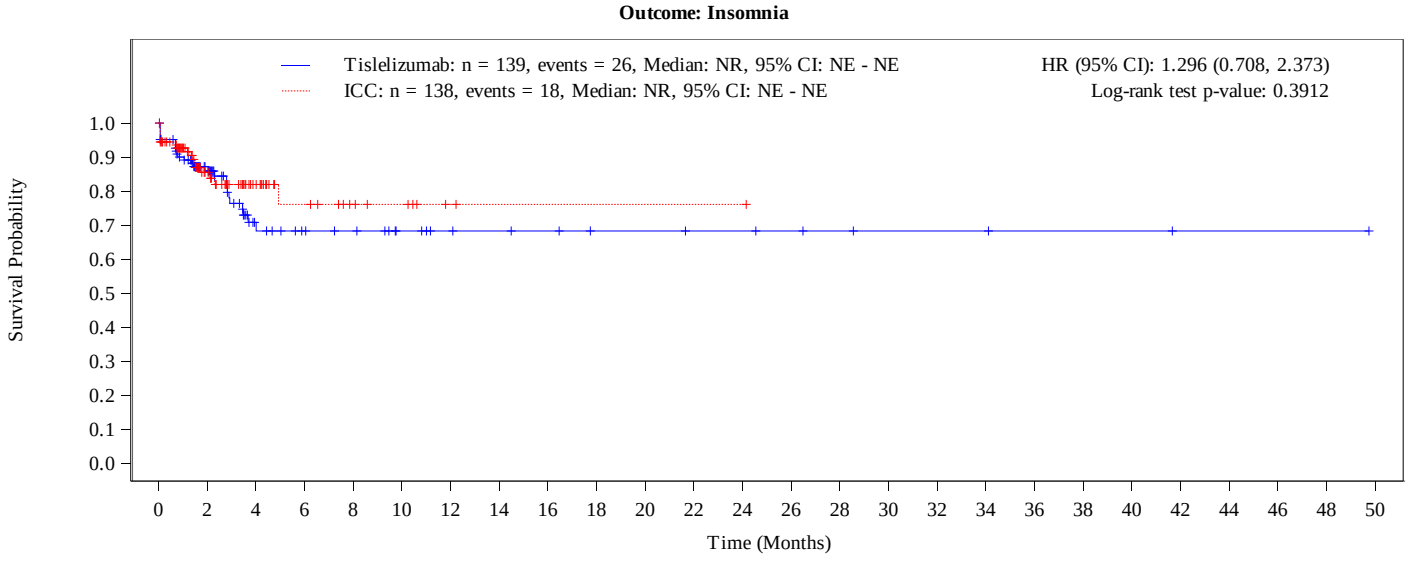


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	67	30	27	24	19	15	13	12	10	10	9	9	8	7	6	6	5	3	3	3	2	2	1	1	0
ICC	138	49	19	9	5	5	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-01-02-b-km-qs-c30-itts-cl.rtf

Figure 14.2.7.1.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	67	28	22	20	15	12	10	9	7	7	6	6	5	4	3	3	3	2	2	2	1	1	1	1	0
ICC	138	52	24	13	8	6	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
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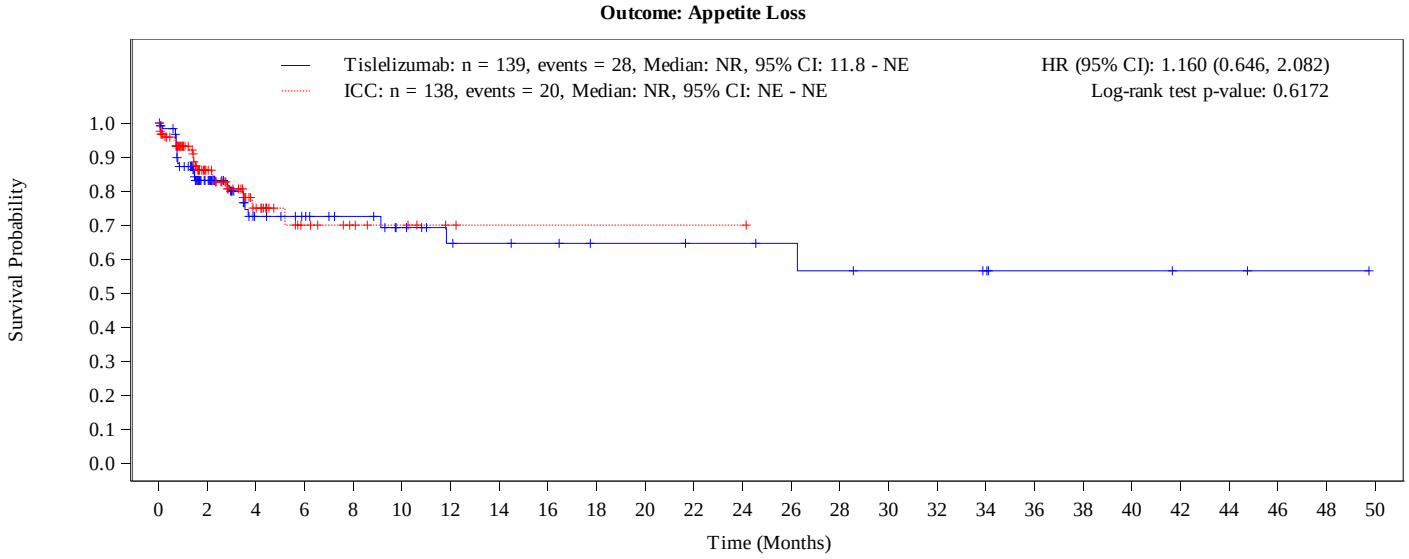
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-01-02-b-km-qs-c30-itts-cl.rtf

Figure 14.2.7.1.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	64	31	27	23	18	14	13	12	10	10	9	9	8	7	6	6	5	3	3	3	2	2	1	1	0
ICC	138	53	23	11	7	5	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
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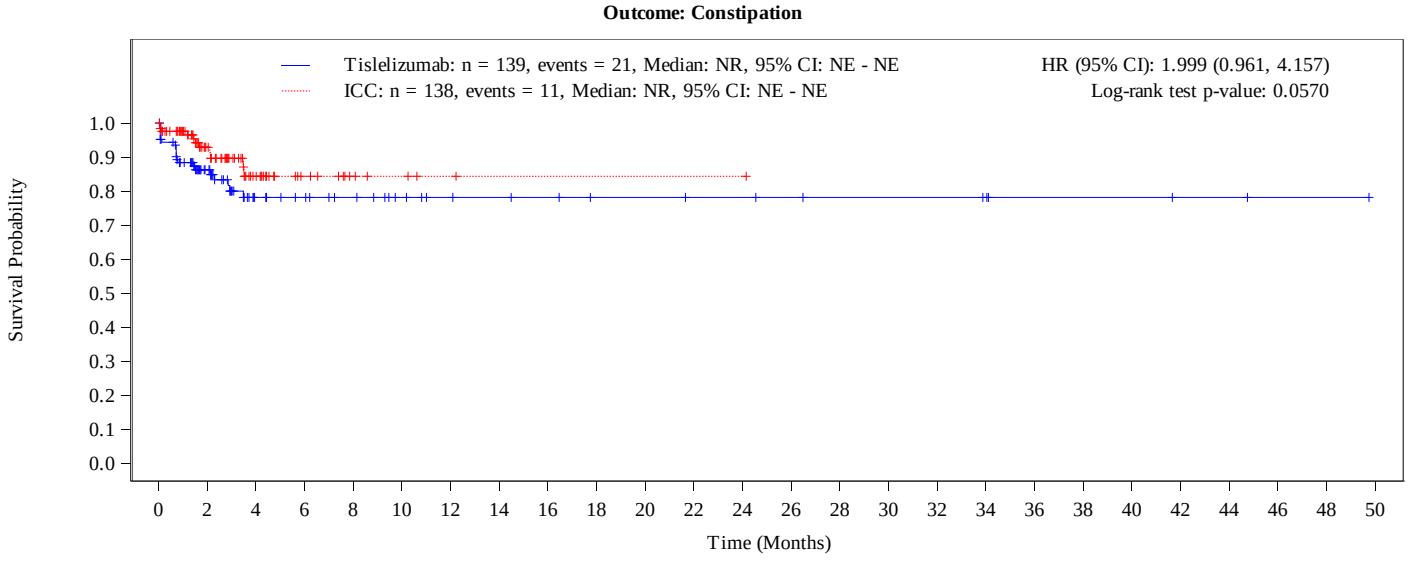
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-01-02-b-km-qs-c30-itts-cl.rtf

Figure 14.2.7.1.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation without Irinotecan

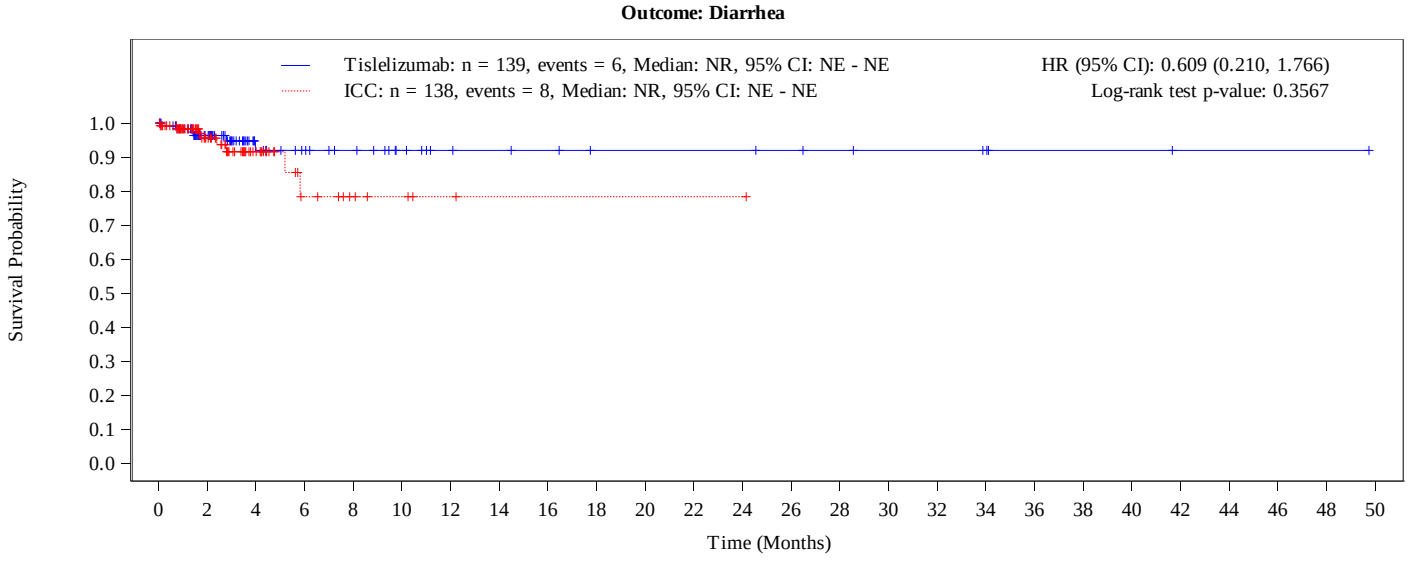


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	63	29	25	21	16	13	12	11	9	9	8	8	7	6	6	6	5	3	3	3	2	2	1	1	0
ICC	138	60	25	12	6	4	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-01-02-b-km-qs-c30-itts-cl.rtf

Figure 14.2.7.1.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation without Irinotecan

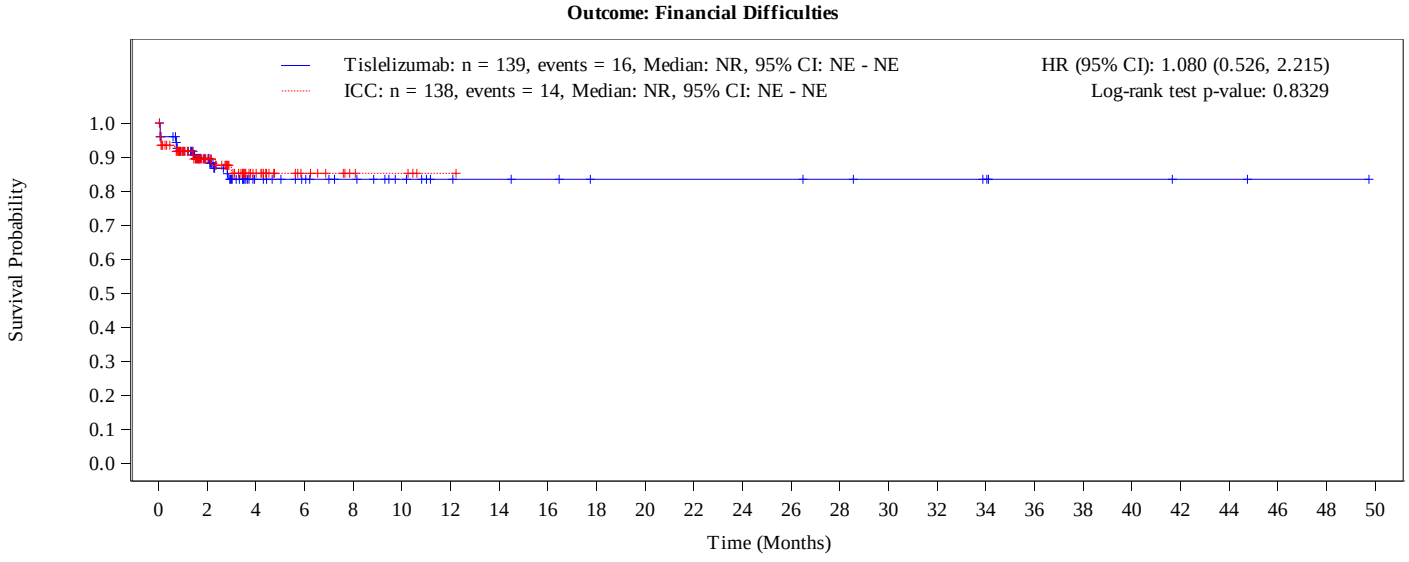


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	72	33	27	23	17	13	11	10	8	8	8	8	7	6	5	5	4	2	2	2	1	1	1	1	0
ICC	138	59	25	10	6	4	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-01-02-b-km-qs-c30-itts-cl.rtf

Figure 14.2.7.1.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30
ITT Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	66	32	26	22	17	13	11	10	8	8	8	8	8	7	6	6	5	3	3	3	2	2	1	1	0
ICC	138	54	23	11	5	4	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-01-02-b-km-qs-c30-itts-cl.rtf

Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Global Health Status/QOL

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	36 (23.7)	NR (9.1, NE)	158	29 (18.4)	NR (4.2, NE)	0.944 (0.577, 1.544)	0.8158
>= 65 Years	104	23 (22.1)	NR (NE, NE)	98	18 (18.4)	NR (NE, NE)	1.063 (0.572, 1.974)	0.8449
Interaction								0.8604
Gender								
Male	217	54 (24.9)	NR (NE, NE)	215	41 (19.1)	NR (NE, NE)	1.025 (0.682, 1.542)	0.9022
Female	39	5 (12.8)	NR (NE, NE)	41	6 (14.6)	NR (1.9, NE)	0.660 (0.198, 2.206)	0.4937
Interaction								0.5257

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Global Health Status/QOL

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	49 (26.1)	NR (NE, NE)	192	38 (19.8)	NR (NE, NE)	1.055 (0.689, 1.614)	0.8029
Non-Smoker	68	10 (14.7)	NR (NE, NE)	63	9 (14.3)	NR (3.5, NE)	0.760 (0.303, 1.905)	0.5523
Interaction								0.4955
ICC Options								
Paclitaxel	83	21 (25.3)	NR (9.1, NE)	85	15 (17.6)	NR (NE, NE)	1.370 (0.705, 2.662)	0.3455
Docetaxel	56	11 (19.6)	NR (NE, NE)	53	15 (28.3)	NR (3.5, NE)	0.582 (0.266, 1.273)	0.1627
Irinotecan	117	27 (23.1)	NR (NE, NE)	118	17 (14.4)	NR (3.5, NE)	0.996 (0.538, 1.844)	0.9895
Interaction								0.1895

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Global Health Status/QOL

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	19 (29.7)	NR (3.7, NE)	63	12 (19.0)	NR (NE, NE)	1.228 (0.592, 2.547)	0.5723
1	192	40 (20.8)	NR (NE, NE)	193	35 (18.1)	NR (4.2, NE)	0.892 (0.566, 1.408)	0.6196
Interaction								0.4362
Region #1								
Asia	201	50 (24.9)	NR (NE, NE)	203	41 (20.2)	NR (4.2, NE)	0.947 (0.625, 1.435)	0.7937
Europe/North America	55	9 (16.4)	NR (9.1, NE)	53	6 (11.3)	NR (NE, NE)	1.208 (0.427, 3.419)	0.7196
Interaction								0.5864

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Global Health Status/QOL

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	41 (23.3)	NR (NE, NE)	178	34 (19.1)	NR (4.2, NE)	0.923 (0.584, 1.458)	0.7274
Japan	25	9 (36.0)	NR (2.1, NE)	25	7 (28.0)	NR (1.6, NE)	1.131 (0.416, 3.076)	0.8074
Europe/North America	55	9 (16.4)	NR (9.1, NE)	53	6 (11.3)	NR (NE, NE)	1.208 (0.427, 3.419)	0.7196
Interaction								0.8187
Race								
Asian and other	203	50 (24.6)	NR (NE, NE)	212	42 (19.8)	NR (4.2, NE)	0.950 (0.628, 1.436)	0.8043
White	53	9 (17.0)	NR (9.1, NE)	44	5 (11.4)	NR (NE, NE)	1.320 (0.440, 3.964)	0.6177
Interaction								0.5078

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Global Health Status/QOL

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	18 (22.5)	NR (NE, NE)	62	9 (14.5)	NR (NE, NE)	1.126 (0.502, 2.529)	0.7710
vCPS < 10%	100	24 (24.0)	NR (NE, NE)	122	24 (19.7)	NR (4.2, NE)	1.034 (0.587, 1.824)	0.9055
Missing	76	17 (22.4)	NR (3.5, NE)	72	14 (19.4)	NR (3.5, NE)	0.865 (0.424, 1.764)	0.6846
Interaction								0.9076

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Physical Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	29 (19.1)	NR (NE, NE)	158	31 (19.6)	10.0 (3.5, NE)	0.668 (0.401, 1.113)	0.1170
>= 65 Years	104	18 (17.3)	NR (NE, NE)	98	21 (21.4)	NR (3.2, NE)	0.599 (0.317, 1.134)	0.1092
Interaction								0.7611
Gender								
Male	217	39 (18.0)	NR (NE, NE)	215	45 (20.9)	NR (4.5, NE)	0.603 (0.391, 0.929)	0.0196
Female	39	8 (20.5)	NR (3.4, NE)	41	7 (17.1)	10.0 (2.7, NE)	0.963 (0.345, 2.692)	0.9426
Interaction								0.3951

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Physical Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	36 (19.1)	NR (NE, NE)	192	44 (22.9)	10.0 (3.5, NE)	0.581 (0.372, 0.907)	0.0149
Non-Smoker	68	11 (16.2)	NR (NE, NE)	63	8 (12.7)	NR (NE, NE)	0.985 (0.395, 2.459)	0.9747
Interaction								0.3924
ICC Options								
Paclitaxel	83	14 (16.9)	NR (NE, NE)	85	22 (25.9)	4.9 (2.8, NE)	0.532 (0.271, 1.045)	0.0615
Docetaxel	56	12 (21.4)	NR (2.9, NE)	53	12 (22.6)	NR (3.5, NE)	0.808 (0.362, 1.804)	0.6009
Irinotecan	117	21 (17.9)	NR (NE, NE)	118	18 (15.3)	NR (3.2, NE)	0.716 (0.377, 1.358)	0.2993
Interaction								0.7773

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Physical Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	12 (18.8)	NR (NE, NE)	63	17 (27.0)	4.5 (2.3, NE)	0.479 (0.226, 1.014)	0.0478
1	192	35 (18.2)	NR (NE, NE)	193	35 (18.1)	10.0 (4.9, NE)	0.718 (0.447, 1.151)	0.1640
Interaction								0.3839
Region #1								
Asia	201	34 (16.9)	NR (NE, NE)	203	39 (19.2)	10.0 (4.5, NE)	0.610 (0.383, 0.971)	0.0341
Europe/North America	55	13 (23.6)	NR (3.6, NE)	53	13 (24.5)	3.5 (2.7, NE)	0.743 (0.342, 1.613)	0.4482
Interaction								0.5904

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Physical Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	30 (17.0)	NR (NE, NE)	178	30 (16.9)	10.0 (4.5, NE)	0.701 (0.421, 1.169)	0.1685
Japan	25	4 (16.0)	NR (NE, NE)	25	9 (36.0)	4.9 (1.7, NE)	0.325 (0.098, 1.073)	0.0508
Europe/North America	55	13 (23.6)	NR (3.6, NE)	53	13 (24.5)	3.5 (2.7, NE)	0.743 (0.342, 1.613)	0.4482
Interaction								0.4147
Race								
Asian and other	203	35 (17.2)	NR (NE, NE)	212	40 (18.9)	10.0 (4.5, NE)	0.628 (0.397, 0.994)	0.0440
White	53	12 (22.6)	NR (3.6, NE)	44	12 (27.3)	3.5 (2.7, NE)	0.677 (0.303, 1.515)	0.3367
Interaction								0.7935

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Physical Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	17 (21.3)	NR (NE, NE)	62	12 (19.4)	NR (10.0, NE)	0.718 (0.341, 1.513)	0.3796
vCPS < 10%	100	18 (18.0)	NR (NE, NE)	122	23 (18.9)	NR (3.5, NE)	0.745 (0.400, 1.386)	0.3481
Missing	76	12 (15.8)	NR (NE, NE)	72	17 (23.6)	3.5 (1.7, NE)	0.446 (0.211, 0.942)	0.0290
Interaction								0.5852

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Role Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	36 (23.7)	NR (9.1, NE)	158	33 (20.9)	10.0 (2.8, NE)	0.767 (0.475, 1.239)	0.2715
>= 65 Years	104	28 (26.9)	NR (NE, NE)	98	29 (29.6)	4.9 (2.1, NE)	0.771 (0.457, 1.302)	0.3210
Interaction								0.8435
Gender								
Male	217	55 (25.3)	NR (NE, NE)	215	48 (22.3)	NR (3.5, NE)	0.859 (0.581, 1.270)	0.4402
Female	39	9 (23.1)	NR (3.1, NE)	41	14 (34.1)	2.7 (1.4, NE)	0.459 (0.196, 1.072)	0.0617
Interaction								0.2389

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Role Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	52 (27.7)	NR (9.1, NE)	192	48 (25.0)	10.0 (3.3, NE)	0.830 (0.558, 1.235)	0.3505
Non-Smoker	68	12 (17.6)	NR (NE, NE)	63	14 (22.2)	3.8 (2.6, NE)	0.576 (0.265, 1.255)	0.1563
Interaction								0.3763
ICC Options								
Paclitaxel	83	25 (30.1)	NR (3.5, NE)	85	32 (37.6)	3.3 (1.7, 10.0)	0.644 (0.379, 1.093)	0.0957
Docetaxel	56	11 (19.6)	NR (NE, NE)	53	10 (18.9)	NR (3.5, NE)	0.995 (0.422, 2.345)	0.9899
Irinotecan	117	28 (23.9)	NR (NE, NE)	118	20 (16.9)	NR (2.8, NE)	0.846 (0.470, 1.521)	0.5714
Interaction								0.6672

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Role Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	12 (18.8)	NR (NE, NE)	63	19 (30.2)	3.5 (2.7, NE)	0.390 (0.185, 0.822)	0.0095
1	192	52 (27.1)	NR (NE, NE)	193	43 (22.3)	10.0 (3.3, NE)	0.940 (0.626, 1.413)	0.7644
Interaction								0.0574
Region #1								
Asia	201	47 (23.4)	NR (NE, NE)	203	50 (24.6)	4.9 (3.3, NE)	0.697 (0.465, 1.043)	0.0737
Europe/North America	55	17 (30.9)	9.1 (3.1, NE)	53	12 (22.6)	NR (2.7, NE)	1.080 (0.513, 2.274)	0.8388
Interaction								0.2407

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Role Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	39 (22.2)	NR (NE, NE)	178	39 (21.9)	10.0 (3.5, NE)	0.728 (0.465, 1.140)	0.1589
Japan	25	8 (32.0)	NR (0.8, NE)	25	11 (44.0)	3.3 (1.3, NE)	0.619 (0.245, 1.562)	0.2854
Europe/North America	55	17 (30.9)	9.1 (3.1, NE)	53	12 (22.6)	NR (2.7, NE)	1.080 (0.513, 2.274)	0.8388
Interaction								0.4409
Race								
Asian and other	203	49 (24.1)	NR (NE, NE)	212	52 (24.5)	4.9 (3.3, NE)	0.722 (0.486, 1.072)	0.1001
White	53	15 (28.3)	9.1 (3.1, NE)	44	10 (22.7)	NR (2.7, NE)	1.022 (0.457, 2.287)	0.9578
Interaction								0.3540

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Role Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	24 (30.0)	NR (4.2, NE)	62	15 (24.2)	10.0 (1.4, NE)	0.871 (0.453, 1.673)	0.6744
vCPS < 10%	100	27 (27.0)	NR (3.7, NE)	122	28 (23.0)	NR (3.3, NE)	0.973 (0.572, 1.655)	0.9184
Missing	76	13 (17.1)	NR (NE, NE)	72	19 (26.4)	3.5 (1.5, NE)	0.436 (0.213, 0.892)	0.0181
Interaction								0.2030

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Emotional Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	18 (11.8)	NR (NE, NE)	158	20 (12.7)	NR (NE, NE)	0.663 (0.349, 1.260)	0.2028
>= 65 Years	104	13 (12.5)	NR (NE, NE)	98	15 (15.3)	NR (NE, NE)	0.665 (0.315, 1.402)	0.2786
Interaction								0.9712
Gender								
Male	217	26 (12.0)	NR (NE, NE)	215	29 (13.5)	NR (NE, NE)	0.636 (0.372, 1.087)	0.0933
Female	39	5 (12.8)	NR (NE, NE)	41	6 (14.6)	NR (2.7, NE)	0.777 (0.236, 2.554)	0.6757
Interaction								0.8792

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Emotional Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	23 (12.2)	NR (NE, NE)	192	26 (13.5)	NR (NE, NE)	0.666 (0.377, 1.174)	0.1547
Non-Smoker	68	8 (11.8)	NR (NE, NE)	63	9 (14.3)	NR (2.7, NE)	0.604 (0.232, 1.578)	0.2980
Interaction								0.8462
ICC Options								
Paclitaxel	83	12 (14.5)	NR (NE, NE)	85	12 (14.1)	NR (NE, NE)	0.873 (0.389, 1.955)	0.7405
Docetaxel	56	8 (14.3)	NR (NE, NE)	53	11 (20.8)	NR (2.9, NE)	0.561 (0.224, 1.406)	0.2052
Irinotecan	117	11 (9.4)	NR (NE, NE)	118	12 (10.2)	NR (NE, NE)	0.550 (0.238, 1.269)	0.1536
Interaction								0.6491

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Emotional Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	9 (14.1)	NR (NE, NE)	63	10 (15.9)	NR (4.5, NE)	0.616 (0.245, 1.548)	0.2954
1	192	22 (11.5)	NR (NE, NE)	193	25 (13.0)	NR (NE, NE)	0.656 (0.368, 1.167)	0.1469
Interaction								0.9945
Region #1								
Asia	201	22 (10.9)	NR (NE, NE)	203	24 (11.8)	NR (NE, NE)	0.681 (0.380, 1.223)	0.1928
Europe/North America	55	9 (16.4)	NR (9.1, NE)	53	11 (20.8)	NR (2.7, NE)	0.600 (0.246, 1.460)	0.2542
Interaction								0.9753

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Emotional Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	17 (9.7)	NR (NE, NE)	178	20 (11.2)	NR (NE, NE)	0.621 (0.323, 1.192)	0.1464
Japan	25	5 (20.0)	NR (7.0, NE)	25	4 (16.0)	NR (NE, NE)	1.023 (0.267, 3.916)	0.9735
Europe/North America	55	9 (16.4)	NR (9.1, NE)	53	11 (20.8)	NR (2.7, NE)	0.600 (0.246, 1.460)	0.2542
Interaction								0.8629
Race								
Asian and other	203	22 (10.8)	NR (NE, NE)	212	26 (12.3)	NR (NE, NE)	0.639 (0.360, 1.134)	0.1205
White	53	9 (17.0)	NR (9.1, NE)	44	9 (20.5)	NR (2.7, NE)	0.689 (0.271, 1.749)	0.4301
Interaction								0.7786

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Emotional Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	7 (8.8)	NR (NE, NE)	62	5 (8.1)	NR (NE, NE)	0.790 (0.248, 2.517)	0.6878
vCPS < 10%	100	11 (11.0)	NR (NE, NE)	122	19 (15.6)	NR (4.5, NE)	0.563 (0.267, 1.187)	0.1239
Missing	76	13 (17.1)	NR (7.0, NE)	72	11 (15.3)	NR (NE, NE)	0.788 (0.350, 1.777)	0.5633
Interaction								0.8136

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Cognitive Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	30 (19.7)	NR (9.1, NE)	158	28 (17.7)	NR (10.0, NE)	0.787 (0.468, 1.323)	0.3593
>= 65 Years	104	21 (20.2)	NR (NE, NE)	98	13 (13.3)	10.2 (10.2, NE)	1.320 (0.658, 2.651)	0.4296
Interaction								0.2790
Gender								
Male	217	41 (18.9)	NR (NE, NE)	215	36 (16.7)	NR (10.2, NE)	0.855 (0.544, 1.342)	0.4906
Female	39	10 (25.6)	NR (2.8, NE)	41	5 (12.2)	10.0 (10.0, NE)	1.786 (0.608, 5.249)	0.2817
Interaction								0.2071

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Cognitive Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	32 (17.0)	NR (NE, NE)	192	33 (17.2)	10.2 (10.0, NE)	0.753 (0.460, 1.231)	0.2522
Non-Smoker	68	19 (27.9)	NR (2.3, NE)	63	8 (12.7)	NR (NE, NE)	1.724 (0.753, 3.945)	0.1879
Interaction								0.0926
ICC Options								
Paclitaxel	83	17 (20.5)	NR (9.1, NE)	85	17 (20.0)	10.0 (3.6, NE)	0.872 (0.443, 1.717)	0.6896
Docetaxel	56	14 (25.0)	NR (3.5, NE)	53	10 (18.9)	NR (NE, NE)	1.193 (0.529, 2.692)	0.6672
Irinotecan	117	20 (17.1)	NR (NE, NE)	118	14 (11.9)	10.2 (10.2, NE)	0.984 (0.492, 1.965)	0.9623
Interaction								0.8773

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Cognitive Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	16 (25.0)	NR (9.1, NE)	63	16 (25.4)	10.2 (3.3, NE)	0.712 (0.352, 1.440)	0.3346
1	192	35 (18.2)	NR (NE, NE)	193	25 (13.0)	NR (10.0, NE)	1.116 (0.666, 1.868)	0.6747
Interaction								0.3695
Region #1								
Asia	201	40 (19.9)	NR (NE, NE)	203	33 (16.3)	10.0 (10.0, NE)	0.931 (0.585, 1.482)	0.7615
Europe/North America	55	11 (20.0)	NR (3.7, NE)	53	8 (15.1)	NR (10.2, NE)	1.109 (0.445, 2.767)	0.8236
Interaction								0.6626

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Cognitive Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	33 (18.8)	NR (NE, NE)	178	27 (15.2)	10.0 (10.0, NE)	0.928 (0.556, 1.549)	0.7735
Japan	25	7 (28.0)	NR (2.1, NE)	25	6 (24.0)	3.6 (3.3, NE)	0.975 (0.323, 2.938)	0.9631
Europe/North America	55	11 (20.0)	NR (3.7, NE)	53	8 (15.1)	NR (10.2, NE)	1.109 (0.445, 2.767)	0.8236
Interaction								0.9105
Race								
Asian and other	203	40 (19.7)	NR (NE, NE)	212	34 (16.0)	10.0 (10.0, NE)	0.929 (0.586, 1.473)	0.7529
White	53	11 (20.8)	NR (3.7, NE)	44	7 (15.9)	NR (10.2, NE)	1.150 (0.444, 2.976)	0.7719
Interaction								0.6248

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Cognitive Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	17 (21.3)	NR (NE, NE)	62	8 (12.9)	NR (10.0, NE)	1.194 (0.513, 2.782)	0.6787
vCPS < 10%	100	20 (20.0)	NR (NE, NE)	122	21 (17.2)	10.2 (10.2, NE)	0.941 (0.508, 1.743)	0.8446
Missing	76	14 (18.4)	NR (NE, NE)	72	12 (16.7)	NR (3.6, NE)	0.855 (0.393, 1.858)	0.6860
Interaction								0.8262

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Social Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	32 (21.1)	NR (NE, NE)	158	25 (15.8)	NR (NE, NE)	1.026 (0.607, 1.736)	0.9214
>= 65 Years	104	23 (22.1)	NR (NE, NE)	98	23 (23.5)	NR (3.5, NE)	0.783 (0.437, 1.402)	0.4032
Interaction								0.5701
Gender								
Male	217	46 (21.2)	NR (NE, NE)	215	40 (18.6)	NR (4.7, NE)	0.916 (0.598, 1.402)	0.6821
Female	39	9 (23.1)	NR (2.9, NE)	41	8 (19.5)	NR (1.9, NE)	0.908 (0.347, 2.380)	0.8439
Interaction								0.9509

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Social Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	42 (22.3)	NR (NE, NE)	192	40 (20.8)	NR (4.2, NE)	0.859 (0.556, 1.328)	0.4887
Non-Smoker	68	13 (19.1)	NR (NE, NE)	63	8 (12.7)	NR (NE, NE)	1.193 (0.492, 2.889)	0.6937
Interaction								0.5327
ICC Options								
Paclitaxel	83	15 (18.1)	NR (NE, NE)	85	18 (21.2)	NR (4.7, NE)	0.759 (0.382, 1.508)	0.4253
Docetaxel	56	10 (17.9)	NR (NE, NE)	53	13 (24.5)	NR (2.8, NE)	0.640 (0.280, 1.463)	0.2802
Irinotecan	117	30 (25.6)	NR (NE, NE)	118	17 (14.4)	NR (3.5, NE)	1.252 (0.686, 2.286)	0.4575
Interaction								0.3393

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Social Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	10 (15.6)	NR (NE, NE)	63	11 (17.5)	NR (3.5, NE)	0.673 (0.284, 1.594)	0.3626
1	192	45 (23.4)	NR (NE, NE)	193	37 (19.2)	NR (4.7, NE)	0.983 (0.635, 1.523)	0.9397
Interaction								0.5537
Region #1								
Asia	201	47 (23.4)	NR (NE, NE)	203	36 (17.7)	NR (4.2, NE)	1.041 (0.673, 1.611)	0.8541
Europe/North America	55	8 (14.5)	NR (NE, NE)	53	12 (22.6)	NR (3.5, NE)	0.540 (0.220, 1.325)	0.1671
Interaction								0.1814

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Social Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	42 (23.9)	NR (NE, NE)	178	29 (16.3)	NR (4.2, NE)	1.154 (0.717, 1.858)	0.5497
Japan	25	5 (20.0)	NR (NE, NE)	25	7 (28.0)	NR (1.3, NE)	0.568 (0.178, 1.811)	0.3298
Europe/North America	55	8 (14.5)	NR (NE, NE)	53	12 (22.6)	NR (3.5, NE)	0.540 (0.220, 1.325)	0.1671
Interaction								0.2165
Race								
Asian and other	203	48 (23.6)	NR (NE, NE)	212	37 (17.5)	NR (NE, NE)	1.066 (0.693, 1.641)	0.7676
White	53	7 (13.2)	NR (NE, NE)	44	11 (25.0)	NR (3.5, NE)	0.456 (0.176, 1.179)	0.0929
Interaction								0.1043

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Social Functioning

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	14 (17.5)	NR (NE, NE)	62	8 (12.9)	NR (NE, NE)	1.028 (0.429, 2.464)	0.9511
vCPS < 10%	100	22 (22.0)	NR (NE, NE)	122	26 (21.3)	NR (4.2, NE)	0.876 (0.495, 1.549)	0.6434
Missing	76	19 (25.0)	NR (2.9, NE)	72	14 (19.4)	NR (3.6, NE)	1.008 (0.504, 2.018)	0.9811
Interaction								0.9289

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Fatigue

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	46 (30.3)	20.9 (3.7, NE)	158	48 (30.4)	3.1 (2.1, NE)	0.651 (0.431, 0.985)	0.0371
>= 65 Years	104	42 (40.4)	3.5 (2.1, NE)	98	35 (35.7)	2.2 (1.5, NE)	0.872 (0.552, 1.379)	0.5501
Interaction								0.4085
Gender								
Male	217	72 (33.2)	11.8 (3.5, NE)	215	73 (34.0)	2.7 (1.7, 3.8)	0.642 (0.459, 0.897)	0.0077
Female	39	16 (41.0)	2.8 (0.7, NE)	41	10 (24.4)	3.3 (1.7, NE)	1.490 (0.672, 3.301)	0.3128
Interaction								0.0648

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Fatigue

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	69 (36.7)	7.0 (2.8, NE)	192	65 (33.9)	2.7 (1.7, 4.5)	0.797 (0.564, 1.125)	0.1867
Non-Smoker	68	19 (27.9)	20.9 (2.8, NE)	63	18 (28.6)	3.5 (1.5, NE)	0.608 (0.315, 1.175)	0.1306
Interaction								0.5396
ICC Options								
Paclitaxel	83	35 (42.2)	7.0 (2.1, 26.3)	85	31 (36.5)	2.7 (1.7, 4.5)	0.930 (0.568, 1.524)	0.7717
Docetaxel	56	19 (33.9)	3.5 (2.1, NE)	53	19 (35.8)	2.3 (1.4, NE)	0.790 (0.415, 1.505)	0.4619
Irinotecan	117	34 (29.1)	20.9 (3.7, NE)	118	33 (28.0)	3.8 (1.1, NE)	0.590 (0.360, 0.967)	0.0307
Interaction								0.2784

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Fatigue

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	28 (43.8)	7.0 (2.8, NE)	63	27 (42.9)	1.7 (1.1, NE)	0.578 (0.333, 1.003)	0.0454
1	192	60 (31.3)	20.9 (3.5, NE)	193	56 (29.0)	3.3 (2.1, NE)	0.820 (0.567, 1.185)	0.2790
Interaction								0.4843
Region #1								
Asia	201	67 (33.3)	20.9 (3.5, NE)	203	68 (33.5)	2.7 (1.7, 3.8)	0.664 (0.470, 0.938)	0.0170
Europe/North America	55	21 (38.2)	3.7 (2.0, NE)	53	15 (28.3)	NR (1.1, NE)	1.142 (0.582, 2.240)	0.6949
Interaction								0.2124

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Fatigue

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	54 (30.7)	20.9 (3.5, NE)	178	56 (31.5)	3.2 (2.1, 4.5)	0.666 (0.455, 0.973)	0.0302
Japan	25	13 (52.0)	7.0 (0.8, NE)	25	12 (48.0)	1.7 (1.6, NE)	0.731 (0.317, 1.684)	0.4509
Europe/North America	55	21 (38.2)	3.7 (2.0, NE)	53	15 (28.3)	NR (1.1, NE)	1.142 (0.582, 2.240)	0.6949
Interaction								0.4075
Race								
Asian and other	203	69 (34.0)	20.9 (3.5, NE)	212	68 (32.1)	3.1 (2.1, 3.8)	0.715 (0.507, 1.007)	0.0488
White	53	19 (35.8)	3.7 (2.1, NE)	44	15 (34.1)	3.3 (0.9, NE)	0.868 (0.435, 1.731)	0.6828
Interaction								0.7190

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Fatigue

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	31 (38.8)	9.1 (2.2, NE)	62	15 (24.2)	NR (3.8, NE)	1.171 (0.630, 2.176)	0.6126
vCPS < 10%	100	33 (33.0)	3.7 (2.8, NE)	122	47 (38.5)	2.3 (1.5, 3.3)	0.624 (0.397, 0.979)	0.0352
Missing	76	24 (31.6)	11.8 (7.0, NE)	72	21 (29.2)	2.1 (1.7, NE)	0.667 (0.357, 1.247)	0.1879
Interaction								0.3210

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Nausea and Vomiting

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	30 (19.7)	NR (NE, NE)	158	20 (12.7)	NR (NE, NE)	1.140 (0.644, 2.018)	0.6493
>= 65 Years	104	12 (11.5)	NR (NE, NE)	98	15 (15.3)	NR (5.2, NE)	0.577 (0.268, 1.241)	0.1532
Interaction								0.1881
Gender								
Male	217	34 (15.7)	NR (NE, NE)	215	30 (14.0)	NR (NE, NE)	0.829 (0.506, 1.360)	0.4542
Female	39	8 (20.5)	NR (3.5, NE)	41	5 (12.2)	NR (NE, NE)	1.411 (0.454, 4.382)	0.5479
Interaction								0.4468

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Nausea and Vomiting

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	30 (16.0)	NR (NE, NE)	192	26 (13.5)	NR (NE, NE)	0.893 (0.526, 1.517)	0.6743
Non-Smoker	68	12 (17.6)	NR (NE, NE)	63	9 (14.3)	NR (3.2, NE)	0.922 (0.386, 2.202)	0.8545
Interaction								0.8959
ICC Options								
Paclitaxel	83	16 (19.3)	NR (NE, NE)	85	11 (12.9)	NR (5.2, NE)	1.384 (0.642, 2.987)	0.4035
Docetaxel	56	10 (17.9)	NR (3.6, NE)	53	4 (7.5)	NR (2.9, NE)	1.844 (0.571, 5.950)	0.2975
Irinotecan	117	16 (13.7)	NR (NE, NE)	118	20 (16.9)	NR (NE, NE)	0.505 (0.258, 0.987)	0.0400
Interaction								0.0250

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Nausea and Vomiting

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	7 (10.9)	NR (NE, NE)	63	10 (15.9)	NR (5.2, NE)	0.498 (0.188, 1.318)	0.1516
1	192	35 (18.2)	NR (NE, NE)	193	25 (13.0)	NR (NE, NE)	1.069 (0.638, 1.793)	0.7972
Interaction								0.2164
Region #1								
Asia	201	31 (15.4)	NR (NE, NE)	203	26 (12.8)	NR (NE, NE)	0.904 (0.534, 1.529)	0.7043
Europe/North America	55	11 (20.0)	NR (3.5, NE)	53	9 (17.0)	NR (2.9, NE)	0.928 (0.382, 2.255)	0.8696
Interaction								0.7968

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Nausea and Vomiting

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	28 (15.9)	NR (NE, NE)	178	25 (14.0)	NR (NE, NE)	0.829 (0.481, 1.428)	0.4950
Japan	25	3 (12.0)	NR (NE, NE)	25	1 (4.0)	NR (5.2, NE)	2.468 (0.252, 24.201)	0.4231
Europe/North America	55	11 (20.0)	NR (3.5, NE)	53	9 (17.0)	NR (2.9, NE)	0.928 (0.382, 2.255)	0.8696
Interaction								0.5934
Race								
Asian and other	203	32 (15.8)	NR (NE, NE)	212	27 (12.7)	NR (NE, NE)	0.924 (0.551, 1.549)	0.7632
White	53	10 (18.9)	NR (3.5, NE)	44	8 (18.2)	NR (2.9, NE)	0.844 (0.331, 2.153)	0.7212
Interaction								0.9736

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Nausea and Vomiting

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	10 (12.5)	NR (NE, NE)	62	4 (6.5)	NR (NE, NE)	1.417 (0.441, 4.549)	0.5552
vCPS < 10%	100	19 (19.0)	NR (NE, NE)	122	21 (17.2)	NR (NE, NE)	0.871 (0.467, 1.624)	0.6609
Missing	76	13 (17.1)	NR (NE, NE)	72	10 (13.9)	NR (3.5, NE)	0.931 (0.405, 2.145)	0.8663
Interaction								0.8039

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Pain

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	39 (25.7)	NR (NE, NE)	158	29 (18.4)	10.0 (3.8, NE)	1.092 (0.673, 1.773)	0.7177
>= 65 Years	104	22 (21.2)	NR (11.8, NE)	98	24 (24.5)	4.9 (3.2, NE)	0.658 (0.366, 1.183)	0.1540
Interaction								0.2220
Gender								
Male	217	53 (24.4)	NR (NE, NE)	215	45 (20.9)	5.9 (3.8, NE)	0.883 (0.590, 1.321)	0.5402
Female	39	8 (20.5)	NR (NE, NE)	41	8 (19.5)	10.0 (3.3, NE)	0.855 (0.319, 2.289)	0.7503
Interaction								0.9053

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Pain

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	50 (26.6)	NR (NE, NE)	192	43 (22.4)	5.9 (3.8, NE)	0.921 (0.610, 1.391)	0.6933
Non-Smoker	68	11 (16.2)	NR (11.8, NE)	63	10 (15.9)	NR (3.2, NE)	0.764 (0.321, 1.823)	0.5407
Interaction								0.6928
ICC Options								
Paclitaxel	83	20 (24.1)	NR (11.8, NE)	85	21 (24.7)	10.0 (3.6, NE)	0.815 (0.438, 1.517)	0.5153
Docetaxel	56	13 (23.2)	NR (2.1, NE)	53	9 (17.0)	NR (NE, NE)	1.312 (0.561, 3.071)	0.5247
Irinotecan	117	28 (23.9)	NR (NE, NE)	118	23 (19.5)	5.9 (3.0, NE)	0.816 (0.465, 1.432)	0.4709
Interaction								0.6272

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Pain

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	20 (31.3)	NR (7.0, NE)	63	14 (22.2)	NR (3.6, NE)	1.113 (0.556, 2.227)	0.7606
1	192	41 (21.4)	NR (NE, NE)	193	39 (20.2)	10.0 (3.3, NE)	0.794 (0.510, 1.237)	0.3011
Interaction								0.3939
Region #1								
Asia	201	47 (23.4)	NR (NE, NE)	203	41 (20.2)	5.9 (3.6, NE)	0.841 (0.549, 1.287)	0.4185
Europe/North America	55	14 (25.5)	NR (2.9, NE)	53	12 (22.6)	NR (2.7, NE)	1.018 (0.470, 2.203)	0.9639
Interaction								0.7467

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Pain

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	41 (23.3)	NR (NE, NE)	178	36 (20.2)	10.0 (3.3, NE)	0.875 (0.557, 1.375)	0.5573
Japan	25	6 (24.0)	NR (7.0, NE)	25	5 (20.0)	4.9 (3.6, NE)	0.576 (0.163, 2.036)	0.3860
Europe/North America	55	14 (25.5)	NR (2.9, NE)	53	12 (22.6)	NR (2.7, NE)	1.018 (0.470, 2.203)	0.9639
Interaction								0.9490
Race								
Asian and other	203	48 (23.6)	NR (NE, NE)	212	42 (19.8)	5.9 (3.8, NE)	0.864 (0.567, 1.317)	0.4909
White	53	13 (24.5)	NR (2.9, NE)	44	11 (25.0)	NR (2.7, NE)	0.924 (0.413, 2.065)	0.8468
Interaction								0.9560

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Pain

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	15 (18.8)	NR (NE, NE)	62	13 (21.0)	10.0 (3.3, NE)	0.612 (0.289, 1.298)	0.1929
vCPS < 10%	100	25 (25.0)	NR (NE, NE)	122	28 (23.0)	NR (3.2, NE)	0.895 (0.521, 1.538)	0.6858
Missing	76	21 (27.6)	NR (7.0, NE)	72	12 (16.7)	4.9 (2.8, NE)	1.355 (0.659, 2.789)	0.3984
Interaction								0.3113

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Dyspnoea

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	29 (19.1)	NR (NE, NE)	158	25 (15.8)	NR (NE, NE)	0.868 (0.506, 1.490)	0.6042
>= 65 Years	104	12 (11.5)	NR (NE, NE)	98	13 (13.3)	10.2 (10.2, NE)	0.647 (0.291, 1.438)	0.2800
Interaction								0.7098
Gender								
Male	217	35 (16.1)	NR (NE, NE)	215	33 (15.3)	NR (10.2, NE)	0.771 (0.477, 1.247)	0.2842
Female	39	6 (15.4)	NR (NE, NE)	41	5 (12.2)	NR (3.3, NE)	1.040 (0.314, 3.442)	0.9484
Interaction								0.7166

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Dyspnoea

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	33 (17.6)	NR (NE, NE)	192	35 (18.2)	NR (10.2, NE)	0.722 (0.446, 1.167)	0.1776
Non-Smoker	68	8 (11.8)	NR (NE, NE)	63	3 (4.8)	NR (3.8, NE)	1.761 (0.463, 6.705)	0.3995
Interaction								0.1871
ICC Options								
Paclitaxel	83	17 (20.5)	NR (NE, NE)	85	15 (17.6)	NR (3.5, NE)	1.054 (0.525, 2.114)	0.8821
Docetaxel	56	8 (14.3)	NR (NE, NE)	53	11 (20.8)	NR (2.9, NE)	0.531 (0.212, 1.331)	0.1690
Irinotecan	117	16 (13.7)	NR (NE, NE)	118	12 (10.2)	10.2 (NE, NE)	0.891 (0.415, 1.914)	0.7646
Interaction								0.5381

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Dyspnoea

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	10 (15.6)	NR (NE, NE)	63	10 (15.9)	NR (10.2, NE)	0.742 (0.306, 1.797)	0.5038
1	192	31 (16.1)	NR (NE, NE)	193	28 (14.5)	NR (3.8, NE)	0.819 (0.489, 1.372)	0.4440
Interaction								0.8924
Region #1								
Asia	201	36 (17.9)	NR (NE, NE)	203	30 (14.8)	NR (NE, NE)	0.897 (0.550, 1.463)	0.6606
Europe/North America	55	5 (9.1)	NR (NE, NE)	53	8 (15.1)	10.2 (3.3, NE)	0.435 (0.140, 1.348)	0.1381
Interaction								0.3644

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Dyspnoea

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	30 (17.0)	NR (NE, NE)	178	23 (12.9)	NR (NE, NE)	0.975 (0.564, 1.686)	0.9283
Japan	25	6 (24.0)	NR (3.1, NE)	25	7 (28.0)	NR (1.7, NE)	0.757 (0.252, 2.271)	0.6147
Europe/North America	55	5 (9.1)	NR (NE, NE)	53	8 (15.1)	10.2 (3.3, NE)	0.435 (0.140, 1.348)	0.1381
Interaction								0.5055
Race								
Asian and other	203	37 (18.2)	NR (NE, NE)	212	31 (14.6)	NR (NE, NE)	0.921 (0.569, 1.491)	0.7375
White	53	4 (7.5)	NR (NE, NE)	44	7 (15.9)	10.2 (2.9, NE)	0.348 (0.100, 1.203)	0.0810
Interaction								0.2352

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Dyspnoea

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	11 (13.8)	NR (NE, NE)	62	11 (17.7)	NR (NE, NE)	0.577 (0.249, 1.337)	0.1913
vCPS < 10%	100	22 (22.0)	NR (3.7, NE)	122	17 (13.9)	10.2 (10.2, NE)	1.355 (0.717, 2.560)	0.3434
Missing	76	8 (10.5)	NR (NE, NE)	72	10 (13.9)	NR (2.8, NE)	0.477 (0.184, 1.235)	0.1172
Interaction								0.0861

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Insomnia

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	25 (16.4)	NR (NE, NE)	158	17 (10.8)	NR (5.9, NE)	1.069 (0.574, 1.990)	0.8320
>= 65 Years	104	22 (21.2)	NR (NE, NE)	98	9 (9.2)	NR (NE, NE)	2.029 (0.932, 4.418)	0.0675
Interaction								0.2047
Gender								
Male	217	37 (17.1)	NR (NE, NE)	215	24 (11.2)	NR (NE, NE)	1.150 (0.685, 1.928)	0.5943
Female	39	10 (25.6)	NR (2.8, NE)	41	2 (4.9)	NR (NE, NE)	4.516 (0.985, 20.699)	0.0330
Interaction								0.0860

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Insomnia

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	35 (18.6)	NR (NE, NE)	192	24 (12.5)	NR (NE, NE)	1.134 (0.673, 1.913)	0.6340
Non-Smoker	68	12 (17.6)	NR (NE, NE)	63	2 (3.2)	NR (NE, NE)	4.611 (1.030, 20.650)	0.0276
Interaction								0.0954
ICC Options								
Paclitaxel	83	17 (20.5)	NR (4.0, NE)	85	8 (9.4)	NR (NE, NE)	2.060 (0.888, 4.776)	0.0840
Docetaxel	56	9 (16.1)	NR (NE, NE)	53	10 (18.9)	NR (2.3, NE)	0.674 (0.271, 1.676)	0.3847
Irinotecan	117	21 (17.9)	NR (NE, NE)	118	8 (6.8)	NR (5.9, NE)	1.678 (0.736, 3.824)	0.2111
Interaction								0.1650

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Insomnia

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	13 (20.3)	NR (NE, NE)	63	9 (14.3)	NR (NE, NE)	1.159 (0.493, 2.725)	0.7304
1	192	34 (17.7)	NR (NE, NE)	193	17 (8.8)	NR (5.9, NE)	1.513 (0.843, 2.716)	0.1605
Interaction								0.4659
Region #1								
Asia	201	36 (17.9)	NR (NE, NE)	203	21 (10.3)	NR (5.9, NE)	1.265 (0.735, 2.178)	0.3904
Europe/North America	55	11 (20.0)	NR (3.7, NE)	53	5 (9.4)	NR (NE, NE)	2.031 (0.704, 5.855)	0.1793
Interaction								0.4251

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Insomnia

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	29 (16.5)	NR (NE, NE)	178	15 (8.4)	NR (NE, NE)	1.425 (0.761, 2.671)	0.2630
Japan	25	7 (28.0)	NR (2.8, NE)	25	6 (24.0)	NR (1.7, NE)	0.966 (0.322, 2.901)	0.9507
Europe/North America	55	11 (20.0)	NR (3.7, NE)	53	5 (9.4)	NR (NE, NE)	2.031 (0.704, 5.855)	0.1793
Interaction								0.5763
Race								
Asian and other	203	36 (17.7)	NR (NE, NE)	212	22 (10.4)	NR (5.9, NE)	1.240 (0.726, 2.118)	0.4267
White	53	11 (20.8)	NR (3.7, NE)	44	4 (9.1)	NR (NE, NE)	2.335 (0.742, 7.348)	0.1342
Interaction								0.3340

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Insomnia

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	16 (20.0)	NR (NE, NE)	62	7 (11.3)	NR (5.9, NE)	1.231 (0.504, 3.010)	0.6459
vCPS < 10%	100	15 (15.0)	NR (NE, NE)	122	10 (8.2)	NR (NE, NE)	1.493 (0.669, 3.330)	0.3231
Missing	76	16 (21.1)	NR (NE, NE)	72	9 (12.5)	NR (4.9, NE)	1.331 (0.585, 3.026)	0.4890
Interaction								0.9490

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Appetite Loss

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	27 (17.8)	NR (NE, NE)	158	23 (14.6)	NR (NE, NE)	0.881 (0.502, 1.544)	0.6542
>= 65 Years	104	20 (19.2)	NR (26.3, NE)	98	17 (17.3)	NR (5.2, NE)	0.792 (0.407, 1.540)	0.4875
Interaction								0.9242
Gender								
Male	217	40 (18.4)	NR (26.3, NE)	215	33 (15.3)	NR (NE, NE)	0.869 (0.543, 1.389)	0.5533
Female	39	7 (17.9)	NR (4.5, NE)	41	7 (17.1)	NR (3.5, NE)	0.723 (0.247, 2.117)	0.5512
Interaction								0.6987

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Appetite Loss

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	31 (16.5)	NR (26.3, NE)	192	31 (16.1)	NR (NE, NE)	0.734 (0.442, 1.218)	0.2259
Non-Smoker	68	16 (23.5)	NR (11.8, NE)	63	9 (14.3)	NR (3.8, NE)	1.223 (0.536, 2.789)	0.6291
Interaction								0.3543
ICC Options								
Paclitaxel	83	20 (24.1)	NR (9.1, NE)	85	13 (15.3)	NR (5.2, NE)	1.287 (0.630, 2.630)	0.4865
Docetaxel	56	8 (14.3)	NR (NE, NE)	53	7 (13.2)	NR (NE, NE)	0.879 (0.316, 2.444)	0.8037
Irinotecan	117	19 (16.2)	NR (NE, NE)	118	20 (16.9)	NR (3.5, NE)	0.631 (0.333, 1.196)	0.1490
Interaction								0.1708

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Appetite Loss

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	12 (18.8)	26.3 (11.8, NE)	63	10 (15.9)	NR (5.2, NE)	0.717 (0.298, 1.729)	0.4567
1	192	35 (18.2)	NR (NE, NE)	193	30 (15.5)	NR (NE, NE)	0.891 (0.546, 1.456)	0.6427
Interaction								0.8940
Region #1								
Asia	201	34 (16.9)	NR (26.3, NE)	203	35 (17.2)	NR (5.2, NE)	0.664 (0.410, 1.076)	0.0913
Europe/North America	55	13 (23.6)	NR (4.5, NE)	53	5 (9.4)	NR (NE, NE)	2.282 (0.807, 6.453)	0.1078
Interaction								0.0406

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Appetite Loss

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	30 (17.0)	NR (NE, NE)	178	29 (16.3)	NR (NE, NE)	0.753 (0.450, 1.260)	0.2742
Japan	25	4 (16.0)	26.3 (11.8, NE)	25	6 (24.0)	NR (2.2, NE)	0.281 (0.066, 1.187)	0.0677
Europe/North America	55	13 (23.6)	NR (4.5, NE)	53	5 (9.4)	NR (NE, NE)	2.282 (0.807, 6.453)	0.1078
Interaction								0.1020
Race								
Asian and other	203	35 (17.2)	NR (26.3, NE)	212	35 (16.5)	NR (5.2, NE)	0.707 (0.438, 1.141)	0.1509
White	53	12 (22.6)	NR (4.5, NE)	44	5 (11.4)	NR (NE, NE)	1.869 (0.653, 5.346)	0.2326
Interaction								0.1125

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Appetite Loss

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	14 (17.5)	NR (NE, NE)	62	7 (11.3)	NR (NE, NE)	1.096 (0.437, 2.748)	0.8436
vCPS < 10%	100	18 (18.0)	NR (NE, NE)	122	21 (17.2)	NR (NE, NE)	0.850 (0.452, 1.597)	0.6088
Missing	76	15 (19.7)	26.3 (11.8, NE)	72	12 (16.7)	NR (2.8, NE)	0.761 (0.346, 1.675)	0.4925
Interaction								0.8752

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Constipation

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	23 (15.1)	NR (NE, NE)	158	19 (12.0)	NR (NE, NE)	0.935 (0.507, 1.725)	0.8298
>= 65 Years	104	14 (13.5)	NR (NE, NE)	98	4 (4.1)	NR (NE, NE)	2.961 (0.973, 9.008)	0.0438
Interaction								0.0885
Gender								
Male	217	32 (14.7)	NR (NE, NE)	215	18 (8.4)	NR (NE, NE)	1.432 (0.802, 2.557)	0.2191
Female	39	5 (12.8)	NR (NE, NE)	41	5 (12.2)	NR (3.5, NE)	0.759 (0.216, 2.668)	0.6640
Interaction								0.4218

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Constipation

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	28 (14.9)	NR (NE, NE)	192	18 (9.4)	NR (NE, NE)	1.322 (0.729, 2.396)	0.3527
Non-Smoker	68	9 (13.2)	NR (NE, NE)	63	5 (7.9)	NR (NE, NE)	1.216 (0.405, 3.648)	0.7268
Interaction								0.9854
ICC Options								
Paclitaxel	83	13 (15.7)	NR (NE, NE)	85	5 (5.9)	NR (NE, NE)	2.635 (0.939, 7.392)	0.0539
Docetaxel	56	8 (14.3)	NR (NE, NE)	53	6 (11.3)	NR (NE, NE)	1.213 (0.420, 3.503)	0.7203
Irinotecan	117	16 (13.7)	NR (NE, NE)	118	12 (10.2)	NR (NE, NE)	0.822 (0.384, 1.761)	0.6123
Interaction								0.2047

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Constipation

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	5 (7.8)	NR (NE, NE)	63	9 (14.3)	NR (NE, NE)	0.446 (0.149, 1.336)	0.1363
1	192	32 (16.7)	NR (NE, NE)	193	14 (7.3)	NR (NE, NE)	1.864 (0.993, 3.500)	0.0477
Interaction								0.0190
Region #1								
Asia	201	30 (14.9)	NR (NE, NE)	203	19 (9.4)	NR (NE, NE)	1.259 (0.707, 2.243)	0.4313
Europe/North America	55	7 (12.7)	NR (NE, NE)	53	4 (7.5)	NR (NE, NE)	1.489 (0.435, 5.100)	0.5227
Interaction								0.8030

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Constipation

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	25 (14.2)	NR (NE, NE)	178	14 (7.9)	NR (NE, NE)	1.378 (0.714, 2.659)	0.3353
Japan	25	5 (20.0)	NR (NE, NE)	25	5 (20.0)	NR (2.1, NE)	0.985 (0.284, 3.413)	0.9806
Europe/North America	55	7 (12.7)	NR (NE, NE)	53	4 (7.5)	NR (NE, NE)	1.489 (0.435, 5.100)	0.5227
Interaction								0.7905
Race								
Asian and other	203	30 (14.8)	NR (NE, NE)	212	19 (9.0)	NR (NE, NE)	1.292 (0.725, 2.301)	0.3813
White	53	7 (13.2)	NR (NE, NE)	44	4 (9.1)	NR (NE, NE)	1.349 (0.394, 4.620)	0.6318
Interaction								0.9534

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Constipation

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	12 (15.0)	NR (NE, NE)	62	6 (9.7)	NR (3.5, NE)	1.158 (0.431, 3.113)	0.7697
vCPS < 10%	100	15 (15.0)	NR (NE, NE)	122	11 (9.0)	NR (NE, NE)	1.419 (0.651, 3.093)	0.3749
Missing	76	10 (13.2)	NR (NE, NE)	72	6 (8.3)	NR (NE, NE)	1.231 (0.445, 3.407)	0.6869
Interaction								0.9499

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Diarrhea

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	8 (5.3)	NR (NE, NE)	158	14 (8.9)	NR (5.8, NE)	0.386 (0.161, 0.927)	0.0269
>= 65 Years	104	6 (5.8)	NR (NE, NE)	98	9 (9.2)	NR (5.2, NE)	0.477 (0.167, 1.367)	0.1581
Interaction								0.8149
Gender								
Male	217	13 (6.0)	NR (NE, NE)	215	19 (8.8)	NR (5.8, NE)	0.466 (0.228, 0.950)	0.0311
Female	39	1 (2.6)	NR (NE, NE)	41	4 (9.8)	NR (3.7, NE)	0.191 (0.021, 1.737)	0.1023
Interaction								0.4397

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Diarrhea

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	13 (6.9)	NR (NE, NE)	192	20 (10.4)	NR (5.8, NE)	0.461 (0.227, 0.933)	0.0272
Non-Smoker	68	1 (1.5)	NR (NE, NE)	63	3 (4.8)	NR (NE, NE)	0.247 (0.026, 2.379)	0.1887
Interaction								0.4997
ICC Options								
Paclitaxel	83	4 (4.8)	NR (NE, NE)	85	5 (5.9)	NR (5.8, NE)	0.640 (0.170, 2.407)	0.5056
Docetaxel	56	2 (3.6)	NR (NE, NE)	53	3 (5.7)	NR (NE, NE)	0.553 (0.092, 3.314)	0.5102
Irinotecan	117	8 (6.8)	NR (NE, NE)	118	15 (12.7)	NR (3.7, NE)	0.306 (0.128, 0.734)	0.0049
Interaction								0.4273

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Diarrhea

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	3 (4.7)	NR (NE, NE)	63	9 (14.3)	NR (5.2, NE)	0.241 (0.065, 0.900)	0.0208
1	192	11 (5.7)	NR (NE, NE)	193	14 (7.3)	NR (5.8, NE)	0.539 (0.243, 1.196)	0.1226
Interaction								0.2771
Region #1								
Asia	201	9 (4.5)	NR (NE, NE)	203	16 (7.9)	NR (5.8, NE)	0.351 (0.153, 0.808)	0.0102
Europe/North America	55	5 (9.1)	NR (NE, NE)	53	7 (13.2)	NR (NE, NE)	0.611 (0.193, 1.931)	0.3937
Interaction								0.5716

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Diarrhea

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	6 (3.4)	NR (NE, NE)	178	13 (7.3)	NR (5.8, NE)	0.285 (0.106, 0.764)	0.0080
Japan	25	3 (12.0)	NR (NE, NE)	25	3 (12.0)	NR (5.2, NE)	0.753 (0.146, 3.879)	0.7333
Europe/North America	55	5 (9.1)	NR (NE, NE)	53	7 (13.2)	NR (NE, NE)	0.611 (0.193, 1.931)	0.3937
Interaction								0.5155
Race								
Asian and other	203	9 (4.4)	NR (NE, NE)	212	16 (7.5)	NR (5.8, NE)	0.359 (0.156, 0.826)	0.0120
White	53	5 (9.4)	NR (NE, NE)	44	7 (15.9)	NR (3.7, NE)	0.549 (0.174, 1.734)	0.2960
Interaction								0.6951

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Diarrhea

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	5 (6.3)	NR (NE, NE)	62	4 (6.5)	NR (5.8, NE)	0.672 (0.177, 2.554)	0.5576
vCPS < 10%	100	5 (5.0)	NR (NE, NE)	122	12 (9.8)	NR (NE, NE)	0.402 (0.141, 1.145)	0.0759
Missing	76	4 (5.3)	NR (NE, NE)	72	7 (9.7)	NR (5.2, NE)	0.358 (0.104, 1.237)	0.0901
Interaction								0.8365

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Financial Difficulties

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	18 (11.8)	NR (28.4, NE)	158	11 (7.0)	NR (NE, NE)	1.285 (0.600, 2.752)	0.5130
>= 65 Years	104	7 (6.7)	NR (NE, NE)	98	17 (17.3)	NR (NE, NE)	0.319 (0.132, 0.773)	0.0073
Interaction								0.0152
Gender								
Male	217	23 (10.6)	NR (28.4, NE)	215	21 (9.8)	NR (NE, NE)	0.853 (0.468, 1.553)	0.5994
Female	39	2 (5.1)	NR (NE, NE)	41	7 (17.1)	NR (3.0, NE)	0.210 (0.043, 1.033)	0.0336
Interaction								0.1313

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Financial Difficulties

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	19 (10.1)	NR (NE, NE)	192	19 (9.9)	NR (NE, NE)	0.791 (0.414, 1.510)	0.4726
Non-Smoker	68	6 (8.8)	NR (NE, NE)	63	9 (14.3)	NR (NE, NE)	0.487 (0.172, 1.376)	0.1604
Interaction								0.4092
ICC Options								
Paclitaxel	83	8 (9.6)	NR (NE, NE)	85	9 (10.6)	NR (NE, NE)	0.817 (0.315, 2.121)	0.6744
Docetaxel	56	8 (14.3)	NR (NE, NE)	53	5 (9.4)	NR (NE, NE)	1.473 (0.482, 4.503)	0.4931
Irinotecan	117	9 (7.7)	NR (28.4, NE)	118	14 (11.9)	NR (NE, NE)	0.406 (0.169, 0.975)	0.0356
Interaction								0.2185

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Financial Difficulties

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	6 (9.4)	NR (28.4, NE)	63	4 (6.3)	NR (NE, NE)	0.980 (0.262, 3.667)	0.9759
1	192	19 (9.9)	NR (NE, NE)	193	24 (12.4)	NR (NE, NE)	0.643 (0.351, 1.177)	0.1442
Interaction								0.3359
Region #1								
Asia	201	22 (10.9)	NR (28.4, NE)	203	23 (11.3)	NR (NE, NE)	0.745 (0.411, 1.348)	0.3239
Europe/North America	55	3 (5.5)	NR (NE, NE)	53	5 (9.4)	NR (NE, NE)	0.444 (0.106, 1.866)	0.2534
Interaction								0.5960

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Financial Difficulties

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	19 (10.8)	NR (28.4, NE)	178	23 (12.9)	NR (NE, NE)	0.634 (0.341, 1.177)	0.1409
Japan	25	3 (12.0)	NR (NE, NE)	25	0 (0.0)	NR (NE, NE)	71668956.880 (0.000, NE)	0.1057
Europe/North America	55	3 (5.5)	NR (NE, NE)	53	5 (9.4)	NR (NE, NE)	0.444 (0.106, 1.866)	0.2534
Interaction								0.9529
Race								
Asian and other	203	22 (10.8)	NR (28.4, NE)	212	24 (11.3)	NR (NE, NE)	0.729 (0.405, 1.313)	0.2859
White	53	3 (5.7)	NR (NE, NE)	44	4 (9.1)	NR (NE, NE)	0.516 (0.115, 2.316)	0.3772
Interaction								0.7280

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Financial Difficulties

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	6 (7.5)	NR (NE, NE)	62	10 (16.1)	NR (NE, NE)	0.335 (0.120, 0.932)	0.0264
vCPS < 10%	100	14 (14.0)	NR (NE, NE)	122	11 (9.0)	NR (NE, NE)	1.321 (0.599, 2.915)	0.4867
Missing	76	5 (6.6)	NR (28.4, NE)	72	7 (9.7)	NR (NE, NE)	0.473 (0.138, 1.618)	0.2184
Interaction								0.0836

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Global Health Status/QOL

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	19 (25.0)	NR (9.1, NE)	76	17 (22.4)	NR (3.5, NE)	0.989 (0.513, 1.905)	0.9731
>= 65 Years	63	13 (20.6)	NR (NE, NE)	62	13 (21.0)	NR (NE, NE)	0.927 (0.429, 2.002)	0.8442
Interaction								0.7806
Gender								
Male	118	30 (25.4)	NR (9.1, NE)	111	27 (24.3)	NR (NE, NE)	0.944 (0.560, 1.592)	0.8277
Female	21	2 (9.5)	NR (NE, NE)	27	3 (11.1)	NR (NE, NE)	0.862 (0.144, 5.163)	0.8699
Interaction								0.8268

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Global Health Status/QOL

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	27 (26.0)	NR (9.1, NE)	105	24 (22.9)	NR (NE, NE)	1.082 (0.623, 1.879)	0.7755
Non-Smoker	35	5 (14.3)	NR (NE, NE)	33	6 (18.2)	NR (3.5, NE)	0.598 (0.181, 1.975)	0.3852
Interaction								0.3264
ICC Options								
Paclitaxel	83	21 (25.3)	NR (9.1, NE)	85	15 (17.6)	NR (NE, NE)	1.370 (0.705, 2.662)	0.3455
Docetaxel	56	11 (19.6)	NR (NE, NE)	53	15 (28.3)	NR (3.5, NE)	0.582 (0.266, 1.273)	0.1627
Interaction								0.0788

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Global Health Status/QOL

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	11 (25.6)	NR (9.1, NE)	42	8 (19.0)	NR (NE, NE)	1.075 (0.428, 2.699)	0.8739
1	96	21 (21.9)	NR (NE, NE)	96	22 (22.9)	NR (3.5, NE)	0.907 (0.498, 1.650)	0.7457
Interaction								0.7079
Region #1								
Asia	103	26 (25.2)	NR (NE, NE)	105	27 (25.7)	NR (3.5, NE)	0.876 (0.511, 1.503)	0.6251
Europe/North America	36	6 (16.7)	NR (9.1, NE)	33	3 (9.1)	NR (NE, NE)	1.619 (0.396, 6.630)	0.4961
Interaction								0.3367

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Global Health Status/QOL

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	17 (21.8)	NR (NE, NE)	80	20 (25.0)	NR (3.5, NE)	0.773 (0.405, 1.477)	0.4265
Japan	25	9 (36.0)	NR (2.1, NE)	25	7 (28.0)	NR (1.6, NE)	1.131 (0.416, 3.076)	0.8074
Europe/North America	36	6 (16.7)	NR (9.1, NE)	33	3 (9.1)	NR (NE, NE)	1.619 (0.396, 6.630)	0.4961
Interaction								0.5007
Race								
Asian and other	105	26 (24.8)	NR (NE, NE)	114	28 (24.6)	NR (NE, NE)	0.881 (0.516, 1.505)	0.6373
White	34	6 (17.6)	NR (9.1, NE)	24	2 (8.3)	NR (NE, NE)	2.080 (0.411, 10.513)	0.3631
Interaction								0.2557

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Global Health Status/QOL

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	10 (22.2)	NR (9.1, NE)	34	6 (17.6)	NR (NE, NE)	1.196 (0.432, 3.309)	0.7275
vCPS < 10%	53	14 (26.4)	NR (2.8, NE)	56	14 (25.0)	NR (NE, NE)	0.921 (0.439, 1.934)	0.8236
Missing	41	8 (19.5)	NR (3.5, NE)	48	10 (20.8)	NR (3.5, NE)	0.816 (0.320, 2.080)	0.6650
Interaction								0.8852

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Physical Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	14 (18.4)	NR (NE, NE)	76	21 (27.6)	4.5 (2.3, NE)	0.553 (0.280, 1.090)	0.0815
>= 65 Years	63	12 (19.0)	NR (NE, NE)	62	13 (21.0)	NR (4.9, NE)	0.741 (0.335, 1.637)	0.4538
Interaction								0.6514
Gender								
Male	118	23 (19.5)	NR (NE, NE)	111	29 (26.1)	NR (3.5, NE)	0.614 (0.354, 1.063)	0.0773
Female	21	3 (14.3)	NR (NE, NE)	27	5 (18.5)	10.0 (1.7, NE)	0.762 (0.182, 3.197)	0.7091
Interaction								0.9120

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Physical Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	20 (19.2)	NR (NE, NE)	105	32 (30.5)	4.9 (2.8, NE)	0.516 (0.294, 0.907)	0.0186
Non-Smoker	35	6 (17.1)	NR (2.9, NE)	33	2 (6.1)	NR (NE, NE)	2.268 (0.457, 11.255)	0.3021
Interaction								0.0977
ICC Options								
Paclitaxel	83	14 (16.9)	NR (NE, NE)	85	22 (25.9)	4.9 (2.8, NE)	0.532 (0.271, 1.045)	0.0615
Docetaxel	56	12 (21.4)	NR (2.9, NE)	53	12 (22.6)	NR (3.5, NE)	0.808 (0.362, 1.804)	0.6009
Interaction								0.5003

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Physical Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	7 (16.3)	NR (NE, NE)	42	12 (28.6)	NR (2.3, NE)	0.395 (0.154, 1.012)	0.0443
1	96	19 (19.8)	NR (NE, NE)	96	22 (22.9)	10.0 (3.5, NE)	0.765 (0.413, 1.418)	0.3918
Interaction								0.2544
Region #1								
Asia	103	19 (18.4)	NR (NE, NE)	105	26 (24.8)	10.0 (3.5, NE)	0.588 (0.324, 1.067)	0.0761
Europe/North America	36	7 (19.4)	NR (3.6, NE)	33	8 (24.2)	3.5 (1.5, NE)	0.718 (0.258, 1.994)	0.5215
Interaction								0.7650

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Physical Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	15 (19.2)	NR (NE, NE)	80	17 (21.3)	10.0 (4.5, NE)	0.759 (0.378, 1.521)	0.4334
Japan	25	4 (16.0)	NR (NE, NE)	25	9 (36.0)	4.9 (1.7, NE)	0.325 (0.098, 1.073)	0.0508
Europe/North America	36	7 (19.4)	NR (3.6, NE)	33	8 (24.2)	3.5 (1.5, NE)	0.718 (0.258, 1.994)	0.5215
Interaction								0.4030
Race								
Asian and other	105	20 (19.0)	NR (NE, NE)	114	27 (23.7)	10.0 (4.5, NE)	0.620 (0.347, 1.111)	0.1035
White	34	6 (17.6)	NR (3.6, NE)	24	7 (29.2)	3.5 (1.5, NE)	0.601 (0.201, 1.795)	0.3540
Interaction								0.9482

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Physical Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	9 (20.0)	NR (3.7, NE)	34	10 (29.4)	10.0 (1.7, NE)	0.568 (0.230, 1.403)	0.2132
vCPS < 10%	53	11 (20.8)	NR (NE, NE)	56	11 (19.6)	NR (3.5, NE)	0.918 (0.397, 2.125)	0.8417
Missing	41	6 (14.6)	NR (2.8, NE)	48	13 (27.1)	3.5 (1.7, NE)	0.430 (0.162, 1.137)	0.0781
Interaction								0.5613

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Role Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	19 (25.0)	NR (9.1, NE)	76	19 (25.0)	10.0 (2.7, NE)	0.848 (0.447, 1.609)	0.6103
>= 65 Years	63	17 (27.0)	NR (3.1, NE)	62	23 (37.1)	3.8 (1.4, NE)	0.635 (0.338, 1.195)	0.1483
Interaction								0.4394
Gender								
Male	118	30 (25.4)	NR (NE, NE)	111	35 (31.5)	4.9 (2.7, NE)	0.693 (0.424, 1.133)	0.1358
Female	21	6 (28.6)	NR (0.2, NE)	27	7 (25.9)	10.0 (2.7, NE)	1.048 (0.351, 3.129)	0.9325
Interaction								0.4456

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Role Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	29 (27.9)	NR (9.1, NE)	105	34 (32.4)	4.9 (2.3, NE)	0.765 (0.464, 1.262)	0.2864
Non-Smoker	35	7 (20.0)	NR (2.3, NE)	33	8 (24.2)	3.8 (2.7, NE)	0.653 (0.237, 1.802)	0.4002
Interaction								0.6775
ICC Options								
Paclitaxel	83	25 (30.1)	NR (3.5, NE)	85	32 (37.6)	3.3 (1.7, 10.0)	0.644 (0.379, 1.093)	0.0957
Docetaxel	56	11 (19.6)	NR (NE, NE)	53	10 (18.9)	NR (3.5, NE)	0.995 (0.422, 2.345)	0.9899
Interaction								0.4613

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Role Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	7 (16.3)	NR (NE, NE)	42	15 (35.7)	3.3 (2.3, NE)	0.301 (0.119, 0.759)	0.0064
1	96	29 (30.2)	NR (2.3, NE)	96	27 (28.1)	4.9 (3.3, NE)	1.039 (0.614, 1.756)	0.8863
Interaction								0.0258
Region #1								
Asia	103	27 (26.2)	NR (NE, NE)	105	35 (33.3)	3.8 (2.3, NE)	0.648 (0.391, 1.075)	0.0857
Europe/North America	36	9 (25.0)	NR (3.1, NE)	33	7 (21.2)	NR (2.7, NE)	1.087 (0.400, 2.955)	0.8692
Interaction								0.2942

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Role Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	19 (24.4)	NR (NE, NE)	80	24 (30.0)	3.8 (2.3, NE)	0.681 (0.372, 1.245)	0.2041
Japan	25	8 (32.0)	NR (0.8, NE)	25	11 (44.0)	3.3 (1.3, NE)	0.619 (0.245, 1.562)	0.2854
Europe/North America	36	9 (25.0)	NR (3.1, NE)	33	7 (21.2)	NR (2.7, NE)	1.087 (0.400, 2.955)	0.8692
Interaction								0.5281
Race								
Asian and other	105	29 (27.6)	NR (NE, NE)	114	37 (32.5)	3.8 (2.3, NE)	0.695 (0.426, 1.134)	0.1366
White	34	7 (20.6)	NR (3.1, NE)	24	5 (20.8)	NR (2.7, NE)	0.978 (0.306, 3.128)	0.9704
Interaction								0.4785

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Role Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	11 (24.4)	NR (9.1, NE)	34	12 (35.3)	10.0 (1.4, NE)	0.599 (0.263, 1.364)	0.2120
vCPS < 10%	53	17 (32.1)	NR (2.3, NE)	56	16 (28.6)	3.8 (2.3, NE)	1.043 (0.526, 2.067)	0.9024
Missing	41	8 (19.5)	NR (NE, NE)	48	14 (29.2)	3.5 (1.7, NE)	0.589 (0.246, 1.412)	0.2248
Interaction								0.4785

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Emotional Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	11 (14.5)	NR (7.0, NE)	76	11 (14.5)	NR (NE, NE)	0.852 (0.369, 1.967)	0.7037
>= 65 Years	63	9 (14.3)	NR (NE, NE)	62	12 (19.4)	NR (NE, NE)	0.693 (0.291, 1.650)	0.4027
Interaction								0.6470
Gender								
Male	118	17 (14.4)	NR (NE, NE)	111	18 (16.2)	NR (NE, NE)	0.740 (0.379, 1.444)	0.3722
Female	21	3 (14.3)	NR (NE, NE)	27	5 (18.5)	NR (1.4, NE)	0.759 (0.181, 3.182)	0.7025
Interaction								0.9029

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Emotional Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	15 (14.4)	NR (NE, NE)	105	16 (15.2)	NR (NE, NE)	0.832 (0.408, 1.693)	0.6092
Non-Smoker	35	5 (14.3)	NR (2.2, NE)	33	7 (21.2)	NR (1.4, NE)	0.455 (0.144, 1.440)	0.1690
Interaction								0.3925
ICC Options								
Paclitaxel	83	12 (14.5)	NR (NE, NE)	85	12 (14.1)	NR (NE, NE)	0.873 (0.389, 1.955)	0.7405
Docetaxel	56	8 (14.3)	NR (NE, NE)	53	11 (20.8)	NR (2.9, NE)	0.561 (0.224, 1.406)	0.2052
Interaction								0.4239

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Emotional Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	5 (11.6)	NR (9.1, NE)	42	6 (14.3)	NR (4.5, NE)	0.595 (0.177, 1.997)	0.3914
1	96	15 (15.6)	NR (NE, NE)	96	17 (17.7)	NR (NE, NE)	0.806 (0.402, 1.615)	0.5410
Interaction								0.7428
Region #1								
Asia	103	15 (14.6)	NR (NE, NE)	105	15 (14.3)	NR (NE, NE)	0.867 (0.423, 1.779)	0.6946
Europe/North America	36	5 (13.9)	NR (9.1, NE)	33	8 (24.2)	NR (1.4, NE)	0.456 (0.145, 1.437)	0.1701
Interaction								0.4550

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Emotional Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	10 (12.8)	NR (NE, NE)	80	11 (13.8)	NR (NE, NE)	0.831 (0.352, 1.957)	0.6697
Japan	25	5 (20.0)	NR (7.0, NE)	25	4 (16.0)	NR (NE, NE)	1.023 (0.267, 3.916)	0.9735
Europe/North America	36	5 (13.9)	NR (9.1, NE)	33	8 (24.2)	NR (1.4, NE)	0.456 (0.145, 1.437)	0.1701
Interaction								0.7532
Race								
Asian and other	105	15 (14.3)	NR (NE, NE)	114	17 (14.9)	NR (NE, NE)	0.789 (0.393, 1.585)	0.5017
White	34	5 (14.7)	NR (9.1, NE)	24	6 (25.0)	NR (1.7, NE)	0.545 (0.162, 1.836)	0.3204
Interaction								0.6979

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Emotional Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	4 (8.9)	NR (NE, NE)	34	2 (5.9)	NR (NE, NE)	1.293 (0.235, 7.127)	0.7674
vCPS < 10%	53	9 (17.0)	NR (NE, NE)	56	13 (23.2)	NR (4.5, NE)	0.649 (0.277, 1.520)	0.3121
Missing	41	7 (17.1)	NR (7.0, NE)	48	8 (16.7)	NR (NE, NE)	0.856 (0.306, 2.394)	0.7655
Interaction								0.7133

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Cognitive Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	16 (21.1)	NR (9.1, NE)	76	17 (22.4)	10.0 (3.3, NE)	0.775 (0.391, 1.538)	0.4610
>= 65 Years	63	15 (23.8)	NR (3.6, NE)	62	10 (16.1)	NR (NE, NE)	1.443 (0.648, 3.216)	0.3634
Interaction								0.3165
Gender								
Male	118	26 (22.0)	NR (9.1, NE)	111	23 (20.7)	NR (NE, NE)	0.939 (0.534, 1.652)	0.8266
Female	21	5 (23.8)	NR (1.6, NE)	27	4 (14.8)	10.0 (10.0, NE)	1.598 (0.426, 6.001)	0.4807
Interaction								0.4898

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Cognitive Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	20 (19.2)	NR (NE, NE)	105	23 (21.9)	10.0 (10.0, NE)	0.784 (0.428, 1.436)	0.4245
Non-Smoker	35	11 (31.4)	2.8 (2.1, NE)	33	4 (12.1)	NR (NE, NE)	2.087 (0.663, 6.565)	0.1951
Interaction								0.1543
ICC Options								
Paclitaxel	83	17 (20.5)	NR (9.1, NE)	85	17 (20.0)	10.0 (3.6, NE)	0.872 (0.443, 1.717)	0.6896
Docetaxel	56	14 (25.0)	NR (3.5, NE)	53	10 (18.9)	NR (NE, NE)	1.193 (0.529, 2.692)	0.6672
Interaction								0.6351

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Cognitive Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	12 (27.9)	NR (3.6, NE)	42	13 (31.0)	3.6 (2.8, NE)	0.662 (0.299, 1.467)	0.2976
1	96	19 (19.8)	NR (NE, NE)	96	14 (14.6)	NR (10.0, NE)	1.298 (0.650, 2.595)	0.4558
Interaction								0.2331
Region #1								
Asia	103	25 (24.3)	NR (NE, NE)	105	22 (21.0)	10.0 (10.0, NE)	1.005 (0.565, 1.787)	0.9857
Europe/North America	36	6 (16.7)	NR (2.8, NE)	33	5 (15.2)	NR (NE, NE)	0.906 (0.272, 3.019)	0.8725
Interaction								0.9791

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Cognitive Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	18 (23.1)	NR (3.6, NE)	80	16 (20.0)	10.0 (10.0, NE)	1.038 (0.529, 2.037)	0.9134
Japan	25	7 (28.0)	NR (2.1, NE)	25	6 (24.0)	3.6 (3.3, NE)	0.975 (0.323, 2.938)	0.9631
Europe/North America	36	6 (16.7)	NR (2.8, NE)	33	5 (15.2)	NR (NE, NE)	0.906 (0.272, 3.019)	0.8725
Interaction								0.9803
Race								
Asian and other	105	25 (23.8)	NR (NE, NE)	114	23 (20.2)	10.0 (10.0, NE)	1.004 (0.568, 1.773)	0.9897
White	34	6 (17.6)	NR (2.8, NE)	24	4 (16.7)	NR (1.5, NE)	0.946 (0.263, 3.396)	0.9320
Interaction								0.9152

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Cognitive Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	10 (22.2)	NR (9.1, NE)	34	6 (17.6)	NR (10.0, NE)	1.153 (0.418, 3.180)	0.7824
vCPS < 10%	53	9 (17.0)	NR (3.5, NE)	56	11 (19.6)	NR (3.3, NE)	0.737 (0.305, 1.780)	0.4940
Missing	41	12 (29.3)	NR (1.6, NE)	48	10 (20.8)	NR (2.1, NE)	1.363 (0.586, 3.167)	0.4602
Interaction								0.5367

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Social Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	12 (15.8)	NR (NE, NE)	76	18 (23.7)	NR (3.1, NE)	0.557 (0.268, 1.158)	0.1084
>= 65 Years	63	13 (20.6)	NR (NE, NE)	62	13 (21.0)	NR (3.6, NE)	0.895 (0.413, 1.941)	0.7764
Interaction								0.3523
Gender								
Male	118	20 (16.9)	NR (NE, NE)	111	27 (24.3)	NR (4.7, NE)	0.614 (0.344, 1.096)	0.0916
Female	21	5 (23.8)	NR (0.7, NE)	27	4 (14.8)	NR (2.3, NE)	1.533 (0.407, 5.773)	0.5229
Interaction								0.2224

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Social Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	18 (17.3)	NR (NE, NE)	105	27 (25.7)	NR (3.6, NE)	0.611 (0.336, 1.112)	0.0996
Non-Smoker	35	7 (20.0)	NR (3.0, NE)	33	4 (12.1)	NR (NE, NE)	1.270 (0.371, 4.347)	0.7002
Interaction								0.2979
ICC Options								
Paclitaxel	83	15 (18.1)	NR (NE, NE)	85	18 (21.2)	NR (4.7, NE)	0.759 (0.382, 1.508)	0.4253
Docetaxel	56	10 (17.9)	NR (NE, NE)	53	13 (24.5)	NR (2.8, NE)	0.640 (0.280, 1.463)	0.2802
Interaction								0.6985

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Social Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	4 (9.3)	NR (NE, NE)	42	8 (19.0)	NR (3.1, NE)	0.374 (0.112, 1.249)	0.0954
1	96	21 (21.9)	NR (NE, NE)	96	23 (24.0)	NR (4.7, NE)	0.834 (0.461, 1.509)	0.5424
Interaction								0.2794
Region #1								
Asia	103	21 (20.4)	NR (NE, NE)	105	24 (22.9)	NR (3.6, NE)	0.757 (0.421, 1.363)	0.3474
Europe/North America	36	4 (11.1)	NR (NE, NE)	33	7 (21.2)	NR (4.7, NE)	0.516 (0.151, 1.766)	0.2786
Interaction								0.5424

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Social Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	16 (20.5)	NR (NE, NE)	80	17 (21.3)	NR (3.1, NE)	0.845 (0.426, 1.675)	0.6259
Japan	25	5 (20.0)	NR (NE, NE)	25	7 (28.0)	NR (1.3, NE)	0.568 (0.178, 1.811)	0.3298
Europe/North America	36	4 (11.1)	NR (NE, NE)	33	7 (21.2)	NR (4.7, NE)	0.516 (0.151, 1.766)	0.2786
Interaction								0.6998
Race								
Asian and other	105	22 (21.0)	NR (NE, NE)	114	25 (21.9)	NR (3.6, NE)	0.800 (0.450, 1.421)	0.4404
White	34	3 (8.8)	NR (NE, NE)	24	6 (25.0)	NR (1.4, NE)	0.378 (0.094, 1.514)	0.1504
Interaction								0.3065

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Social Functioning

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	5 (11.1)	NR (NE, NE)	34	7 (20.6)	NR (2.3, NE)	0.476 (0.150, 1.509)	0.1967
vCPS < 10%	53	10 (18.9)	NR (NE, NE)	56	12 (21.4)	NR (3.1, NE)	0.794 (0.343, 1.840)	0.5842
Missing	41	10 (24.4)	NR (2.1, NE)	48	12 (25.0)	4.7 (2.8, NE)	0.889 (0.383, 2.064)	0.7796
Interaction								0.6409

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Fatigue

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	27 (35.5)	7.0 (2.8, NE)	76	28 (36.8)	2.7 (1.7, 4.5)	0.767 (0.450, 1.307)	0.3208
>= 65 Years	63	27 (42.9)	3.5 (1.4, NE)	62	22 (35.5)	2.2 (1.7, NE)	1.062 (0.598, 1.888)	0.8324
Interaction								0.5078
Gender								
Male	118	46 (39.0)	7.0 (2.8, 26.3)	111	45 (40.5)	2.3 (1.7, 3.8)	0.755 (0.496, 1.147)	0.1783
Female	21	8 (38.1)	2.8 (0.2, NE)	27	5 (18.5)	3.3 (1.7, NE)	2.131 (0.690, 6.588)	0.1737
Interaction								0.0889

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Fatigue

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	43 (41.3)	3.7 (2.1, 26.3)	105	40 (38.1)	2.3 (1.7, NE)	0.982 (0.634, 1.520)	0.9326
Non-Smoker	35	11 (31.4)	11.8 (2.0, NE)	33	10 (30.3)	3.5 (1.4, NE)	0.609 (0.255, 1.455)	0.2573
Interaction								0.4491
ICC Options								
Paclitaxel	83	35 (42.2)	7.0 (2.1, 26.3)	85	31 (36.5)	2.7 (1.7, 4.5)	0.930 (0.568, 1.524)	0.7717
Docetaxel	56	19 (33.9)	3.5 (2.1, NE)	53	19 (35.8)	2.3 (1.4, NE)	0.790 (0.415, 1.505)	0.4619
Interaction								0.6173

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Fatigue

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	17 (39.5)	9.1 (3.5, NE)	42	18 (42.9)	2.3 (1.4, NE)	0.495 (0.248, 0.990)	0.0404
1	96	37 (38.5)	2.9 (1.4, NE)	96	32 (33.3)	2.7 (1.7, NE)	1.199 (0.746, 1.926)	0.4426
Interaction								0.0842
Region #1								
Asia	103	39 (37.9)	7.0 (2.8, NE)	105	43 (41.0)	2.2 (1.7, 3.5)	0.705 (0.453, 1.098)	0.1118
Europe/North America	36	15 (41.7)	2.8 (0.7, NE)	33	7 (21.2)	NR (1.7, NE)	2.130 (0.861, 5.271)	0.0914
Interaction								0.0360

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Fatigue

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	26 (33.3)	NR (2.1, NE)	80	31 (38.8)	2.3 (1.5, 4.5)	0.710 (0.420, 1.200)	0.1874
Japan	25	13 (52.0)	7.0 (0.8, NE)	25	12 (48.0)	1.7 (1.6, NE)	0.731 (0.317, 1.684)	0.4509
Europe/North America	36	15 (41.7)	2.8 (0.7, NE)	33	7 (21.2)	NR (1.7, NE)	2.130 (0.861, 5.271)	0.0914
Interaction								0.1057
Race								
Asian and other	105	41 (39.0)	7.0 (2.8, NE)	114	43 (37.7)	2.3 (1.7, 3.8)	0.794 (0.514, 1.229)	0.2905
White	34	13 (38.2)	2.8 (0.7, NE)	24	7 (29.2)	NR (1.7, NE)	1.470 (0.581, 3.719)	0.4085
Interaction								0.2584

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Fatigue

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	15 (33.3)	9.1 (2.8, NE)	34	10 (29.4)	NR (2.1, NE)	1.004 (0.450, 2.240)	0.9920
vCPS < 10%	53	25 (47.2)	2.1 (1.4, NE)	56	24 (42.9)	2.3 (1.5, 3.8)	1.019 (0.581, 1.786)	0.9476
Missing	41	14 (34.1)	11.8 (2.8, NE)	48	16 (33.3)	2.1 (1.7, 3.5)	0.663 (0.301, 1.460)	0.2905
Interaction								0.8517

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Nausea and Vomiting

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	17 (22.4)	NR (3.6, NE)	76	8 (10.5)	NR (NE, NE)	1.861 (0.802, 4.322)	0.1390
>= 65 Years	63	9 (14.3)	NR (NE, NE)	62	7 (11.3)	NR (5.2, NE)	1.101 (0.406, 2.986)	0.8491
Interaction								0.4192
Gender								
Male	118	21 (17.8)	NR (NE, NE)	111	13 (11.7)	NR (NE, NE)	1.333 (0.666, 2.667)	0.4134
Female	21	5 (23.8)	NR (0.7, NE)	27	2 (7.4)	NR (NE, NE)	3.568 (0.692, 18.397)	0.1028
Interaction								0.3993

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Nausea and Vomiting

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	19 (18.3)	NR (NE, NE)	105	12 (11.4)	NR (5.2, NE)	1.501 (0.727, 3.100)	0.2669
Non-Smoker	35	7 (20.0)	NR (2.9, NE)	33	3 (9.1)	NR (3.2, NE)	1.591 (0.410, 6.170)	0.4972
Interaction								0.9730
ICC Options								
Paclitaxel	83	16 (19.3)	NR (NE, NE)	85	11 (12.9)	NR (5.2, NE)	1.384 (0.642, 2.987)	0.4035
Docetaxel	56	10 (17.9)	NR (3.6, NE)	53	4 (7.5)	NR (2.9, NE)	1.844 (0.571, 5.950)	0.2975
Interaction								0.5685

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Nausea and Vomiting

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	5 (11.6)	NR (NE, NE)	42	4 (9.5)	NR (5.2, NE)	0.915 (0.244, 3.432)	0.8947
1	96	21 (21.9)	NR (NE, NE)	96	11 (11.5)	NR (NE, NE)	1.801 (0.867, 3.741)	0.1074
Interaction								0.4253
Region #1								
Asia	103	19 (18.4)	NR (NE, NE)	105	9 (8.6)	NR (NE, NE)	1.861 (0.840, 4.124)	0.1179
Europe/North America	36	7 (19.4)	NR (2.1, NE)	33	6 (18.2)	NR (2.2, NE)	1.026 (0.343, 3.066)	0.9635
Interaction								0.3364

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Nausea and Vomiting

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	16 (20.5)	NR (NE, NE)	80	8 (10.0)	NR (NE, NE)	1.839 (0.786, 4.301)	0.1508
Japan	25	3 (12.0)	NR (NE, NE)	25	1 (4.0)	NR (5.2, NE)	2.468 (0.252, 24.201)	0.4231
Europe/North America	36	7 (19.4)	NR (2.1, NE)	33	6 (18.2)	NR (2.2, NE)	1.026 (0.343, 3.066)	0.9635
Interaction								0.5988
Race								
Asian and other	105	20 (19.0)	NR (NE, NE)	114	10 (8.8)	NR (NE, NE)	1.845 (0.861, 3.950)	0.1077
White	34	6 (17.6)	NR (2.1, NE)	24	5 (20.8)	NR (2.2, NE)	0.896 (0.272, 2.951)	0.8562
Interaction								0.2636

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Nausea and Vomiting

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	7 (15.6)	NR (NE, NE)	34	1 (2.9)	NR (NE, NE)	5.508 (0.677, 44.827)	0.0720
vCPS < 10%	53	11 (20.8)	NR (3.6, NE)	56	8 (14.3)	NR (3.2, NE)	1.223 (0.491, 3.043)	0.6646
Missing	41	8 (19.5)	NR (2.8, NE)	48	6 (12.5)	NR (3.5, NE)	1.495 (0.516, 4.332)	0.4497
Interaction								0.4925

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Pain

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	20 (26.3)	NR (7.0, NE)	76	14 (18.4)	NR (3.8, NE)	1.347 (0.679, 2.669)	0.3880
>= 65 Years	63	13 (20.6)	NR (11.8, NE)	62	16 (25.8)	4.9 (3.2, NE)	0.671 (0.319, 1.410)	0.2851
Interaction								0.1987
Gender								
Male	118	30 (25.4)	NR (11.8, NE)	111	26 (23.4)	NR (3.6, NE)	0.962 (0.566, 1.635)	0.8860
Female	21	3 (14.3)	NR (1.6, NE)	27	4 (14.8)	10.0 (10.0, NE)	0.847 (0.188, 3.823)	0.8271
Interaction								0.8464

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Pain

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	28 (26.9)	NR (7.0, NE)	105	26 (24.8)	10.0 (3.8, NE)	1.017 (0.594, 1.740)	0.9515
Non-Smoker	35	5 (14.3)	NR (11.8, NE)	33	4 (12.1)	NR (2.7, NE)	0.818 (0.215, 3.119)	0.7682
Interaction								0.8287
ICC Options								
Paclitaxel	83	20 (24.1)	NR (11.8, NE)	85	21 (24.7)	10.0 (3.6, NE)	0.815 (0.438, 1.517)	0.5153
Docetaxel	56	13 (23.2)	NR (2.1, NE)	53	9 (17.0)	NR (NE, NE)	1.312 (0.561, 3.071)	0.5247
Interaction								0.4920

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Pain

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	13 (30.2)	NR (7.0, NE)	42	8 (19.0)	NR (3.6, NE)	1.201 (0.490, 2.942)	0.6867
1	96	20 (20.8)	NR (NE, NE)	96	22 (22.9)	10.0 (4.9, NE)	0.853 (0.464, 1.567)	0.6042
Interaction								0.4408
Region #1								
Asia	103	24 (23.3)	NR (11.8, NE)	105	25 (23.8)	10.0 (3.6, NE)	0.782 (0.443, 1.380)	0.3898
Europe/North America	36	9 (25.0)	NR (2.0, NE)	33	5 (15.2)	NR (2.7, NE)	1.788 (0.599, 5.336)	0.2891
Interaction								0.2143

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Pain

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	18 (23.1)	NR (NE, NE)	80	20 (25.0)	10.0 (3.2, NE)	0.840 (0.443, 1.590)	0.5867
Japan	25	6 (24.0)	NR (7.0, NE)	25	5 (20.0)	4.9 (3.6, NE)	0.576 (0.163, 2.036)	0.3860
Europe/North America	36	9 (25.0)	NR (2.0, NE)	33	5 (15.2)	NR (2.7, NE)	1.788 (0.599, 5.336)	0.2891
Interaction								0.4797
Race								
Asian and other	105	25 (23.8)	NR (11.8, NE)	114	26 (22.8)	10.0 (3.6, NE)	0.822 (0.471, 1.434)	0.4847
White	34	8 (23.5)	NR (2.0, NE)	24	4 (16.7)	NR (2.7, NE)	1.706 (0.514, 5.669)	0.3766
Interaction								0.3055

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Pain

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	8 (17.8)	NR (NE, NE)	34	8 (23.5)	NR (2.6, NE)	0.649 (0.243, 1.735)	0.3830
vCPS < 10%	53	15 (28.3)	NR (2.9, NE)	56	12 (21.4)	NR (3.8, NE)	1.268 (0.593, 2.709)	0.5354
Missing	41	10 (24.4)	11.8 (7.0, NE)	48	10 (20.8)	4.9 (2.8, NE)	0.940 (0.377, 2.347)	0.8939
Interaction								0.6351

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Dyspnoea

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	17 (22.4)	NR (3.6, NE)	76	15 (19.7)	NR (3.5, NE)	0.947 (0.471, 1.901)	0.8771
>= 65 Years	63	8 (12.7)	NR (NE, NE)	62	11 (17.7)	NR (2.9, NE)	0.614 (0.246, 1.535)	0.2909
Interaction								0.5035
Gender								
Male	118	22 (18.6)	NR (NE, NE)	111	21 (18.9)	NR (3.8, NE)	0.850 (0.466, 1.548)	0.5926
Female	21	3 (14.3)	NR (NE, NE)	27	5 (18.5)	NR (1.7, NE)	0.692 (0.163, 2.932)	0.6144
Interaction								0.6746

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Dyspnoea

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	21 (20.2)	NR (NE, NE)	105	24 (22.9)	NR (3.3, NE)	0.779 (0.432, 1.403)	0.4008
Non-Smoker	35	4 (11.4)	NR (NE, NE)	33	2 (6.1)	NR (3.8, NE)	1.425 (0.260, 7.805)	0.6819
Interaction								0.4854
ICC Options								
Paclitaxel	83	17 (20.5)	NR (NE, NE)	85	15 (17.6)	NR (3.5, NE)	1.054 (0.525, 2.114)	0.8821
Docetaxel	56	8 (14.3)	NR (NE, NE)	53	11 (20.8)	NR (2.9, NE)	0.531 (0.212, 1.331)	0.1690
Interaction								0.2482

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Dyspnoea

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	7 (16.3)	NR (NE, NE)	42	8 (19.0)	NR (2.8, NE)	0.664 (0.239, 1.841)	0.4255
1	96	18 (18.8)	NR (NE, NE)	96	18 (18.8)	NR (3.3, NE)	0.890 (0.462, 1.715)	0.7264
Interaction								0.5879
Region #1								
Asia	103	21 (20.4)	NR (NE, NE)	105	21 (20.0)	NR (3.8, NE)	0.834 (0.454, 1.531)	0.5551
Europe/North America	36	4 (11.1)	NR (NE, NE)	33	5 (15.2)	NR (2.8, NE)	0.681 (0.182, 2.554)	0.5671
Interaction								0.8441

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Dyspnoea

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	15 (19.2)	NR (3.6, NE)	80	14 (17.5)	NR (3.8, NE)	0.962 (0.464, 1.995)	0.9174
Japan	25	6 (24.0)	NR (3.1, NE)	25	7 (28.0)	NR (1.7, NE)	0.757 (0.252, 2.271)	0.6147
Europe/North America	36	4 (11.1)	NR (NE, NE)	33	5 (15.2)	NR (2.8, NE)	0.681 (0.182, 2.554)	0.5671
Interaction								0.7421
Race								
Asian and other	105	22 (21.0)	NR (NE, NE)	114	22 (19.3)	NR (3.8, NE)	0.878 (0.485, 1.590)	0.6670
White	34	3 (8.8)	NR (NE, NE)	24	4 (16.7)	NR (2.8, NE)	0.524 (0.117, 2.358)	0.3920
Interaction								0.5969

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Dyspnoea

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	7 (15.6)	NR (NE, NE)	34	9 (26.5)	NR (1.7, NE)	0.561 (0.209, 1.508)	0.2419
vCPS < 10%	53	12 (22.6)	NR (3.6, NE)	56	8 (14.3)	NR (3.5, NE)	1.474 (0.602, 3.608)	0.3901
Missing	41	6 (14.6)	NR (3.6, NE)	48	9 (18.8)	NR (2.8, NE)	0.604 (0.212, 1.722)	0.3360
Interaction								0.1957

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Insomnia

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	12 (15.8)	NR (NE, NE)	76	10 (13.2)	NR (NE, NE)	0.997 (0.429, 2.315)	0.9943
>= 65 Years	63	14 (22.2)	NR (4.0, NE)	62	8 (12.9)	NR (4.9, NE)	1.652 (0.691, 3.949)	0.2506
Interaction								0.3891
Gender								
Male	118	21 (17.8)	NR (NE, NE)	111	16 (14.4)	NR (NE, NE)	1.101 (0.574, 2.114)	0.7696
Female	21	5 (23.8)	4.0 (1.4, NE)	27	2 (7.4)	NR (NE, NE)	2.968 (0.573, 15.372)	0.1737
Interaction								0.2535

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Insomnia

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	18 (17.3)	NR (NE, NE)	105	16 (15.2)	NR (NE, NE)	1.035 (0.527, 2.033)	0.9203
Non-Smoker	35	8 (22.9)	NR (2.9, NE)	33	2 (6.1)	NR (NE, NE)	3.040 (0.645, 14.330)	0.1386
Interaction								0.2056
ICC Options								
Paclitaxel	83	17 (20.5)	NR (4.0, NE)	85	8 (9.4)	NR (NE, NE)	2.060 (0.888, 4.776)	0.0840
Docetaxel	56	9 (16.1)	NR (NE, NE)	53	10 (18.9)	NR (2.3, NE)	0.674 (0.271, 1.676)	0.3847
Interaction								0.0725

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Insomnia

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	9 (20.9)	NR (NE, NE)	42	7 (16.7)	NR (NE, NE)	1.104 (0.410, 2.975)	0.8412
1	96	17 (17.7)	NR (4.0, NE)	96	11 (11.5)	NR (4.9, NE)	1.428 (0.668, 3.051)	0.3537
Interaction								0.5489
Region #1								
Asia	103	21 (20.4)	NR (NE, NE)	105	14 (13.3)	NR (NE, NE)	1.292 (0.656, 2.547)	0.4536
Europe/North America	36	5 (13.9)	NR (4.0, NE)	33	4 (12.1)	NR (NE, NE)	1.156 (0.310, 4.312)	0.8285
Interaction								0.8779

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Insomnia

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	14 (17.9)	NR (NE, NE)	80	8 (10.0)	NR (NE, NE)	1.585 (0.664, 3.783)	0.2919
Japan	25	7 (28.0)	NR (2.8, NE)	25	6 (24.0)	NR (1.7, NE)	0.966 (0.322, 2.901)	0.9507
Europe/North America	36	5 (13.9)	NR (4.0, NE)	33	4 (12.1)	NR (NE, NE)	1.156 (0.310, 4.312)	0.8285
Interaction								0.7463
Race								
Asian and other	105	21 (20.0)	NR (NE, NE)	114	15 (13.2)	NR (NE, NE)	1.258 (0.647, 2.447)	0.4937
White	34	5 (14.7)	NR (4.0, NE)	24	3 (12.5)	NR (NE, NE)	1.330 (0.317, 5.576)	0.6947
Interaction								0.9737

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Insomnia

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	8 (17.8)	NR (4.0, NE)	34	5 (14.7)	NR (NE, NE)	1.013 (0.329, 3.118)	0.9818
vCPS < 10%	53	9 (17.0)	NR (NE, NE)	56	6 (10.7)	NR (NE, NE)	1.445 (0.514, 4.064)	0.4796
Missing	41	9 (22.0)	NR (2.8, NE)	48	7 (14.6)	NR (4.9, NE)	1.429 (0.531, 3.846)	0.4738
Interaction								0.8950

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Appetite Loss

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	18 (23.7)	NR (3.7, NE)	76	11 (14.5)	NR (NE, NE)	1.433 (0.675, 3.041)	0.3439
>= 65 Years	63	10 (15.9)	NR (11.8, NE)	62	9 (14.5)	NR (5.2, NE)	0.766 (0.297, 1.972)	0.5790
Interaction								0.3965
Gender								
Male	118	25 (21.2)	NR (11.8, NE)	111	16 (14.4)	NR (NE, NE)	1.209 (0.638, 2.292)	0.5587
Female	21	3 (14.3)	NR (NE, NE)	27	4 (14.8)	NR (3.5, NE)	0.777 (0.170, 3.559)	0.7447
Interaction								0.4115

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Appetite Loss

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	18 (17.3)	NR (26.3, NE)	105	17 (16.2)	NR (5.2, NE)	0.877 (0.445, 1.727)	0.7037
Non-Smoker	35	10 (28.6)	NR (1.5, NE)	33	3 (9.1)	NR (3.8, NE)	2.307 (0.630, 8.445)	0.1900
Interaction								0.2104
ICC Options								
Paclitaxel	83	20 (24.1)	NR (9.1, NE)	85	13 (15.3)	NR (5.2, NE)	1.287 (0.630, 2.630)	0.4865
Docetaxel	56	8 (14.3)	NR (NE, NE)	53	7 (13.2)	NR (NE, NE)	0.879 (0.316, 2.444)	0.8037
Interaction								0.4661

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Appetite Loss

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	9 (20.9)	26.3 (9.1, NE)	42	5 (11.9)	NR (5.2, NE)	1.016 (0.325, 3.174)	0.9786
1	96	19 (19.8)	NR (NE, NE)	96	15 (15.6)	NR (NE, NE)	1.164 (0.591, 2.293)	0.6572
Interaction								0.7057
Region #1								
Asia	103	19 (18.4)	NR (26.3, NE)	105	19 (18.1)	NR (5.2, NE)	0.754 (0.393, 1.446)	0.3916
Europe/North America	36	9 (25.0)	NR (2.8, NE)	33	1 (3.0)	NR (NE, NE)	8.415 (1.056, 67.043)	0.0160
Interaction								0.0333

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Appetite Loss

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	15 (19.2)	NR (NE, NE)	80	13 (16.3)	NR (3.8, NE)	1.030 (0.490, 2.166)	0.9375
Japan	25	4 (16.0)	26.3 (11.8, NE)	25	6 (24.0)	NR (2.2, NE)	0.281 (0.066, 1.187)	0.0677
Europe/North America	36	9 (25.0)	NR (2.8, NE)	33	1 (3.0)	NR (NE, NE)	8.415 (1.056, 67.043)	0.0160
Interaction								0.0590
Race								
Asian and other	105	20 (19.0)	NR (26.3, NE)	114	19 (16.7)	NR (5.2, NE)	0.837 (0.440, 1.590)	0.5842
White	34	8 (23.5)	NR (2.8, NE)	24	1 (4.2)	NR (NE, NE)	6.172 (0.764, 49.869)	0.0509
Interaction								0.0777

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Appetite Loss

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	10 (22.2)	NR (3.7, NE)	34	4 (11.8)	NR (3.5, NE)	1.644 (0.512, 5.279)	0.3971
vCPS < 10%	53	11 (20.8)	NR (3.5, NE)	56	7 (12.5)	NR (NE, NE)	1.526 (0.591, 3.937)	0.3767
Missing	41	7 (17.1)	26.3 (11.8, NE)	48	9 (18.8)	NR (2.8, NE)	0.570 (0.191, 1.704)	0.3050
Interaction								0.4983

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Constipation

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	13 (17.1)	NR (NE, NE)	76	10 (13.2)	NR (3.5, NE)	1.208 (0.529, 2.760)	0.6511
>= 65 Years	63	8 (12.7)	NR (NE, NE)	62	1 (1.6)	NR (NE, NE)	8.301 (1.038, 66.384)	0.0163
Interaction								0.1016
Gender								
Male	118	20 (16.9)	NR (NE, NE)	111	7 (6.3)	NR (NE, NE)	2.715 (1.148, 6.423)	0.0173
Female	21	1 (4.8)	NR (NE, NE)	27	4 (14.8)	NR (3.5, NE)	0.254 (0.027, 2.355)	0.1894
Interaction								0.0520

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Constipation

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	16 (15.4)	NR (NE, NE)	105	9 (8.6)	NR (NE, NE)	1.847 (0.816, 4.182)	0.1329
Non-Smoker	35	5 (14.3)	NR (2.9, NE)	33	2 (6.1)	NR (NE, NE)	1.912 (0.371, 9.860)	0.4277
Interaction								0.9787
ICC Options								
Paclitaxel	83	13 (15.7)	NR (NE, NE)	85	5 (5.9)	NR (NE, NE)	2.635 (0.939, 7.392)	0.0539
Docetaxel	56	8 (14.3)	NR (NE, NE)	53	6 (11.3)	NR (NE, NE)	1.213 (0.420, 3.503)	0.7203
Interaction								0.2867

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Constipation

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	2 (4.7)	NR (NE, NE)	42	3 (7.1)	NR (NE, NE)	0.539 (0.090, 3.241)	0.4929
1	96	19 (19.8)	NR (NE, NE)	96	8 (8.3)	NR (NE, NE)	2.533 (1.109, 5.789)	0.0212
Interaction								0.1227
Region #1								
Asia	103	18 (17.5)	NR (NE, NE)	105	11 (10.5)	NR (NE, NE)	1.602 (0.756, 3.393)	0.2118
Europe/North America	36	3 (8.3)	NR (NE, NE)	33	0 (0.0)	NR (NE, NE)	71243685.865 (0.000, NE)	0.1052
Interaction								0.9885

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Constipation

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	13 (16.7)	NR (NE, NE)	80	6 (7.5)	NR (NE, NE)	2.196 (0.834, 5.778)	0.0998
Japan	25	5 (20.0)	NR (NE, NE)	25	5 (20.0)	NR (2.1, NE)	0.985 (0.284, 3.413)	0.9806
Europe/North America	36	3 (8.3)	NR (NE, NE)	33	0 (0.0)	NR (NE, NE)	71243685.865 (0.000, NE)	0.1052
Interaction								0.5013

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Constipation

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	18 (17.1)	NR (NE, NE)	114	11 (9.6)	NR (NE, NE)	1.670 (0.788, 3.538)	0.1735
White	34	3 (8.8)	NR (NE, NE)	24	0 (0.0)	NR (NE, NE)	62214220.628 (0.000, NE)	0.1342
Interaction								0.9895
Baseline PD-L1 Status								
vCPS >= 10%	45	7 (15.6)	NR (NE, NE)	34	5 (14.7)	NR (3.5, NE)	1.025 (0.324, 3.245)	0.9667
vCPS < 10%	53	10 (18.9)	NR (NE, NE)	56	3 (5.4)	NR (NE, NE)	3.485 (0.959, 12.671)	0.0425
Missing	41	4 (9.8)	NR (NE, NE)	48	3 (6.3)	NR (NE, NE)	1.567 (0.351, 7.001)	0.5500
Interaction								0.3863

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Diarrhea

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	3 (3.9)	--	76	6 (7.9)	--	--	--
>= 65 Years	63	3 (4.8)	--	62	2 (3.2)	--	--	--
Interaction								--
Gender								
Male	118	6 (5.1)	NR (NE, NE)	111	7 (6.3)	NR (5.8, NE)	0.649 (0.216, 1.946)	0.4358
Female	21	0 (0.0)	NR (NE, NE)	27	1 (3.7)	NR (NE, NE)	0.000 (0.000, NE)	0.3613
Interaction								0.9935

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Diarrhea

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	5 (4.8)	NR (NE, NE)	105	8 (7.6)	NR (5.8, NE)	0.513 (0.166, 1.586)	0.2379
Non-Smoker	35	1 (2.9)	NR (NE, NE)	33	0 (0.0)	NR (NE, NE)	21508137.648 (0.000, NE)	0.4054
Interaction								0.9930
ICC Options								
Paclitaxel	83	4 (4.8)	--	85	5 (5.9)	--	--	--
Docetaxel	56	2 (3.6)	--	53	3 (5.7)	--	--	--
Interaction								--

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Diarrhea

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	2 (4.7)	--	42	3 (7.1)	--	--	--
1	96	4 (4.2)	--	96	5 (5.2)	--	--	--
Interaction								--
Region #1								
Asia	103	6 (5.8)	NR (NE, NE)	105	7 (6.7)	NR (5.8, NE)	0.664 (0.221, 1.998)	0.4627
Europe/North America	36	0 (0.0)	NR (NE, NE)	33	1 (3.0)	NR (NE, NE)	0.000 (0.000, NE)	0.3173
Interaction								0.9920

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Diarrhea

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	3 (3.8)	--	80	4 (5.0)	--	--	--
Japan	25	3 (12.0)	--	25	3 (12.0)	--	--	--
Europe/North America	36	0 (0.0)	--	33	1 (3.0)	--	--	--
Interaction								--
Race								
Asian and other	105	6 (5.7)	NR (NE, NE)	114	7 (6.1)	NR (5.8, NE)	0.683 (0.227, 2.058)	0.4950
White	34	0 (0.0)	NR (NE, NE)	24	1 (4.2)	NR (NE, NE)	0.000 (0.000, NE)	0.2850
Interaction								0.9919

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Diarrhea

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	2 (4.4)	--	34	3 (8.8)	--	--	--
vCPS < 10%	53	3 (5.7)	--	56	1 (1.8)	--	--	--
Missing	41	1 (2.4)	--	48	4 (8.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Financial Difficulties

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	10 (13.2)	NR (NE, NE)	76	6 (7.9)	NR (NE, NE)	1.520 (0.552, 4.185)	0.4105
>= 65 Years	63	6 (9.5)	NR (NE, NE)	62	8 (12.9)	NR (NE, NE)	0.682 (0.236, 1.970)	0.4753
Interaction								0.2971
Gender								
Male	118	15 (12.7)	NR (NE, NE)	111	10 (9.0)	NR (NE, NE)	1.345 (0.604, 2.995)	0.4624
Female	21	1 (4.8)	NR (2.8, NE)	27	4 (14.8)	NR (3.0, NE)	0.227 (0.025, 2.065)	0.1518
Interaction								0.1947

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Financial Difficulties

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	12 (11.5)	NR (NE, NE)	105	11 (10.5)	NR (NE, NE)	1.076 (0.474, 2.440)	0.8598
Non-Smoker	35	4 (11.4)	NR (NE, NE)	33	3 (9.1)	NR (3.0, NE)	0.983 (0.220, 4.397)	0.9819
Interaction								0.9602
ICC Options								
Paclitaxel	83	8 (9.6)	NR (NE, NE)	85	9 (10.6)	NR (NE, NE)	0.817 (0.315, 2.121)	0.6744
Docetaxel	56	8 (14.3)	NR (NE, NE)	53	5 (9.4)	NR (NE, NE)	1.473 (0.482, 4.503)	0.4931
Interaction								0.4254

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Financial Difficulties

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	4 (9.3)	NR (NE, NE)	42	1 (2.4)	NR (NE, NE)	3.050 (0.340, 27.394)	0.2948
1	96	12 (12.5)	NR (NE, NE)	96	13 (13.5)	NR (NE, NE)	0.880 (0.401, 1.930)	0.7465
Interaction								0.2493
Region #1								
Asia	103	14 (13.6)	NR (NE, NE)	105	11 (10.5)	NR (NE, NE)	1.192 (0.541, 2.628)	0.6594
Europe/North America	36	2 (5.6)	NR (NE, NE)	33	3 (9.1)	NR (NE, NE)	0.508 (0.085, 3.055)	0.4487
Interaction								0.4860

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Financial Difficulties

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	11 (14.1)	NR (NE, NE)	80	11 (13.8)	NR (NE, NE)	0.964 (0.418, 2.225)	0.9312
Japan	25	3 (12.0)	NR (NE, NE)	25	0 (0.0)	NR (NE, NE)	71668956.880 (0.000, NE)	0.1057
Europe/North America	36	2 (5.6)	NR (NE, NE)	33	3 (9.1)	NR (NE, NE)	0.508 (0.085, 3.055)	0.4487
Interaction								0.8944
Race								
Asian and other	105	14 (13.3)	NR (NE, NE)	114	12 (10.5)	NR (NE, NE)	1.136 (0.525, 2.457)	0.7439
White	34	2 (5.9)	NR (NE, NE)	24	2 (8.3)	NR (NE, NE)	0.662 (0.093, 4.719)	0.6766
Interaction								0.7012

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 05JUN2024 19:38 t-14-02-06-02-01-02-b-s-eff-tteqs-subgrp-c30-itts-cl.rtf

Table 14.2.6.2.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Financial Difficulties

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	6 (13.3)	NR (NE, NE)	34	6 (17.6)	NR (3.0, NE)	0.661 (0.212, 2.066)	0.4705
vCPS < 10%	53	6 (11.3)	NR (NE, NE)	56	4 (7.1)	NR (NE, NE)	1.434 (0.404, 5.088)	0.5736
Missing	41	4 (9.8)	NR (NE, NE)	48	4 (8.3)	NR (NE, NE)	1.187 (0.297, 4.744)	0.8065
Interaction								0.6440

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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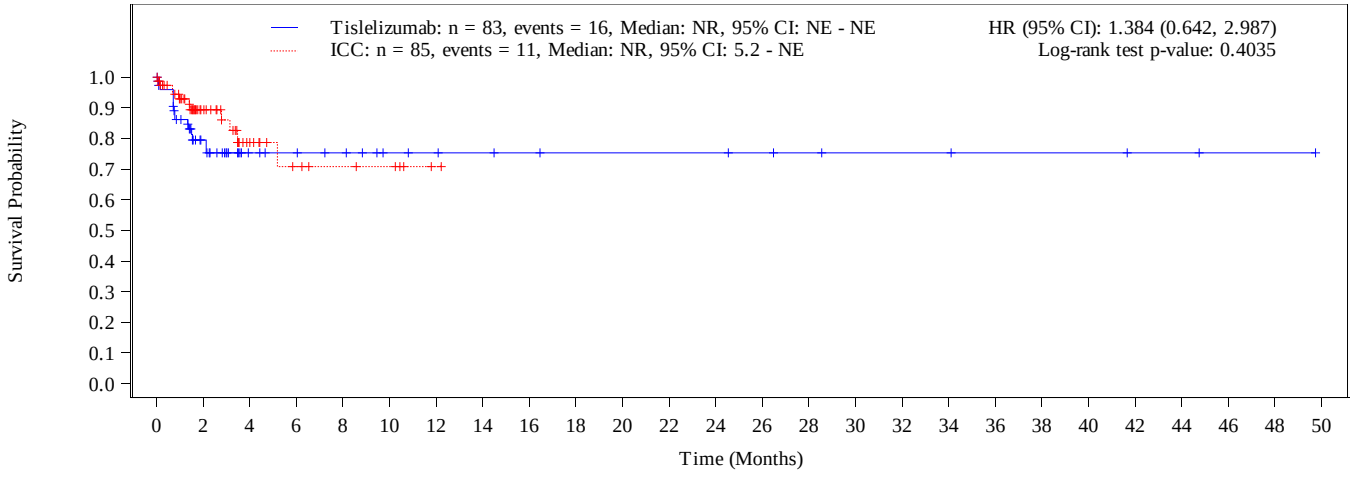
Figure 14.2.7.1.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Nausea and Vomiting

ICC Options: Paclitaxel



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	83	38	19	17	15	11	10	9	8	7	7	7	7	6	5	4	4	4	3	3	3	2	2	1	1	0
ICC	85	35	15	8	6	5	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
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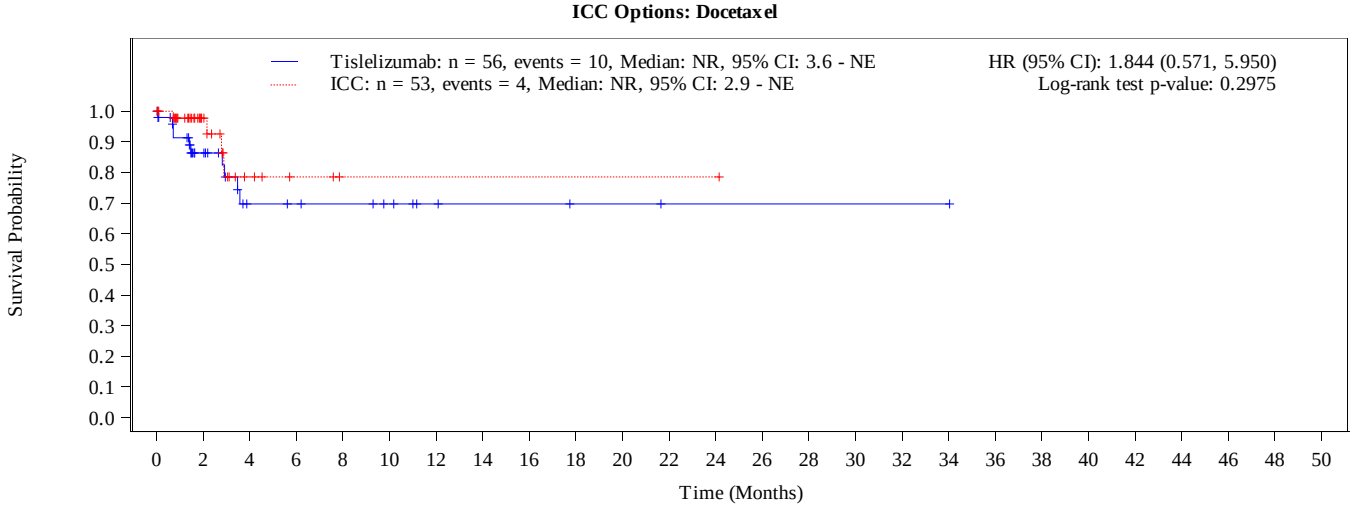
Figure 14.2.7.1.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Nausea and Vomiting



Number of Patients at Risk:

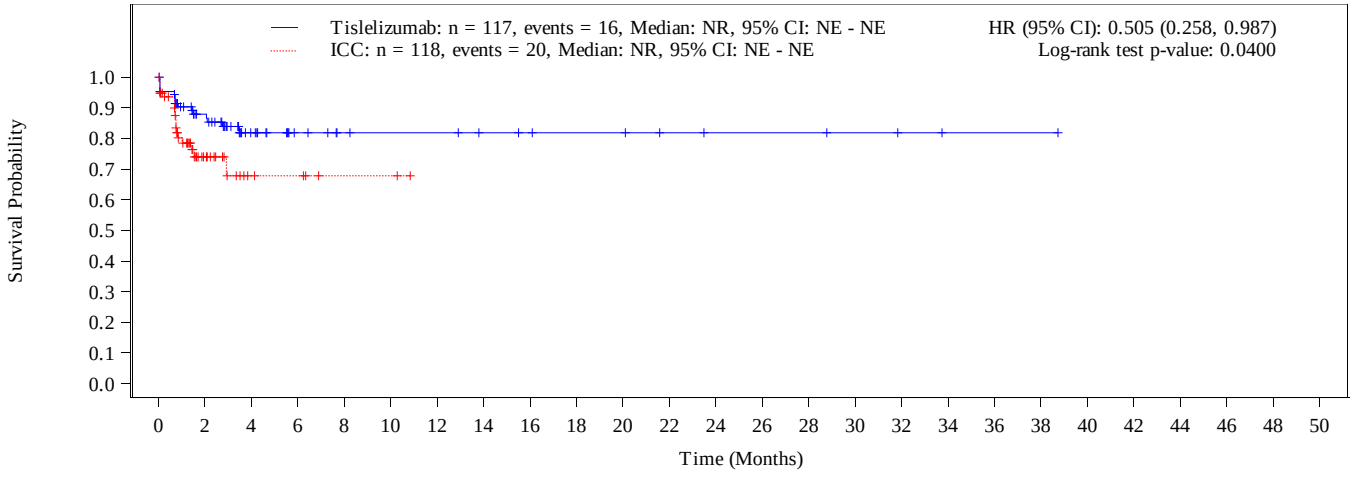
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	56	26	11	10	9	7	4	3	3	2	2	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0
ICC	53	20	6	3	1	1	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 05JUN2024 20:06 f-14-02-07-01-02-s-km-tteqs-subgrp-c30-itt-cl.rtf

Figure 14.2.7.1.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Nausea and Vomiting

ICC Options: Irinotecan



Number of Patients at Risk:

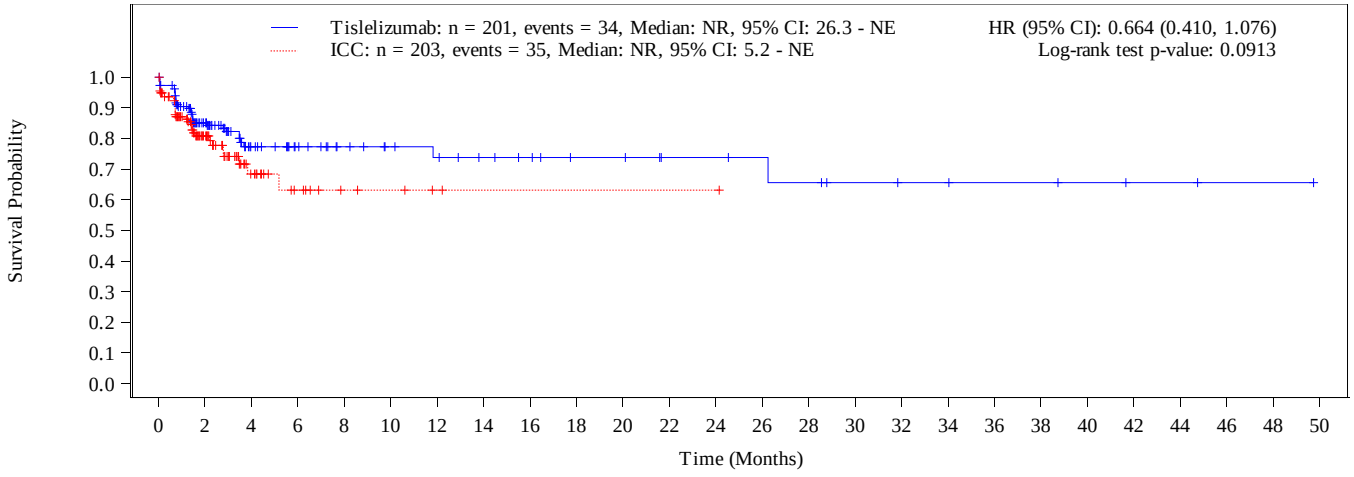
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	117	68	28	17	12	11	11	9	8	7	7	5	4	4	4	3	2	1	1	1	0	0	0	0	0	0
ICC	118	21	6	5	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 05JUN2024 20:06 f-14-02-07-01-02-s-km-tteqs-subgrp-c30-itt-cl.rtf

Figure 14.2.7.1.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Appetite Loss

Region #1: Asia



Number of Patients at Risk:

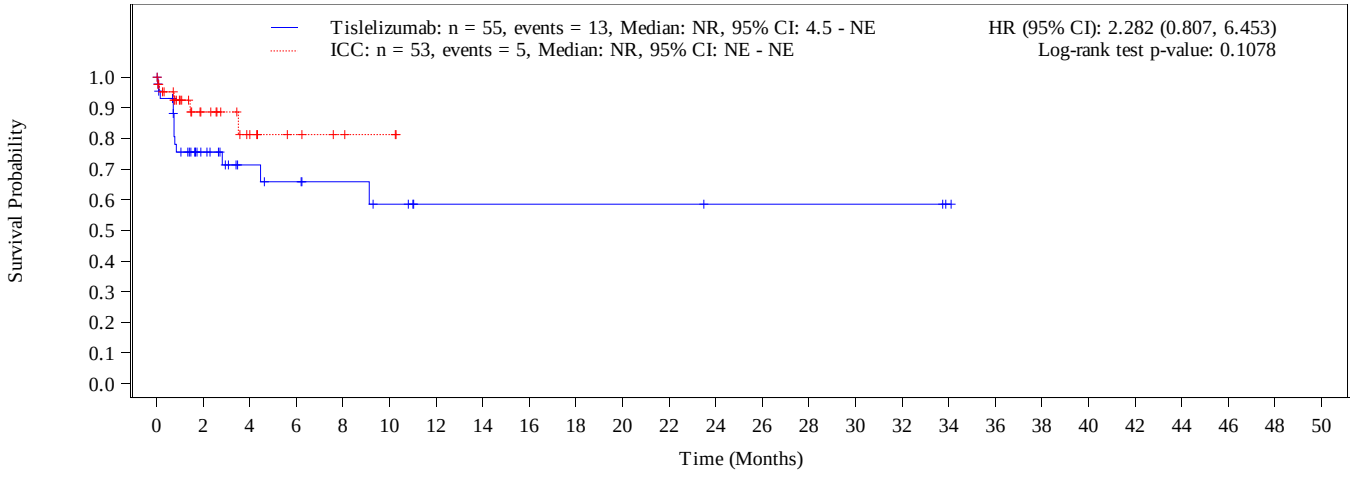
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	201	104	48	36	27	23	21	18	16	13	13	10	10	9	8	6	5	5	4	4	3	2	2	1	1	0
ICC	203	59	20	10	5	4	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 05JUN2024 20:06 f-14-02-07-01-02-s-km-tteqs-subgrp-c30-itt-cl.rtf

Figure 14.2.7.1.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Appetite Loss

Region #1: Europe/North America



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	55	22	13	11	9	7	4	4	4	4	4	4	3	3	3	3	3	1	0	0	0	0	0	0	0	0
ICC	53	18	9	5	3	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
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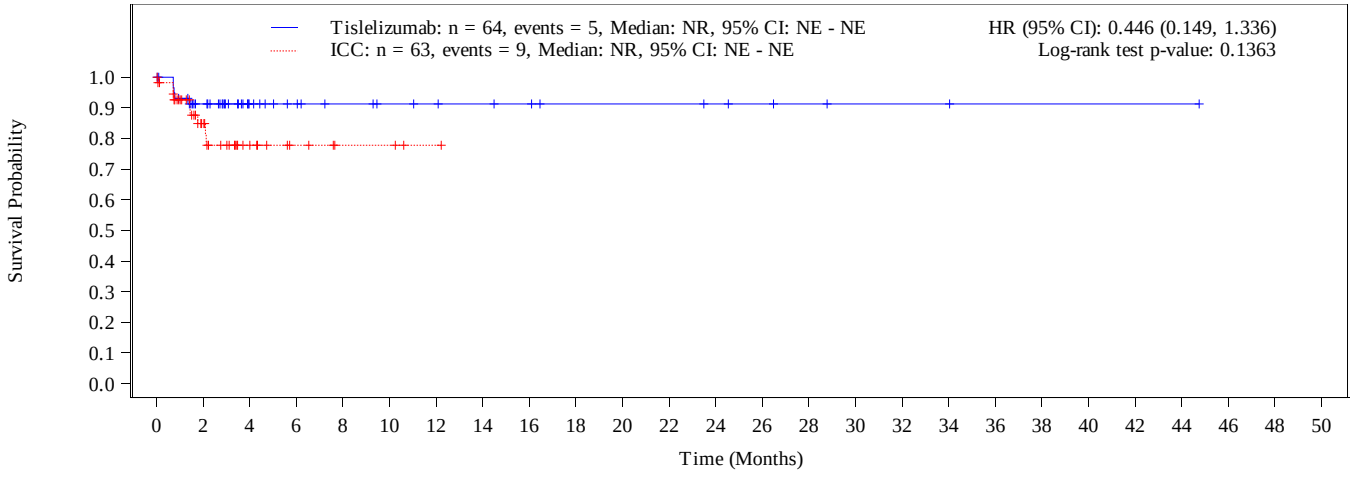
Figure 14.2.7.1.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Constipation

ECOG Performance Score: 0



Number of Patients at Risk:

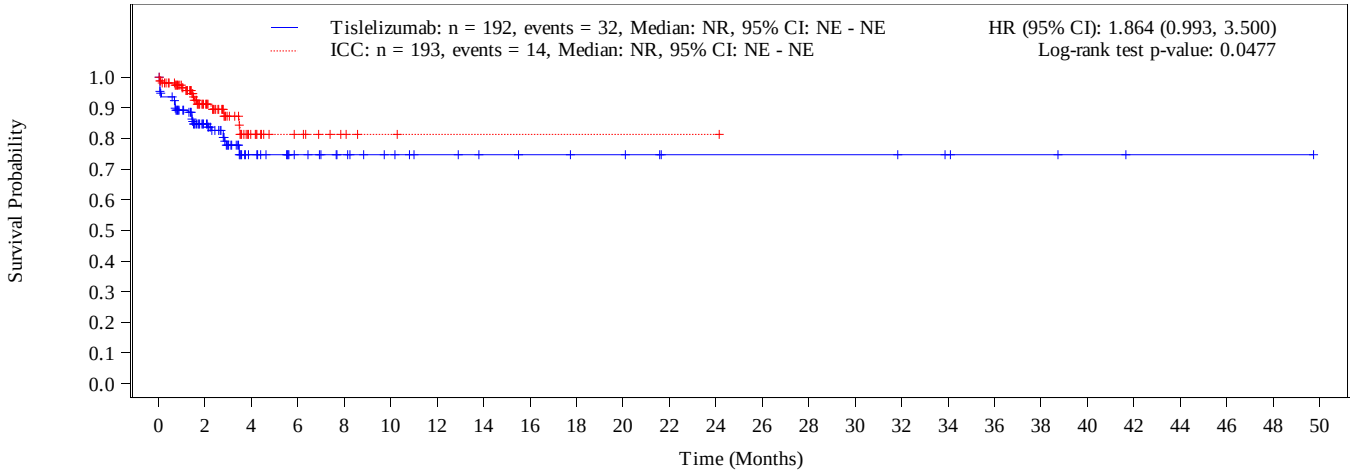
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	64	42	21	16	13	11	10	9	8	6	6	6	5	4	3	2	2	2	1	1	1	1	1	0	0	0
ICC	63	27	12	6	3	3	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 05JUN2024 20:06 f-14-02-07-01-02-s-km-tteqs-subgrp-c30-itt-cl.rtf

Figure 14.2.7.1.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Constipation

ECOG Performance Score: 1



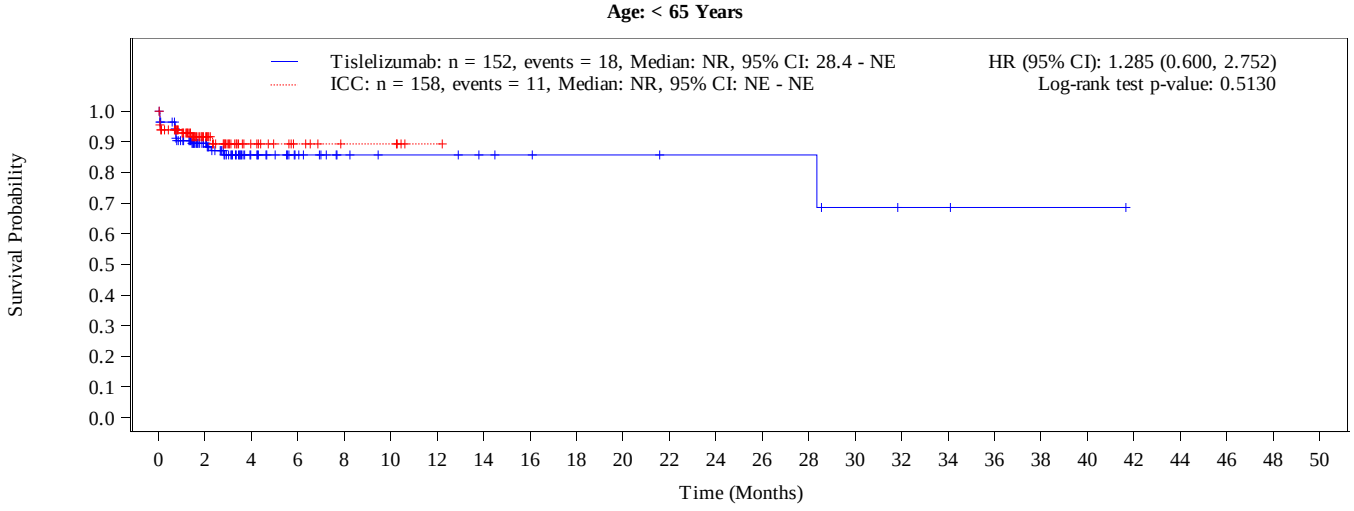
Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	192	86	34	25	20	16	13	11	10	9	9	6	6	6	6	6	5	4	3	3	2	1	1	1	1	0
ICC	193	60	18	10	4	2	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 05JUN2024 20:06 f-14-02-07-01-02-s-km-tteqs-subgrp-c30-itt-cl.rtf

Figure 14.2.7.1.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Financial Difficulties



Number of Patients at Risk:

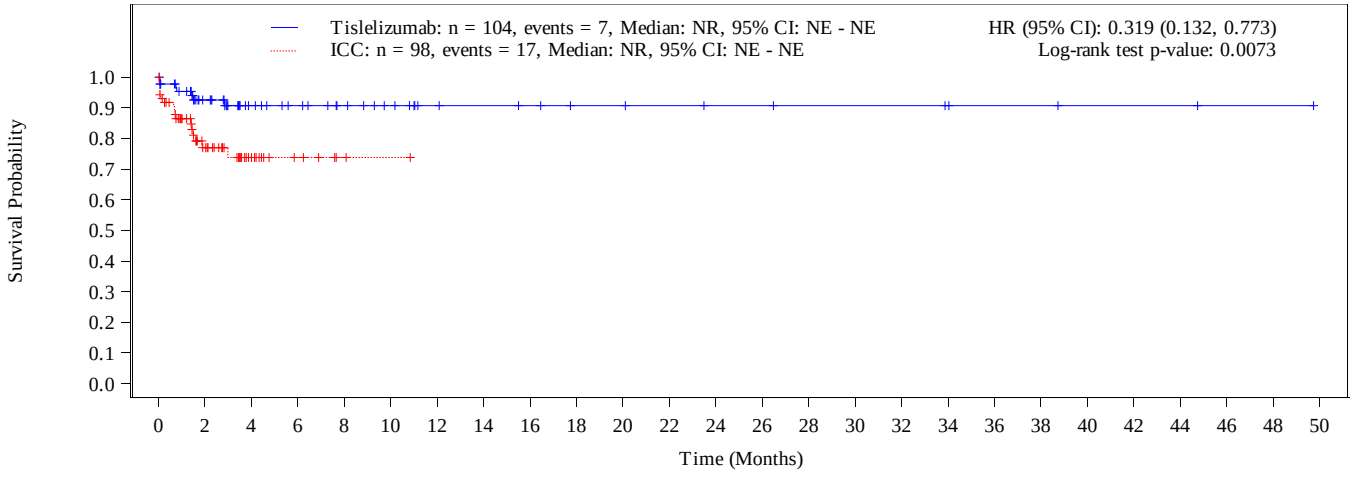
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	152	80	32	19	12	10	10	8	7	6	6	5	5	5	5	3	2	2	1	1	1	0	0	0	0	0
ICC	158	46	17	9	5	5	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 05JUN2024 20:06 f-14-02-07-01-02-s-km-tteqs-subgrp-c30-itt-cl.rtf

Figure 14.2.7.1.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set

Outcome: Financial Difficulties

Age: >= 65 Years



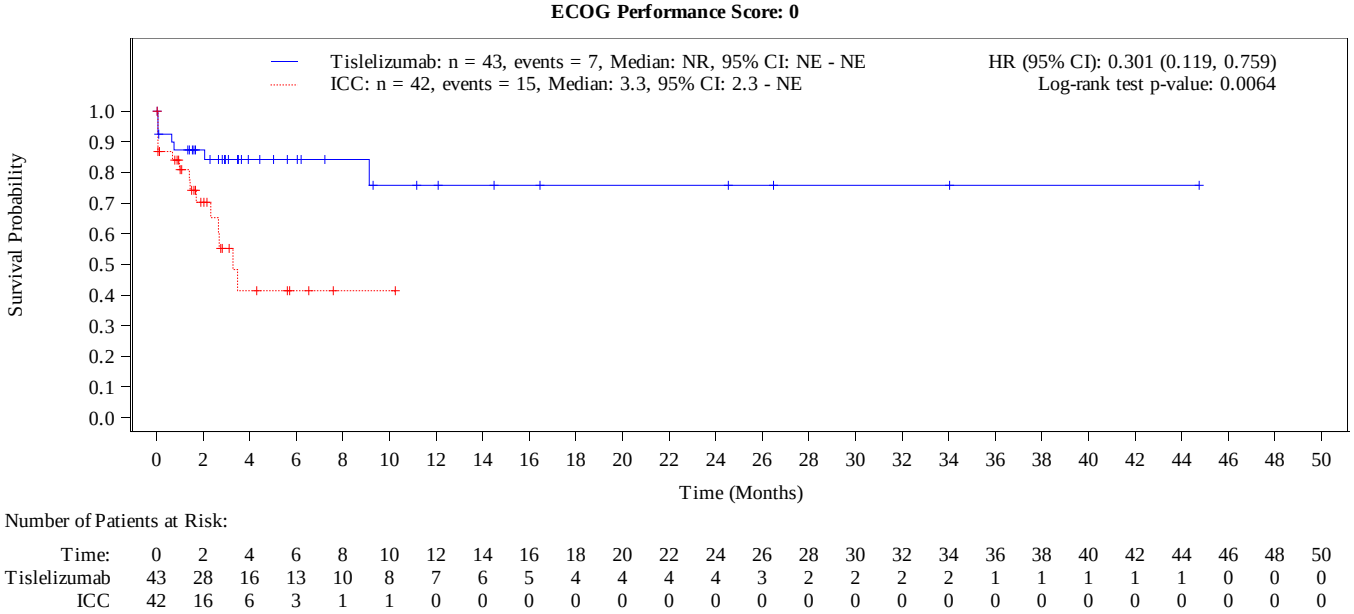
Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	104	56	32	27	22	18	13	11	10	8	8	7	6	6	5	5	5	4	3	3	2	2	2	1	1	0
ICC	98	34	14	6	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 05JUN2024 20:06 f-14-02-07-01-02-s-km-tteqs-subgrp-c30-itt-cl.rtf

Figure 14.2.7.1.2.b.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Role Functioning



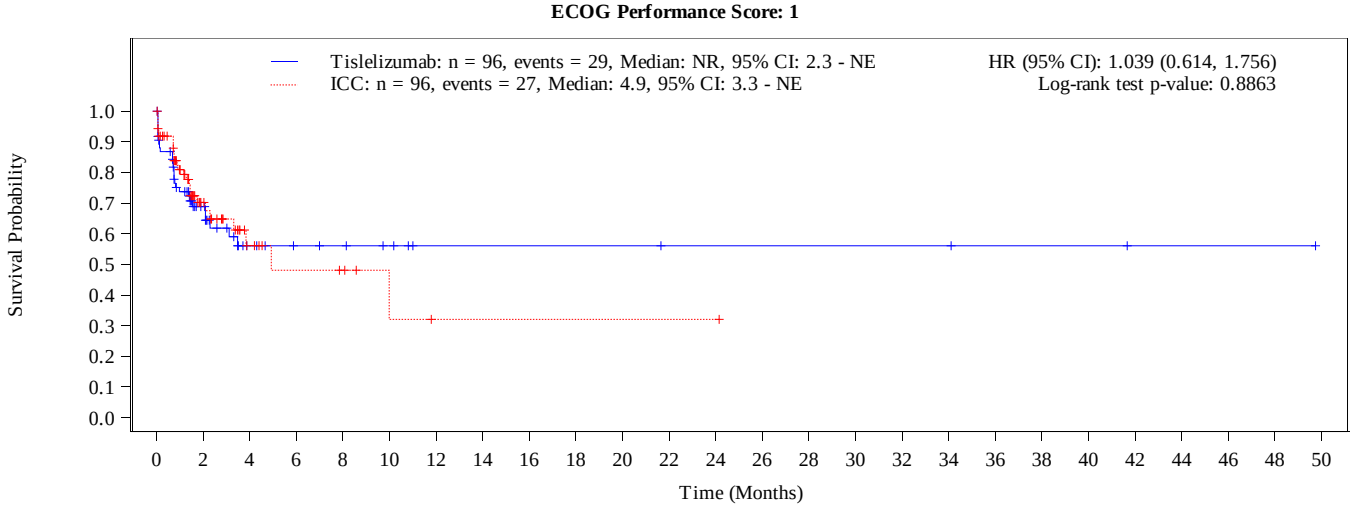
Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	43	28	16	13	10	8	7	6	5	4	4	4	4	3	2	2	2	2	1	1	1	1	1	0	0	0
ICC	42	16	6	3	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 05JUN2024 20:06 f-14-02-07-01-02-b-s-km-tteqs-subgrp-c30-itts-cl.rtf

Figure 14.2.7.1.2.b.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Role Functioning



Number of Patients at Risk:

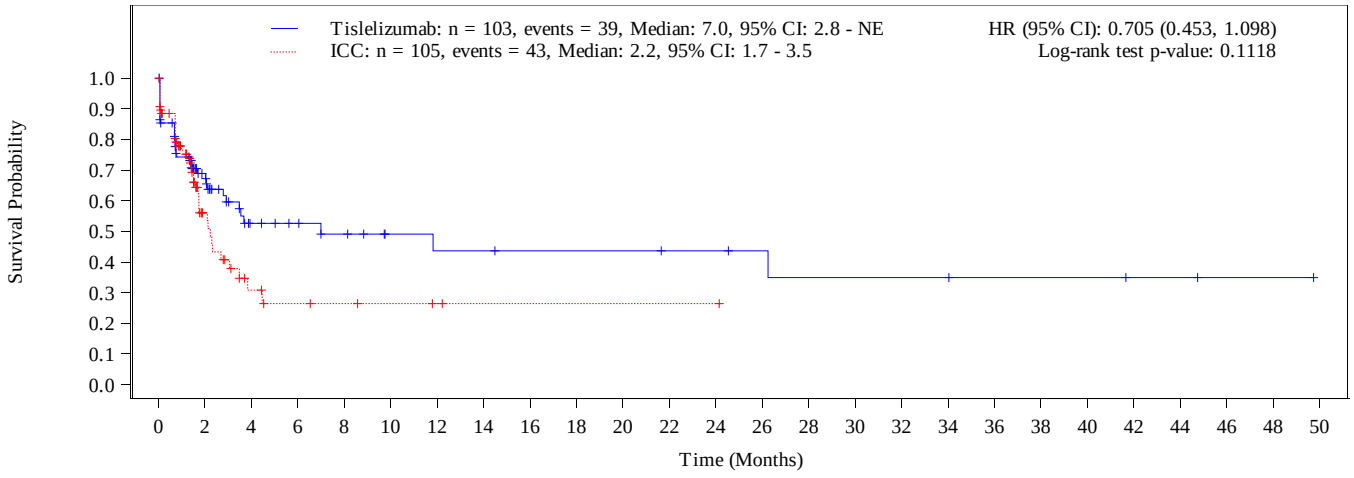
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	96	32	13	10	9	7	4	4	4	4	4	3	3	3	3	3	3	3	2	2	2	1	1	1	1	0
ICC	96	27	10	6	5	2	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 05JUN2024 20:06 f-14-02-07-01-02-b-s-km-tteqs-subgrp-c30-itts-cl.rtf

Figure 14.2.7.1.2.b.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Fatigue

Region #1: Asia



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	103	41	19	16	13	9	8	8	7	7	7	6	6	5	4	4	4	4	3	3	3	2	2	1	1	0
ICC	105	22	8	5	4	3	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
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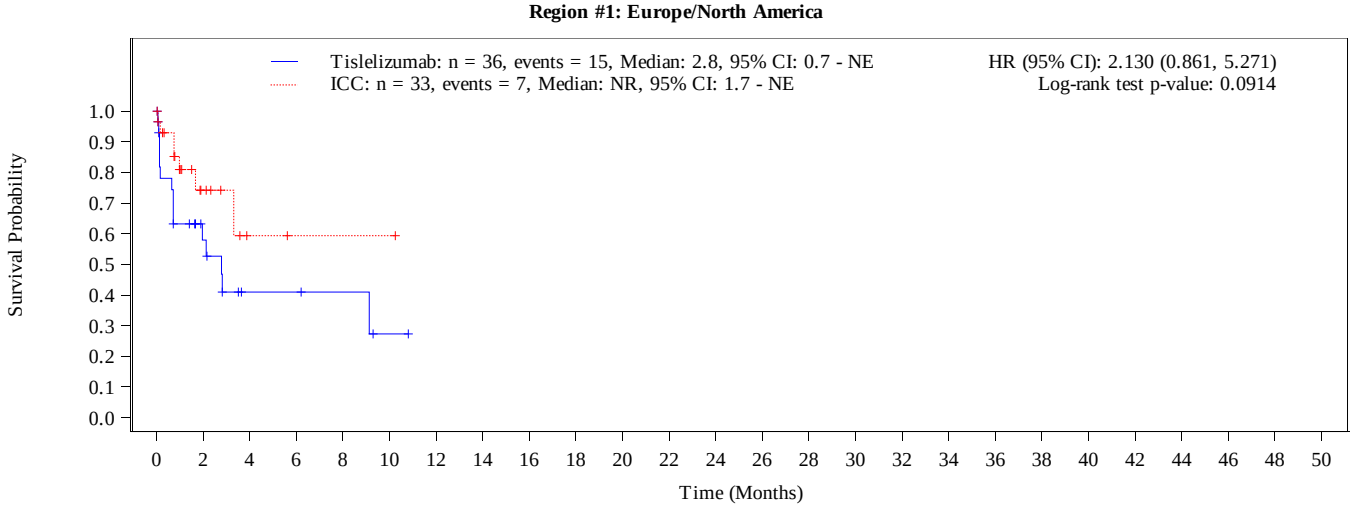
Figure 14.2.7.1.2.b.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Fatigue



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	36	11	4	4	3	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ICC	33	9	2	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
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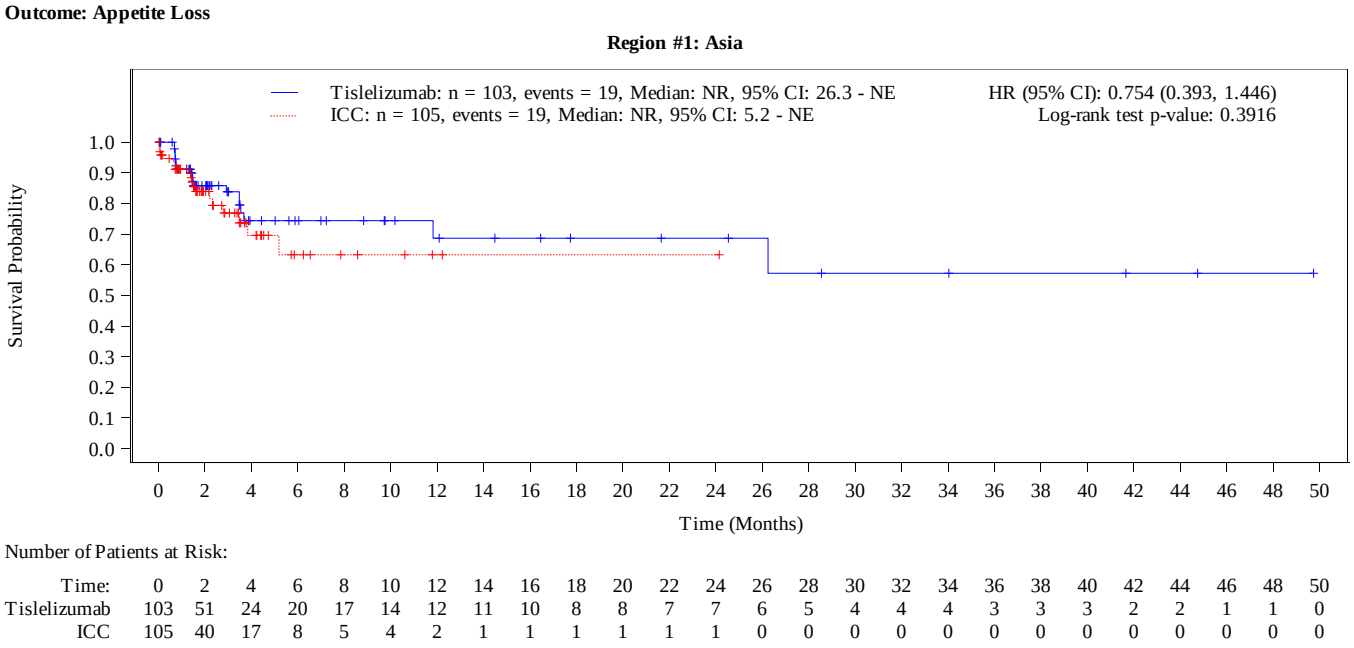
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 05JUN2024 20:06 f-14-02-07-01-02-b-s-km-tteqs-subgrp-c30-itts-cl.rtf

Figure 14.2.7.1.2.b.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	103	51	24	20	17	14	12	11	10	8	8	7	7	6	5	4	4	4	3	3	3	2	2	1	1	0
ICC	105	40	17	8	5	4	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
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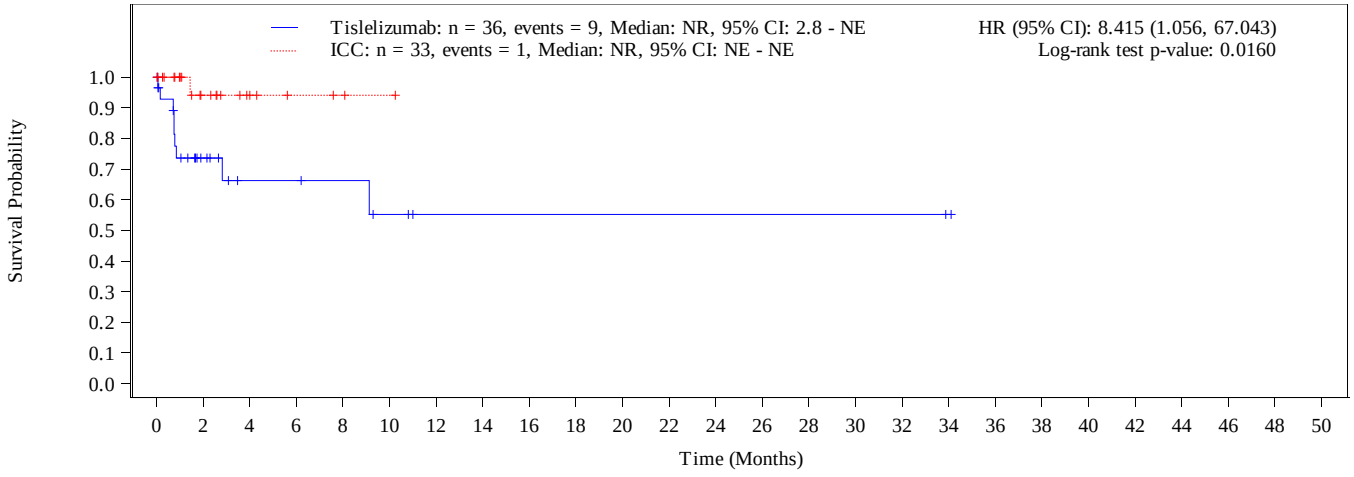
Figure 14.2.7.1.2.b.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-C30 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Appetite Loss

Region #1: Europe/North America



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	36	13	7	7	6	4	2	2	2	2	2	2	2	2	2	2	2	1	0	0	0	0	0	0	0	0
ICC	33	13	6	3	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-C30 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 05JUN2024 20:06 f-14-02-07-01-02-b-s-km-tteqs-subgrp-c30-itts-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: QLQ-OES18 index-score

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	239		246	
	Mean (SD)	14.7 (11.81)		16.3 (13.20)	
	Median	12.8		13.3	
	Min, Max	0, 68		0, 62	
Cycle 1	n	138	131	131	126
	Mean (SD)	15.5 (12.35)	-0.1 (8.15)	17.5 (13.70)	1.0 (8.91)
	Median	13.1	0.0	15.0	0.0
	Min, Max	0, 59	-24, 34	0, 68	-32, 51
Cycle 2	n	221	210	173	170
	Mean (SD)	15.8 (14.80)	2.4 (11.33)	16.9 (12.93)	2.1 (9.61)
	Median	11.7	0.6	14.4	1.4
	Min, Max	0, 90	-24, 90	0, 69	-34, 38
Cycle 3	n	179	169	90	88
	Mean (SD)	14.7 (11.63)	1.3 (9.36)	15.3 (11.99)	1.1 (10.55)
	Median	11.9	0.0	12.4	0.7
	Min, Max	0, 54	-27, 43	0, 53	-31, 40

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-qs-chg-oes-itt-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: QLQ-OES18 index-score

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	145	137	74	73
	Mean (SD)	13.3 (11.03)	0.7 (9.70)	15.1 (10.70)	1.4 (10.53)
	Median	11.7	0.0	12.1	1.4
	Min, Max	0, 53	-40, 37	0, 43	-35, 30
Cycle 5	n	110	104	45	43
	Mean (SD)	11.9 (10.67)	-1.0 (10.15)	14.3 (16.29)	0.9 (13.29)
	Median	10.0	0.0	8.9	0.0
	Min, Max	0, 52	-38, 29	0, 82	-37, 52
Cycle 6	n	98	93	37	35
	Mean (SD)	11.1 (10.90)	-0.6 (8.63)	15.5 (15.36)	3.0 (12.05)
	Median	9.2	0.0	10.0	1.4
	Min, Max	0, 54	-23, 31	0, 67	-20, 41
End of Treatment	n	75	73	83	81
	Mean (SD)	18.8 (17.15)	6.0 (14.19)	22.2 (16.44)	7.7 (13.19)
	Median	13.9	3.1	18.6	6.1
	Min, Max	0, 71	-23, 55	0, 83	-28, 69

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-qs-chg-oes-itt-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: QLQ-OES18 index-score

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	115	111	97	96
	Mean (SD)	19.8 (16.53)	5.8 (14.01)	21.7 (14.62)	6.8 (12.17)
	Median	15.3	1.7	19.2	4.3
	Min, Max	0, 74	-25, 46	0, 70	-20, 45
Worst Post-Baseline Value	n	244	228	225	218
	Mean (SD)	23.6 (16.80)	9.7 (13.91)	24.7 (16.48)	9.1 (12.45)
	Median	20.7	6.7	21.1	6.9
	Min, Max	0, 90	-18, 90	0, 83	-20, 69

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-qs-chg-oes-itt-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Dysphagia

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	240		248	
	Mean (SD)	35.3 (35.22)		34.8 (34.57)	
	Median	33.3		22.2	
	Min, Max	0, 100		0, 100	
Cycle 1	n	138	132	132	129
	Mean (SD)	38.2 (38.09)	-0.7 (23.97)	43.4 (35.82)	4.8 (20.45)
	Median	22.2	0.0	33.3	0.0
	Min, Max	0, 100	-100, 100	0, 100	-67, 100
Cycle 2	n	224	213	174	171
	Mean (SD)	35.7 (37.52)	1.5 (26.06)	37.9 (34.56)	6.5 (28.68)
	Median	22.2	0.0	33.3	0.0
	Min, Max	0, 100	-100, 100	0, 100	-100, 100
Cycle 3	n	180	170	91	89
	Mean (SD)	37.3 (38.00)	5.1 (28.07)	38.2 (34.55)	4.6 (29.14)
	Median	22.2	0.0	33.3	0.0
	Min, Max	0, 100	-100, 100	0, 100	-78, 100

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-qs-chg-oes-itt-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Dysphagia

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	146	138	76	74
	Mean (SD)	34.2 (37.56)	1.4 (27.14)	39.6 (35.76)	5.3 (35.19)
	Median	22.2	0.0	33.3	0.0
	Min, Max	0, 100	-100, 100	0, 100	-100, 100
Cycle 5	n	110	104	45	43
	Mean (SD)	36.5 (39.54)	2.7 (29.36)	37.3 (39.29)	-0.9 (39.54)
	Median	22.2	0.0	22.2	0.0
	Min, Max	0, 100	-67, 100	0, 100	-100, 100
Cycle 6	n	99	93	37	35
	Mean (SD)	33.8 (38.55)	1.6 (28.50)	36.0 (36.23)	2.7 (37.15)
	Median	11.1	0.0	33.3	0.0
	Min, Max	0, 100	-100, 100	0, 100	-100, 100
End of Treatment	n	76	74	83	81
	Mean (SD)	41.2 (37.92)	5.7 (35.53)	42.2 (37.05)	3.3 (28.94)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-100, 78	0, 100	-100, 78

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-qs-chg-oes-itt-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Dysphagia

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	116	112	97	96
	Mean (SD)	45.3 (38.77)	5.5 (33.12)	50.7 (36.00)	12.3 (35.38)
	Median	38.9	0.0	44.4	0.0
	Min, Max	0, 100	-100, 100	0, 100	-100, 100
Worst Post-Baseline Value	n	246	231	226	221
	Mean (SD)	52.0 (38.59)	18.3 (30.76)	52.5 (35.03)	17.6 (30.85)
	Median	44.4	11.1	44.4	11.1
	Min, Max	0, 100	-100, 100	0, 100	-56, 100

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-qs-chg-oes-itt-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Eating

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	240		246	
	Mean (SD)	17.6 (19.83)		19.6 (21.10)	
	Median	8.3		16.7	
	Min, Max	0, 100		0, 100	
Cycle 1	n	138	132	131	126
	Mean (SD)	19.3 (22.82)	1.5 (13.46)	20.2 (22.46)	-0.4 (15.34)
	Median	8.3	0.0	16.7	0.0
	Min, Max	0, 100	-50, 58	0, 100	-50, 75
Cycle 2	n	222	211	174	171
	Mean (SD)	19.0 (23.29)	3.0 (17.79)	19.8 (22.94)	1.5 (16.67)
	Median	8.3	0.0	16.7	0.0
	Min, Max	0, 100	-67, 100	0, 100	-50, 75
Cycle 3	n	180	170	90	88
	Mean (SD)	17.0 (21.21)	1.0 (19.29)	14.7 (19.15)	-2.8 (17.68)
	Median	8.3	0.0	8.3	0.0
	Min, Max	0, 100	-83, 75	0, 92	-50, 67

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-qs-chg-oes-itt-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Eating

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	146	138	75	73
	Mean (SD)	14.6 (18.36)	-0.2 (17.16)	17.9 (21.60)	2.5 (19.68)
	Median	8.3	0.0	8.3	0.0
	Min, Max	0, 100	-67, 83	0, 100	-42, 75
Cycle 5	n	110	104	45	43
	Mean (SD)	12.1 (15.79)	-2.9 (16.62)	15.7 (22.49)	2.1 (21.60)
	Median	8.3	0.0	8.3	0.0
	Min, Max	0, 75	-67, 42	0, 100	-58, 67
Cycle 6	n	99	93	37	35
	Mean (SD)	12.2 (15.76)	-2.5 (15.92)	18.7 (26.60)	6.7 (22.94)
	Median	8.3	0.0	8.3	0.0
	Min, Max	0, 67	-67, 42	0, 100	-58, 67
End of Treatment	n	75	73	83	81
	Mean (SD)	25.1 (28.43)	8.0 (23.13)	26.5 (25.74)	9.2 (22.54)
	Median	16.7	0.0	16.7	8.3
	Min, Max	0, 100	-33, 100	0, 100	-42, 75

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-qs-chg-oes-itt-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Eating

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	116	112	97	96
	Mean (SD)	23.3 (24.66)	6.8 (21.76)	24.7 (22.58)	6.1 (17.21)
	Median	16.7	0.0	16.7	8.3
	Min, Max	0, 100	-67, 75	0, 92	-58, 42
Worst Post-Baseline Value	n	245	230	225	218
	Mean (SD)	30.7 (27.07)	14.3 (22.08)	31.3 (25.98)	11.7 (20.51)
	Median	25.0	8.3	25.0	8.3
	Min, Max	0, 100	-67, 100	0, 100	-50, 75

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-qs-chg-oes-itt-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Reflux

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	240		248	
	Mean (SD)	12.2 (17.48)		12.7 (17.96)	
	Median	0.0		0.0	
	Min, Max	0, 100		0, 100	
Cycle 1	n	138	132	132	129
	Mean (SD)	12.6 (18.44)	-0.8 (13.64)	13.4 (17.77)	1.8 (15.90)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 67	0, 67	-67, 50
Cycle 2	n	224	213	174	171
	Mean (SD)	11.2 (17.04)	-0.1 (16.23)	12.8 (18.91)	1.8 (18.35)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-50, 83
Cycle 3	n	181	171	91	89
	Mean (SD)	10.6 (17.57)	-0.8 (16.25)	12.3 (18.73)	1.5 (19.08)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-50, 83	0, 83	-33, 67

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-qs-chg-oes-itt-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Reflux

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	146	138	76	74
	Mean (SD)	9.1 (15.91)	-1.6 (14.78)	11.4 (16.60)	0.5 (15.35)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 83	-50, 83	0, 67	-33, 50
Cycle 5	n	110	104	45	43
	Mean (SD)	7.7 (12.91)	-1.4 (16.77)	10.4 (18.56)	0.0 (18.18)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 50	-83, 33	0, 67	-50, 50
Cycle 6	n	99	93	37	35
	Mean (SD)	7.6 (13.10)	0.2 (14.22)	12.6 (21.66)	1.4 (22.28)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 50	-67, 33	0, 83	-50, 67
End of Treatment	n	76	74	83	81
	Mean (SD)	14.9 (23.19)	5.4 (20.66)	17.9 (21.74)	6.2 (21.80)
	Median	0.0	0.0	16.7	0.0
	Min, Max	0, 100	-50, 83	0, 83	-67, 83

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-qs-chg-oes-itt-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Reflux

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	117	113	97	96
	Mean (SD)	14.2 (17.81)	4.0 (18.54)	14.1 (16.90)	1.9 (18.87)
	Median	16.7	0.0	16.7	0.0
	Min, Max	0, 83	-50, 50	0, 67	-67, 67
Worst Post-Baseline Value	n	246	231	226	221
	Mean (SD)	20.8 (22.88)	9.1 (20.54)	21.7 (22.49)	10.0 (20.82)
	Median	16.7	0.0	16.7	0.0
	Min, Max	0, 100	-50, 100	0, 100	-67, 83

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-qs-chg-oes-itt-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Pain

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	240		248	
	Mean (SD)	11.8 (14.64)		11.9 (18.20)	
	Median	11.1		0.0	
	Min, Max	0, 67		0, 100	
Cycle 1	n	138	132	132	129
	Mean (SD)	11.7 (14.42)	-1.0 (11.61)	12.8 (19.42)	1.3 (13.01)
	Median	11.1	0.0	0.0	0.0
	Min, Max	0, 78	-44, 44	0, 100	-44, 89
Cycle 2	n	224	213	174	171
	Mean (SD)	12.2 (17.90)	1.1 (15.43)	10.3 (15.30)	-0.3 (11.01)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-44, 22
Cycle 3	n	181	171	91	89
	Mean (SD)	11.1 (16.28)	-0.1 (13.15)	8.9 (13.73)	0.2 (11.00)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-44, 44	0, 78	-44, 33

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-qs-chg-oes-itt-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Pain

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	146	138	76	74
	Mean (SD)	9.1 (12.46)	-1.8 (13.87)	7.6 (10.14)	1.4 (12.47)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 56	-67, 33	0, 33	-22, 33
Cycle 5	n	110	104	45	43
	Mean (SD)	8.4 (11.96)	-1.6 (13.88)	7.4 (11.84)	1.3 (13.33)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 56	-67, 44	0, 33	-22, 33
Cycle 6	n	99	93	37	35
	Mean (SD)	7.7 (12.03)	-1.1 (14.29)	8.1 (14.26)	1.9 (15.36)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-56, 56	0, 67	-22, 67
End of Treatment	n	76	74	83	81
	Mean (SD)	16.7 (23.08)	5.5 (19.86)	17.0 (20.63)	6.4 (17.47)
	Median	11.1	0.0	11.1	0.0
	Min, Max	0, 100	-33, 89	0, 100	-44, 67

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-qs-chg-oes-itt-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Pain

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	117	113	97	96
	Mean (SD)	14.5 (17.35)	3.6 (17.66)	14.7 (18.04)	4.2 (15.23)
	Median	11.1	0.0	11.1	0.0
	Min, Max	0, 67	-44, 67	0, 78	-22, 44
Worst Post-Baseline Value	n	246	231	226	221
	Mean (SD)	20.4 (21.32)	9.3 (18.56)	19.2 (19.78)	7.9 (14.86)
	Median	11.1	0.0	11.1	0.0
	Min, Max	0, 100	-33, 100	0, 100	-22, 89

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-qs-chg-oes-itt-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Trouble swallowing saliva

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	240		248	
	Mean (SD)	11.7 (23.08)		11.2 (24.30)	
	Median	0.0		0.0	
	Min, Max	0, 100		0, 100	
Cycle 1	n	138	132	132	129
	Mean (SD)	12.1 (21.29)	-1.8 (22.30)	10.6 (24.13)	1.0 (23.55)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 100	0, 100	-67, 100
Cycle 2	n	223	212	174	171
	Mean (SD)	12.6 (24.34)	2.4 (25.13)	10.3 (22.27)	1.4 (25.91)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 100	0, 100	-100, 100
Cycle 3	n	181	171	91	89
	Mean (SD)	12.5 (24.65)	1.9 (29.53)	10.6 (24.28)	2.2 (28.34)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 100	0, 100	-100, 100

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-qs-chg-oes-itt-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Trouble swallowing saliva

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	146	138	76	74
	Mean (SD)	8.2 (18.18)	-1.7 (26.81)	11.0 (21.35)	-0.5 (26.74)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 100	0, 100	-100, 67
Cycle 5	n	110	104	45	43
	Mean (SD)	6.7 (20.09)	-4.2 (23.08)	7.4 (23.45)	-2.3 (19.78)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 100	0, 100	-100, 33
Cycle 6	n	99	93	37	35
	Mean (SD)	5.7 (17.20)	-3.9 (19.57)	9.0 (25.64)	-1.9 (22.78)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 33	0, 100	-100, 67
End of Treatment	n	76	74	83	81
	Mean (SD)	14.0 (25.68)	5.4 (27.04)	17.7 (29.60)	9.5 (28.50)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-qs-chg-oes-itt-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Trouble swallowing saliva

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	117	113	97	96
	Mean (SD)	14.5 (28.16)	4.1 (31.85)	12.0 (25.09)	1.7 (29.96)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 100	0, 100	-100, 100
Worst Post-Baseline Value	n	246	231	226	221
	Mean (SD)	27.4 (34.21)	15.9 (35.28)	22.6 (32.31)	12.1 (31.86)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 100	0, 100	-100, 100

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-qs-chg-oes-itt-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Choked when swallowing

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	240		248	
	Mean (SD)	14.2 (18.88)		14.2 (22.11)	
	Median	0.0		0.0	
	Min, Max	0, 67		0, 100	
Cycle 1	n	138	132	131	128
	Mean (SD)	13.5 (21.93)	-1.3 (20.76)	13.5 (21.79)	-4.2 (20.06)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 67
Cycle 2	n	224	213	174	171
	Mean (SD)	15.2 (22.05)	1.6 (21.42)	14.9 (22.24)	0.6 (24.38)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-100, 67
Cycle 3	n	181	171	91	89
	Mean (SD)	13.8 (21.07)	-1.2 (22.55)	13.6 (24.83)	2.6 (25.24)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-33, 100

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-qs-chg-oes-itt-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Choked when swallowing

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	146	138	76	74
	Mean (SD)	11.2 (19.68)	-2.7 (22.80)	11.4 (18.50)	-0.9 (22.05)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 67	-67, 67
Cycle 5	n	110	104	45	43
	Mean (SD)	10.9 (19.21)	-4.2 (24.00)	11.9 (24.78)	-0.0 (20.57)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 67	0, 100	-67, 67
Cycle 6	n	99	93	37	35
	Mean (SD)	10.1 (16.81)	-3.2 (22.01)	9.9 (17.33)	0.0 (21.39)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-67, 67	0, 67	-33, 67
End of Treatment	n	76	74	83	81
	Mean (SD)	14.9 (25.18)	4.1 (26.43)	18.9 (29.54)	5.8 (27.78)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-qs-chg-oes-itt-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Choked when swallowing

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	117	113	97	96
	Mean (SD)	16.8 (26.49)	2.4 (29.79)	17.9 (25.94)	3.8 (24.12)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 67
Worst Post-Baseline Value	n	246	231	225	220
	Mean (SD)	27.2 (29.41)	13.0 (29.89)	25.5 (29.59)	10.3 (27.68)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-qs-chg-oes-itt-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Dry mouth

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	239		248	
	Mean (SD)	16.3 (20.24)		19.9 (24.34)	
	Median	0.0		0.0	
	Min, Max	0, 100		0, 100	
Cycle 1	n	138	131	132	129
	Mean (SD)	18.1 (20.19)	1.3 (18.21)	22.2 (23.90)	2.6 (21.49)
	Median	0.0	0.0	33.3	0.0
	Min, Max	0, 100	-33, 67	0, 100	-67, 100
Cycle 2	n	224	212	174	171
	Mean (SD)	19.5 (25.49)	4.6 (23.52)	21.8 (23.41)	3.3 (24.16)
	Median	0.0	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100
Cycle 3	n	181	171	91	89
	Mean (SD)	17.5 (22.92)	1.8 (23.22)	20.9 (24.67)	1.5 (25.08)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 67

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-qs-chg-oes-itt-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Dry mouth

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	146	138	76	74
	Mean (SD)	17.8 (22.88)	5.6 (23.34)	18.4 (20.65)	0.9 (28.12)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 67	-100, 67
Cycle 5	n	110	104	45	43
	Mean (SD)	13.3 (18.73)	0.6 (20.24)	15.6 (23.14)	-2.3 (25.61)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-67, 67	0, 100	-67, 67
Cycle 6	n	99	93	37	35
	Mean (SD)	13.1 (20.10)	1.1 (20.53)	20.7 (26.47)	5.7 (26.18)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 67	0, 100	-33, 67
End of Treatment	n	76	74	83	81
	Mean (SD)	20.2 (25.58)	8.1 (29.10)	25.7 (24.04)	9.9 (25.52)
	Median	0.0	0.0	33.3	0.0
	Min, Max	0, 100	-67, 100	0, 100	-33, 100

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-qs-chg-oes-itt-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Dry mouth

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	117	113	97	96
	Mean (SD)	22.5 (26.20)	5.9 (26.81)	28.5 (28.05)	12.2 (28.66)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100
Worst Post-Baseline Value	n	246	230	226	221
	Mean (SD)	32.5 (27.75)	17.1 (26.93)	35.1 (27.88)	16.4 (28.18)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-qs-chg-oes-itt-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Trouble with taste

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	239		247	
	Mean (SD)	7.9 (18.00)		14.0 (24.80)	
	Median	0.0		0.0	
	Min, Max	0, 100		0, 100	
Cycle 1	n	138	131	131	127
	Mean (SD)	10.1 (17.83)	2.3 (19.48)	12.2 (21.96)	0.5 (19.69)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 67	0, 100	-67, 67
Cycle 2	n	223	211	174	171
	Mean (SD)	9.7 (20.51)	3.2 (22.31)	17.2 (25.27)	3.5 (23.17)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 67
Cycle 3	n	179	169	90	88
	Mean (SD)	9.1 (17.94)	2.2 (21.56)	13.7 (24.93)	-0.0 (26.26)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 67	0, 100	-100, 67

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-qs-chg-oes-itt-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Trouble with taste

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	145	137	76	73
	Mean (SD)	8.5 (17.91)	2.9 (18.73)	15.8 (25.22)	5.0 (25.86)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 67
Cycle 5	n	110	104	45	43
	Mean (SD)	5.2 (13.69)	-1.6 (18.22)	14.1 (25.11)	3.1 (27.04)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-100, 67	0, 100	-100, 67
Cycle 6	n	99	93	37	35
	Mean (SD)	4.7 (12.61)	-1.8 (20.48)	18.0 (30.02)	8.6 (24.71)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-100, 67	0, 100	-33, 100
End of Treatment	n	76	74	83	81
	Mean (SD)	13.6 (22.56)	6.8 (24.04)	20.1 (29.88)	9.1 (28.39)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 67	0, 100	-67, 100

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-qs-chg-oes-itt-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Trouble with taste

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	116	112	97	96
	Mean (SD)	17.2 (27.27)	11.6 (29.92)	19.9 (27.91)	7.6 (21.35)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 100	0, 100	-33, 67
Worst Post-Baseline Value	n	245	229	225	219
	Mean (SD)	21.8 (27.45)	14.7 (27.08)	26.7 (29.88)	12.5 (27.95)
	Median	0.0	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-qs-chg-oes-itt-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Trouble with coughing

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	239		248	
	Mean (SD)	11.0 (20.60)		13.2 (22.37)	
	Median	0.0		0.0	
	Min, Max	0, 100		0, 100	
Cycle 1	n	138	131	132	129
	Mean (SD)	11.4 (19.93)	-0.5 (16.53)	16.4 (23.11)	2.8 (17.69)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 33	0, 100	-67, 33
Cycle 2	n	224	212	173	170
	Mean (SD)	14.1 (23.27)	4.4 (21.81)	13.7 (22.14)	2.9 (20.78)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 67
Cycle 3	n	181	171	91	89
	Mean (SD)	11.6 (19.73)	2.7 (18.59)	12.8 (21.53)	2.2 (22.36)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 67	0, 100	-67, 100

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-qs-chg-oes-itt-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Trouble with coughing

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	146	138	75	74
	Mean (SD)	12.3 (19.58)	4.1 (19.92)	12.4 (19.59)	1.4 (23.69)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-67, 67	0, 67	-67, 67
Cycle 5	n	110	104	45	43
	Mean (SD)	10.9 (18.68)	3.2 (20.52)	14.1 (25.11)	7.0 (27.75)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-67, 67	0, 100	-67, 100
Cycle 6	n	98	93	37	35
	Mean (SD)	10.2 (19.39)	3.9 (20.17)	12.6 (25.28)	4.8 (29.31)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-67, 67	0, 100	-67, 100
End of Treatment	n	76	74	83	81
	Mean (SD)	17.5 (26.37)	8.1 (28.57)	22.5 (29.04)	12.8 (28.17)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-qs-chg-oes-itt-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Trouble with coughing

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	117	113	97	96
	Mean (SD)	16.0 (24.21)	6.8 (23.64)	22.0 (29.61)	13.2 (31.15)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 100
Worst Post-Baseline Value	n	246	230	226	221
	Mean (SD)	25.3 (28.16)	15.2 (25.98)	29.6 (30.00)	17.8 (27.25)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-qs-chg-oes-itt-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Trouble talking

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	240		248	
	Mean (SD)	9.6 (20.59)		11.3 (21.79)	
	Median	0.0		0.0	
	Min, Max	0, 100		0, 100	
Cycle 1	n	138	132	132	129
	Mean (SD)	8.5 (20.56)	-0.5 (15.94)	12.9 (23.89)	-0.8 (21.03)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 67	0, 100	-100, 100
Cycle 2	n	224	213	174	171
	Mean (SD)	11.3 (23.65)	3.6 (19.76)	10.0 (20.35)	0.4 (17.71)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-100, 67
Cycle 3	n	181	171	91	89
	Mean (SD)	9.4 (20.28)	2.3 (17.18)	9.9 (20.78)	-0.4 (20.41)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-100, 100

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-qs-chg-oes-itt-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Trouble talking

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	146	138	76	74
	Mean (SD)	8.4 (18.70)	1.2 (15.81)	9.6 (18.71)	-1.8 (17.35)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 67	-67, 33
Cycle 5	n	110	104	45	43
	Mean (SD)	7.6 (20.02)	-0.6 (20.24)	9.6 (22.04)	1.6 (20.51)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 67
Cycle 6	n	99	93	37	35
	Mean (SD)	6.7 (18.43)	-0.4 (15.92)	9.0 (21.73)	-0.0 (21.39)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 67
End of Treatment	n	76	74	83	81
	Mean (SD)	11.4 (25.85)	2.7 (21.19)	14.1 (24.48)	5.3 (24.98)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-qs-chg-oes-itt-cl.rtf

Table 14.2.6.3.1:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: Trouble talking

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	117	113	97	96
	Mean (SD)	14.8 (27.49)	6.5 (23.08)	12.0 (23.66)	4.9 (26.48)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100
Worst Post-Baseline Value	n	246	231	226	221
	Mean (SD)	19.4 (29.19)	11.3 (25.22)	19.6 (27.64)	8.3 (23.28)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-qs-chg-oes-itt-cl.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: QLQ-OES18 index-score

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	127		132	
	Mean (SD)	16.3 (11.65)		17.2 (13.93)	
	Median	15.0		13.9	
	Min, Max	0, 68		0, 62	
Cycle 1	n	82	77	81	78
	Mean (SD)	17.2 (11.88)	0.1 (7.10)	17.5 (14.39)	0.4 (8.97)
	Median	14.9	0.0	14.4	0.0
	Min, Max	0, 58	-24, 34	0, 68	-21, 51
Cycle 2	n	123	113	97	96
	Mean (SD)	17.7 (15.48)	3.0 (10.18)	16.3 (13.41)	1.0 (9.14)
	Median	13.9	0.8	12.8	0.6
	Min, Max	0, 88	-14, 53	0, 69	-34, 36
Cycle 3	n	97	88	56	55
	Mean (SD)	17.2 (12.24)	2.3 (10.58)	14.3 (11.55)	-0.7 (8.68)
	Median	13.9	0.4	11.4	0.0
	Min, Max	0, 54	-27, 43	0, 44	-31, 20

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-b-qs-chg-oes-itts-cl.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: QLQ-OES18 index-score

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	76	68	50	50
	Mean (SD)	16.6 (11.47)	2.4 (10.73)	15.0 (10.34)	0.6 (10.43)
	Median	14.6	0.0	12.1	1.7
	Min, Max	0, 53	-40, 37	0, 43	-35, 26
Cycle 5	n	57	52	32	31
	Mean (SD)	15.3 (10.84)	1.1 (10.12)	15.4 (18.73)	1.1 (14.94)
	Median	13.3	0.1	8.1	0.0
	Min, Max	0, 44	-38, 29	0, 82	-37, 52
Cycle 6	n	54	49	26	25
	Mean (SD)	13.4 (12.11)	0.5 (9.59)	16.2 (17.38)	3.0 (13.55)
	Median	10.8	0.0	9.9	1.4
	Min, Max	0, 54	-21, 31	0, 67	-20, 41
End of Treatment	n	41	39	46	45
	Mean (SD)	22.1 (17.69)	8.1 (13.89)	22.4 (16.81)	6.8 (14.09)
	Median	16.7	4.7	17.9	5.0
	Min, Max	0, 71	-15, 55	0, 83	-28, 69

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-b-qs-chg-oes-itts-cl.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: QLQ-OES18 index-score

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	70	66	62	61
	Mean (SD)	24.1 (17.12)	8.3 (14.47)	20.7 (15.21)	6.0 (11.27)
	Median	18.6	3.1	16.8	3.6
	Min, Max	0, 74	-25, 46	0, 66	-20, 45
Worst Post-Baseline Value	n	136	124	127	122
	Mean (SD)	26.2 (17.50)	11.1 (13.56)	25.3 (17.41)	8.8 (13.09)
	Median	23.2	6.8	20.8	6.7
	Min, Max	0, 88	-13, 55	0, 83	-20, 69

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-b-qs-chg-oes-itts-cl.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Dysphagia

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		134	
	Mean (SD)	46.3 (36.35)		38.8 (36.35)	
	Median	44.4		33.3	
	Min, Max	0, 100		0, 100	
Cycle 1	n	82	78	82	81
	Mean (SD)	50.1 (39.24)	-1.9 (23.65)	46.2 (37.67)	3.4 (20.23)
	Median	44.4	0.0	44.4	0.0
	Min, Max	0, 100	-100, 67	0, 100	-44, 100
Cycle 2	n	124	114	97	96
	Mean (SD)	44.8 (39.92)	1.2 (26.83)	41.2 (36.11)	7.2 (27.31)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-100, 100	0, 100	-67, 100
Cycle 3	n	97	88	57	56
	Mean (SD)	49.4 (38.72)	7.2 (30.70)	39.4 (35.95)	3.4 (29.05)
	Median	44.4	0.0	33.3	0.0
	Min, Max	0, 100	-100, 100	0, 100	-78, 67

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-b-qs-chg-oes-itts-cl.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Dysphagia

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	76	68	52	51
	Mean (SD)	48.4 (38.56)	4.6 (27.83)	41.7 (37.27)	2.8 (32.95)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-100, 100	0, 100	-89, 67
Cycle 5	n	57	52	32	31
	Mean (SD)	52.4 (41.24)	5.3 (28.73)	39.2 (40.01)	-1.4 (38.89)
	Median	44.4	0.0	33.3	0.0
	Min, Max	0, 100	-67, 100	0, 100	-100, 89
Cycle 6	n	54	49	26	25
	Mean (SD)	44.2 (41.32)	1.4 (27.37)	37.6 (37.72)	0.4 (35.21)
	Median	44.4	0.0	33.3	0.0
	Min, Max	0, 100	-67, 100	0, 100	-100, 67
End of Treatment	n	41	39	46	45
	Mean (SD)	53.7 (37.59)	5.4 (37.28)	50.2 (39.39)	1.7 (32.56)
	Median	55.6	0.0	50.0	0.0
	Min, Max	0, 100	-89, 78	0, 100	-100, 78

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-b-qs-chg-oes-itts-cl.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Dysphagia

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	70	66	62	61
	Mean (SD)	54.4 (37.98)	4.9 (33.43)	54.7 (38.14)	11.1 (37.07)
	Median	66.7	0.0	55.6	0.0
	Min, Max	0, 100	-67, 100	0, 100	-100, 100
Worst Post-Baseline Value	n	136	125	128	125
	Mean (SD)	60.7 (38.06)	17.4 (32.83)	56.3 (36.53)	17.2 (30.41)
	Median	66.7	11.1	55.6	11.1
	Min, Max	0, 100	-100, 100	0, 100	-44, 100

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-b-qs-chg-oes-itts-cl.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Eating

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		132	
	Mean (SD)	20.4 (20.57)		20.8 (23.38)	
	Median	16.7		16.7	
	Min, Max	0, 100		0, 100	
Cycle 1	n	82	78	81	78
	Mean (SD)	22.7 (25.54)	2.4 (15.13)	21.0 (23.13)	-0.5 (13.91)
	Median	16.7	0.0	8.3	0.0
	Min, Max	0, 100	-50, 58	0, 92	-33, 33
Cycle 2	n	124	114	97	96
	Mean (SD)	21.6 (24.97)	3.3 (16.47)	19.3 (23.44)	0.1 (16.15)
	Median	16.7	0.0	16.7	0.0
	Min, Max	0, 100	-33, 67	0, 92	-50, 50
Cycle 3	n	98	89	56	55
	Mean (SD)	20.0 (24.86)	0.8 (21.76)	13.1 (15.56)	-5.3 (16.77)
	Median	8.3	0.0	8.3	0.0
	Min, Max	0, 100	-83, 75	0, 67	-50, 25

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-b-qs-chg-oes-itts-cl.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Eating

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	76	68	51	50
	Mean (SD)	18.4 (20.34)	1.2 (17.05)	17.5 (21.10)	0.5 (19.95)
	Median	8.3	0.0	8.3	0.0
	Min, Max	0, 100	-25, 83	0, 83	-42, 58
Cycle 5	n	57	52	32	31
	Mean (SD)	14.3 (17.66)	-1.1 (14.76)	17.2 (25.66)	1.9 (25.34)
	Median	8.3	0.0	8.3	0.0
	Min, Max	0, 75	-42, 42	0, 100	-58, 67
Cycle 6	n	54	49	26	25
	Mean (SD)	14.8 (16.64)	-0.2 (13.97)	21.5 (30.20)	7.7 (26.45)
	Median	8.3	0.0	8.3	0.0
	Min, Max	0, 58	-25, 42	0, 100	-58, 67
End of Treatment	n	41	39	46	45
	Mean (SD)	29.9 (30.28)	9.4 (22.88)	27.7 (28.92)	9.4 (25.29)
	Median	25.0	0.0	16.7	8.3
	Min, Max	0, 100	-33, 67	0, 100	-42, 75

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-b-qs-chg-oes-itts-cl.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Eating

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	71	67	62	61
	Mean (SD)	27.7 (25.07)	8.6 (19.46)	24.3 (25.17)	5.2 (17.82)
	Median	25.0	8.3	16.7	8.3
	Min, Max	0, 100	-25, 67	0, 92	-58, 42
Worst Post-Baseline Value	n	136	125	127	122
	Mean (SD)	34.3 (28.74)	15.7 (21.29)	33.2 (27.44)	12.2 (21.94)
	Median	25.0	8.3	25.0	8.3
	Min, Max	0, 100	-50, 83	0, 100	-50, 75

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-b-qs-chg-oes-itts-cl.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Reflux

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		134	
	Mean (SD)	11.6 (16.93)		11.6 (18.42)	
	Median	0.0		0.0	
	Min, Max	0, 83		0, 100	
Cycle 1	n	82	78	82	81
	Mean (SD)	12.0 (20.33)	-0.2 (14.83)	13.2 (18.65)	2.3 (17.43)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 67	0, 67	-67, 50
Cycle 2	n	124	114	97	96
	Mean (SD)	10.6 (17.05)	-0.0 (14.37)	12.7 (20.09)	3.3 (20.47)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-50, 67	0, 100	-50, 83
Cycle 3	n	98	89	57	56
	Mean (SD)	12.4 (20.91)	1.3 (19.17)	11.4 (17.86)	2.4 (19.44)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-50, 83	0, 83	-33, 67

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-b-qs-chg-oes-itts-cl.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Reflux

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	76	68	52	51
	Mean (SD)	9.4 (17.92)	-1.5 (17.21)	12.5 (16.13)	3.3 (15.28)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 83	-50, 83	0, 67	-33, 50
Cycle 5	n	57	52	32	31
	Mean (SD)	8.5 (13.03)	0.3 (17.92)	10.4 (17.84)	1.1 (20.61)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 33	-83, 33	0, 67	-50, 50
Cycle 6	n	54	49	26	25
	Mean (SD)	7.4 (12.81)	1.0 (16.10)	12.2 (21.89)	2.7 (25.77)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 50	-67, 33	0, 83	-50, 67
End of Treatment	n	41	39	46	45
	Mean (SD)	16.3 (24.58)	7.7 (19.81)	15.6 (21.49)	4.8 (24.00)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-17, 83	0, 83	-67, 83

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-b-qs-chg-oes-itts-cl.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Reflux

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	71	67	62	61
	Mean (SD)	14.6 (16.41)	3.7 (18.76)	14.0 (16.31)	2.2 (19.12)
	Median	16.7	0.0	8.3	0.0
	Min, Max	0, 67	-33, 50	0, 67	-67, 33
Worst Post-Baseline Value	n	136	125	128	125
	Mean (SD)	20.7 (24.80)	9.5 (21.20)	23.2 (22.93)	12.0 (23.05)
	Median	16.7	0.0	16.7	16.7
	Min, Max	0, 100	-33, 83	0, 100	-67, 83

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-b-qs-chg-oes-itts-cl.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Pain

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		134	
	Mean (SD)	11.5 (13.97)		12.9 (19.69)	
	Median	11.1		11.1	
	Min, Max	0, 67		0, 100	
Cycle 1	n	82	78	82	81
	Mean (SD)	11.9 (15.40)	-0.1 (12.60)	13.6 (21.21)	1.4 (14.95)
	Median	11.1	0.0	0.0	0.0
	Min, Max	0, 78	-44, 44	0, 100	-44, 89
Cycle 2	n	124	114	97	96
	Mean (SD)	12.5 (18.07)	1.7 (16.14)	10.7 (17.34)	-0.9 (11.01)
	Median	0.0	0.0	11.1	0.0
	Min, Max	0, 100	-33, 100	0, 100	-44, 22
Cycle 3	n	98	89	57	56
	Mean (SD)	11.8 (17.02)	-0.2 (14.21)	8.5 (13.53)	-1.1 (8.83)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-44, 44	0, 78	-22, 17

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-b-qs-chg-oes-itts-cl.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Pain

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	76	68	52	51
	Mean (SD)	9.6 (13.00)	-1.0 (15.45)	7.5 (9.77)	0.0 (11.76)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 44	-67, 33	0, 33	-22, 33
Cycle 5	n	57	52	32	31
	Mean (SD)	9.6 (13.52)	0.0 (15.40)	7.6 (11.79)	0.7 (14.33)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 56	-67, 44	0, 33	-22, 33
Cycle 6	n	54	49	26	25
	Mean (SD)	8.2 (13.51)	-0.2 (15.96)	9.0 (16.03)	1.8 (17.77)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-56, 56	0, 67	-22, 67
End of Treatment	n	41	39	46	45
	Mean (SD)	20.6 (26.59)	9.1 (23.34)	16.9 (22.92)	4.9 (16.68)
	Median	11.1	0.0	11.1	0.0
	Min, Max	0, 100	-33, 89	0, 100	-33, 67

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-b-qs-chg-oes-itts-cl.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Pain

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	71	67	62	61
	Mean (SD)	16.3 (18.39)	6.1 (19.66)	13.6 (18.70)	2.6 (15.23)
	Median	11.1	0.0	11.1	0.0
	Min, Max	0, 67	-33, 67	0, 78	-22, 44
Worst Post-Baseline Value	n	136	125	128	125
	Mean (SD)	21.9 (22.38)	11.0 (20.23)	20.1 (21.60)	7.8 (15.22)
	Median	22.2	11.1	11.1	11.1
	Min, Max	0, 100	-33, 100	0, 100	-22, 89

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-b-qs-chg-oes-itts-cl.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Trouble swallowing saliva

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		134	
	Mean (SD)	12.8 (24.07)		11.7 (24.61)	
	Median	0.0		0.0	
	Min, Max	0, 100		0, 100	
Cycle 1	n	82	78	82	81
	Mean (SD)	11.4 (18.31)	-1.7 (17.73)	11.4 (25.78)	1.2 (24.41)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-100, 33	0, 100	-67, 100
Cycle 2	n	123	113	97	96
	Mean (SD)	13.8 (25.22)	2.9 (25.02)	9.6 (21.49)	0.0 (26.05)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 100	0, 100	-100, 100
Cycle 3	n	98	89	57	56
	Mean (SD)	11.9 (24.52)	-0.4 (31.58)	9.9 (23.54)	-3.0 (28.62)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 100	0, 100	-100, 100

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-b-qs-chg-oes-itts-cl.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Trouble swallowing saliva

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	76	68	52	51
	Mean (SD)	10.1 (19.64)	-1.0 (31.00)	9.0 (17.61)	-5.9 (27.25)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 100	0, 67	-100, 67
Cycle 5	n	57	52	32	31
	Mean (SD)	9.4 (22.50)	-1.9 (25.06)	9.4 (27.09)	-4.3 (22.35)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 100	0, 100	-100, 33
Cycle 6	n	54	49	26	25
	Mean (SD)	6.8 (19.83)	-3.4 (19.54)	12.8 (29.93)	-2.7 (27.08)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 33	0, 100	-100, 67
End of Treatment	n	41	39	46	45
	Mean (SD)	11.4 (17.65)	3.4 (22.68)	18.8 (32.70)	11.1 (31.78)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-67, 67	0, 100	-67, 100

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-b-qs-chg-oes-itts-cl.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Trouble swallowing saliva

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	71	67	62	61
	Mean (SD)	19.7 (32.16)	7.0 (35.55)	9.7 (22.08)	1.6 (27.51)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 100	0, 100	-100, 100
Worst Post-Baseline Value	n	136	125	128	125
	Mean (SD)	27.7 (34.08)	16.3 (33.23)	23.7 (33.50)	12.5 (33.24)
	Median	33.3	0.0	0.0	0.0
	Min, Max	0, 100	-100, 100	0, 100	-100, 100

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-b-qs-chg-oes-itts-cl.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Choked when swallowing

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		134	
	Mean (SD)	14.1 (19.89)		15.7 (24.08)	
	Median	0.0		0.0	
	Min, Max	0, 67		0, 100	
Cycle 1	n	82	78	81	80
	Mean (SD)	15.0 (22.32)	-0.4 (17.40)	11.1 (20.41)	-5.8 (20.39)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 67	0, 100	-67, 67
Cycle 2	n	124	114	97	96
	Mean (SD)	16.1 (22.69)	2.6 (18.36)	10.7 (18.97)	-3.1 (24.70)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 67	0, 100	-100, 67
Cycle 3	n	98	89	57	56
	Mean (SD)	12.9 (21.21)	-1.9 (23.76)	11.1 (22.12)	1.8 (21.48)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-33, 100

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-b-qs-chg-oes-itts-cl.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Choked when swallowing

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	76	68	52	51
	Mean (SD)	11.8 (20.87)	-1.5 (21.88)	10.9 (18.34)	-0.0 (22.11)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 67	-67, 67
Cycle 5	n	57	52	32	31
	Mean (SD)	12.3 (18.51)	-0.6 (23.33)	12.5 (27.76)	1.1 (21.92)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-67, 33	0, 100	-67, 67
Cycle 6	n	54	49	26	25
	Mean (SD)	9.3 (16.40)	-2.7 (21.34)	7.7 (17.15)	-1.3 (20.37)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-67, 33	0, 67	-33, 67
End of Treatment	n	41	39	46	45
	Mean (SD)	15.4 (23.68)	4.3 (24.40)	18.1 (26.95)	5.2 (28.39)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-67, 67	0, 100	-67, 100

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-b-qs-chg-oes-itts-cl.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Choked when swallowing

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	71	67	62	61
	Mean (SD)	18.8 (28.58)	4.5 (30.65)	15.1 (26.08)	3.3 (23.34)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 67
Worst Post-Baseline Value	n	136	125	127	124
	Mean (SD)	27.5 (29.50)	13.6 (28.11)	24.9 (29.69)	9.7 (28.12)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-b-qs-chg-oes-itts-cl.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Dry mouth

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	127		134	
	Mean (SD)	18.1 (20.47)		19.9 (24.90)	
	Median	0.0		0.0	
	Min, Max	0, 100		0, 100	
Cycle 1	n	82	77	82	81
	Mean (SD)	18.7 (22.28)	0.4 (18.33)	21.5 (24.21)	2.1 (20.65)
	Median	0.0	0.0	33.3	0.0
	Min, Max	0, 100	-33, 67	0, 100	-67, 100
Cycle 2	n	124	113	97	96
	Mean (SD)	22.0 (27.51)	5.3 (23.39)	18.9 (23.52)	-0.0 (21.08)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 67	0, 100	-67, 67
Cycle 3	n	98	89	57	56
	Mean (SD)	20.7 (24.18)	3.7 (20.37)	16.4 (22.82)	-2.4 (22.79)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 67	0, 100	-67, 33

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-b-qs-chg-oes-itts-cl.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Dry mouth

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	76	68	52	51
	Mean (SD)	21.1 (26.58)	7.4 (26.29)	16.0 (19.23)	0.0 (27.49)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 67	-100, 67
Cycle 5	n	57	52	32	31
	Mean (SD)	14.6 (18.92)	0.0 (18.67)	14.6 (25.31)	-2.2 (27.13)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-67, 33	0, 100	-67, 67
Cycle 6	n	54	49	26	25
	Mean (SD)	14.8 (23.05)	2.0 (20.87)	17.9 (27.05)	5.3 (26.67)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 67	0, 100	-33, 67
End of Treatment	n	41	39	46	45
	Mean (SD)	25.2 (28.66)	14.5 (26.26)	21.7 (23.54)	7.4 (26.49)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-33, 100

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-b-qs-chg-oes-itts-cl.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Dry mouth

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	71	67	62	61
	Mean (SD)	28.2 (29.63)	10.0 (29.60)	25.8 (31.02)	12.0 (31.64)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100
Worst Post-Baseline Value	n	136	124	128	125
	Mean (SD)	37.3 (30.38)	19.9 (27.19)	33.9 (28.98)	15.2 (29.18)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-b-qs-chg-oes-itts-cl.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Trouble with taste

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	127		133	
	Mean (SD)	8.7 (20.23)		15.3 (26.75)	
	Median	0.0		0.0	
	Min, Max	0, 100		0, 100	
Cycle 1	n	82	77	81	79
	Mean (SD)	11.0 (18.93)	3.0 (20.36)	12.8 (23.90)	0.0 (19.97)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 67	0, 100	-67, 67
Cycle 2	n	124	113	97	96
	Mean (SD)	10.2 (21.75)	3.8 (23.88)	18.2 (28.88)	2.4 (24.78)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 67
Cycle 3	n	97	88	56	55
	Mean (SD)	11.3 (20.35)	4.5 (25.36)	12.5 (25.87)	-3.0 (25.88)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 67	0, 100	-100, 67

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-b-qs-chg-oes-itts-cl.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Trouble with taste

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	76	68	52	50
	Mean (SD)	11.4 (21.47)	6.4 (20.97)	17.3 (27.61)	4.0 (27.47)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 67
Cycle 5	n	57	52	32	31
	Mean (SD)	5.3 (12.26)	-1.3 (19.76)	15.6 (28.06)	3.2 (30.25)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 33	-100, 33	0, 100	-100, 67
Cycle 6	n	54	49	26	25
	Mean (SD)	6.8 (15.02)	-0.7 (24.99)	16.7 (33.00)	6.7 (27.22)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-100, 67	0, 100	-33, 100
End of Treatment	n	41	39	46	45
	Mean (SD)	16.3 (24.86)	11.1 (24.58)	16.7 (27.89)	5.2 (24.57)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 67	0, 100	-67, 67

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-b-qs-chg-oes-itts-cl.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Trouble with taste

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	71	67	62	61
	Mean (SD)	22.1 (28.70)	16.9 (31.98)	17.7 (30.01)	7.7 (18.65)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-100, 100	0, 100	-33, 67
Worst Post-Baseline Value	n	136	124	127	123
	Mean (SD)	24.8 (28.97)	17.7 (29.89)	26.2 (31.32)	10.6 (27.10)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-b-qs-chg-oes-itts-cl.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Trouble with coughing

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	127		134	
	Mean (SD)	10.0 (18.46)		14.4 (23.64)	
	Median	0.0		0.0	
	Min, Max	0, 67		0, 100	
Cycle 1	n	82	77	82	81
	Mean (SD)	10.2 (17.91)	0.0 (15.29)	15.4 (22.34)	1.2 (17.03)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-33, 33	0, 100	-67, 33
Cycle 2	n	124	113	97	96
	Mean (SD)	14.0 (24.08)	4.7 (22.21)	12.4 (21.69)	1.0 (19.62)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 67
Cycle 3	n	98	89	57	56
	Mean (SD)	13.6 (21.32)	4.9 (19.17)	14.0 (23.53)	1.2 (24.59)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 67	0, 100	-67, 100

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-b-qs-chg-oes-itts-cl.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Trouble with coughing

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	76	68	51	51
	Mean (SD)	14.5 (21.32)	5.4 (19.62)	13.7 (20.20)	1.3 (27.46)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-33, 67	0, 67	-67, 67
Cycle 5	n	57	52	32	31
	Mean (SD)	15.2 (21.89)	7.1 (22.23)	15.6 (28.06)	7.5 (31.87)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-33, 67	0, 100	-67, 100
Cycle 6	n	54	49	26	25
	Mean (SD)	11.7 (21.63)	5.4 (19.66)	15.4 (28.64)	6.7 (34.69)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 67	-33, 67	0, 100	-67, 100
End of Treatment	n	41	39	46	45
	Mean (SD)	17.9 (26.97)	11.1 (25.74)	22.5 (29.02)	13.3 (27.89)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-33, 100

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-b-qs-chg-oes-itts-cl.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Trouble with coughing

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	71	67	62	61
	Mean (SD)	20.7 (27.81)	9.5 (25.82)	22.0 (30.74)	11.5 (32.14)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100
Worst Post-Baseline Value	n	136	124	128	125
	Mean (SD)	26.2 (29.37)	17.5 (26.36)	31.5 (31.11)	18.4 (29.77)
	Median	33.3	0.0	33.3	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-b-qs-chg-oes-itts-cl.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Trouble talking

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		134	
	Mean (SD)	10.4 (22.04)		11.7 (22.11)	
	Median	0.0		0.0	
	Min, Max	0, 100		0, 100	
Cycle 1	n	82	78	82	81
	Mean (SD)	9.3 (21.77)	-0.4 (14.71)	13.0 (23.86)	-1.2 (17.83)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 67	0, 100	-67, 67
Cycle 2	n	124	114	97	96
	Mean (SD)	12.1 (25.62)	4.1 (19.90)	9.6 (19.81)	0.0 (14.51)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 67	-33, 33
Cycle 3	n	98	89	57	56
	Mean (SD)	10.9 (21.82)	4.5 (20.84)	9.9 (19.89)	0.0 (15.57)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 67	-67, 33

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-b-qs-chg-oes-itts-cl.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Trouble talking

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	76	68	52	51
	Mean (SD)	11.0 (20.65)	4.4 (19.87)	9.6 (17.88)	-1.3 (19.96)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 67	-67, 33
Cycle 5	n	57	52	32	31
	Mean (SD)	11.1 (23.85)	3.2 (23.11)	11.5 (24.84)	3.2 (23.34)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-67, 100	0, 100	-67, 67
Cycle 6	n	54	49	26	25
	Mean (SD)	9.9 (23.01)	2.0 (18.52)	11.5 (24.84)	2.7 (23.41)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 67
End of Treatment	n	41	39	46	45
	Mean (SD)	14.6 (28.91)	5.1 (21.00)	15.9 (24.08)	5.2 (26.55)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-b-qs-chg-oes-itts-cl.rtf

Table 14.2.6.3.1.b:
Summary of EORTC QLQ-OES18 Scores by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: Trouble talking

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	71	67	62	61
	Mean (SD)	17.8 (29.19)	9.5 (24.49)	9.7 (22.08)	3.3 (24.87)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100
Worst Post-Baseline Value	n	136	125	128	125
	Mean (SD)	22.5 (30.87)	14.1 (26.53)	21.4 (28.60)	9.6 (24.25)
	Median	0.0	0.0	0.0	0.0
	Min, Max	0, 100	-33, 100	0, 100	-67, 100

Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-03-01-b-qs-chg-oes-itts-cl.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Dysphagia									
Cycle 4	138		2.38 (2.25)	74		7.87 (2.88)	-5.48 (-12.51, 1.55)	-0.20 (-0.46, 0.06)	0.1258
Cycle 6	93		2.23 (2.70)	35		2.39 (4.10)	-0.16 (-9.73, 9.42)	-0.01 (-0.34, 0.33)	0.9740
Overall Treatment Effect	228	35.32 (35.22)	3.05 (1.61)	208	34.83 (34.57)	5.45 (1.98)	-2.40 (-7.19, 2.39)	-0.12 (-0.36, 0.12)	0.3258

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Only patients with baseline and postbaseline value are included in analysis.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab.

[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Negative differences favor tislelizumab.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-03-01-01-eff-mmrmqs-o18-itt-cl.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Eating									
Cycle 4	138		0.32 (1.44)	73		2.41 (1.86)	-2.09 (-6.60, 2.41)	-0.12 (-0.38, 0.14)	0.3613
Cycle 6	93		0.01 (1.57)	35		4.88 (2.22)	-4.87 (-10.11, 0.36)	-0.27 (-0.56, 0.02)	0.0680
Overall Treatment Effect	227	17.57 (19.83)	0.44 (1.06)	205	19.61 (21.10)	1.24 (1.24)	-0.80 (-3.81, 2.22)	-0.06 (-0.28, 0.16)	0.6028

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Negative differences favor tislelizumab.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
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Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Reflux									
Cycle 4	138		-1.99 (1.16)	74		1.86 (1.51)	-3.85 (-7.48, -0.22)	-0.28 (-0.55, -0.02)	0.0378
Cycle 6	93		-1.14 (1.47)	35		-0.01 (2.23)	-1.13 (-6.32, 4.05)	-0.07 (-0.41, 0.26)	0.6670
Overall Treatment Effect	228	12.22 (17.48)	-1.15 (0.91)	208	12.70 (17.96)	1.03 (1.10)	-2.17 (-4.82, 0.48)	-0.19 (-0.43, 0.04)	0.1076

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Negative differences favor tislelizumab.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
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Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Pain (OES18)									
Cycle 4	138		-1.34 (1.01)	74		0.41 (1.34)	-1.75 (-4.97, 1.48)	-0.15 (-0.42, 0.12)	0.2864
Cycle 6	93		-0.74 (1.31)	35		2.14 (2.02)	-2.89 (-7.60, 1.83)	-0.21 (-0.56, 0.13)	0.2284
Overall Treatment Effect	228	11.76 (14.64)	-0.26 (0.72)	208	11.92 (18.20)	0.81 (0.91)	-1.07 (-3.23, 1.09)	-0.12 (-0.37, 0.13)	0.3301

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Negative differences favor tislelizumab.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-03-01-01-eff-mmrmqs-o18-itt-cl.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Trouble swallowing saliva									
Cycle 4	138		-1.94 (1.68)	74		-1.04 (2.24)	-0.90 (-6.32, 4.52)	-0.05 (-0.32, 0.23)	0.7443
Cycle 6	93		-3.85 (1.65)	35		-3.37 (2.52)	-0.47 (-6.33, 5.39)	-0.03 (-0.37, 0.32)	0.8741
Overall Treatment Effect	228	11.67 (23.08)	-1.23 (1.10)	208	11.16 (24.30)	-1.47 (1.35)	0.24 (-2.99, 3.47)	0.02 (-0.22, 0.26)	0.8848

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Negative differences favor tislelizumab.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-03-01-01-eff-mmrmqs-o18-itt-cl.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Choked when swallowing									
Cycle 4	138		-3.14 (1.60)	74		-1.82 (2.11)	-1.33 (-6.44, 3.79)	-0.07 (-0.34, 0.20)	0.6103
Cycle 6	93		-3.99 (1.68)	35		-1.03 (2.60)	-2.96 (-8.99, 3.08)	-0.17 (-0.52, 0.18)	0.3346
Overall Treatment Effect	228	14.17 (18.88)	-2.07 (1.07)	207	14.25 (22.11)	-0.48 (1.31)	-1.59 (-4.74, 1.56)	-0.12 (-0.36, 0.12)	0.3202

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Only patients with baseline and postbaseline value are included in analysis.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab.

[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Negative differences favor tislelizumab.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

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Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Dry mouth									
Cycle 4	138		2.87 (1.87)	74		1.92 (2.45)	0.95 (-5.00, 6.90)	0.04 (-0.23, 0.31)	0.7530
Cycle 6	93		0.35 (2.01)	35		5.52 (3.06)	-5.17 (-12.30, 1.97)	-0.24 (-0.58, 0.09)	0.1546
Overall Treatment Effect	227	16.32 (20.24)	0.79 (1.21)	208	19.89 (24.34)	2.63 (1.47)	-1.84 (-5.38, 1.69)	-0.12 (-0.36, 0.11)	0.3062

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Negative differences favor tislelizumab.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
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Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Trouble with taste									
Cycle 4	137		1.07 (1.72)	73		7.03 (2.21)	-5.97 (-11.38, -0.56)	-0.29 (-0.55, -0.03)	0.0307
Cycle 6	93		-0.58 (1.97)	35		9.34 (2.79)	-9.93 (-16.57, -3.29)	-0.44 (-0.74, -0.14)	0.0036
Overall Treatment Effect	226	7.95 (18.00)	-0.06 (1.25)	206	14.04 (24.80)	4.53 (1.49)	-4.59 (-8.24, -0.93)	-0.29 (-0.52, -0.06)	0.0140

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Negative differences favor tislelizumab.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-03-01-01-eff-mmrmqs-o18-itt-cl.rtf

Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Trouble with coughing									
Cycle 4	138		3.02 (1.66)	74		2.90 (2.21)	0.12 (-5.23, 5.48)	0.01 (-0.27, 0.28)	0.9647
Cycle 6	93		4.13 (2.12)	35		5.12 (3.25)	-0.98 (-8.58, 6.61)	-0.04 (-0.38, 0.30)	0.7989
Overall Treatment Effect	227	11.02 (20.60)	2.53 (1.14)	208	13.17 (22.37)	4.13 (1.44)	-1.60 (-5.06, 1.86)	-0.12 (-0.37, 0.13)	0.3636

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Negative differences favor tislelizumab.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
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Table 14.2.6.3.1.1:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Trouble talking									
Cycle 4	138		0.43 (1.27)	74		-0.17 (1.62)	0.60 (-3.32, 4.51)	0.04 (-0.22, 0.30)	0.7644
Cycle 6	93		0.35 (1.40)	35		0.02 (1.93)	0.34 (-4.24, 4.91)	0.02 (-0.26, 0.30)	0.8847
Overall Treatment Effect	228	9.58 (20.59)	0.65 (1.05)	208	11.29 (21.79)	0.27 (1.23)	0.38 (-2.61, 3.38)	0.03 (-0.20, 0.25)	0.8010

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Negative differences favor tislelizumab.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
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Table 14.2.6.3.1.1.b:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Dysphagia									
Cycle 4	68		5.56 (3.24)	51		3.69 (3.72)	1.86 (-7.77, 11.50)	0.07 (-0.28, 0.41)	0.7031
Cycle 6	49		2.02 (3.58)	25		0.09 (4.65)	1.94 (-9.59, 13.47)	0.07 (-0.34, 0.47)	0.7397
Overall Treatment Effect	123	46.27 (36.35)	3.90 (2.23)	119	38.81 (36.35)	3.34 (2.56)	0.56 (-5.97, 7.08)	0.03 (-0.29, 0.34)	0.8660

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

Only patients with baseline and postbaseline value are included in analysis.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab.

[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Negative differences favor tislelizumab.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

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Table 14.2.6.3.1.1.b:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Eating									
Cycle 4	68		1.52 (2.12)	50		0.17 (2.45)	1.35 (-4.97, 7.67)	0.07 (-0.27, 0.42)	0.6726
Cycle 6	49		0.93 (2.32)	25		3.85 (2.98)	-2.92 (-10.31, 4.47)	-0.15 (-0.53, 0.23)	0.4349
Overall Treatment Effect	123	20.44 (20.57)	1.09 (1.40)	116	20.83 (23.38)	-0.59 (1.57)	1.68 (-2.32, 5.68)	0.12 (-0.17, 0.42)	0.4077

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Negative differences favor tislelizumab.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
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Table 14.2.6.3.1.1.b:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Reflux									
Cycle 4	68		-1.37 (1.75)	51		4.28 (2.02)	-5.65 (-10.84, -0.47)	-0.37 (-0.72, -0.03)	0.0328
Cycle 6	49		-0.56 (2.28)	25		1.48 (2.99)	-2.04 (-9.42, 5.34)	-0.11 (-0.50, 0.28)	0.5846
Overall Treatment Effect	123	11.59 (16.93)	-0.35 (1.39)	119	11.57 (18.42)	2.57 (1.58)	-2.93 (-6.94, 1.08)	-0.22 (-0.52, 0.08)	0.1516

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Negative differences favor tislelizumab.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-03-01-01-b-eff-mmrmqs-o18-itts-cl.rtf

Table 14.2.6.3.1.1.b:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Pain (OES18)									
Cycle 4	68		-0.44 (1.53)	51		-0.47 (1.76)	0.04 (-4.51, 4.58)	0.00 (-0.34, 0.35)	0.9874
Cycle 6	49		1.45 (2.09)	25		2.83 (2.76)	-1.37 (-8.21, 5.47)	-0.08 (-0.49, 0.33)	0.6914
Overall Treatment Effect	123	11.55 (13.97)	0.66 (1.09)	119	12.85 (19.69)	0.51 (1.27)	0.14 (-3.06, 3.35)	0.01 (-0.30, 0.33)	0.9300

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Negative differences favor tislelizumab.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-03-01-01-b-eff-mmrmqs-o18-itts-cl.rtf

Table 14.2.6.3.1.1.b:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Trouble swallowing saliva									
Cycle 4	68		-1.04 (2.43)	51		-4.03 (2.81)	2.99 (-4.27, 10.26)	0.15 (-0.21, 0.51)	0.4162
Cycle 6	49		-3.09 (2.51)	25		-5.19 (3.34)	2.10 (-6.13, 10.32)	0.11 (-0.31, 0.52)	0.6139
Overall Treatment Effect	123	12.76 (24.07)	-0.93 (1.53)	119	11.69 (24.61)	-3.32 (1.78)	2.39 (-2.07, 6.85)	0.17 (-0.15, 0.48)	0.2923

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Negative differences favor tislelizumab.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-03-01-01-b-eff-mmrmqs-o18-itts-cl.rtf

Table 14.2.6.3.1.1.b:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Choked when swallowing									
Cycle 4	68		-2.80 (2.26)	51		-2.54 (2.62)	-0.26 (-7.02, 6.51)	-0.01 (-0.37, 0.35)	0.9403
Cycle 6	49		-4.18 (2.32)	25		-4.23 (3.22)	0.05 (-7.79, 7.89)	0.00 (-0.46, 0.47)	0.9902
Overall Treatment Effect	123	14.06 (19.89)	-1.73 (1.35)	118	15.67 (24.08)	-2.64 (1.59)	0.91 (-3.08, 4.89)	0.07 (-0.25, 0.40)	0.6528

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Negative differences favor tislelizumab.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-03-01-01-b-eff-mmrmqs-o18-itts-cl.rtf

Table 14.2.6.3.1.1.b:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
Dry mouth									
Cycle 4	68		7.27 (2.86)	51		0.19 (3.26)	7.08 (-1.39, 15.55)	0.29 (-0.06, 0.63)	0.1007
Cycle 6	49		2.18 (2.97)	25		2.86 (4.05)	-0.69 (-10.58, 9.21)	-0.03 (-0.47, 0.41)	0.8906
Overall Treatment Effect	122	18.11 (20.47)	2.93 (1.62)	119	19.90 (24.90)	0.14 (1.85)	2.78 (-1.90, 7.46)	0.18 (-0.13, 0.49)	0.2425

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Negative differences favor tislelizumab.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-03-01-01-b-eff-mmrmqs-o18-itts-cl.rtf

Table 14.2.6.3.1.1.b:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Trouble with taste									
Cycle 4	68		6.21 (2.74)	50		7.71 (3.10)	-1.49 (-9.59, 6.60)	-0.06 (-0.38, 0.26)	0.7158
Cycle 6	49		5.09 (3.17)	25		8.24 (3.83)	-3.15 (-12.94, 6.64)	-0.11 (-0.45, 0.23)	0.5249
Overall Treatment Effect	122	8.66 (20.23)	2.85 (1.95)	117	15.29 (26.75)	3.90 (2.14)	-1.05 (-6.63, 4.53)	-0.05 (-0.35, 0.24)	0.7103

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Negative differences favor tislelizumab.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-03-01-01-b-eff-mmrmqs-o18-itts-cl.rtf

Table 14.2.6.3.1.1.b:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Trouble with coughing									
Cycle 4	68		5.18 (2.54)	51		2.66 (2.93)	2.52 (-5.09, 10.13)	0.12 (-0.24, 0.47)	0.5131
Cycle 6	49		7.18 (3.18)	25		7.19 (4.20)	-0.01 (-10.42, 10.40)	-0.00 (-0.40, 0.40)	0.9987
Overall Treatment Effect	122	9.97 (18.46)	4.49 (1.66)	119	14.43 (23.64)	4.05 (1.94)	0.44 (-4.49, 5.36)	0.03 (-0.29, 0.35)	0.8615

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Negative differences favor tislelizumab.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-03-01-01-b-eff-mmrmqs-o18-itts-cl.rtf

Table 14.2.6.3.1.1.b:
EORTC QLQ-OES18: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
Domain	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Total No. of Patients**	**Mean at Baseline (SD) [a]**	**Mean Change from Baseline (SE) [b]**	**Difference in Mean Change from Baseline (95% CI) [c]**	**Hedges'g (95% CI) [d]**	**2-sided p-value [e]**
Trouble talking									
Cycle 4	68		3.68 (2.12)	51		-0.23 (2.40)	3.92 (-2.32, 10.16)	0.20 (-0.12, 0.52)	0.2166
Cycle 6	49		3.74 (2.09)	25		0.99 (2.46)	2.75 (-3.53, 9.03)	0.14 (-0.18, 0.47)	0.3881
Overall Treatment Effect	123	10.42 (22.04)	2.75 (1.53)	119	11.69 (22.11)	0.34 (1.70)	2.41 (-1.97, 6.78)	0.16 (-0.13, 0.46)	0.2797

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with baseline and postbaseline value are included in analysis.
The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.
[a] Sample mean and SD at baseline based on the patients with baseline value.
[b] Modelled mean change from baseline for treatment arm. Negative differences favor tislelizumab.
[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Negative differences favor tislelizumab.
[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.
[e] P-value was calculated based on testing whether treatment effect is zero or not.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-03-01-01-b-eff-mmrmqs-o18-itts-cl.rtf

Table 14.2.6.3.1.2:
Analyses of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Dysphagia	256	63 (24.6)	NR (NE, NE)	256	63 (24.6)	NR (3.3, NE)	0.781 (0.548, 1.113)	0.1632
Eating	256	36 (14.1)	NR (NE, NE)	256	27 (10.5)	NR (NE, NE)	1.111 (0.671, 1.839)	0.6810
Reflux	256	32 (12.5)	NR (NE, NE)	256	45 (17.6)	NR (NE, NE)	0.517 (0.325, 0.823)	0.0044
Pain	256	49 (19.1)	NR (NE, NE)	256	44 (17.2)	NR (NE, NE)	0.938 (0.619, 1.421)	0.7603
Trouble Swallowing Saliva	256	23 (9.0)	NR (NE, NE)	256	17 (6.6)	NR (NE, NE)	1.099 (0.584, 2.068)	0.7680
Choked When Swallowing	256	23 (9.0)	NR (NE, NE)	256	23 (9.0)	NR (NE, NE)	0.798 (0.446, 1.430)	0.4458
Dry Mouth	256	50 (19.5)	NR (NE, NE)	256	37 (14.5)	NR (NE, NE)	1.024 (0.664, 1.578)	0.9140
Trouble With Taste	256	35 (13.7)	NR (NE, NE)	256	30 (11.7)	NR (NE, NE)	0.862 (0.524, 1.418)	0.5569

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-tte-qlq.sas 05JUN2024 19:37 t-14-02-06-03-01-02-eff-tte-qlq-o18-itt-cl.rtf

Table 14.2.6.3.1.2:
Analyses of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Trouble With Coughing	256	43 (16.8)	NR (NE, NE)	256	30 (11.7)	NR (NE, NE)	1.174 (0.733, 1.878)	0.5017
Trouble Talking	256	25 (9.8)	NR (NE, NE)	256	11 (4.3)	NR (NE, NE)	1.978 (0.970, 4.033)	0.0550

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-tte-qlq.sas 05JUN2024 19:37 t-14-02-06-03-01-02-eff-tte-qlq-o18-itt-cl.rtf

Table 14.2.6.3.1.2.b:
Analyses of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Dysphagia	139	39 (28.1)	NR (NE, NE)	138	37 (26.8)	NR (4.9, NE)	0.960 (0.612, 1.508)	0.8587
Eating	139	23 (16.5)	NR (NE, NE)	138	17 (12.3)	NR (NE, NE)	1.188 (0.631, 2.236)	0.5919
Reflux	139	19 (13.7)	NR (NE, NE)	138	27 (19.6)	NR (NE, NE)	0.598 (0.332, 1.077)	0.0812
Pain	139	32 (23.0)	NR (NE, NE)	138	25 (18.1)	NR (4.9, NE)	1.300 (0.768, 2.200)	0.3211
Trouble Swallowing Saliva	139	12 (8.6)	NR (NE, NE)	138	7 (5.1)	NR (NE, NE)	1.588 (0.624, 4.043)	0.3259
Choked When Swallowing	139	13 (9.4)	NR (NE, NE)	138	13 (9.4)	NR (NE, NE)	0.848 (0.391, 1.839)	0.6747
Dry Mouth	139	28 (20.1)	NR (11.8, NE)	138	18 (13.0)	NR (NE, NE)	1.402 (0.771, 2.551)	0.2626
Trouble With Taste	139	23 (16.5)	NR (NE, NE)	138	15 (10.9)	NR (NE, NE)	1.362 (0.707, 2.623)	0.3510

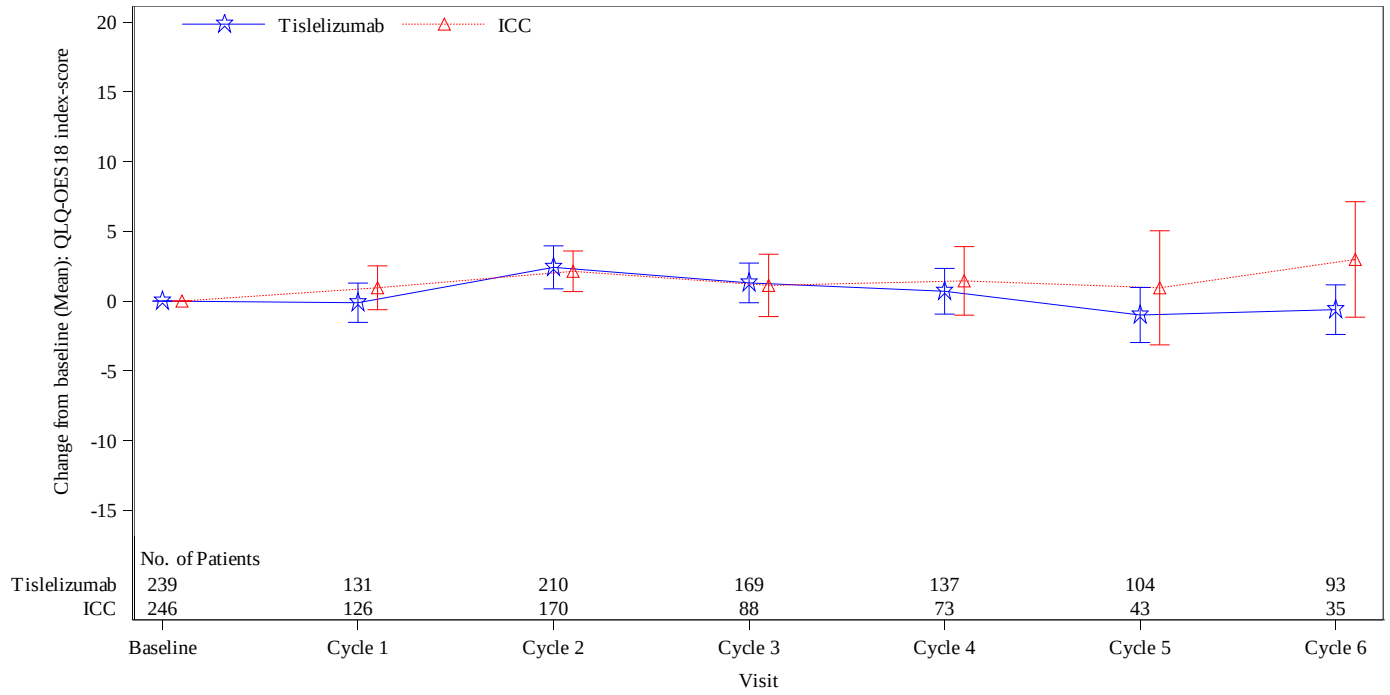
Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-tte-qlq.sas 05JUN2024 19:37 t-14-02-06-03-01-02-b-eff-tte-qlq-o18-itts-cl.rtf

Table 14.2.6.3.1.2.b:
Analyses of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Trouble With Coughing	139	26 (18.7)	NR (NE, NE)	138	18 (13.0)	NR (NE, NE)	1.330 (0.728, 2.430)	0.3500
Trouble Talking	139	17 (12.2)	NR (NE, NE)	138	6 (4.3)	NR (NE, NE)	2.561 (1.005, 6.529)	0.0408

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-tte-qlq.sas 05JUN2024 19:37 t-14-02-06-03-01-02-b-eff-tte-qlq-o18-itts-cl.rtf

Figure 14.2.7.2:
Summary of EORTC QLQ-OES18 Scores by Visit
ITT Analysis Set



Source: Listing 16.2.6.6.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
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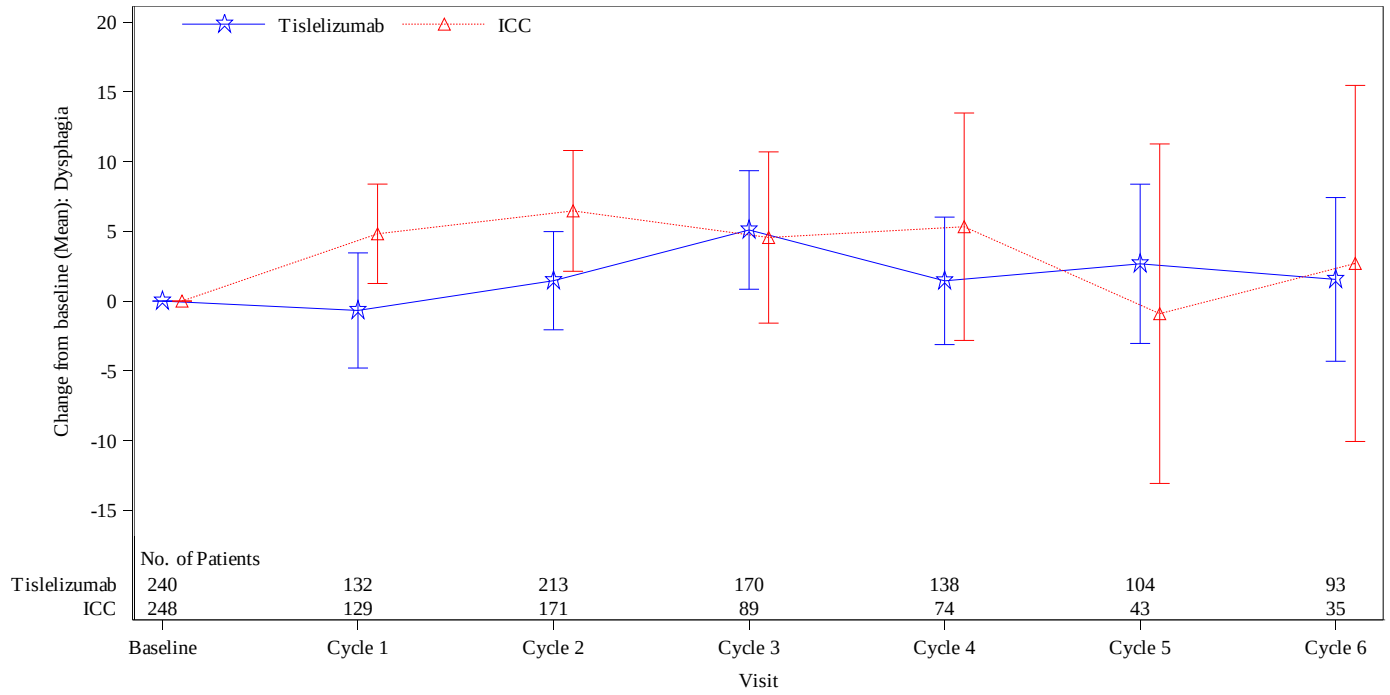

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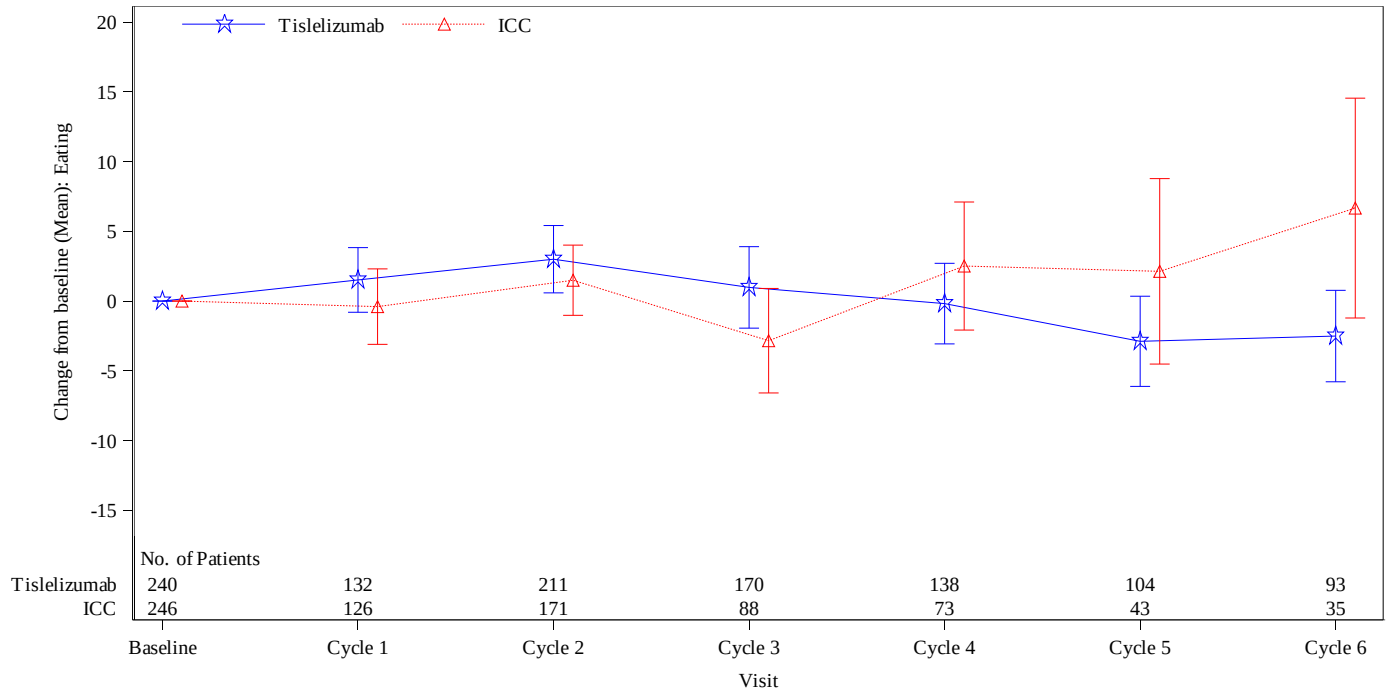

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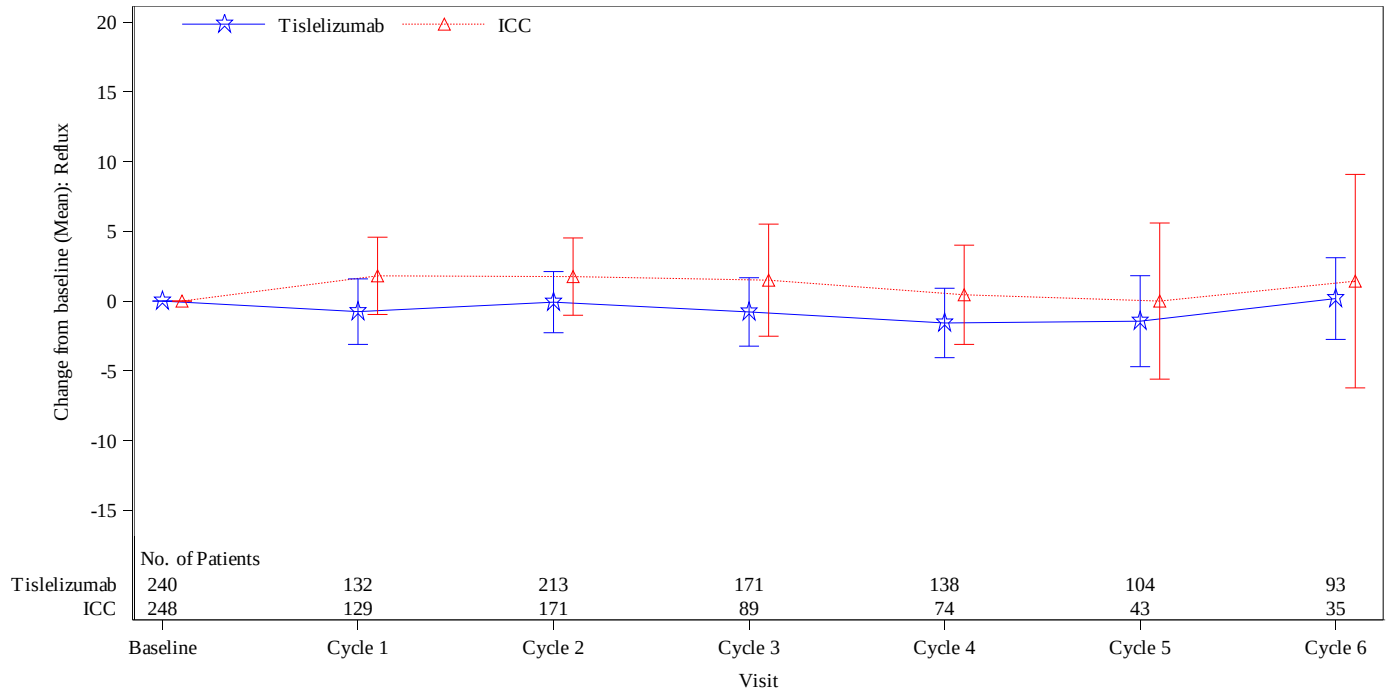

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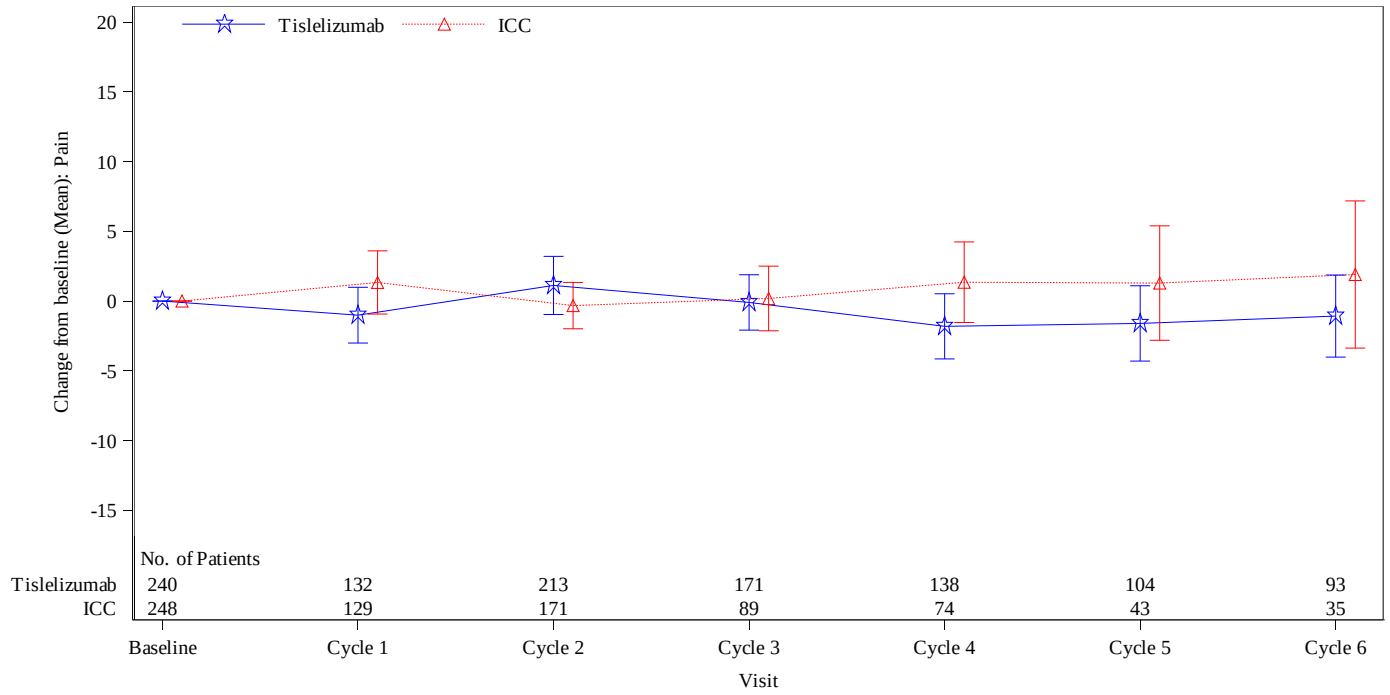

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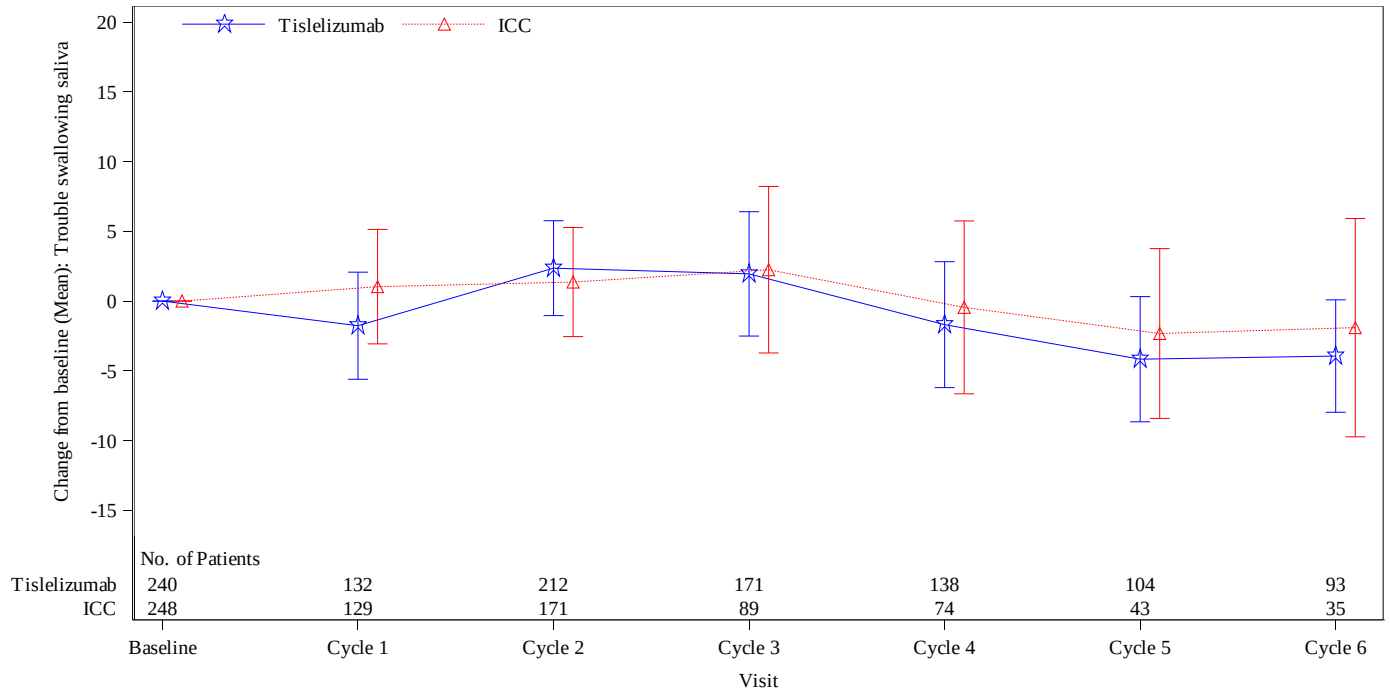

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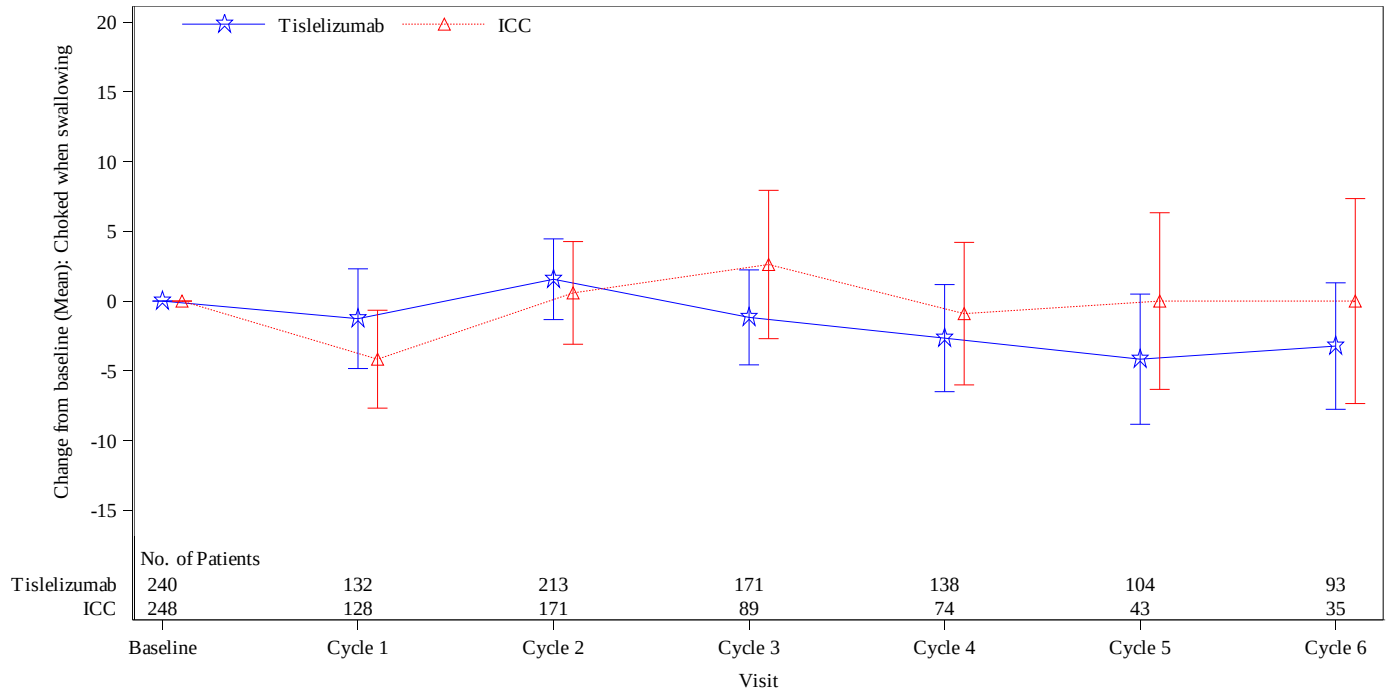

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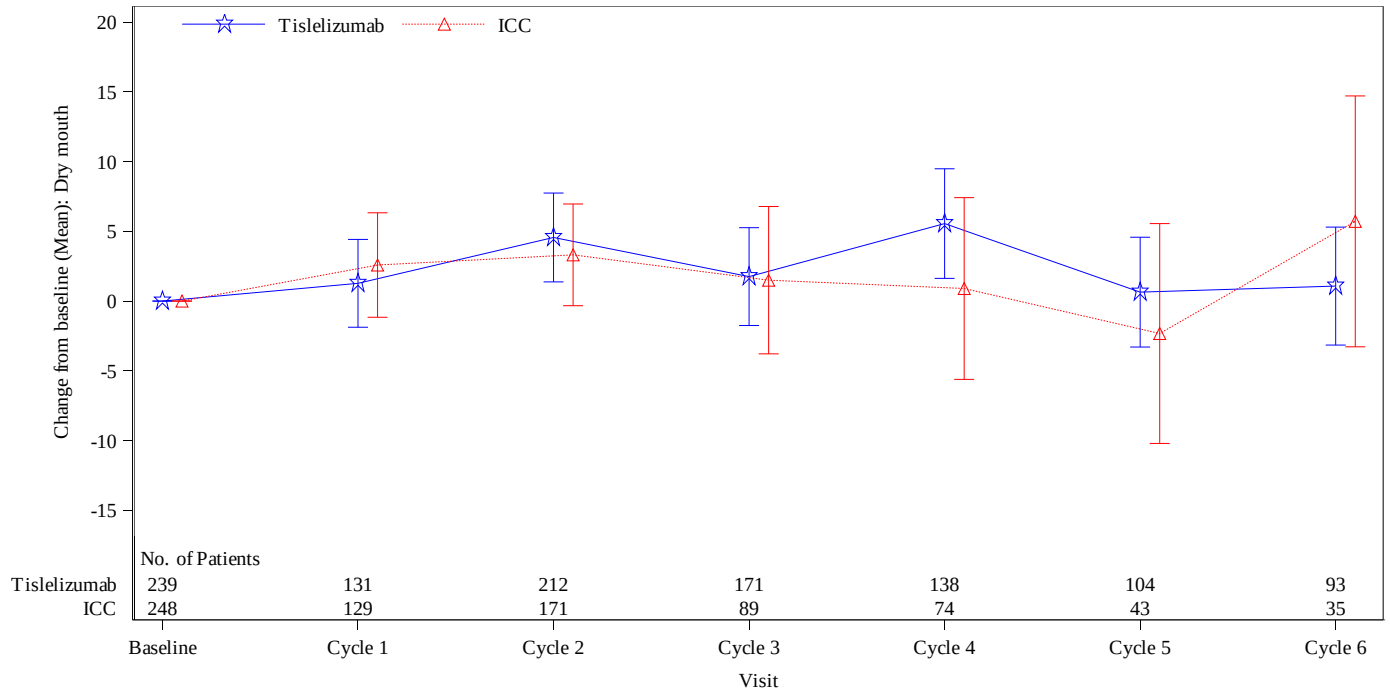

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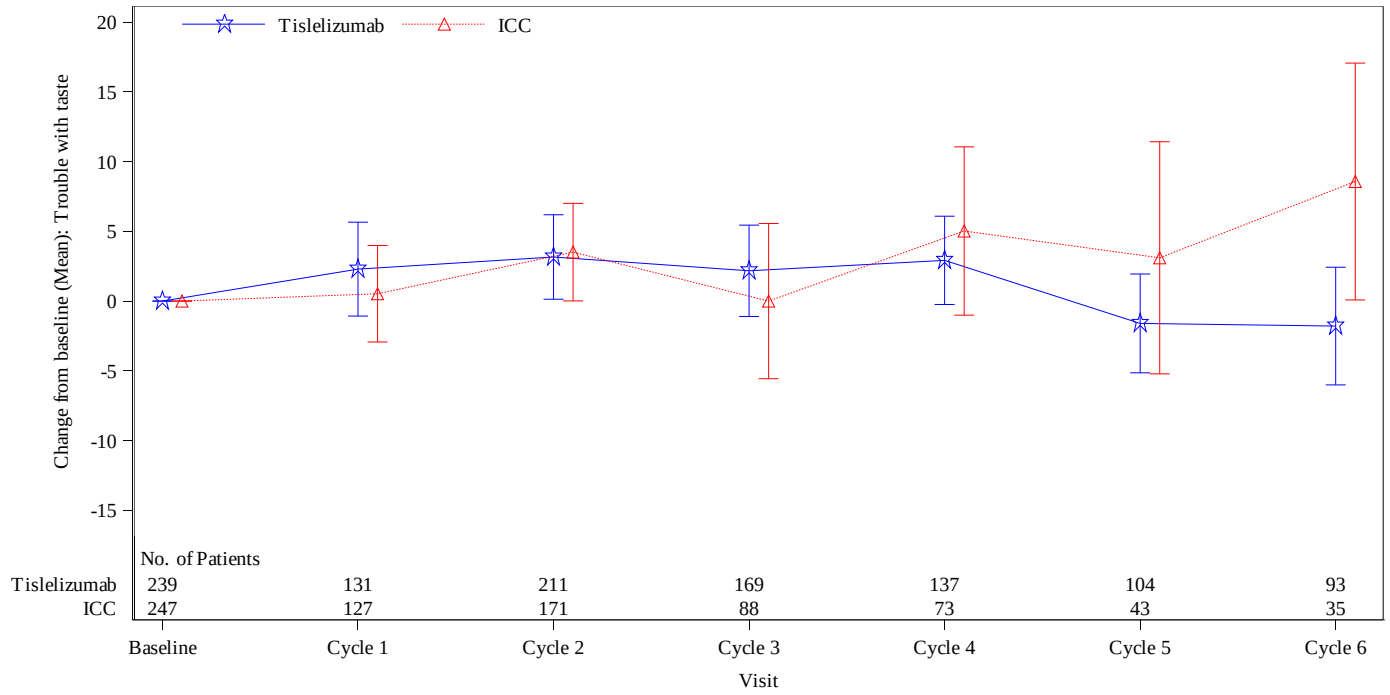

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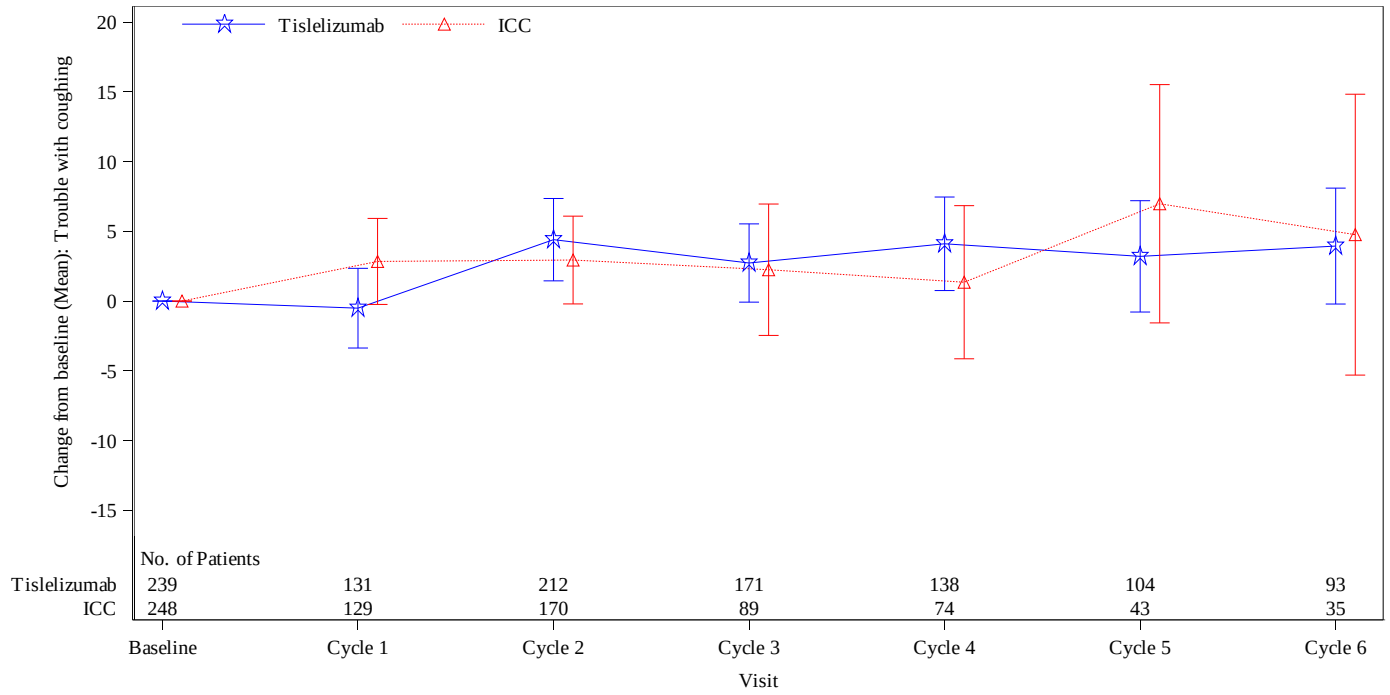

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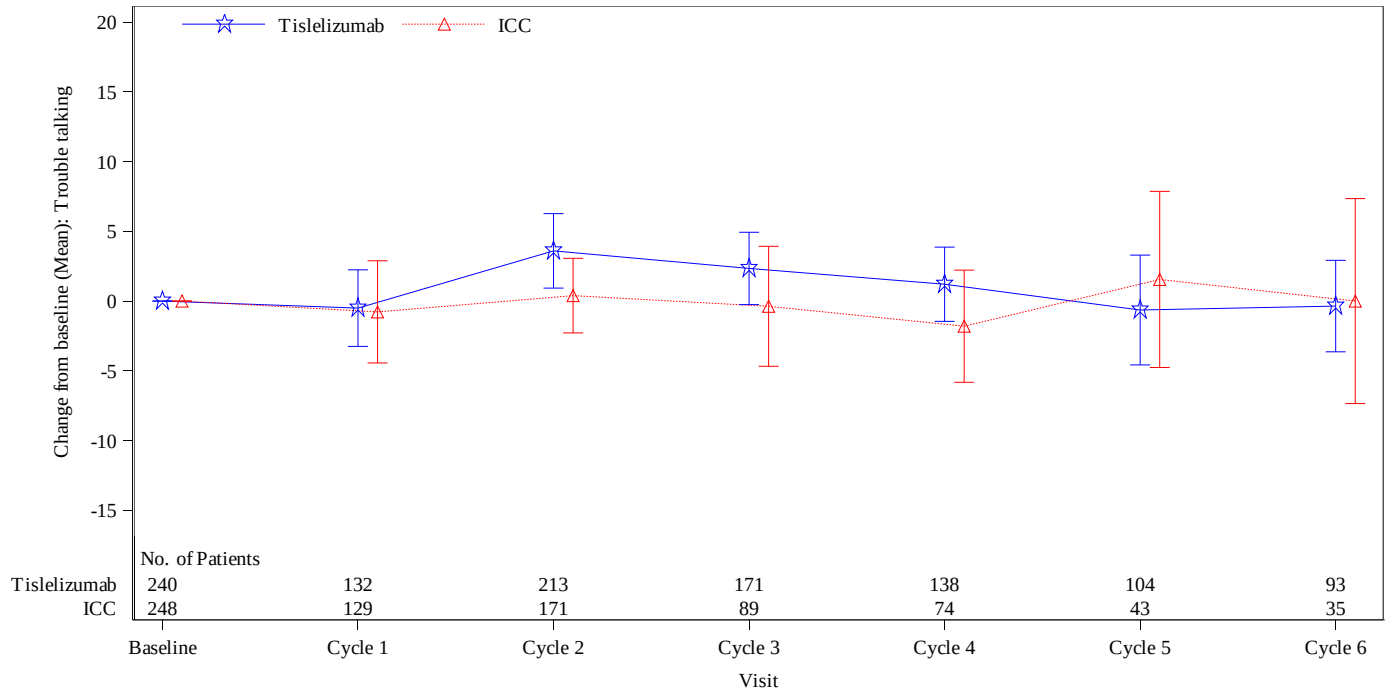

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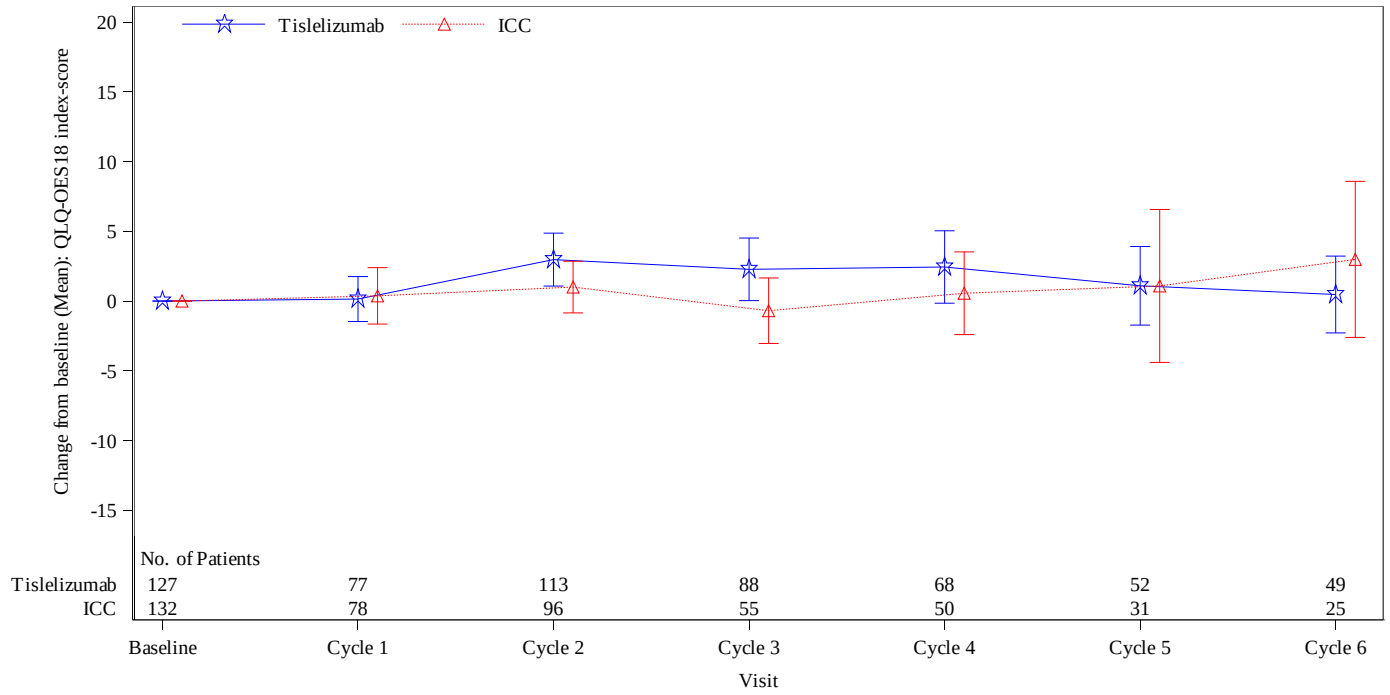
Figure 14.2.7.2.b:
Summary of EORTC QLQ-OES18 Scores by Visit
ITT Analysis Set - Subpopulation without Irinotecan



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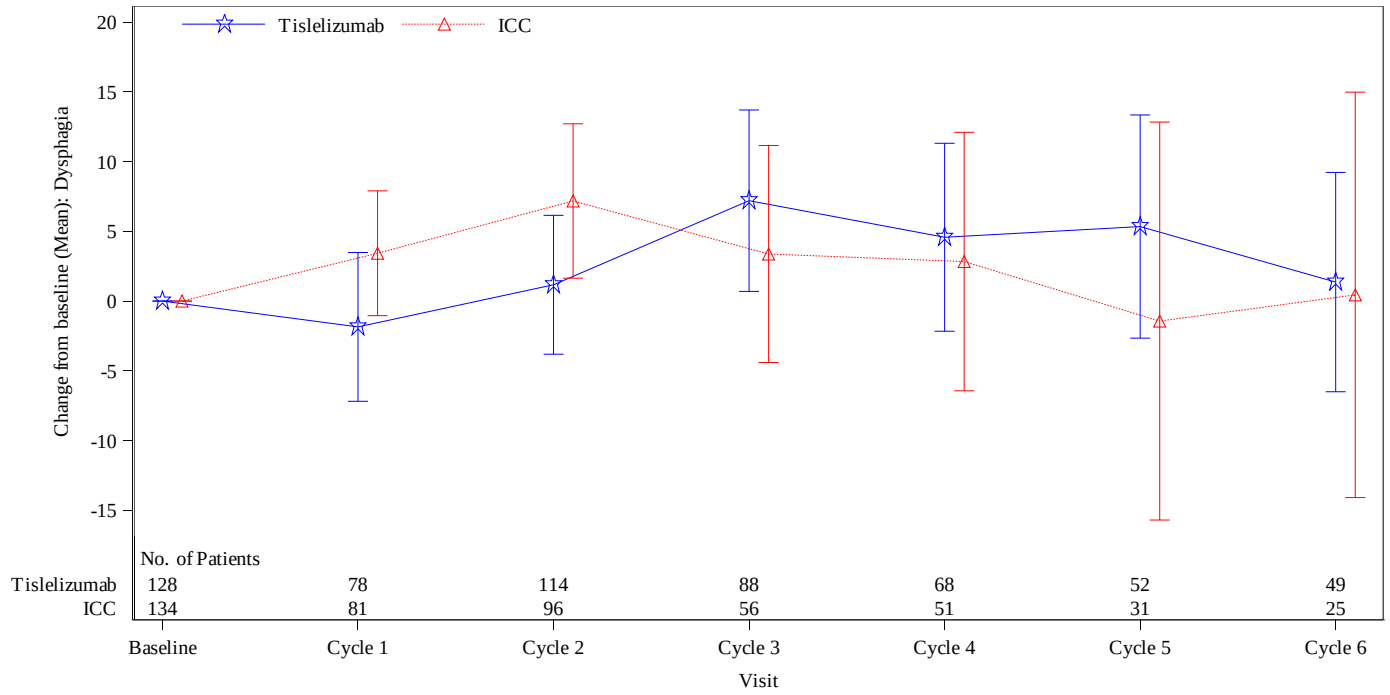

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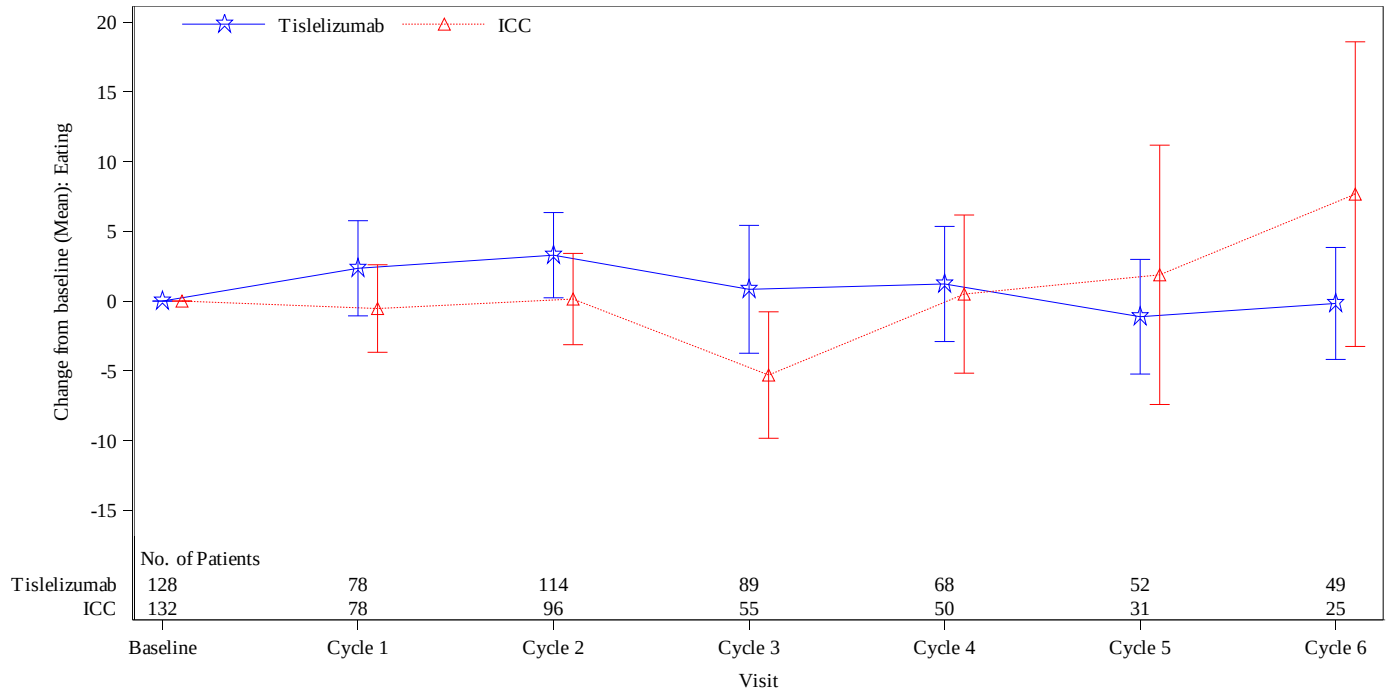

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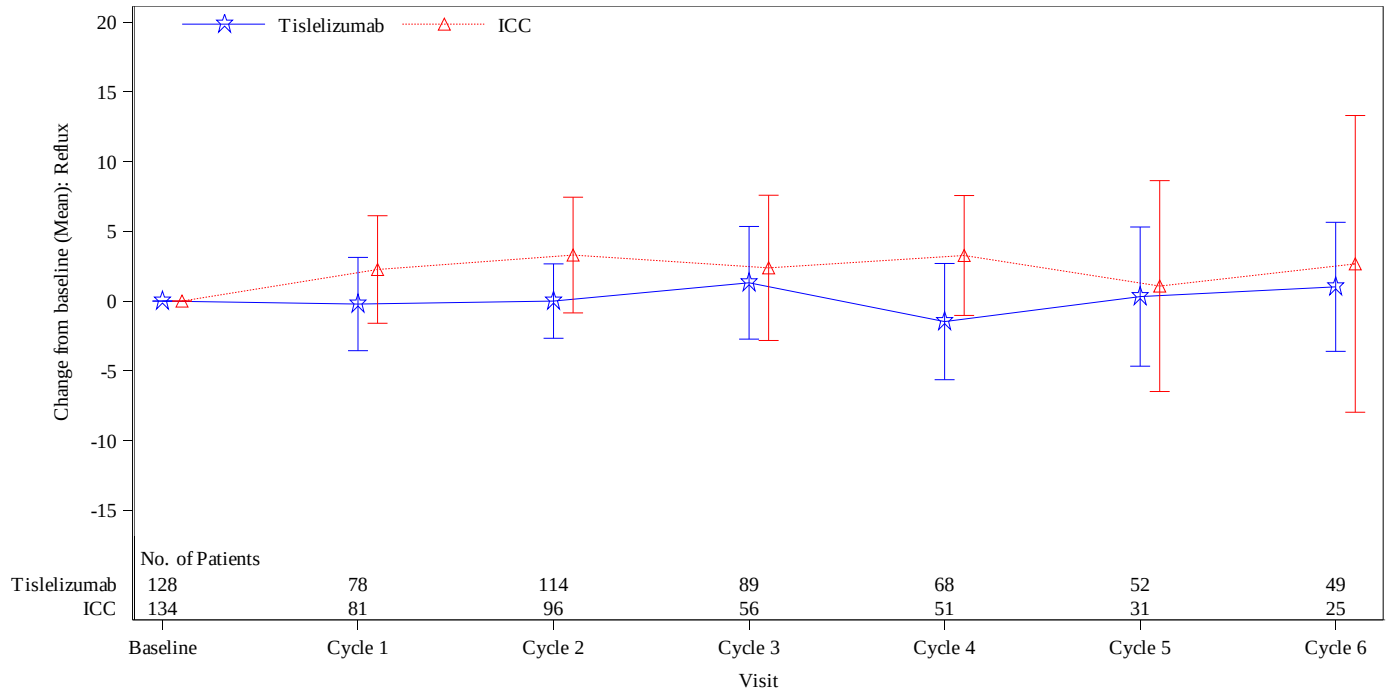

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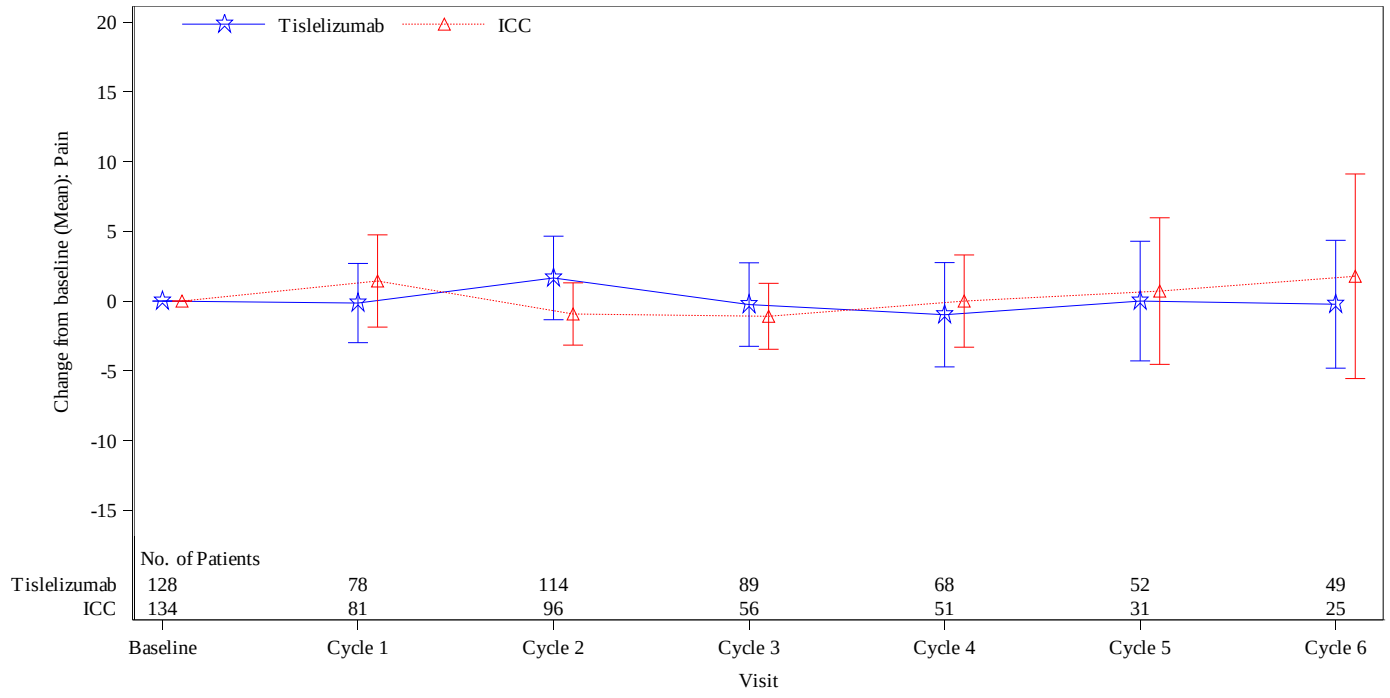

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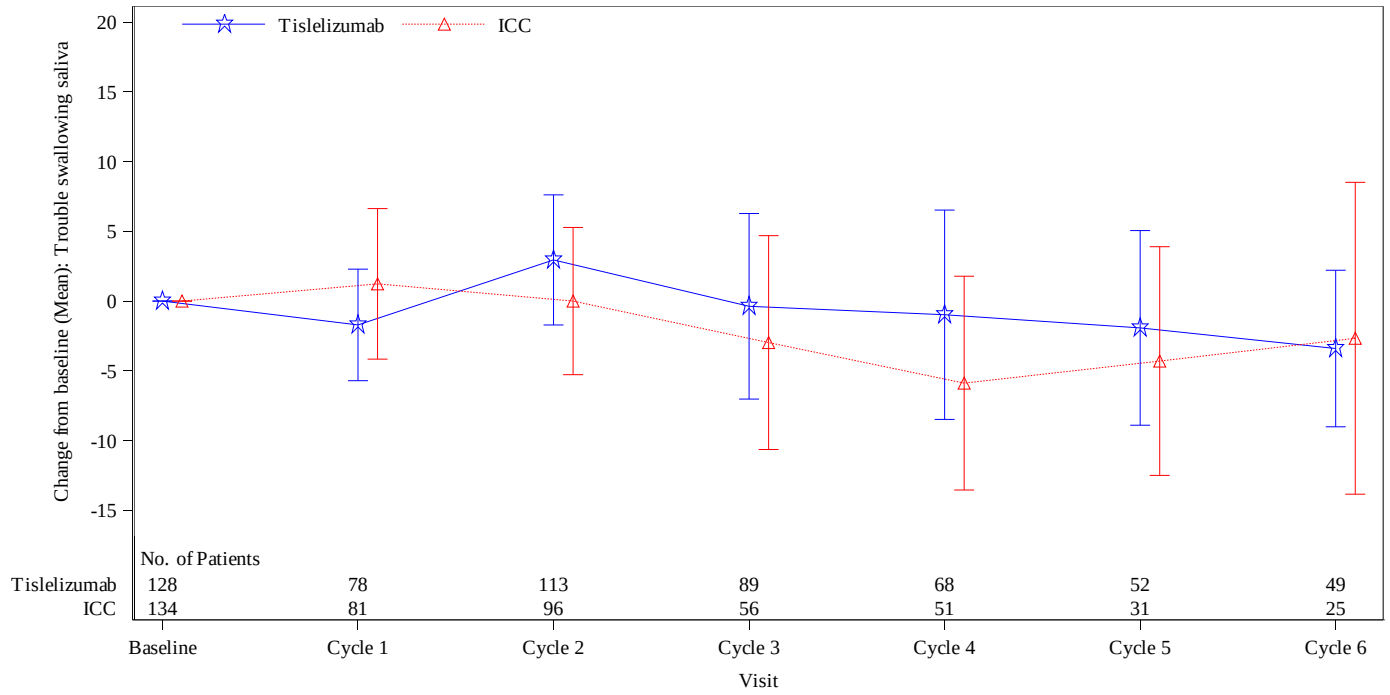

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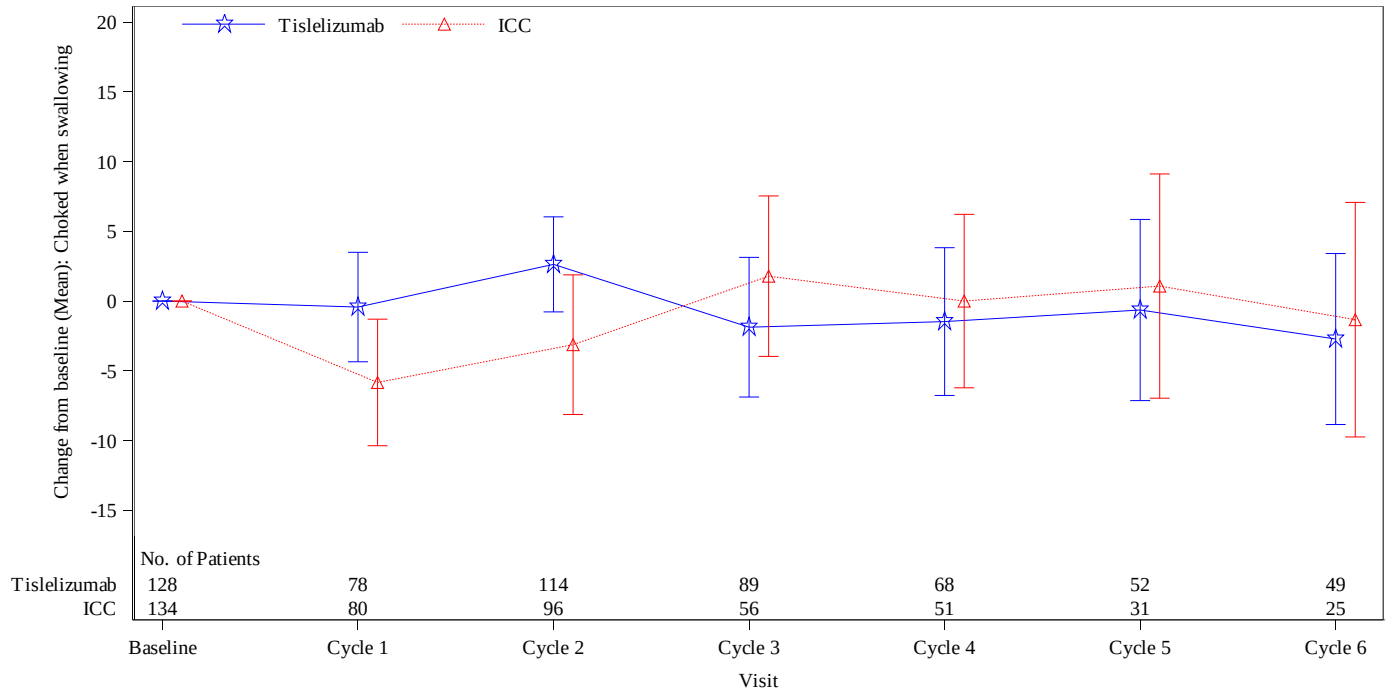

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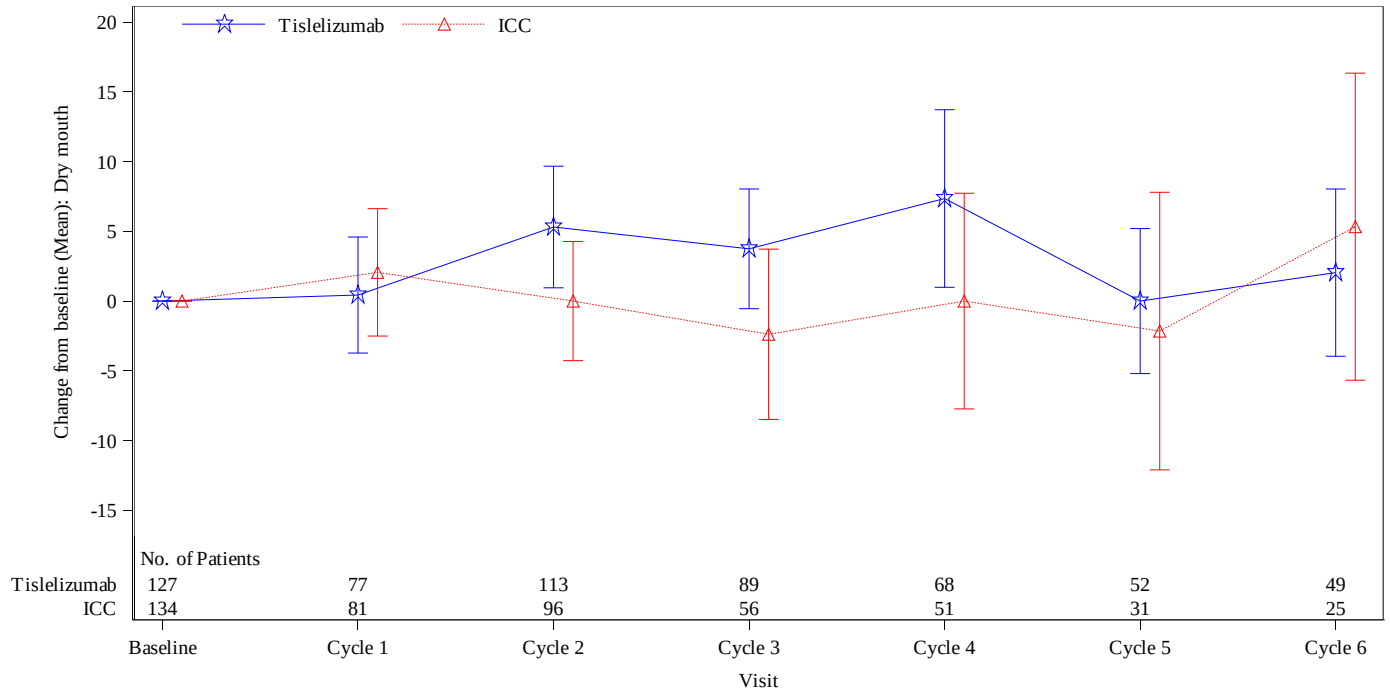

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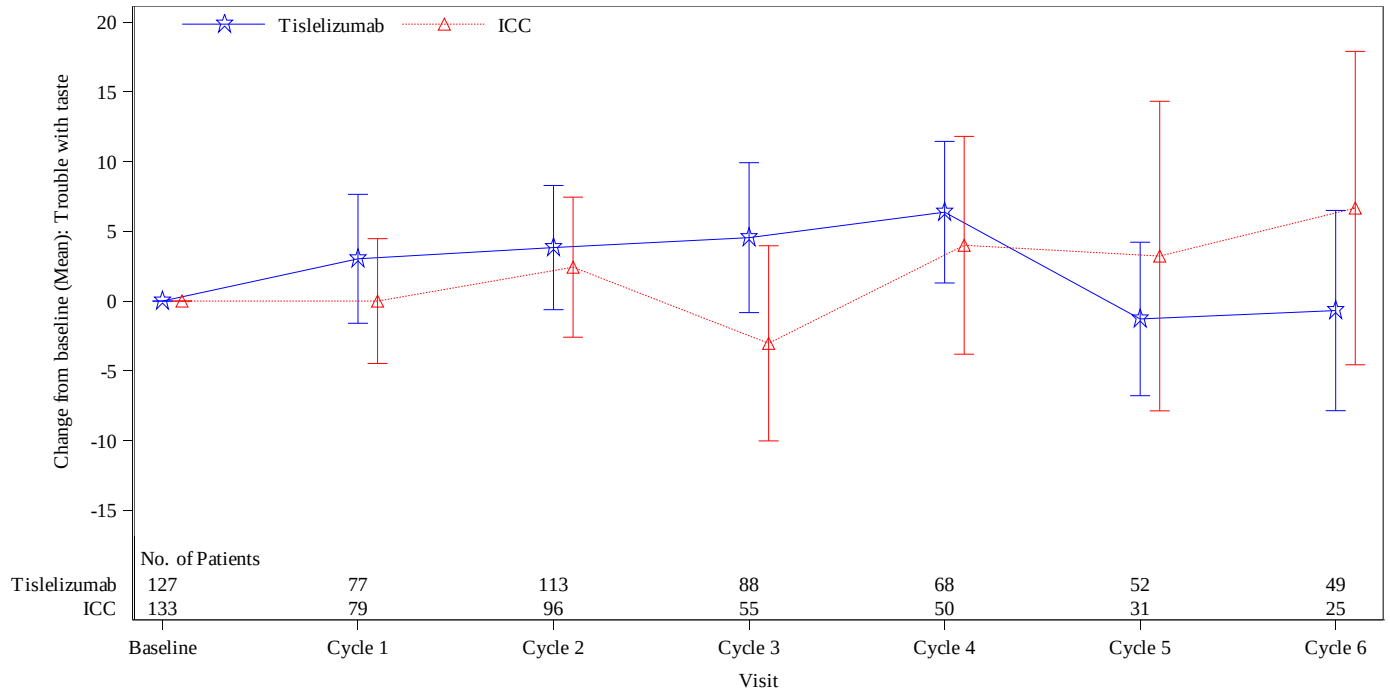

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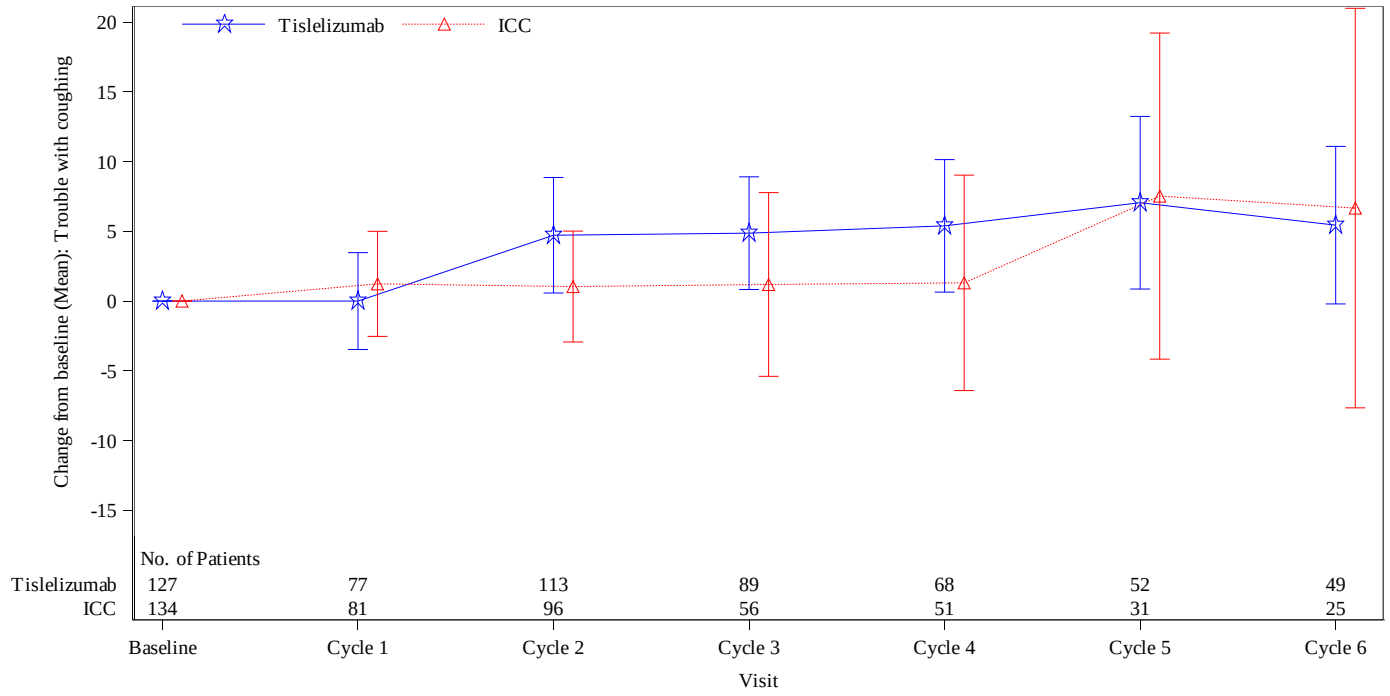

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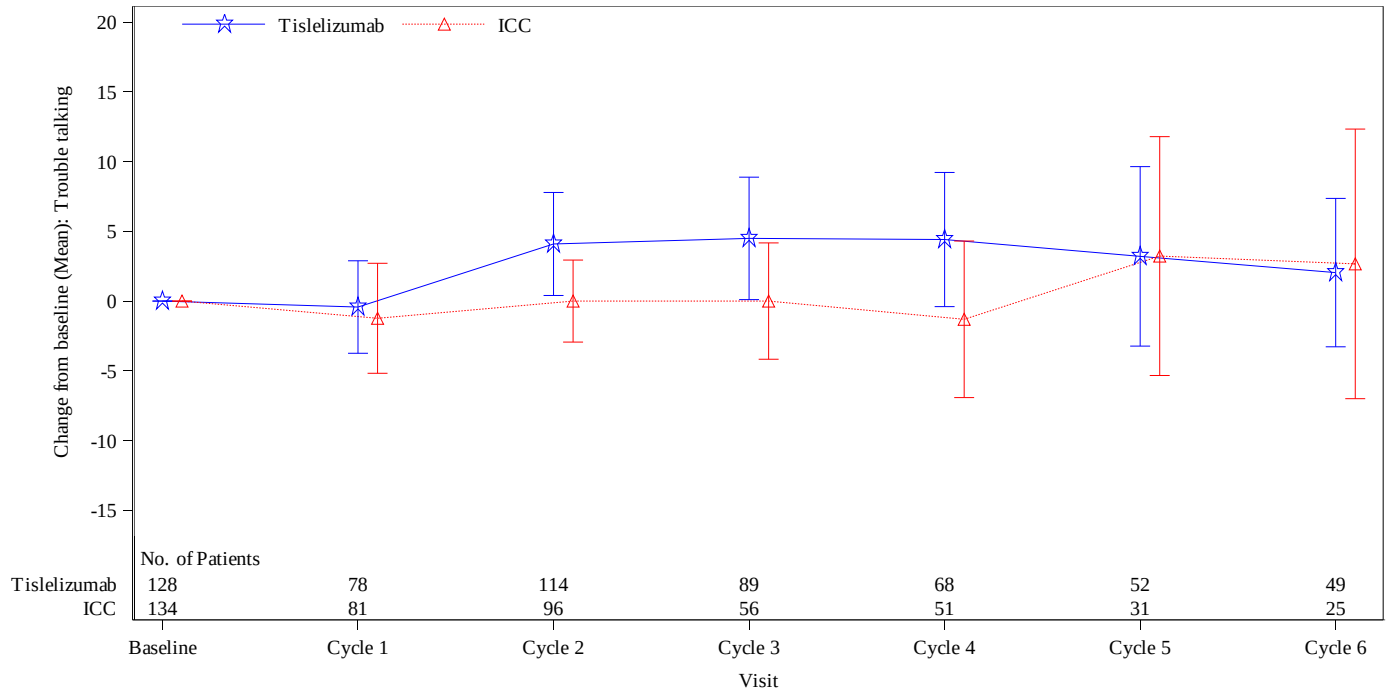

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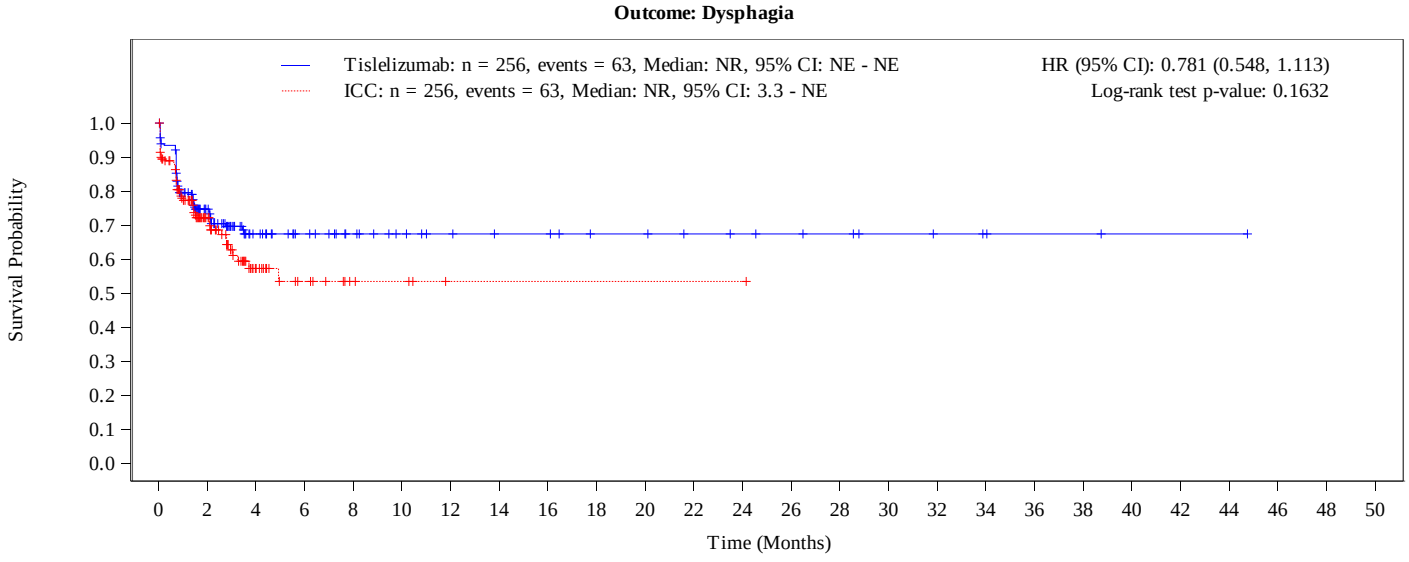
Figure 14.2.7.2.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set

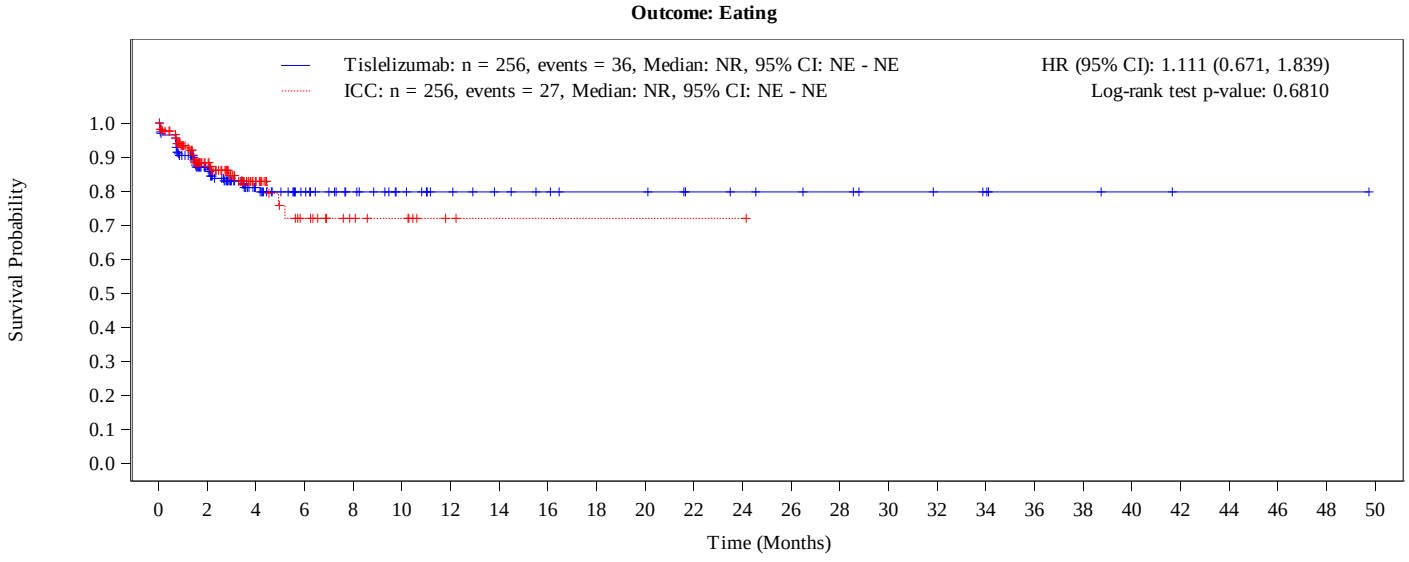


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	256	108	45	33	25	20	17	15	15	12	12	10	9	8	7	5	4	3	2	2	1	1	1	0	0	0
ICC	256	64	22	11	5	4	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-02-02-km-qs-o18-itt-cl.rtf

Figure 14.2.7.2.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set

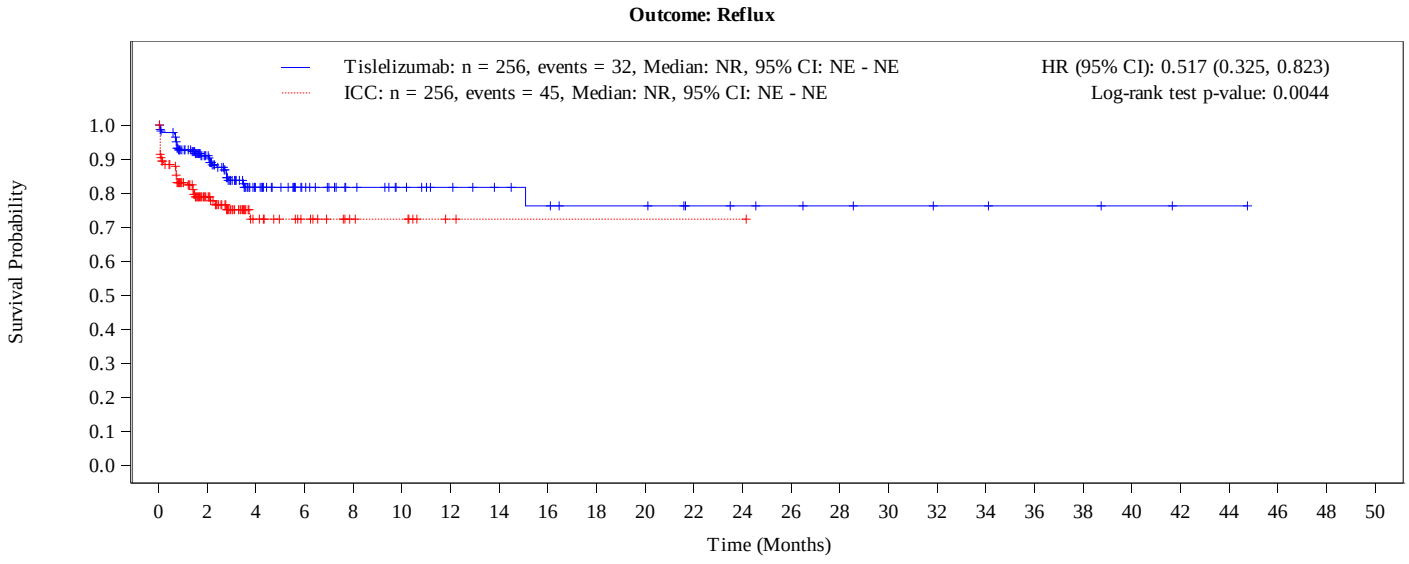


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	256	133	63	45	35	28	23	19	17	15	15	12	11	10	9	7	6	5	3	3	2	1	1	1	1	0
ICC	256	84	32	16	9	7	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-02-02-km-qs-o18-itt-cl.rtf

Figure 14.2.7.2.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set

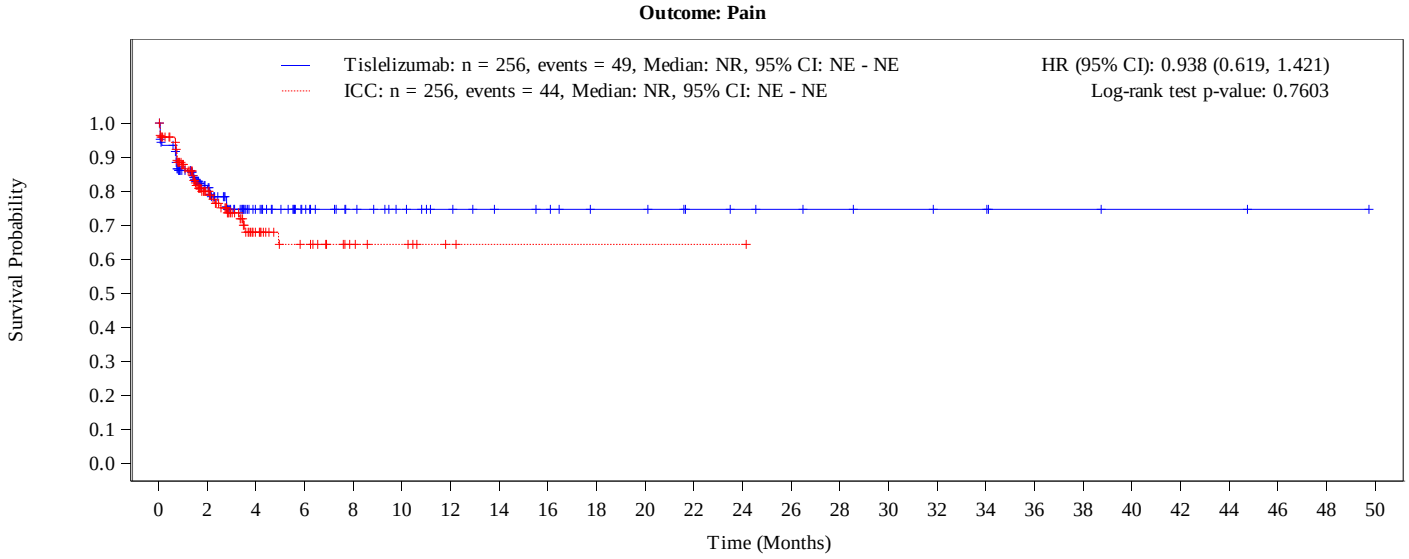


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	256	138	58	40	29	24	20	16	14	12	12	9	8	7	6	5	4	4	3	3	2	1	1	0	0	0
ICC	256	75	24	16	8	7	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-02-02-km-qs-o18-itt-cl.rtf

Figure 14.2.7.2.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set

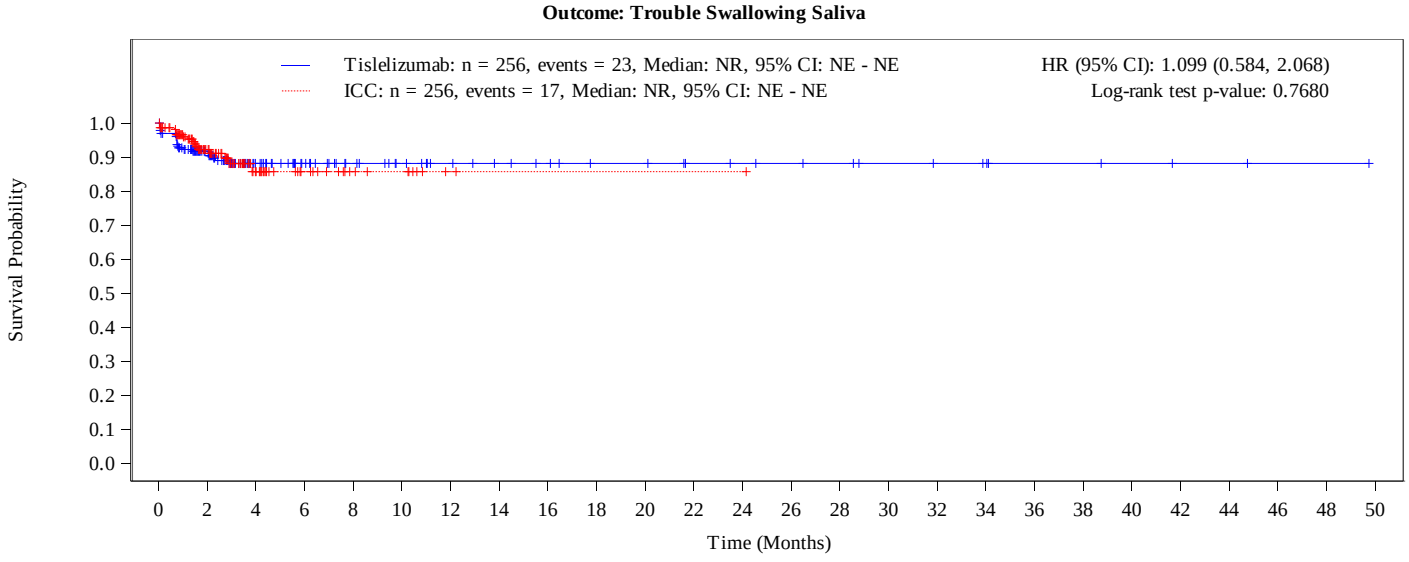


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	256	126	54	38	29	24	20	17	16	13	13	10	9	8	7	6	5	5	3	3	2	2	2	1	1	0
ICC	256	76	26	16	8	6	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-02-02-km-qs-o18-itt-cl.rtf

Figure 14.2.7.2.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set

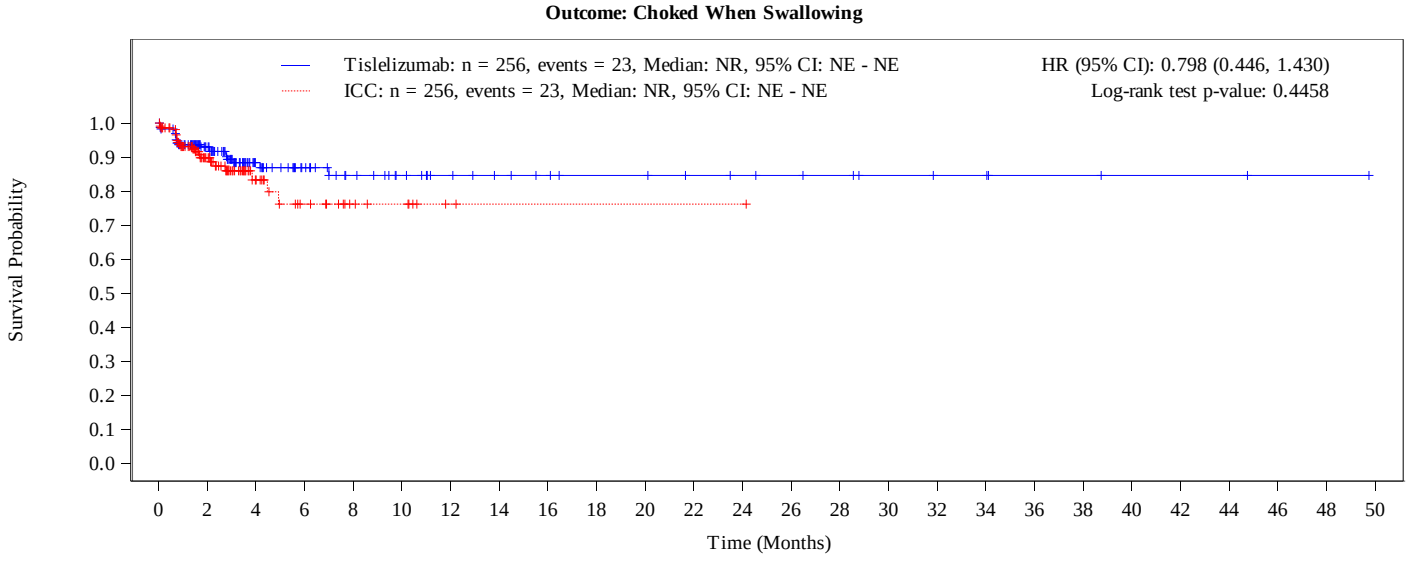


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	256	140	65	47	36	30	25	21	19	16	16	13	12	11	10	8	7	6	4	4	3	2	2	1	1	0
ICC	256	86	33	18	10	8	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-02-02-km-qs-o18-itt-cl.rtf

Figure 14.2.7.2.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set

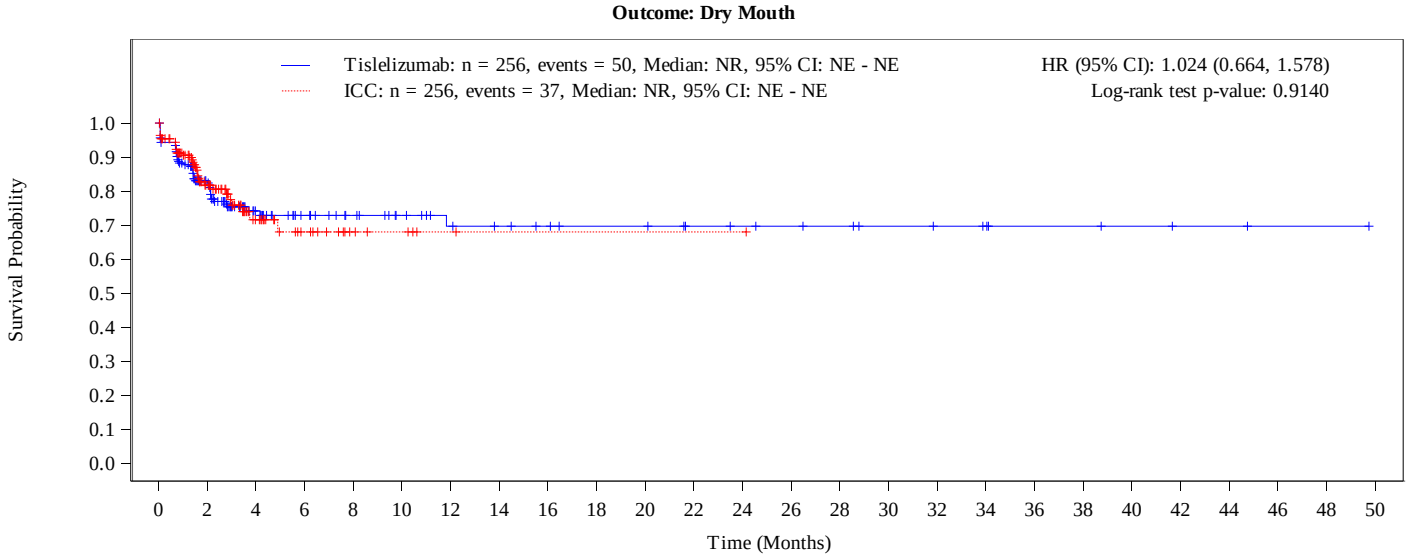


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	256	140	59	43	32	26	21	17	15	13	13	11	10	9	8	6	5	5	3	3	2	2	2	1	1	0
ICC	256	82	29	17	9	7	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-02-02-km-qs-o18-itt-cl.rtf

Figure 14.2.7.2.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set

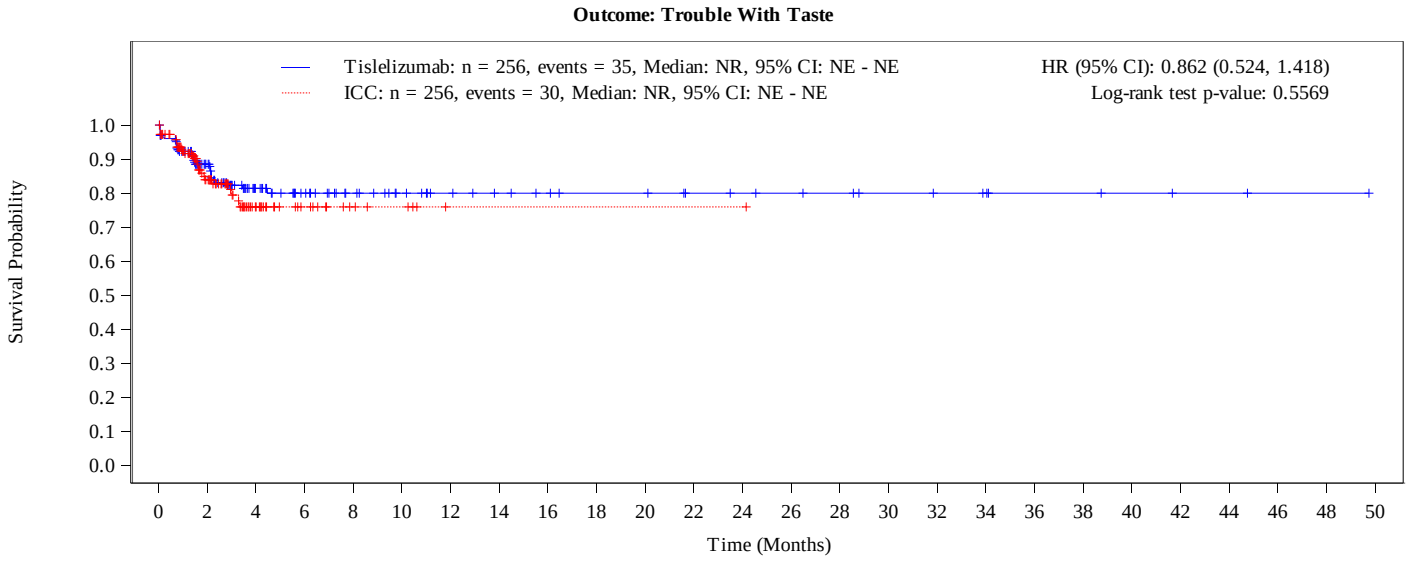


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	256	126	56	41	33	27	22	20	18	16	16	13	12	11	10	8	7	6	4	4	3	2	2	1	1	0
ICC	256	75	28	15	7	5	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-02-02-km-qs-o18-itt-cl.rtf

Figure 14.2.7.2.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set

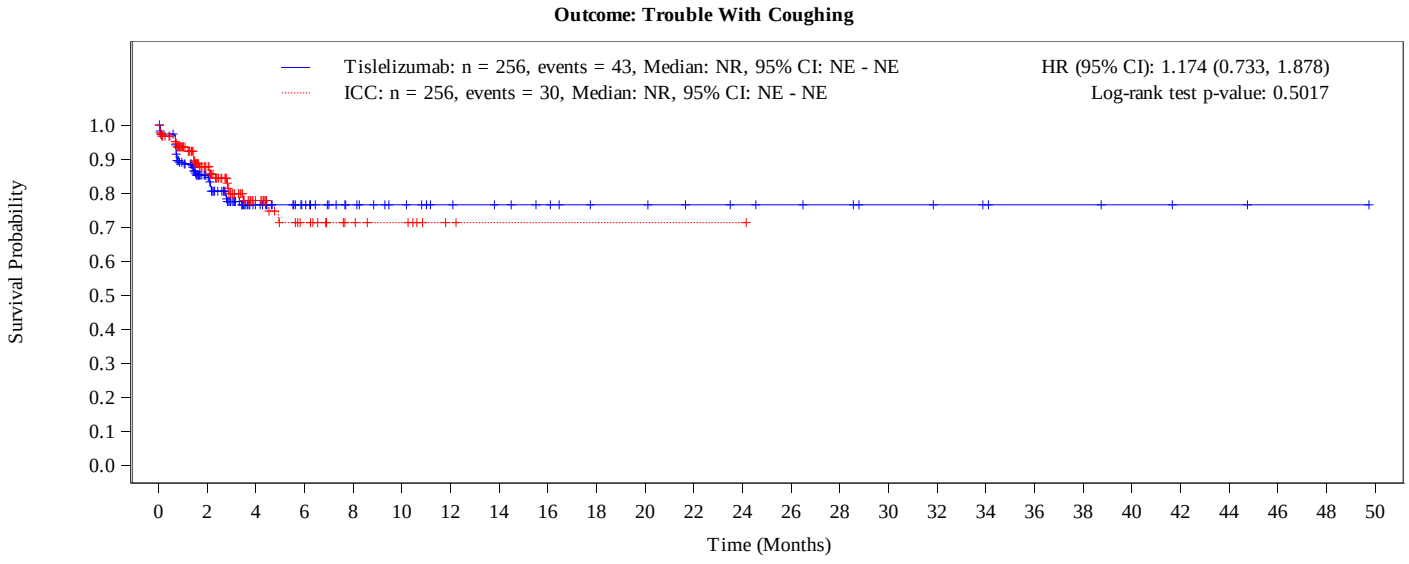


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	256	136	63	46	36	29	24	20	18	16	16	13	12	11	10	8	7	6	4	4	3	2	2	1	1	0
ICC	256	78	28	14	7	5	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-02-02-km-qs-o18-itt-cl.rtf

Figure 14.2.7.2.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set

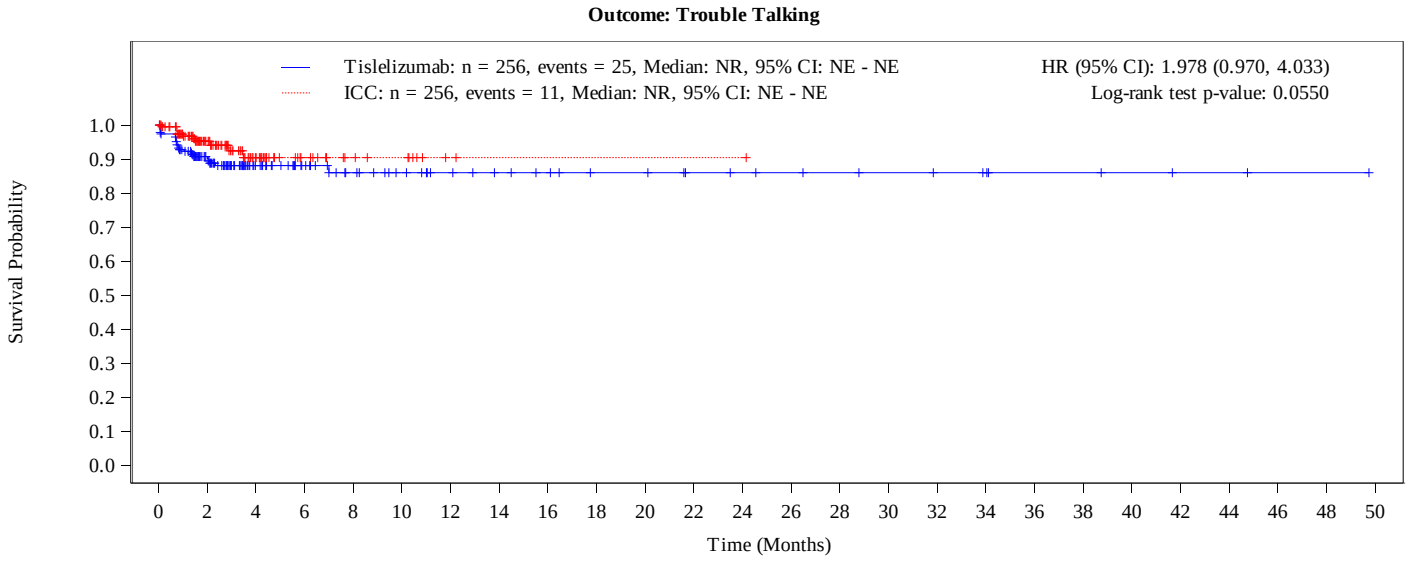


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	256	128	53	40	30	25	21	19	17	14	14	12	11	10	9	7	6	5	4	4	3	2	2	1	1	0
ICC	256	86	31	17	9	7	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-02-02-km-qs-o18-itt-cl.rtf

Figure 14.2.7.2.2:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set

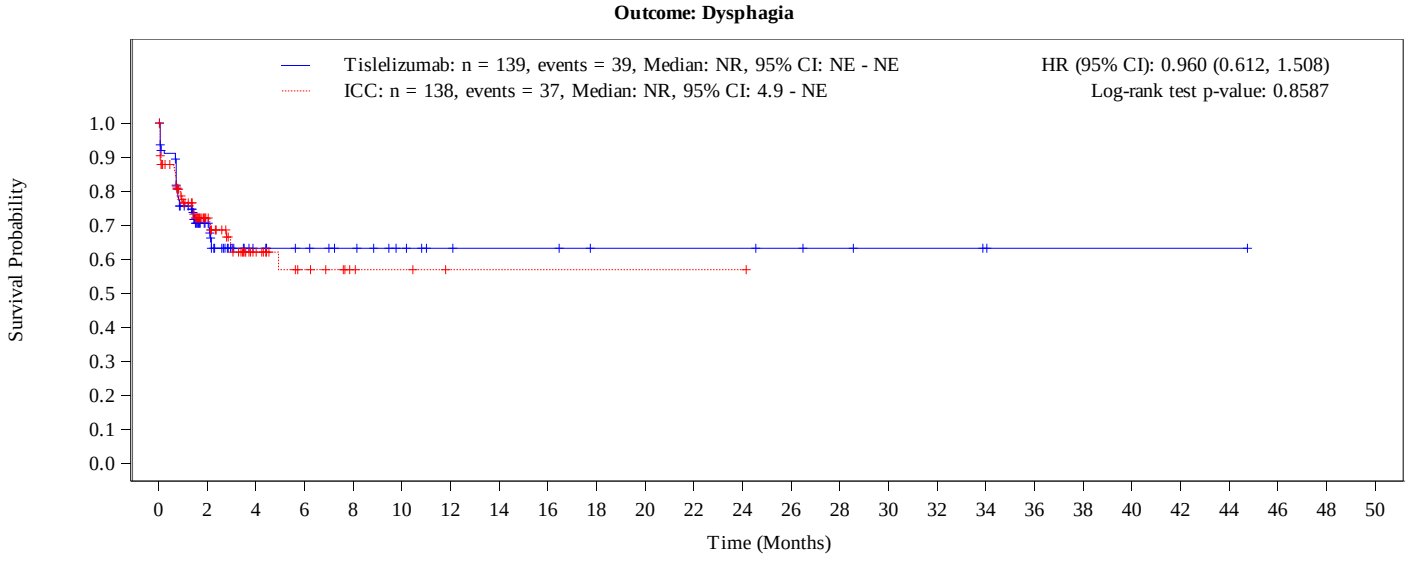


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	256	140	65	47	35	29	24	20	18	15	15	12	11	10	9	8	7	6	4	4	3	2	2	1	1	0
ICC	256	87	35	18	10	8	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-02-02-km-qs-o18-itt-cl.rtf

Figure 14.2.7.2.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation without Irinotecan

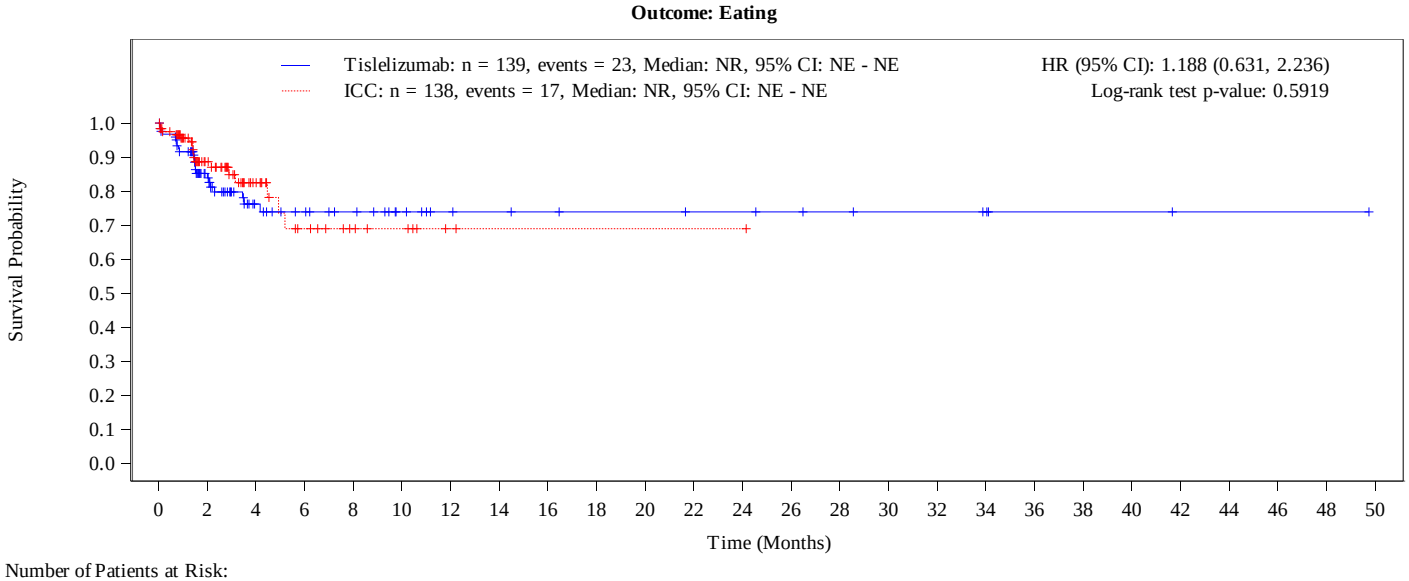


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	50	22	19	16	12	9	8	8	6	6	6	6	5	4	3	3	2	1	1	1	1	1	0	0	0
ICC	138	43	18	9	4	3	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-02-02-b-km-qs-o18-itts-cl.rtf

Figure 14.2.7.2.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation without Irinotecan

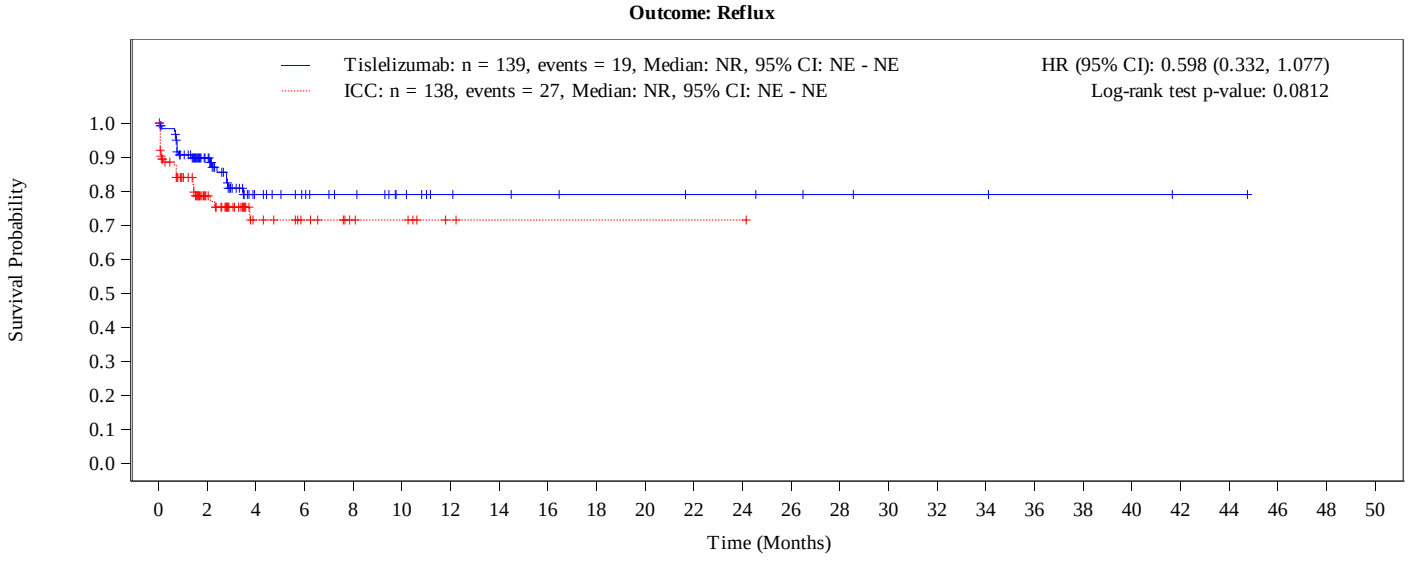


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	65	33	27	23	17	13	11	10	9	9	8	8	7	6	5	5	4	2	2	2	1	1	1	1	0
ICC	138	56	25	13	8	6	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-02-02-b-km-qs-o18-itts-cl.rtf

Figure 14.2.7.2.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation without Irinotecan

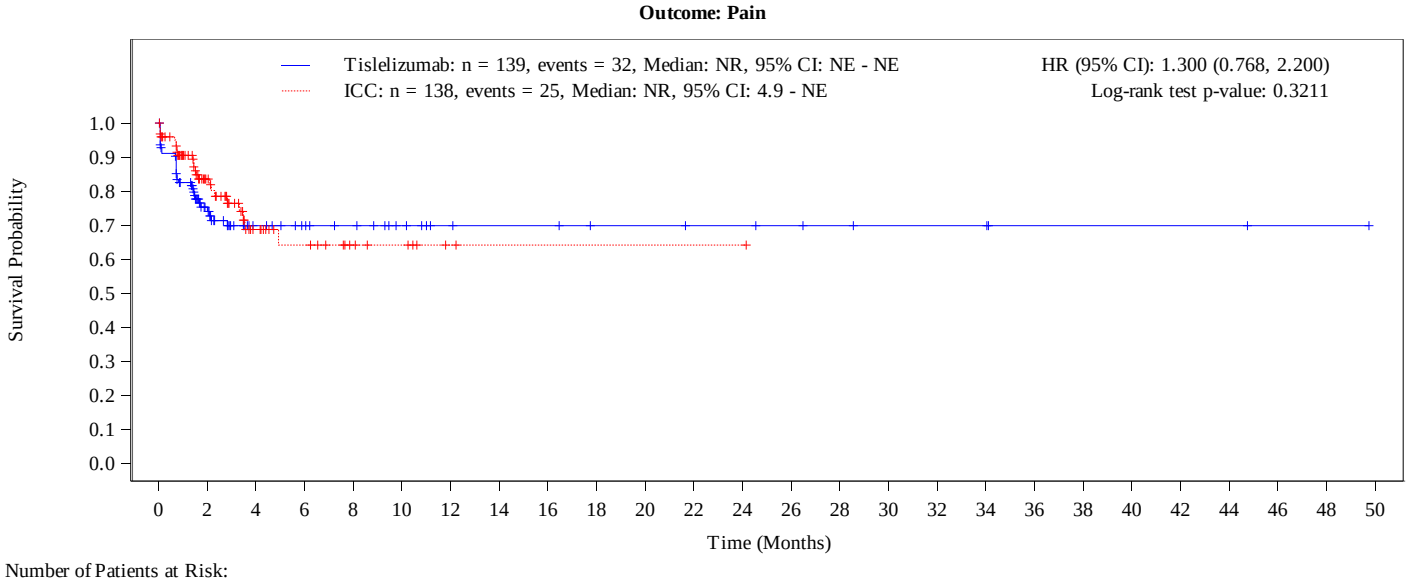


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	69	30	24	20	15	11	9	8	7	7	6	6	5	4	3	3	3	2	2	2	1	1	0	0	0
ICC	138	50	17	12	7	6	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-02-02-b-km-qs-o18-itts-cl.rtf

Figure 14.2.7.2.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation without Irinotecan

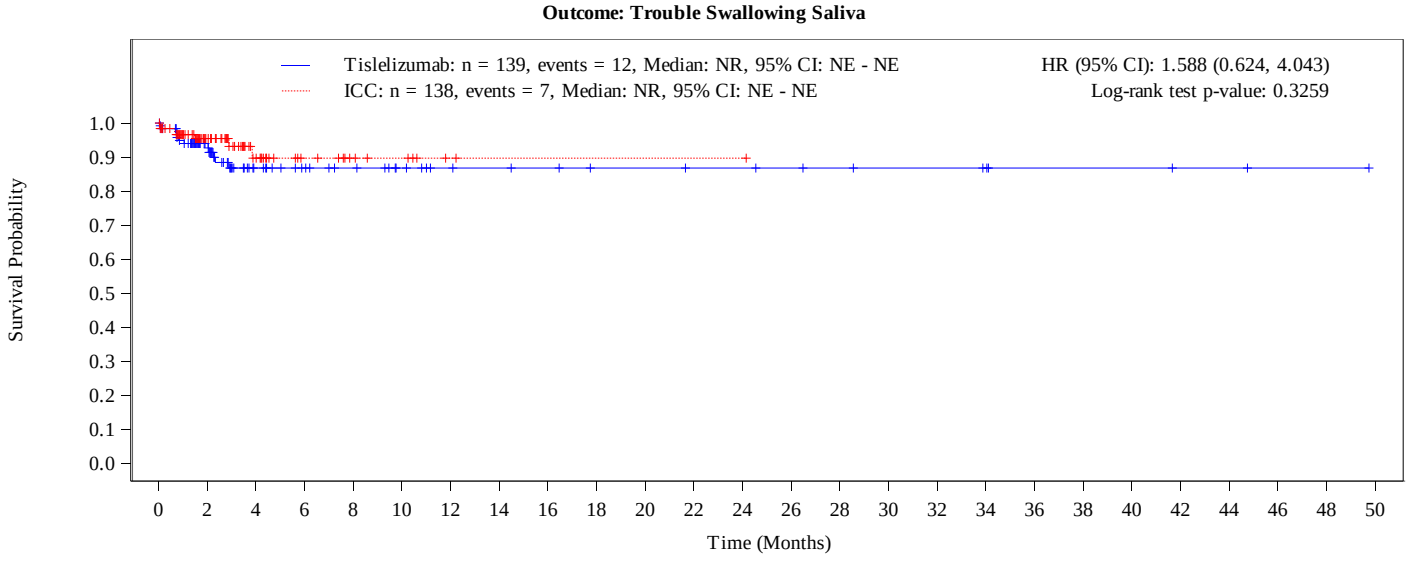


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	59	28	23	20	15	11	10	10	8	8	7	7	6	5	4	4	4	2	2	2	2	2	1	1	0
ICC	138	52	21	14	8	6	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-02-02-b-km-qs-o18-itts-cl.rtf

Figure 14.2.7.2.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation without Irinotecan

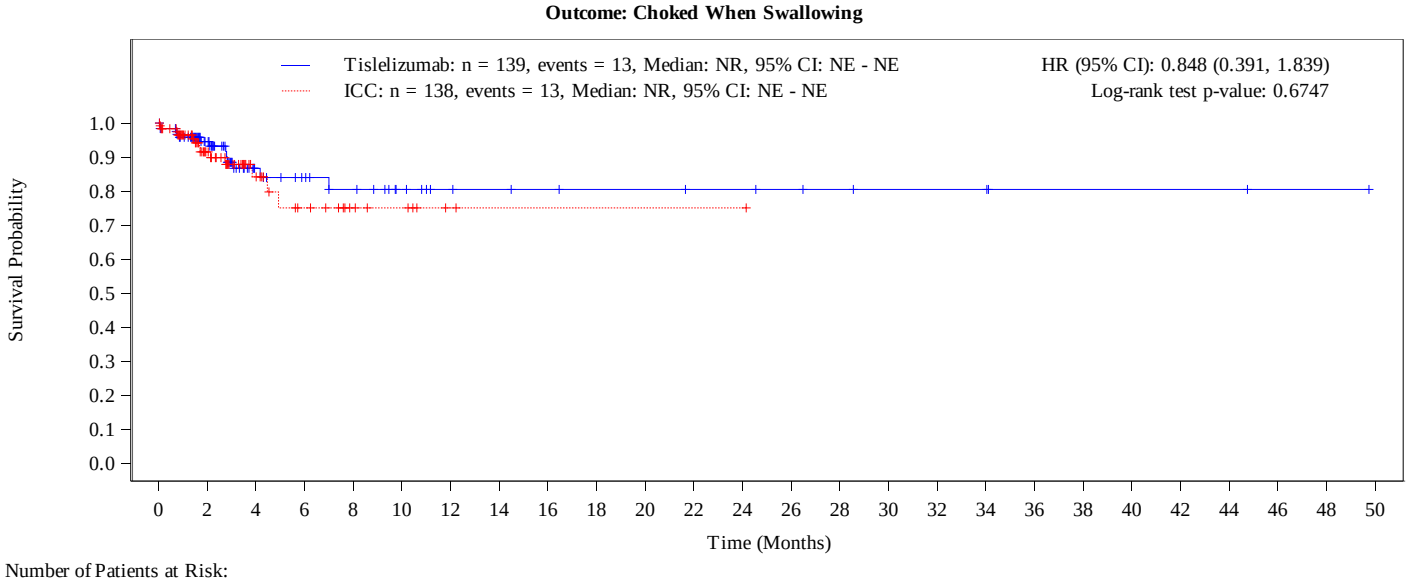


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	72	35	28	24	19	15	13	12	10	10	9	9	8	7	6	6	5	3	3	3	2	2	1	1	0
ICC	138	59	25	13	8	6	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-02-02-b-km-qs-o18-itts-cl.rtf

Figure 14.2.7.2.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	72	32	26	22	16	12	10	9	8	8	7	7	6	5	4	4	4	2	2	2	2	2	1	1	0
ICC	138	56	23	14	8	6	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
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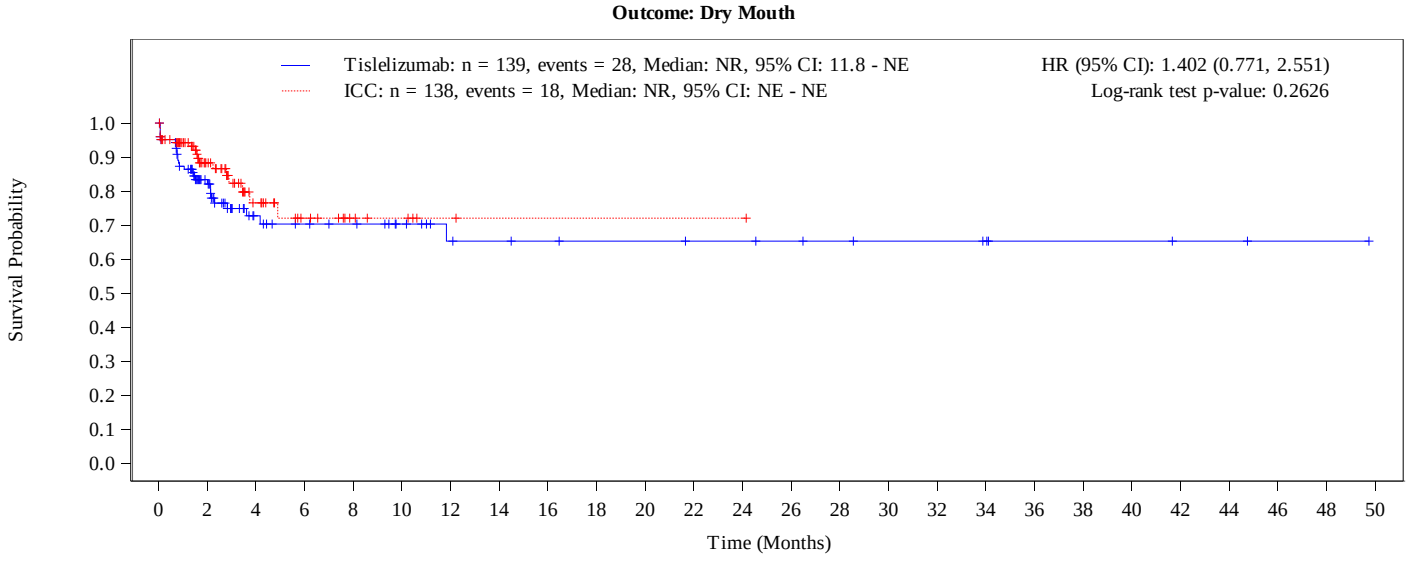
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-02-02-b-km-qs-o18-itts-cl.rtf

Figure 14.2.7.2.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	64	30	25	23	18	13	12	11	10	10	9	9	8	7	6	6	5	3	3	3	2	2	1	1	0
ICC	138	55	23	13	7	5	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
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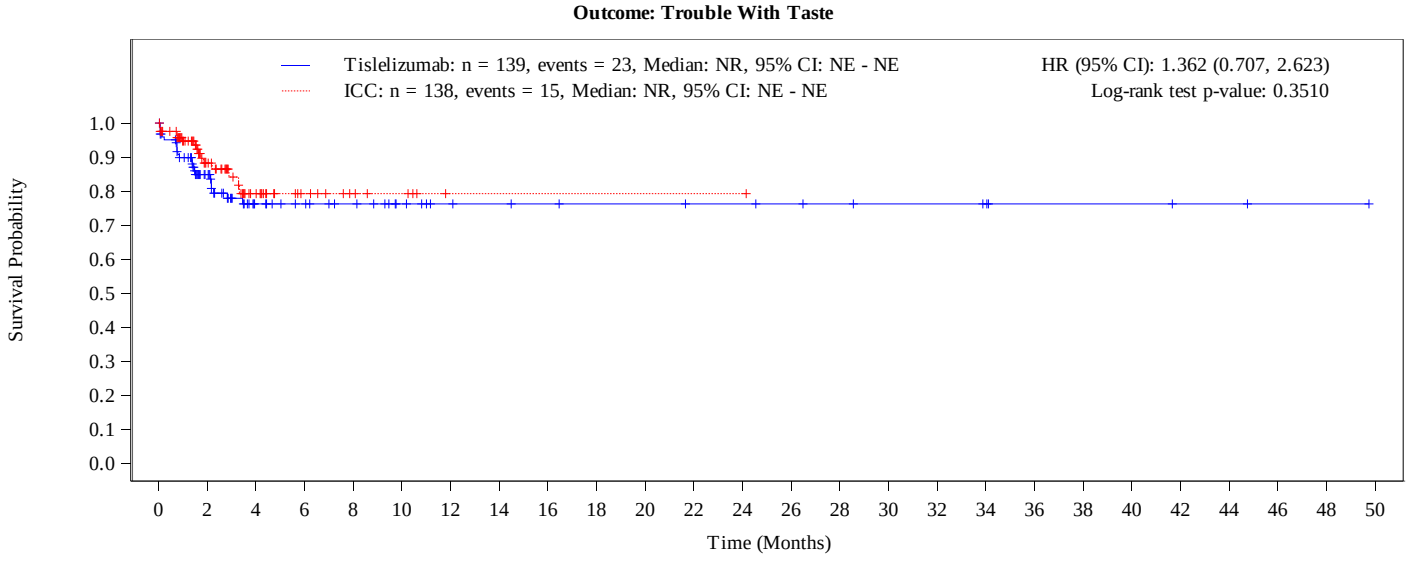
Figure 14.2.7.2.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation without Irinotecan

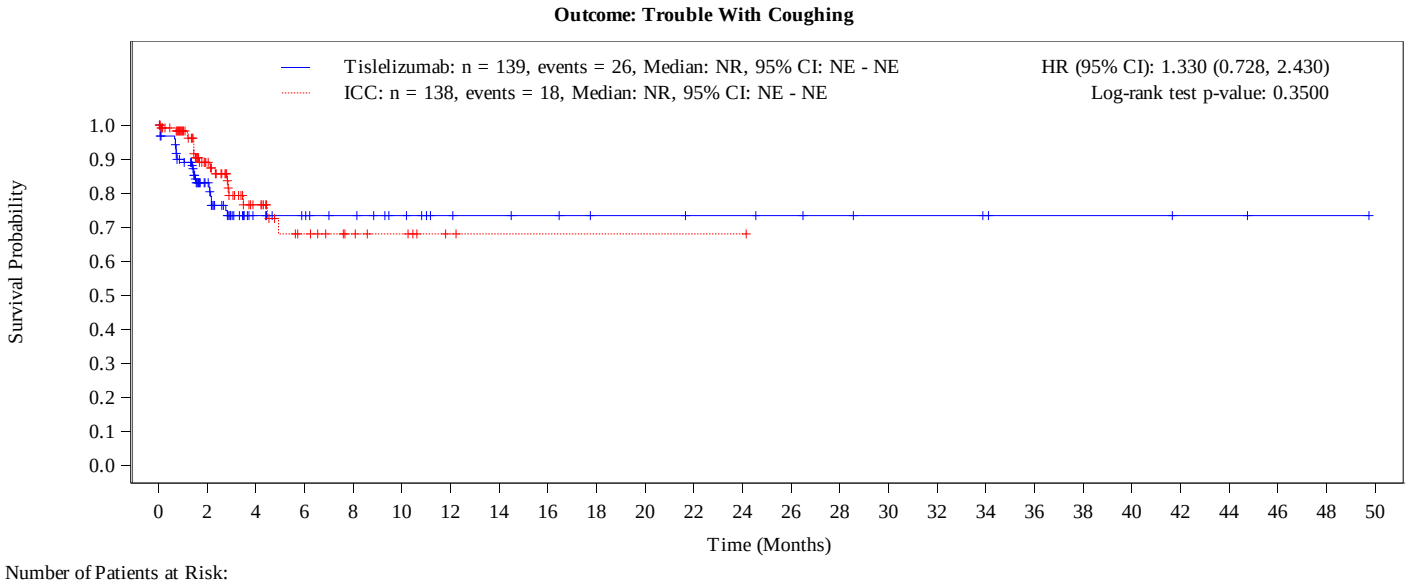


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	66	33	28	24	18	14	12	11	10	10	9	9	8	7	6	6	5	3	3	3	2	2	1	1	0
ICC	138	54	24	12	7	5	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-02-02-b-km-qs-o18-itts-cl.rtf

Figure 14.2.7.2.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation without Irinotecan

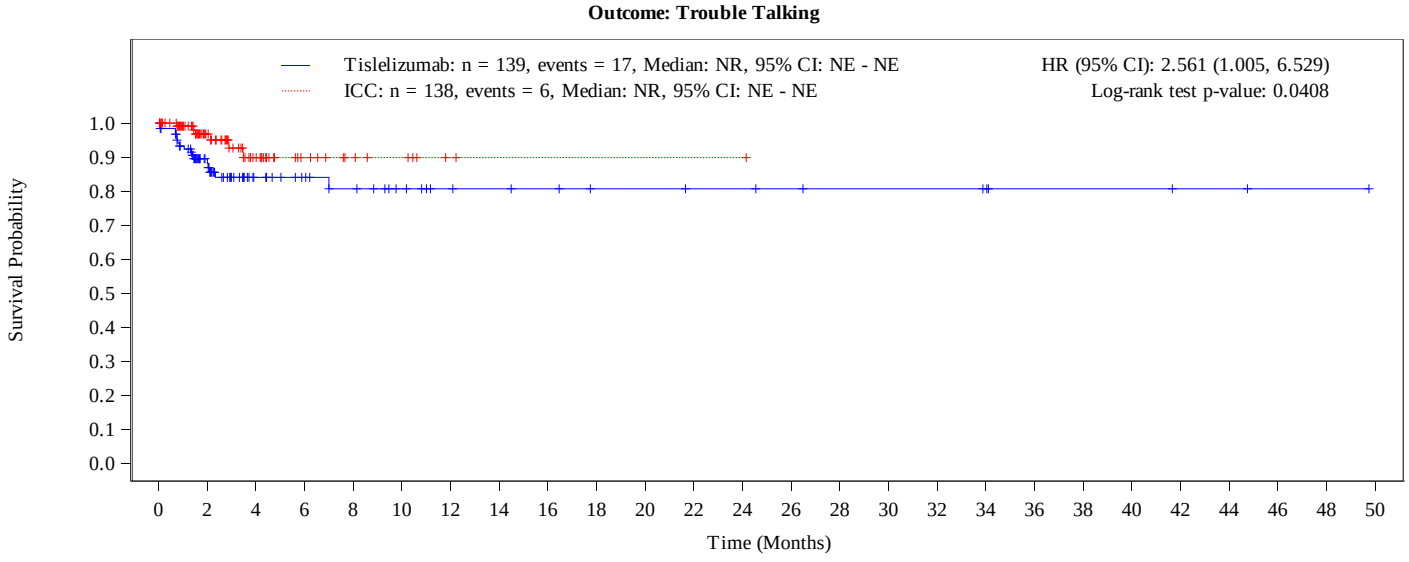


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	64	28	24	21	17	13	12	11	9	9	8	8	7	6	5	5	4	3	3	3	2	2	1	1	0
ICC	138	57	24	13	8	6	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-02-02-b-km-qs-o18-itts-cl.rtf

Figure 14.2.7.2.2.b:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18
ITT Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	68	33	27	23	18	14	12	11	9	9	8	8	7	6	6	6	5	3	3	3	2	2	1	1	0
ICC	138	58	26	13	8	6	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Dysphagia

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	38 (25.0)	NR (NE, NE)	158	35 (22.2)	NR (3.1, NE)	0.856 (0.540, 1.357)	0.5011
>= 65 Years	104	25 (24.0)	NR (NE, NE)	98	28 (28.6)	NR (2.1, NE)	0.702 (0.408, 1.205)	0.1911
Interaction								0.5848
Gender								
Male	217	57 (26.3)	NR (NE, NE)	215	54 (25.1)	NR (3.1, NE)	0.823 (0.566, 1.195)	0.2966
Female	39	6 (15.4)	NR (NE, NE)	41	9 (22.0)	NR (1.4, NE)	0.597 (0.212, 1.677)	0.3197
Interaction								0.4238

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 05JUN2024 19:38 t-14-02-06-03-01-02-s-eff-tteqs-subgrp-o18-itt-cl.rtf

Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Dysphagia

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	47 (25.0)	NR (NE, NE)	192	50 (26.0)	NR (3.1, NE)	0.755 (0.506, 1.127)	0.1608
Non-Smoker	68	16 (23.5)	NR (NE, NE)	63	13 (20.6)	NR (2.6, NE)	0.889 (0.426, 1.853)	0.7497
Interaction								0.7815
ICC Options								
Paclitaxel	83	25 (30.1)	NR (2.1, NE)	85	23 (27.1)	NR (3.1, NE)	1.045 (0.593, 1.843)	0.8757
Docetaxel	56	14 (25.0)	NR (2.2, NE)	53	14 (26.4)	NR (2.1, NE)	0.863 (0.411, 1.811)	0.6919
Irinotecan	117	24 (20.5)	NR (NE, NE)	118	26 (22.0)	3.7 (2.6, NE)	0.563 (0.320, 0.991)	0.0411
Interaction								0.3459

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 05JUN2024 19:38 t-14-02-06-03-01-02-s-eff-tteqs-subgrp-o18-itt-cl.rtf

Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Dysphagia

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	17 (26.6)	NR (NE, NE)	63	21 (33.3)	4.9 (3.0, NE)	0.635 (0.334, 1.208)	0.1568
1	192	46 (24.0)	NR (NE, NE)	193	42 (21.8)	NR (3.7, NE)	0.857 (0.563, 1.305)	0.4648
Interaction								0.4506
Region #1								
Asia	201	52 (25.9)	NR (NE, NE)	203	49 (24.1)	NR (3.7, NE)	0.824 (0.557, 1.220)	0.3249
Europe/North America	55	11 (20.0)	NR (NE, NE)	53	14 (26.4)	NR (2.8, NE)	0.631 (0.286, 1.392)	0.2461
Interaction								0.5852

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 05JUN2024 19:38 t-14-02-06-03-01-02-s-eff-tteqs-subgrp-o18-itt-cl.rtf

Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Dysphagia

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	45 (25.6)	NR (NE, NE)	178	42 (23.6)	NR (3.1, NE)	0.812 (0.532, 1.239)	0.3261
Japan	25	7 (28.0)	NR (0.8, NE)	25	7 (28.0)	4.9 (4.9, NE)	0.921 (0.319, 2.658)	0.8752
Europe/North America	55	11 (20.0)	NR (NE, NE)	53	14 (26.4)	NR (2.8, NE)	0.631 (0.286, 1.392)	0.2461
Interaction								0.8596
Race								
Asian and other	203	52 (25.6)	NR (NE, NE)	212	51 (24.1)	NR (3.7, NE)	0.810 (0.549, 1.194)	0.2780
White	53	11 (20.8)	NR (NE, NE)	44	12 (27.3)	3.3 (2.8, NE)	0.670 (0.295, 1.522)	0.3318
Interaction								0.7173

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 05JUN2024 19:38 t-14-02-06-03-01-02-s-eff-tteqs-subgrp-o18-itt-cl.rtf

Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Dysphagia

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	17 (21.3)	NR (NE, NE)	62	10 (16.1)	NR (3.0, NE)	1.010 (0.460, 2.217)	0.9809
vCPS < 10%	100	30 (30.0)	NR (NE, NE)	122	31 (25.4)	NR (3.1, NE)	1.015 (0.614, 1.677)	0.9540
Missing	76	16 (21.1)	NR (NE, NE)	72	22 (30.6)	4.9 (1.0, NE)	0.485 (0.253, 0.927)	0.0225
Interaction								0.1464

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 05JUN2024 19:38 t-14-02-06-03-01-02-s-eff-tteqs-subgrp-o18-itt-cl.rtf

Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Eating

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	23 (15.1)	NR (NE, NE)	158	11 (7.0)	NR (NE, NE)	1.710 (0.832, 3.515)	0.1372
>= 65 Years	104	13 (12.5)	NR (NE, NE)	98	16 (16.3)	NR (4.9, NE)	0.555 (0.264, 1.166)	0.1137
Interaction								0.0504
Gender								
Male	217	33 (15.2)	NR (NE, NE)	215	21 (9.8)	NR (NE, NE)	1.191 (0.687, 2.064)	0.5310
Female	39	3 (7.7)	NR (NE, NE)	41	6 (14.6)	NR (NE, NE)	0.435 (0.109, 1.740)	0.2233
Interaction								0.1055

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Eating

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	28 (14.9)	NR (NE, NE)	192	23 (12.0)	NR (NE, NE)	0.947 (0.544, 1.649)	0.8471
Non-Smoker	68	8 (11.8)	NR (NE, NE)	63	4 (6.3)	NR (NE, NE)	1.470 (0.441, 4.904)	0.5261
Interaction								0.6199
ICC Options								
Paclitaxel	83	17 (20.5)	NR (NE, NE)	85	11 (12.9)	NR (4.9, NE)	1.421 (0.664, 3.039)	0.3623
Docetaxel	56	6 (10.7)	NR (NE, NE)	53	6 (11.3)	NR (NE, NE)	0.747 (0.239, 2.330)	0.6130
Irinotecan	117	13 (11.1)	NR (NE, NE)	118	10 (8.5)	NR (NE, NE)	0.981 (0.427, 2.257)	0.9643
Interaction								0.5304

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Eating

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	8 (12.5)	NR (NE, NE)	63	8 (12.7)	NR (5.2, NE)	0.749 (0.279, 2.013)	0.5646
1	192	28 (14.6)	NR (NE, NE)	193	19 (9.8)	NR (NE, NE)	1.128 (0.628, 2.026)	0.6858
Interaction								0.5039
Region #1								
Asia	201	27 (13.4)	NR (NE, NE)	203	20 (9.9)	NR (NE, NE)	1.007 (0.562, 1.804)	0.9802
Europe/North America	55	9 (16.4)	NR (NE, NE)	53	7 (13.2)	NR (2.9, NE)	1.026 (0.381, 2.763)	0.9596
Interaction								0.9338

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Eating

Subgroup	Tislelizumab (N = 256) Total No. of Patients	Tislelizumab (N = 256) Patients with events n (%)	Tislelizumab (N = 256) Median time to event (95% CI) [a]	ICC (N = 256) Total No. of Patients	ICC (N = 256) Patients with events n (%)	ICC (N = 256) Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Region #2								
Asia (excluding Japan)	176	23 (13.1)	NR (NE, NE)	178	14 (7.9)	NR (NE, NE)	1.249 (0.640, 2.437)	0.5111
Japan	25	4 (16.0)	NR (NE, NE)	25	6 (24.0)	5.2 (4.9, NE)	0.464 (0.127, 1.699)	0.2330
Europe/North America	55	9 (16.4)	NR (NE, NE)	53	7 (13.2)	NR (2.9, NE)	1.026 (0.381, 2.763)	0.9596
Interaction								0.4653
Race								
Asian and other	203	28 (13.8)	NR (NE, NE)	212	20 (9.4)	NR (NE, NE)	1.074 (0.603, 1.916)	0.8059
White	53	8 (15.1)	NR (NE, NE)	44	7 (15.9)	NR (2.9, NE)	0.798 (0.288, 2.208)	0.6621
Interaction								0.5603

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Eating

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	14 (17.5)	NR (NE, NE)	62	9 (14.5)	NR (NE, NE)	0.912 (0.393, 2.115)	0.8295
vCPS < 10%	100	15 (15.0)	NR (NE, NE)	122	12 (9.8)	NR (4.5, NE)	1.181 (0.550, 2.533)	0.6681
Missing	76	7 (9.2)	NR (NE, NE)	72	6 (8.3)	NR (4.9, NE)	0.856 (0.285, 2.572)	0.7815
Interaction								0.7841

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Reflux

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	14 (9.2)	NR (NE, NE)	158	27 (17.1)	NR (NE, NE)	0.384 (0.200, 0.737)	0.0025
>= 65 Years	104	18 (17.3)	NR (15.1, NE)	98	18 (18.4)	NR (NE, NE)	0.705 (0.364, 1.367)	0.2959
Interaction								0.1236
Gender								
Male	217	24 (11.1)	NR (NE, NE)	215	34 (15.8)	NR (NE, NE)	0.490 (0.288, 0.836)	0.0070
Female	39	8 (20.5)	NR (2.8, NE)	41	11 (26.8)	NR (1.4, NE)	0.581 (0.232, 1.454)	0.2330
Interaction								0.8902

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Reflux

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	27 (14.4)	NR (15.1, NE)	192	32 (16.7)	NR (NE, NE)	0.631 (0.375, 1.062)	0.0775
Non-Smoker	68	5 (7.4)	NR (NE, NE)	63	13 (20.6)	NR (2.3, NE)	0.237 (0.083, 0.673)	0.0031
Interaction								0.0745
ICC Options								
Paclitaxel	83	11 (13.3)	NR (NE, NE)	85	16 (18.8)	NR (NE, NE)	0.581 (0.269, 1.254)	0.1591
Docetaxel	56	8 (14.3)	NR (NE, NE)	53	11 (20.8)	NR (NE, NE)	0.598 (0.239, 1.493)	0.2615
Irinotecan	117	13 (11.1)	NR (15.1, NE)	118	18 (15.3)	NR (NE, NE)	0.412 (0.195, 0.871)	0.0156
Interaction								0.8138

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Reflux

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	11 (17.2)	NR (NE, NE)	63	9 (14.3)	NR (NE, NE)	0.969 (0.400, 2.349)	0.9447
1	192	21 (10.9)	NR (NE, NE)	193	36 (18.7)	NR (NE, NE)	0.403 (0.233, 0.697)	0.0007
Interaction								0.1467
Region #1								
Asia	201	22 (10.9)	NR (NE, NE)	203	35 (17.2)	NR (NE, NE)	0.431 (0.250, 0.742)	0.0016
Europe/North America	55	10 (18.2)	NR (NE, NE)	53	10 (18.9)	NR (NE, NE)	0.803 (0.334, 1.933)	0.6222
Interaction								0.2471

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Reflux

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	17 (9.7)	NR (NE, NE)	178	35 (19.7)	NR (NE, NE)	0.321 (0.178, 0.581)	<0.0001
Japan	25	5 (20.0)	NR (NE, NE)	25	0 (0.0)	NR (NE, NE)	66175219.841 (0.000, NE)	0.0462
Europe/North America	55	10 (18.2)	NR (NE, NE)	53	10 (18.9)	NR (NE, NE)	0.803 (0.334, 1.933)	0.6222
Interaction								0.2475
Race								
Asian and other	203	23 (11.3)	NR (NE, NE)	212	38 (17.9)	NR (NE, NE)	0.428 (0.253, 0.725)	0.0010
White	53	9 (17.0)	NR (NE, NE)	44	7 (15.9)	NR (NE, NE)	0.950 (0.353, 2.556)	0.9187
Interaction								0.1664

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Reflux

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	10 (12.5)	NR (15.1, NE)	62	10 (16.1)	NR (3.7, NE)	0.549 (0.225, 1.338)	0.1782
vCPS < 10%	100	13 (13.0)	NR (NE, NE)	122	21 (17.2)	NR (NE, NE)	0.551 (0.274, 1.106)	0.0864
Missing	76	9 (11.8)	NR (NE, NE)	72	14 (19.4)	NR (NE, NE)	0.452 (0.194, 1.049)	0.0536
Interaction								0.8690

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Pain

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	33 (21.7)	NR (NE, NE)	158	22 (13.9)	NR (NE, NE)	1.217 (0.708, 2.092)	0.4715
>= 65 Years	104	16 (15.4)	NR (NE, NE)	98	22 (22.4)	NR (3.3, NE)	0.551 (0.288, 1.056)	0.0668
Interaction								0.0622
Gender								
Male	217	42 (19.4)	NR (NE, NE)	215	36 (16.7)	NR (NE, NE)	0.908 (0.580, 1.420)	0.6693
Female	39	7 (17.9)	NR (NE, NE)	41	8 (19.5)	NR (1.8, NE)	0.799 (0.287, 2.220)	0.6649
Interaction								0.7232

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Pain

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	39 (20.7)	NR (NE, NE)	192	35 (18.2)	NR (4.9, NE)	0.934 (0.591, 1.478)	0.7696
Non-Smoker	68	10 (14.7)	NR (NE, NE)	63	9 (14.3)	NR (NE, NE)	0.755 (0.304, 1.875)	0.5414
Interaction								0.6582
ICC Options								
Paclitaxel	83	24 (28.9)	NR (NE, NE)	85	15 (17.6)	NR (4.9, NE)	1.659 (0.870, 3.163)	0.1162
Docetaxel	56	8 (14.3)	NR (NE, NE)	53	10 (18.9)	NR (3.5, NE)	0.664 (0.261, 1.687)	0.3822
Irinotecan	117	17 (14.5)	NR (NE, NE)	118	19 (16.1)	NR (NE, NE)	0.546 (0.279, 1.068)	0.0702
Interaction								0.0481

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Pain

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	11 (17.2)	NR (NE, NE)	63	15 (23.8)	NR (3.5, NE)	0.568 (0.260, 1.243)	0.1465
1	192	38 (19.8)	NR (NE, NE)	193	29 (15.0)	NR (4.9, NE)	1.044 (0.642, 1.697)	0.8612
Interaction								0.1603
Region #1								
Asia	201	39 (19.4)	NR (NE, NE)	203	31 (15.3)	NR (NE, NE)	0.996 (0.620, 1.600)	0.9862
Europe/North America	55	10 (18.2)	NR (NE, NE)	53	13 (24.5)	3.5 (2.5, NE)	0.628 (0.274, 1.440)	0.2628
Interaction								0.3042

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Pain

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	29 (16.5)	NR (NE, NE)	178	27 (15.2)	NR (NE, NE)	0.824 (0.486, 1.396)	0.4668
Japan	25	10 (40.0)	NR (1.4, NE)	25	4 (16.0)	NR (4.9, NE)	2.454 (0.766, 7.863)	0.1122
Europe/North America	55	10 (18.2)	NR (NE, NE)	53	13 (24.5)	3.5 (2.5, NE)	0.628 (0.274, 1.440)	0.2628
Interaction								0.1520
Race								
Asian and other	203	39 (19.2)	NR (NE, NE)	212	32 (15.1)	NR (NE, NE)	0.984 (0.615, 1.575)	0.9474
White	53	10 (18.9)	NR (NE, NE)	44	12 (27.3)	3.5 (1.8, NE)	0.622 (0.267, 1.449)	0.2616
Interaction								0.2942

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Pain

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	13 (16.3)	NR (NE, NE)	62	14 (22.6)	NR (2.5, NE)	0.483 (0.225, 1.035)	0.0547
vCPS < 10%	100	21 (21.0)	NR (NE, NE)	122	23 (18.9)	NR (3.5, NE)	0.919 (0.507, 1.665)	0.7783
Missing	76	15 (19.7)	NR (NE, NE)	72	7 (9.7)	NR (4.9, NE)	1.755 (0.714, 4.316)	0.2073
Interaction								0.1232

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Trouble Swallowing Saliva

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	15 (9.9)	NR (NE, NE)	158	9 (5.7)	NR (NE, NE)	1.316 (0.573, 3.020)	0.5143
>= 65 Years	104	8 (7.7)	NR (NE, NE)	98	8 (8.2)	NR (NE, NE)	0.796 (0.298, 2.128)	0.6479
Interaction								0.4762
Gender								
Male	217	18 (8.3)	NR (NE, NE)	215	14 (6.5)	NR (NE, NE)	1.003 (0.497, 2.023)	0.9927
Female	39	5 (12.8)	NR (NE, NE)	41	3 (7.3)	NR (NE, NE)	1.463 (0.347, 6.175)	0.6014
Interaction								0.5870

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Trouble Swallowing Saliva

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	13 (6.9)	NR (NE, NE)	192	14 (7.3)	NR (NE, NE)	0.763 (0.358, 1.629)	0.4829
Non-Smoker	68	10 (14.7)	NR (NE, NE)	63	3 (4.8)	NR (3.8, NE)	2.387 (0.653, 8.729)	0.1735
Interaction								0.1069
ICC Options								
Paclitaxel	83	9 (10.8)	NR (NE, NE)	85	3 (3.5)	NR (NE, NE)	2.849 (0.771, 10.523)	0.0998
Docetaxel	56	3 (5.4)	NR (NE, NE)	53	4 (7.5)	NR (NE, NE)	0.612 (0.136, 2.756)	0.5181
Irinotecan	117	11 (9.4)	NR (NE, NE)	118	10 (8.5)	NR (NE, NE)	0.771 (0.324, 1.833)	0.5530
Interaction								0.1718

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Trouble Swallowing Saliva

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	8 (12.5)	NR (NE, NE)	63	3 (4.8)	NR (NE, NE)	2.323 (0.614, 8.782)	0.1984
1	192	15 (7.8)	NR (NE, NE)	193	14 (7.3)	NR (NE, NE)	0.814 (0.392, 1.693)	0.5806
Interaction								0.2148
Region #1								
Asia	201	18 (9.0)	NR (NE, NE)	203	13 (6.4)	NR (NE, NE)	1.073 (0.524, 2.200)	0.8454
Europe/North America	55	5 (9.1)	NR (NE, NE)	53	4 (7.5)	NR (NE, NE)	1.063 (0.285, 3.971)	0.9272
Interaction								0.9391

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Trouble Swallowing Saliva

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	15 (8.5)	NR (NE, NE)	178	13 (7.3)	NR (NE, NE)	0.885 (0.419, 1.869)	0.7477
Japan	25	3 (12.0)	NR (NE, NE)	25	0 (0.0)	NR (NE, NE)	67914557.397 (0.000, NE)	0.1172
Europe/North America	55	5 (9.1)	NR (NE, NE)	53	4 (7.5)	NR (NE, NE)	1.063 (0.285, 3.971)	0.9272
Interaction								0.9440
Race								
Asian and other	203	18 (8.9)	NR (NE, NE)	212	13 (6.1)	NR (NE, NE)	1.103 (0.538, 2.261)	0.7878
White	53	5 (9.4)	NR (NE, NE)	44	4 (9.1)	NR (NE, NE)	0.970 (0.260, 3.621)	0.9634
Interaction								0.9233

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Trouble Swallowing Saliva

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	5 (6.3)	NR (NE, NE)	62	5 (8.1)	NR (NE, NE)	0.594 (0.171, 2.060)	0.4061
vCPS < 10%	100	10 (10.0)	NR (NE, NE)	122	6 (4.9)	NR (NE, NE)	1.697 (0.615, 4.684)	0.3002
Missing	76	8 (10.5)	NR (NE, NE)	72	6 (8.3)	NR (NE, NE)	1.004 (0.347, 2.905)	0.9945
Interaction								0.3811

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Choked When Swallowing

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	16 (10.5)	NR (NE, NE)	158	11 (7.0)	NR (NE, NE)	1.091 (0.504, 2.364)	0.8236
>= 65 Years	104	7 (6.7)	NR (NE, NE)	98	12 (12.2)	NR (4.9, NE)	0.416 (0.163, 1.067)	0.0596
Interaction								0.1016
Gender								
Male	217	20 (9.2)	NR (NE, NE)	215	19 (8.8)	NR (NE, NE)	0.745 (0.395, 1.404)	0.3594
Female	39	3 (7.7)	NR (NE, NE)	41	4 (9.8)	NR (2.8, NE)	0.613 (0.136, 2.755)	0.5172
Interaction								0.7320

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Choked When Swallowing

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	20 (10.6)	NR (NE, NE)	192	17 (8.9)	NR (NE, NE)	0.875 (0.456, 1.680)	0.6879
Non-Smoker	68	3 (4.4)	NR (NE, NE)	63	6 (9.5)	NR (3.8, NE)	0.363 (0.090, 1.461)	0.1367
Interaction								0.1794
ICC Options								
Paclitaxel	83	8 (9.6)	NR (NE, NE)	85	11 (12.9)	NR (4.9, NE)	0.600 (0.241, 1.494)	0.2666
Docetaxel	56	5 (8.9)	NR (NE, NE)	53	2 (3.8)	NR (NE, NE)	2.091 (0.402, 10.861)	0.3699
Irinotecan	117	10 (8.5)	NR (NE, NE)	118	10 (8.5)	NR (NE, NE)	0.740 (0.305, 1.790)	0.4992
Interaction								0.3789

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Choked When Swallowing

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	6 (9.4)	NR (NE, NE)	63	7 (11.1)	NR (4.5, NE)	0.617 (0.204, 1.864)	0.3863
1	192	17 (8.9)	NR (NE, NE)	193	16 (8.3)	NR (NE, NE)	0.772 (0.388, 1.536)	0.4582
Interaction								0.6967
Region #1								
Asia	201	18 (9.0)	NR (NE, NE)	203	16 (7.9)	NR (NE, NE)	0.773 (0.391, 1.531)	0.4581
Europe/North America	55	5 (9.1)	NR (NE, NE)	53	7 (13.2)	NR (NE, NE)	0.569 (0.180, 1.801)	0.3290
Interaction								0.6182

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Choked When Swallowing

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	14 (8.0)	NR (NE, NE)	178	13 (7.3)	NR (NE, NE)	0.768 (0.358, 1.645)	0.4937
Japan	25	4 (16.0)	NR (7.0, NE)	25	3 (12.0)	NR (4.9, NE)	0.863 (0.182, 4.101)	0.8525
Europe/North America	55	5 (9.1)	NR (NE, NE)	53	7 (13.2)	NR (NE, NE)	0.569 (0.180, 1.801)	0.3290
Interaction								0.8537
Race								
Asian and other	203	18 (8.9)	NR (NE, NE)	212	17 (8.0)	NR (NE, NE)	0.734 (0.375, 1.439)	0.3649
White	53	5 (9.4)	NR (NE, NE)	44	6 (13.6)	NR (NE, NE)	0.620 (0.189, 2.039)	0.4247
Interaction								0.7342

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Choked When Swallowing

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	6 (7.5)	NR (NE, NE)	62	6 (9.7)	NR (NE, NE)	0.586 (0.188, 1.825)	0.3494
vCPS < 10%	100	5 (5.0)	NR (NE, NE)	122	14 (11.5)	NR (4.5, NE)	0.308 (0.110, 0.857)	0.0171
Missing	76	12 (15.8)	NR (7.0, NE)	72	3 (4.2)	NR (4.9, NE)	3.138 (0.881, 11.176)	0.0621
Interaction								0.0216

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Dry Mouth

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	31 (20.4)	NR (NE, NE)	158	15 (9.5)	NR (NE, NE)	1.675 (0.903, 3.107)	0.0962
>= 65 Years	104	19 (18.3)	NR (NE, NE)	98	22 (22.4)	NR (2.9, NE)	0.622 (0.334, 1.161)	0.1295
Interaction								0.0364
Gender								
Male	217	44 (20.3)	NR (NE, NE)	215	31 (14.4)	NR (NE, NE)	1.069 (0.672, 1.699)	0.7752
Female	39	6 (15.4)	NR (NE, NE)	41	6 (14.6)	NR (1.9, NE)	0.847 (0.272, 2.637)	0.7735
Interaction								0.6739

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Dry Mouth

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	37 (19.7)	NR (NE, NE)	192	28 (14.6)	NR (4.9, NE)	1.059 (0.646, 1.734)	0.8195
Non-Smoker	68	13 (19.1)	NR (11.8, NE)	63	9 (14.3)	NR (NE, NE)	0.954 (0.404, 2.254)	0.9137
Interaction								0.8422
ICC Options								
Paclitaxel	83	19 (22.9)	NR (11.8, NE)	85	9 (10.6)	NR (NE, NE)	2.042 (0.919, 4.540)	0.0731
Docetaxel	56	9 (16.1)	NR (4.2, NE)	53	9 (17.0)	NR (2.9, NE)	0.769 (0.302, 1.960)	0.5768
Irinotecan	117	22 (18.8)	NR (NE, NE)	118	19 (16.1)	NR (3.0, NE)	0.710 (0.380, 1.327)	0.2772
Interaction								0.0759

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Dry Mouth

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	16 (25.0)	NR (11.8, NE)	63	5 (7.9)	NR (NE, NE)	2.336 (0.848, 6.436)	0.0897
1	192	34 (17.7)	NR (NE, NE)	193	32 (16.6)	NR (3.7, NE)	0.822 (0.506, 1.335)	0.4237
Interaction								0.0558
Region #1								
Asia	201	38 (18.9)	NR (NE, NE)	203	27 (13.3)	NR (NE, NE)	1.067 (0.648, 1.755)	0.7974
Europe/North America	55	12 (21.8)	NR (2.8, NE)	53	10 (18.9)	NR (1.9, NE)	0.932 (0.401, 2.165)	0.8697
Interaction								0.8330

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Dry Mouth

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	31 (17.6)	NR (NE, NE)	178	23 (12.9)	NR (4.9, NE)	1.012 (0.588, 1.742)	0.9648
Japan	25	7 (28.0)	NR (11.8, NE)	25	4 (16.0)	NR (NE, NE)	1.528 (0.437, 5.345)	0.5033
Europe/North America	55	12 (21.8)	NR (2.8, NE)	53	10 (18.9)	NR (1.9, NE)	0.932 (0.401, 2.165)	0.8697
Interaction								0.8287
Race								
Asian and other	203	38 (18.7)	NR (NE, NE)	212	28 (13.2)	NR (NE, NE)	1.059 (0.647, 1.732)	0.8188
White	53	12 (22.6)	NR (2.8, NE)	44	9 (20.5)	NR (1.9, NE)	0.916 (0.384, 2.182)	0.8416
Interaction								0.8393

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Dry Mouth

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	8 (10.0)	NR (NE, NE)	62	8 (12.9)	NR (3.7, NE)	0.490 (0.182, 1.318)	0.1474
vCPS < 10%	100	22 (22.0)	NR (NE, NE)	122	20 (16.4)	NR (NE, NE)	1.080 (0.588, 1.983)	0.8029
Missing	76	20 (26.3)	NR (3.6, NE)	72	9 (12.5)	NR (NE, NE)	1.715 (0.775, 3.795)	0.1740
Interaction								0.1975

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Trouble With Taste

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	19 (12.5)	NR (NE, NE)	158	16 (10.1)	NR (NE, NE)	0.892 (0.457, 1.744)	0.7377
>= 65 Years	104	16 (15.4)	NR (NE, NE)	98	14 (14.3)	NR (NE, NE)	0.835 (0.405, 1.721)	0.6233
Interaction								0.9946
Gender								
Male	217	28 (12.9)	NR (NE, NE)	215	23 (10.7)	NR (NE, NE)	0.898 (0.515, 1.563)	0.7014
Female	39	7 (17.9)	NR (4.5, NE)	41	7 (17.1)	NR (1.9, NE)	0.738 (0.253, 2.153)	0.5727
Interaction								0.8408

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Trouble With Taste

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	26 (13.8)	NR (NE, NE)	192	26 (13.5)	NR (NE, NE)	0.735 (0.425, 1.273)	0.2684
Non-Smoker	68	9 (13.2)	NR (NE, NE)	63	4 (6.3)	NR (NE, NE)	1.670 (0.513, 5.436)	0.3858
Interaction								0.2740
ICC Options								
Paclitaxel	83	13 (15.7)	NR (NE, NE)	85	7 (8.2)	NR (NE, NE)	1.780 (0.709, 4.465)	0.2122
Docetaxel	56	10 (17.9)	NR (NE, NE)	53	8 (15.1)	NR (2.9, NE)	1.052 (0.413, 2.681)	0.9142
Irinotecan	117	12 (10.3)	NR (NE, NE)	118	15 (12.7)	NR (NE, NE)	0.437 (0.200, 0.956)	0.0329
Interaction								0.0641

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Trouble With Taste

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	7 (10.9)	NR (NE, NE)	63	8 (12.7)	NR (NE, NE)	0.583 (0.210, 1.623)	0.2952
1	192	28 (14.6)	NR (NE, NE)	193	22 (11.4)	NR (NE, NE)	0.972 (0.554, 1.704)	0.9194
Interaction								0.4732
Region #1								
Asia	201	24 (11.9)	NR (NE, NE)	203	19 (9.4)	NR (NE, NE)	0.949 (0.518, 1.739)	0.8646
Europe/North America	55	11 (20.0)	NR (4.5, NE)	53	11 (20.8)	NR (1.9, NE)	0.749 (0.322, 1.742)	0.4989
Interaction								0.7751

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Trouble With Taste

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	22 (12.5)	NR (NE, NE)	178	13 (7.3)	NR (NE, NE)	1.275 (0.640, 2.540)	0.4869
Japan	25	2 (8.0)	NR (NE, NE)	25	6 (24.0)	NR (2.2, NE)	0.259 (0.052, 1.298)	0.0770
Europe/North America	55	11 (20.0)	NR (4.5, NE)	53	11 (20.8)	NR (1.9, NE)	0.749 (0.322, 1.742)	0.4989
Interaction								0.1909
Race								
Asian and other	203	24 (11.8)	NR (NE, NE)	212	21 (9.9)	NR (NE, NE)	0.878 (0.487, 1.584)	0.6643
White	53	11 (20.8)	NR (4.5, NE)	44	9 (20.5)	NR (1.9, NE)	0.837 (0.345, 2.035)	0.6941
Interaction								0.9567

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Trouble With Taste

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	8 (10.0)	NR (NE, NE)	62	2 (3.2)	NR (NE, NE)	2.495 (0.528, 11.795)	0.2310
vCPS < 10%	100	17 (17.0)	NR (NE, NE)	122	19 (15.6)	NR (NE, NE)	0.838 (0.435, 1.617)	0.5969
Missing	76	10 (13.2)	NR (NE, NE)	72	9 (12.5)	NR (NE, NE)	0.771 (0.311, 1.911)	0.5726
Interaction								0.4744

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Trouble With Coughing

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	27 (17.8)	NR (NE, NE)	158	19 (12.0)	NR (NE, NE)	1.093 (0.606, 1.971)	0.7675
>= 65 Years	104	16 (15.4)	NR (NE, NE)	98	11 (11.2)	NR (4.9, NE)	1.138 (0.526, 2.461)	0.7423
Interaction								0.9268
Gender								
Male	217	36 (16.6)	NR (NE, NE)	215	27 (12.6)	NR (NE, NE)	1.017 (0.616, 1.678)	0.9485
Female	39	7 (17.9)	NR (NE, NE)	41	3 (7.3)	NR (NE, NE)	2.228 (0.575, 8.635)	0.2331
Interaction								0.3689

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Trouble With Coughing

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	37 (19.7)	NR (NE, NE)	192	27 (14.1)	NR (NE, NE)	1.158 (0.704, 1.904)	0.5604
Non-Smoker	68	6 (8.8)	NR (NE, NE)	63	3 (4.8)	NR (3.5, NE)	1.080 (0.266, 4.385)	0.9144
Interaction								0.8727
ICC Options								
Paclitaxel	83	12 (14.5)	NR (NE, NE)	85	13 (15.3)	NR (4.9, NE)	0.830 (0.378, 1.822)	0.6422
Docetaxel	56	14 (25.0)	NR (2.8, NE)	53	5 (9.4)	NR (3.5, NE)	2.704 (0.973, 7.516)	0.0460
Irinotecan	117	17 (14.5)	NR (NE, NE)	118	12 (10.2)	NR (NE, NE)	0.956 (0.452, 2.019)	0.9047
Interaction								0.1427

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Trouble With Coughing

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	13 (20.3)	NR (NE, NE)	63	7 (11.1)	NR (NE, NE)	1.526 (0.606, 3.841)	0.3637
1	192	30 (15.6)	NR (NE, NE)	193	23 (11.9)	NR (4.9, NE)	1.001 (0.580, 1.727)	0.9974
Interaction								0.5214
Region #1								
Asia	201	36 (17.9)	NR (NE, NE)	203	24 (11.8)	NR (NE, NE)	1.143 (0.680, 1.921)	0.6110
Europe/North America	55	7 (12.7)	NR (NE, NE)	53	6 (11.3)	NR (NE, NE)	0.972 (0.326, 2.904)	0.9598
Interaction								0.7111

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Trouble With Coughing

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	31 (17.6)	NR (NE, NE)	178	19 (10.7)	NR (NE, NE)	1.230 (0.693, 2.183)	0.4763
Japan	25	5 (20.0)	NR (NE, NE)	25	5 (20.0)	NR (4.9, NE)	0.842 (0.241, 2.938)	0.7861
Europe/North America	55	7 (12.7)	NR (NE, NE)	53	6 (11.3)	NR (NE, NE)	0.972 (0.326, 2.904)	0.9598
Interaction								0.8062
Race								
Asian and other	203	37 (18.2)	NR (NE, NE)	212	24 (11.3)	NR (NE, NE)	1.213 (0.724, 2.032)	0.4613
White	53	6 (11.3)	NR (NE, NE)	44	6 (13.6)	NR (2.9, NE)	0.728 (0.234, 2.266)	0.5814
Interaction								0.3730

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Trouble With Coughing

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	12 (15.0)	NR (NE, NE)	62	2 (3.2)	NR (NE, NE)	3.809 (0.852, 17.038)	0.0589
vCPS < 10%	100	18 (18.0)	NR (NE, NE)	122	18 (14.8)	NR (4.5, NE)	1.012 (0.526, 1.948)	0.9715
Missing	76	13 (17.1)	NR (NE, NE)	72	10 (13.9)	NR (3.5, NE)	0.880 (0.384, 2.014)	0.7597
Interaction								0.2799

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Trouble Talking

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	19 (12.5)	NR (NE, NE)	158	7 (4.4)	NR (NE, NE)	2.181 (0.913, 5.210)	0.0714
>= 65 Years	104	6 (5.8)	NR (NE, NE)	98	4 (4.1)	NR (NE, NE)	1.155 (0.325, 4.109)	0.8232
Interaction								0.4325
Gender								
Male	217	23 (10.6)	NR (NE, NE)	215	9 (4.2)	NR (NE, NE)	2.004 (0.924, 4.347)	0.0719
Female	39	2 (5.1)	NR (NE, NE)	41	2 (4.9)	NR (NE, NE)	0.935 (0.132, 6.644)	0.9468
Interaction								0.4053

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Trouble Talking

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	18 (9.6)	NR (NE, NE)	192	8 (4.2)	NR (NE, NE)	1.828 (0.792, 4.220)	0.1511
Non-Smoker	68	7 (10.3)	NR (NE, NE)	63	3 (4.8)	NR (3.5, NE)	1.703 (0.437, 6.629)	0.4355
Interaction								0.8854
ICC Options								
Paclitaxel	83	12 (14.5)	NR (NE, NE)	85	3 (3.5)	NR (NE, NE)	3.754 (1.057, 13.330)	0.0277
Docetaxel	56	5 (8.9)	NR (NE, NE)	53	3 (5.7)	NR (3.5, NE)	1.307 (0.309, 5.532)	0.7149
Irinotecan	117	8 (6.8)	NR (NE, NE)	118	5 (4.2)	NR (NE, NE)	1.311 (0.428, 4.010)	0.6331
Interaction								0.3038

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Trouble Talking

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	6 (9.4)	NR (NE, NE)	63	2 (3.2)	NR (NE, NE)	2.159 (0.430, 10.831)	0.3384
1	192	19 (9.9)	NR (NE, NE)	193	9 (4.7)	NR (NE, NE)	1.725 (0.779, 3.822)	0.1723
Interaction								0.7198
Region #1								
Asia	201	20 (10.0)	NR (NE, NE)	203	7 (3.4)	NR (NE, NE)	2.196 (0.923, 5.223)	0.0676
Europe/North America	55	5 (9.1)	NR (NE, NE)	53	4 (7.5)	NR (NE, NE)	1.065 (0.285, 3.978)	0.9254
Interaction								0.3479

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Trouble Talking

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	17 (9.7)	NR (NE, NE)	178	6 (3.4)	NR (NE, NE)	2.276 (0.895, 5.791)	0.0752
Japan	25	3 (12.0)	NR (7.0, NE)	25	1 (4.0)	NR (NE, NE)	1.964 (0.191, 20.233)	0.5642
Europe/North America	55	5 (9.1)	NR (NE, NE)	53	4 (7.5)	NR (NE, NE)	1.065 (0.285, 3.978)	0.9254
Interaction								0.6427
Race								
Asian and other	203	20 (9.9)	NR (NE, NE)	212	7 (3.3)	NR (NE, NE)	2.249 (0.946, 5.348)	0.0594
White	53	5 (9.4)	NR (NE, NE)	44	4 (9.1)	NR (NE, NE)	0.966 (0.259, 3.610)	0.9594
Interaction								0.2735

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Trouble Talking

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	6 (7.5)	NR (NE, NE)	62	0 (0.0)	NR (NE, NE)	19657350.792 (0.000, NE)	0.0565
vCPS < 10%	100	15 (15.0)	NR (NE, NE)	122	5 (4.1)	NR (NE, NE)	3.212 (1.166, 8.847)	0.0167
Missing	76	4 (5.3)	NR (NE, NE)	72	6 (8.3)	NR (3.5, NE)	0.414 (0.114, 1.500)	0.1665
Interaction								0.0746

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Dysphagia

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	25 (32.9)	NR (2.1, NE)	76	18 (23.7)	NR (3.1, NE)	1.333 (0.727, 2.445)	0.3420
>= 65 Years	63	14 (22.2)	NR (NE, NE)	62	19 (30.6)	NR (2.1, NE)	0.664 (0.333, 1.326)	0.2360
Interaction								0.1341
Gender								
Male	118	37 (31.4)	NR (2.2, NE)	111	31 (27.9)	NR (3.1, NE)	1.062 (0.659, 1.711)	0.8015
Female	21	2 (9.5)	NR (NE, NE)	27	6 (22.2)	NR (1.4, NE)	0.403 (0.081, 1.996)	0.2490
Interaction								0.2194

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Dysphagia

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	29 (27.9)	NR (NE, NE)	105	30 (28.6)	NR (3.0, NE)	0.925 (0.555, 1.543)	0.7625
Non-Smoker	35	10 (28.6)	NR (1.3, NE)	33	7 (21.2)	NR (1.4, NE)	1.065 (0.405, 2.801)	0.8962
Interaction								0.7333
ICC Options								
Paclitaxel	83	25 (30.1)	NR (2.1, NE)	85	23 (27.1)	NR (3.1, NE)	1.045 (0.593, 1.843)	0.8757
Docetaxel	56	14 (25.0)	NR (2.2, NE)	53	14 (26.4)	NR (2.1, NE)	0.863 (0.411, 1.811)	0.6919
Interaction								0.6746

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Dysphagia

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	12 (27.9)	NR (2.2, NE)	42	12 (28.6)	NR (3.0, NE)	0.869 (0.390, 1.937)	0.7273
1	96	27 (28.1)	NR (2.2, NE)	96	25 (26.0)	NR (2.8, NE)	1.023 (0.594, 1.763)	0.9327
Interaction								0.7522
Region #1								
Asia	103	31 (30.1)	NR (2.2, NE)	105	31 (29.5)	NR (2.8, NE)	0.925 (0.562, 1.522)	0.7545
Europe/North America	36	8 (22.2)	NR (2.1, NE)	33	6 (18.2)	NR (3.0, NE)	1.230 (0.427, 3.547)	0.6994
Interaction								0.6393

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Dysphagia

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	24 (30.8)	NR (2.1, NE)	80	24 (30.0)	NR (2.1, NE)	0.949 (0.538, 1.672)	0.8534
Japan	25	7 (28.0)	NR (0.8, NE)	25	7 (28.0)	4.9 (4.9, NE)	0.921 (0.319, 2.658)	0.8752
Europe/North America	36	8 (22.2)	NR (2.1, NE)	33	6 (18.2)	NR (3.0, NE)	1.230 (0.427, 3.547)	0.6994
Interaction								0.8899
Race								
Asian and other	105	31 (29.5)	NR (2.2, NE)	114	33 (28.9)	NR (2.8, NE)	0.901 (0.551, 1.471)	0.6696
White	34	8 (23.5)	NR (0.9, NE)	24	4 (16.7)	NR (3.0, NE)	1.606 (0.484, 5.336)	0.4319
Interaction								0.3817

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Dysphagia

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	11 (24.4)	NR (NE, NE)	34	7 (20.6)	NR (2.1, NE)	1.137 (0.439, 2.944)	0.7896
vCPS < 10%	53	20 (37.7)	NR (1.4, NE)	56	15 (26.8)	NR (2.8, NE)	1.350 (0.690, 2.643)	0.3716
Missing	41	8 (19.5)	NR (2.2, NE)	48	15 (31.3)	NR (1.0, NE)	0.575 (0.244, 1.358)	0.1904
Interaction								0.2732

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Eating

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	14 (18.4)	NR (NE, NE)	76	7 (9.2)	NR (NE, NE)	1.856 (0.749, 4.599)	0.1731
>= 65 Years	63	9 (14.3)	NR (NE, NE)	62	10 (16.1)	NR (4.9, NE)	0.685 (0.276, 1.703)	0.4130
Interaction								0.1570
Gender								
Male	118	21 (17.8)	NR (NE, NE)	111	14 (12.6)	NR (5.2, NE)	1.272 (0.646, 2.504)	0.4845
Female	21	2 (9.5)	NR (NE, NE)	27	3 (11.1)	NR (NE, NE)	0.709 (0.118, 4.250)	0.7050
Interaction								0.4283

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Eating

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	18 (17.3)	NR (NE, NE)	105	14 (13.3)	NR (5.2, NE)	1.170 (0.581, 2.356)	0.6599
Non-Smoker	35	5 (14.3)	NR (NE, NE)	33	3 (9.1)	NR (3.2, NE)	1.170 (0.280, 4.900)	0.8284
Interaction								0.9160
ICC Options								
Paclitaxel	83	17 (20.5)	NR (NE, NE)	85	11 (12.9)	NR (4.9, NE)	1.421 (0.664, 3.039)	0.3623
Docetaxel	56	6 (10.7)	NR (NE, NE)	53	6 (11.3)	NR (NE, NE)	0.747 (0.239, 2.330)	0.6130
Interaction								0.3752

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Eating

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	6 (14.0)	NR (NE, NE)	42	5 (11.9)	NR (5.2, NE)	0.951 (0.289, 3.130)	0.9346
1	96	17 (17.7)	NR (NE, NE)	96	12 (12.5)	NR (4.9, NE)	1.287 (0.614, 2.700)	0.5019
Interaction								0.6817
Region #1								
Asia	103	16 (15.5)	NR (NE, NE)	105	14 (13.3)	NR (5.2, NE)	0.978 (0.477, 2.009)	0.9524
Europe/North America	36	7 (19.4)	NR (2.1, NE)	33	3 (9.1)	NR (2.9, NE)	1.983 (0.512, 7.677)	0.3112
Interaction								0.4110

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Eating

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	12 (15.4)	NR (NE, NE)	80	8 (10.0)	NR (NE, NE)	1.414 (0.577, 3.461)	0.4456
Japan	25	4 (16.0)	NR (NE, NE)	25	6 (24.0)	5.2 (4.9, NE)	0.464 (0.127, 1.699)	0.2330
Europe/North America	36	7 (19.4)	NR (2.1, NE)	33	3 (9.1)	NR (2.9, NE)	1.983 (0.512, 7.677)	0.3112
Interaction								0.2839
Race								
Asian and other	105	17 (16.2)	NR (NE, NE)	114	14 (12.3)	NR (5.2, NE)	1.083 (0.533, 2.203)	0.8240
White	34	6 (17.6)	NR (2.1, NE)	24	3 (12.5)	NR (2.9, NE)	1.399 (0.349, 5.604)	0.6336
Interaction								0.7877

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Eating

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	9 (20.0)	NR (NE, NE)	34	5 (14.7)	NR (NE, NE)	1.274 (0.426, 3.805)	0.6630
vCPS < 10%	53	9 (17.0)	NR (4.2, NE)	56	7 (12.5)	NR (4.5, NE)	1.102 (0.409, 2.969)	0.8468
Missing	41	5 (12.2)	NR (NE, NE)	48	5 (10.4)	NR (4.9, NE)	1.075 (0.310, 3.728)	0.9092
Interaction								0.9905

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Reflux

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	7 (9.2)	NR (NE, NE)	76	12 (15.8)	NR (NE, NE)	0.502 (0.197, 1.279)	0.1379
>= 65 Years	63	12 (19.0)	NR (NE, NE)	62	15 (24.2)	NR (3.7, NE)	0.656 (0.307, 1.405)	0.2712
Interaction								0.6001
Gender								
Male	118	14 (11.9)	NR (NE, NE)	111	21 (18.9)	NR (NE, NE)	0.533 (0.271, 1.050)	0.0625
Female	21	5 (23.8)	NR (2.2, NE)	27	6 (22.2)	NR (1.4, NE)	0.959 (0.292, 3.150)	0.9443
Interaction								0.4363

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Reflux

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	17 (16.3)	NR (NE, NE)	105	19 (18.1)	NR (NE, NE)	0.814 (0.423, 1.569)	0.5363
Non-Smoker	35	2 (5.7)	NR (NE, NE)	33	8 (24.2)	NR (1.4, NE)	0.165 (0.035, 0.778)	0.0088
Interaction								0.0488
ICC Options								
Paclitaxel	83	11 (13.3)	NR (NE, NE)	85	16 (18.8)	NR (NE, NE)	0.581 (0.269, 1.254)	0.1591
Docetaxel	56	8 (14.3)	NR (NE, NE)	53	11 (20.8)	NR (NE, NE)	0.598 (0.239, 1.493)	0.2615
Interaction								0.9825

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Reflux

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	8 (18.6)	NR (NE, NE)	42	5 (11.9)	NR (NE, NE)	1.395 (0.456, 4.270)	0.5566
1	96	11 (11.5)	NR (NE, NE)	96	22 (22.9)	NR (3.7, NE)	0.425 (0.206, 0.877)	0.0161
Interaction								0.0998
Region #1								
Asia	103	13 (12.6)	NR (NE, NE)	105	19 (18.1)	NR (NE, NE)	0.572 (0.282, 1.161)	0.1145
Europe/North America	36	6 (16.7)	NR (2.9, NE)	33	8 (24.2)	NR (1.4, NE)	0.614 (0.213, 1.771)	0.3590
Interaction								0.9181

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Reflux

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	8 (10.3)	NR (NE, NE)	80	19 (23.8)	NR (3.7, NE)	0.357 (0.156, 0.818)	0.0099
Japan	25	5 (20.0)	NR (NE, NE)	25	0 (0.0)	NR (NE, NE)	66175219.841 (0.000, NE)	0.0462
Europe/North America	36	6 (16.7)	NR (2.9, NE)	33	8 (24.2)	NR (1.4, NE)	0.614 (0.213, 1.771)	0.3590
Interaction								0.7177
Race								
Asian and other	105	14 (13.3)	NR (NE, NE)	114	22 (19.3)	NR (NE, NE)	0.556 (0.284, 1.088)	0.0794
White	34	5 (14.7)	NR (2.9, NE)	24	5 (20.8)	NR (1.5, NE)	0.711 (0.205, 2.461)	0.5875
Interaction								0.7196

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Reflux

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	6 (13.3)	NR (NE, NE)	34	6 (17.6)	NR (3.7, NE)	0.697 (0.224, 2.168)	0.5282
vCPS < 10%	53	7 (13.2)	NR (NE, NE)	56	11 (19.6)	NR (NE, NE)	0.529 (0.204, 1.368)	0.1794
Missing	41	6 (14.6)	NR (2.8, NE)	48	10 (20.8)	NR (NE, NE)	0.644 (0.234, 1.773)	0.3830
Interaction								0.9518

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Pain

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	20 (26.3)	NR (2.8, NE)	76	11 (14.5)	NR (3.5, NE)	1.834 (0.878, 3.829)	0.0984
>= 65 Years	63	12 (19.0)	NR (NE, NE)	62	14 (22.6)	NR (3.3, NE)	0.768 (0.354, 1.667)	0.5007
Interaction								0.1077
Gender								
Male	118	29 (24.6)	NR (NE, NE)	111	21 (18.9)	NR (4.9, NE)	1.261 (0.719, 2.211)	0.4132
Female	21	3 (14.3)	NR (1.7, NE)	27	4 (14.8)	NR (3.3, NE)	0.872 (0.193, 3.936)	0.8588
Interaction								0.6745

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Pain

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	28 (26.9)	NR (NE, NE)	105	19 (18.1)	NR (4.9, NE)	1.568 (0.875, 2.809)	0.1233
Non-Smoker	35	4 (11.4)	NR (NE, NE)	33	6 (18.2)	NR (1.5, NE)	0.415 (0.116, 1.477)	0.1598
Interaction								0.0627
ICC Options								
Paclitaxel	83	24 (28.9)	NR (NE, NE)	85	15 (17.6)	NR (4.9, NE)	1.659 (0.870, 3.163)	0.1162
Docetaxel	56	8 (14.3)	NR (NE, NE)	53	10 (18.9)	NR (3.5, NE)	0.664 (0.261, 1.687)	0.3822
Interaction								0.1142

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Pain

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	7 (16.3)	NR (NE, NE)	42	9 (21.4)	NR (3.5, NE)	0.635 (0.236, 1.709)	0.3584
1	96	25 (26.0)	NR (NE, NE)	96	16 (16.7)	NR (4.9, NE)	1.659 (0.885, 3.110)	0.1080
Interaction								0.0976
Region #1								
Asia	103	26 (25.2)	NR (NE, NE)	105	20 (19.0)	NR (4.9, NE)	1.264 (0.705, 2.265)	0.4259
Europe/North America	36	6 (16.7)	NR (NE, NE)	33	5 (15.2)	NR (3.3, NE)	1.130 (0.344, 3.713)	0.8392
Interaction								0.8176

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Pain

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	16 (20.5)	NR (NE, NE)	80	16 (20.0)	NR (3.5, NE)	0.986 (0.493, 1.972)	0.9681
Japan	25	10 (40.0)	NR (1.4, NE)	25	4 (16.0)	NR (4.9, NE)	2.454 (0.766, 7.863)	0.1122
Europe/North America	36	6 (16.7)	NR (NE, NE)	33	5 (15.2)	NR (3.3, NE)	1.130 (0.344, 3.713)	0.8392
Interaction								0.4163
Race								
Asian and other	105	26 (24.8)	NR (NE, NE)	114	21 (18.4)	NR (4.9, NE)	1.244 (0.700, 2.213)	0.4513
White	34	6 (17.6)	NR (NE, NE)	24	4 (16.7)	NR (3.3, NE)	1.258 (0.354, 4.470)	0.7207
Interaction								0.9327

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Pain

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	8 (17.8)	NR (NE, NE)	34	7 (20.6)	NR (NE, NE)	0.765 (0.277, 2.116)	0.6035
vCPS < 10%	53	14 (26.4)	NR (2.2, NE)	56	13 (23.2)	NR (2.8, NE)	1.099 (0.516, 2.339)	0.8054
Missing	41	10 (24.4)	NR (1.7, NE)	48	5 (10.4)	NR (3.5, NE)	2.441 (0.832, 7.160)	0.0869
Interaction								0.2726

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble Swallowing Saliva

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	7 (9.2)	NR (NE, NE)	76	2 (2.6)	NR (NE, NE)	3.125 (0.648, 15.059)	0.1339
>= 65 Years	63	5 (7.9)	NR (NE, NE)	62	5 (8.1)	NR (NE, NE)	0.847 (0.244, 2.939)	0.7934
Interaction								0.2132
Gender								
Male	118	10 (8.5)	NR (NE, NE)	111	7 (6.3)	NR (NE, NE)	1.222 (0.465, 3.212)	0.6839
Female	21	2 (9.5)	NR (2.9, NE)	27	0 (0.0)	NR (NE, NE)	76446444.087 (0.000, NE)	0.1720
Interaction								0.9918

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble Swallowing Saliva

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	9 (8.7)	NR (NE, NE)	105	6 (5.7)	NR (NE, NE)	1.450 (0.516, 4.079)	0.4776
Non-Smoker	35	3 (8.6)	NR (NE, NE)	33	1 (3.0)	NR (3.8, NE)	2.192 (0.228, 21.111)	0.4862
Interaction								0.7080
ICC Options								
Paclitaxel	83	9 (10.8)	NR (NE, NE)	85	3 (3.5)	NR (NE, NE)	2.849 (0.771, 10.523)	0.0998
Docetaxel	56	3 (5.4)	NR (NE, NE)	53	4 (7.5)	NR (NE, NE)	0.612 (0.136, 2.756)	0.5181
Interaction								0.1188

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble Swallowing Saliva

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	5 (11.6)	NR (NE, NE)	42	1 (2.4)	NR (NE, NE)	4.428 (0.516, 37.970)	0.1358
1	96	7 (7.3)	NR (NE, NE)	96	6 (6.3)	NR (NE, NE)	1.066 (0.358, 3.176)	0.9080
Interaction								0.2893
Region #1								
Asia	103	8 (7.8)	NR (NE, NE)	105	6 (5.7)	NR (NE, NE)	1.141 (0.395, 3.297)	0.8071
Europe/North America	36	4 (11.1)	NR (NE, NE)	33	1 (3.0)	NR (2.9, NE)	3.816 (0.426, 34.174)	0.1957
Interaction								0.3089

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble Swallowing Saliva

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	5 (6.4)	NR (NE, NE)	80	6 (7.5)	NR (NE, NE)	0.757 (0.231, 2.484)	0.6446
Japan	25	3 (12.0)	NR (NE, NE)	25	0 (0.0)	NR (NE, NE)	67914557.397 (0.000, NE)	0.1172
Europe/North America	36	4 (11.1)	NR (NE, NE)	33	1 (3.0)	NR (2.9, NE)	3.816 (0.426, 34.174)	0.1957
Interaction								0.4117
Race								
Asian and other	105	8 (7.6)	NR (NE, NE)	114	6 (5.3)	NR (NE, NE)	1.193 (0.413, 3.448)	0.7436
White	34	4 (11.8)	NR (NE, NE)	24	1 (4.2)	NR (2.9, NE)	3.285 (0.367, 29.405)	0.2573
Interaction								0.3929

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble Swallowing Saliva

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	3 (6.7)	--	34	2 (5.9)	--	--	--
vCPS < 10%	53	4 (7.5)	--	56	2 (3.6)	--	--	--
Missing	41	5 (12.2)	--	48	3 (6.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Choked When Swallowing

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	7 (9.2)	NR (7.0, NE)	76	5 (6.6)	NR (NE, NE)	1.202 (0.381, 3.796)	0.7529
>= 65 Years	63	6 (9.5)	NR (NE, NE)	62	8 (12.9)	NR (4.9, NE)	0.610 (0.210, 1.769)	0.3577
Interaction								0.3436
Gender								
Male	118	12 (10.2)	NR (NE, NE)	111	11 (9.9)	NR (NE, NE)	0.848 (0.373, 1.928)	0.6930
Female	21	1 (4.8)	NR (1.7, NE)	27	2 (7.4)	NR (2.8, NE)	0.561 (0.051, 6.210)	0.6331
Interaction								0.6947

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Choked When Swallowing

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	12 (11.5)	NR (NE, NE)	105	10 (9.5)	NR (NE, NE)	1.036 (0.446, 2.405)	0.9350
Non-Smoker	35	1 (2.9)	NR (NE, NE)	33	3 (9.1)	NR (3.8, NE)	0.242 (0.025, 2.332)	0.1828
Interaction								0.1975
ICC Options								
Paclitaxel	83	8 (9.6)	NR (NE, NE)	85	11 (12.9)	NR (4.9, NE)	0.600 (0.241, 1.494)	0.2666
Docetaxel	56	5 (8.9)	NR (NE, NE)	53	2 (3.8)	NR (NE, NE)	2.091 (0.402, 10.861)	0.3699
Interaction								0.2354

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Choked When Swallowing

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	5 (11.6)	NR (NE, NE)	42	4 (9.5)	NR (4.5, NE)	0.969 (0.258, 3.644)	0.9628
1	96	8 (8.3)	NR (NE, NE)	96	9 (9.4)	NR (4.9, NE)	0.771 (0.297, 2.003)	0.5923
Interaction								0.8388
Region #1								
Asia	103	10 (9.7)	NR (NE, NE)	105	10 (9.5)	NR (4.9, NE)	0.780 (0.322, 1.886)	0.5796
Europe/North America	36	3 (8.3)	NR (NE, NE)	33	3 (9.1)	NR (2.8, NE)	0.844 (0.170, 4.193)	0.8347
Interaction								0.9257

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Choked When Swallowing

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	6 (7.7)	NR (NE, NE)	80	7 (8.8)	NR (4.5, NE)	0.755 (0.253, 2.249)	0.6127
Japan	25	4 (16.0)	NR (7.0, NE)	25	3 (12.0)	NR (4.9, NE)	0.863 (0.182, 4.101)	0.8525
Europe/North America	36	3 (8.3)	NR (NE, NE)	33	3 (9.1)	NR (2.8, NE)	0.844 (0.170, 4.193)	0.8347
Interaction								0.9828
Race								
Asian and other	105	10 (9.5)	NR (NE, NE)	114	11 (9.6)	NR (4.9, NE)	0.725 (0.306, 1.718)	0.4623
White	34	3 (8.8)	NR (NE, NE)	24	2 (8.3)	NR (NE, NE)	1.134 (0.189, 6.799)	0.8897
Interaction								0.6539

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Choked When Swallowing

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	2 (4.4)	NR (NE, NE)	34	3 (8.8)	NR (NE, NE)	0.471 (0.079, 2.821)	0.3986
vCPS < 10%	53	4 (7.5)	NR (NE, NE)	56	7 (12.5)	NR (3.8, NE)	0.474 (0.139, 1.621)	0.2234
Missing	41	7 (17.1)	NR (7.0, NE)	48	3 (6.3)	NR (4.9, NE)	2.555 (0.657, 9.940)	0.1603
Interaction								0.1339

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Dry Mouth

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	18 (23.7)	NR (4.2, NE)	76	7 (9.2)	NR (NE, NE)	2.604 (1.087, 6.238)	0.0253
>= 65 Years	63	10 (15.9)	NR (11.8, NE)	62	11 (17.7)	NR (3.7, NE)	0.751 (0.314, 1.797)	0.5162
Interaction								0.0598
Gender								
Male	118	26 (22.0)	NR (11.8, NE)	111	16 (14.4)	NR (NE, NE)	1.398 (0.747, 2.617)	0.2895
Female	21	2 (9.5)	NR (NE, NE)	27	2 (7.4)	NR (NE, NE)	1.256 (0.176, 8.951)	0.8194
Interaction								0.8488

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Dry Mouth

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	20 (19.2)	NR (NE, NE)	105	16 (15.2)	NR (4.9, NE)	1.215 (0.629, 2.348)	0.5588
Non-Smoker	35	8 (22.9)	NR (2.3, NE)	33	2 (6.1)	NR (NE, NE)	2.814 (0.592, 13.386)	0.1746
Interaction								0.2840
ICC Options								
Paclitaxel	83	19 (22.9)	NR (11.8, NE)	85	9 (10.6)	NR (NE, NE)	2.042 (0.919, 4.540)	0.0731
Docetaxel	56	9 (16.1)	NR (4.2, NE)	53	9 (17.0)	NR (2.9, NE)	0.769 (0.302, 1.960)	0.5768
Interaction								0.1281

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Dry Mouth

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	13 (30.2)	NR (3.6, NE)	42	3 (7.1)	NR (NE, NE)	3.487 (0.986, 12.329)	0.0379
1	96	15 (15.6)	NR (NE, NE)	96	15 (15.6)	NR (3.7, NE)	0.975 (0.476, 1.997)	0.9448
Interaction								0.0781
Region #1								
Asia	103	22 (21.4)	NR (11.8, NE)	105	14 (13.3)	NR (4.9, NE)	1.430 (0.728, 2.807)	0.2945
Europe/North America	36	6 (16.7)	NR (2.8, NE)	33	4 (12.1)	NR (2.9, NE)	1.306 (0.368, 4.639)	0.6772
Interaction								0.8911

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Dry Mouth

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	15 (19.2)	NR (4.2, NE)	80	10 (12.5)	NR (4.9, NE)	1.491 (0.669, 3.322)	0.3225
Japan	25	7 (28.0)	NR (11.8, NE)	25	4 (16.0)	NR (NE, NE)	1.528 (0.437, 5.345)	0.5033
Europe/North America	36	6 (16.7)	NR (2.8, NE)	33	4 (12.1)	NR (2.9, NE)	1.306 (0.368, 4.639)	0.6772
Interaction								0.9887
Race								
Asian and other	105	22 (21.0)	NR (11.8, NE)	114	15 (13.2)	NR (4.9, NE)	1.391 (0.718, 2.694)	0.3231
White	34	6 (17.6)	NR (2.8, NE)	24	3 (12.5)	NR (2.9, NE)	1.458 (0.364, 5.839)	0.5911
Interaction								0.9436

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Dry Mouth

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	3 (6.7)	NR (NE, NE)	34	4 (11.8)	NR (3.4, NE)	0.461 (0.102, 2.079)	0.3023
vCPS < 10%	53	12 (22.6)	NR (4.2, NE)	56	8 (14.3)	NR (NE, NE)	1.454 (0.594, 3.558)	0.4068
Missing	41	13 (31.7)	11.8 (1.4, NE)	48	6 (12.5)	NR (NE, NE)	2.541 (0.952, 6.781)	0.0517
Interaction								0.1689

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble With Taste

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	14 (18.4)	NR (NE, NE)	76	8 (10.5)	NR (NE, NE)	1.639 (0.687, 3.911)	0.2580
>= 65 Years	63	9 (14.3)	NR (NE, NE)	62	7 (11.3)	NR (NE, NE)	1.139 (0.423, 3.067)	0.7961
Interaction								0.6367
Gender								
Male	118	20 (16.9)	NR (NE, NE)	111	11 (9.9)	NR (NE, NE)	1.614 (0.773, 3.371)	0.1968
Female	21	3 (14.3)	NR (1.4, NE)	27	4 (14.8)	NR (1.8, NE)	0.846 (0.187, 3.825)	0.8259
Interaction								0.4374

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble With Taste

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	17 (16.3)	NR (NE, NE)	105	14 (13.3)	NR (NE, NE)	1.142 (0.562, 2.322)	0.7122
Non-Smoker	35	6 (17.1)	NR (2.2, NE)	33	1 (3.0)	NR (NE, NE)	4.570 (0.550, 37.970)	0.1221
Interaction								0.2166
ICC Options								
Paclitaxel	83	13 (15.7)	NR (NE, NE)	85	7 (8.2)	NR (NE, NE)	1.780 (0.709, 4.465)	0.2122
Docetaxel	56	10 (17.9)	NR (NE, NE)	53	8 (15.1)	NR (2.9, NE)	1.052 (0.413, 2.681)	0.9142
Interaction								0.4199

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble With Taste

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	6 (14.0)	NR (NE, NE)	42	6 (14.3)	NR (NE, NE)	0.750 (0.241, 2.340)	0.6189
1	96	17 (17.7)	NR (NE, NE)	96	9 (9.4)	NR (NE, NE)	1.864 (0.830, 4.185)	0.1234
Interaction								0.2283
Region #1								
Asia	103	16 (15.5)	NR (NE, NE)	105	11 (10.5)	NR (NE, NE)	1.357 (0.629, 2.927)	0.4330
Europe/North America	36	7 (19.4)	NR (2.2, NE)	33	4 (12.1)	NR (2.9, NE)	1.574 (0.460, 5.382)	0.4654
Interaction								0.7785

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble With Taste

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	14 (17.9)	NR (NE, NE)	80	5 (6.3)	NR (NE, NE)	2.790 (1.005, 7.747)	0.0392
Japan	25	2 (8.0)	NR (NE, NE)	25	6 (24.0)	NR (2.2, NE)	0.259 (0.052, 1.298)	0.0770
Europe/North America	36	7 (19.4)	NR (2.2, NE)	33	4 (12.1)	NR (2.9, NE)	1.574 (0.460, 5.382)	0.4654
Interaction								0.0475
Race								
Asian and other	105	16 (15.2)	NR (NE, NE)	114	13 (11.4)	NR (NE, NE)	1.193 (0.573, 2.484)	0.6345
White	34	7 (20.6)	NR (2.2, NE)	24	2 (8.3)	NR (2.9, NE)	2.819 (0.585, 13.579)	0.1768
Interaction								0.3131

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble With Taste

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	4 (8.9)	NR (NE, NE)	34	2 (5.9)	NR (NE, NE)	1.465 (0.268, 8.016)	0.6560
vCPS < 10%	53	10 (18.9)	NR (NE, NE)	56	7 (12.5)	NR (NE, NE)	1.443 (0.549, 3.791)	0.4537
Missing	41	9 (22.0)	NR (2.2, NE)	48	6 (12.5)	NR (NE, NE)	1.712 (0.608, 4.820)	0.2999
Interaction								0.9659

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble With Coughing

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	16 (21.1)	NR (NE, NE)	76	11 (14.5)	NR (4.5, NE)	1.417 (0.657, 3.055)	0.3680
>= 65 Years	63	10 (15.9)	NR (NE, NE)	62	7 (11.3)	NR (4.9, NE)	1.186 (0.449, 3.132)	0.7298
Interaction								0.8336
Gender								
Male	118	22 (18.6)	NR (NE, NE)	111	16 (14.4)	NR (4.9, NE)	1.216 (0.639, 2.316)	0.5491
Female	21	4 (19.0)	NR (1.1, NE)	27	2 (7.4)	NR (NE, NE)	2.794 (0.512, 15.262)	0.2153
Interaction								0.5054

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble With Coughing

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	23 (22.1)	NR (NE, NE)	105	16 (15.2)	NR (4.9, NE)	1.464 (0.773, 2.772)	0.2368
Non-Smoker	35	3 (8.6)	NR (NE, NE)	33	2 (6.1)	NR (3.5, NE)	0.945 (0.157, 5.686)	0.9514
Interaction								0.6879
ICC Options								
Paclitaxel	83	12 (14.5)	NR (NE, NE)	85	13 (15.3)	NR (4.9, NE)	0.830 (0.378, 1.822)	0.6422
Docetaxel	56	14 (25.0)	NR (2.8, NE)	53	5 (9.4)	NR (3.5, NE)	2.704 (0.973, 7.516)	0.0460
Interaction								0.0751

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble With Coughing

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	11 (25.6)	NR (NE, NE)	42	4 (9.5)	NR (NE, NE)	2.416 (0.768, 7.601)	0.1179
1	96	15 (15.6)	NR (NE, NE)	96	14 (14.6)	NR (4.9, NE)	1.009 (0.486, 2.095)	0.9800
Interaction								0.2314
Region #1								
Asia	103	21 (20.4)	NR (NE, NE)	105	14 (13.3)	NR (4.9, NE)	1.412 (0.718, 2.779)	0.3130
Europe/North America	36	5 (13.9)	NR (NE, NE)	33	4 (12.1)	NR (2.9, NE)	1.071 (0.286, 4.007)	0.9191
Interaction								0.6621

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble With Coughing

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	16 (20.5)	NR (NE, NE)	80	9 (11.3)	NR (4.5, NE)	1.801 (0.796, 4.076)	0.1499
Japan	25	5 (20.0)	NR (NE, NE)	25	5 (20.0)	NR (4.9, NE)	0.842 (0.241, 2.938)	0.7861
Europe/North America	36	5 (13.9)	NR (NE, NE)	33	4 (12.1)	NR (2.9, NE)	1.071 (0.286, 4.007)	0.9191
Interaction								0.5499
Race								
Asian and other	105	22 (21.0)	NR (NE, NE)	114	14 (12.3)	NR (4.9, NE)	1.547 (0.791, 3.025)	0.1970
White	34	4 (11.8)	NR (NE, NE)	24	4 (16.7)	NR (2.9, NE)	0.699 (0.174, 2.808)	0.6118
Interaction								0.2916

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble With Coughing

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	6 (13.3)	NR (NE, NE)	34	2 (5.9)	NR (NE, NE)	2.357 (0.475, 11.694)	0.2785
vCPS < 10%	53	12 (22.6)	NR (NE, NE)	56	8 (14.3)	NR (4.5, NE)	1.482 (0.605, 3.628)	0.3855
Missing	41	8 (19.5)	NR (2.8, NE)	48	8 (16.7)	NR (3.5, NE)	1.133 (0.425, 3.022)	0.8024
Interaction								0.7912

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble Talking

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	11 (14.5)	NR (7.0, NE)	76	3 (3.9)	NR (NE, NE)	3.354 (0.934, 12.045)	0.0487
>= 65 Years	63	6 (9.5)	NR (NE, NE)	62	3 (4.8)	NR (NE, NE)	1.764 (0.440, 7.066)	0.4162
Interaction								0.4725
Gender								
Male	118	16 (13.6)	NR (NE, NE)	111	5 (4.5)	NR (NE, NE)	2.763 (1.010, 7.559)	0.0388
Female	21	1 (4.8)	NR (NE, NE)	27	1 (3.7)	NR (NE, NE)	1.243 (0.078, 19.934)	0.8776
Interaction								0.5289

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble Talking

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	13 (12.5)	NR (NE, NE)	105	5 (4.8)	NR (NE, NE)	2.440 (0.867, 6.867)	0.0805
Non-Smoker	35	4 (11.4)	NR (NE, NE)	33	1 (3.0)	NR (3.5, NE)	2.956 (0.330, 26.497)	0.3074
Interaction								0.8602
ICC Options								
Paclitaxel	83	12 (14.5)	NR (NE, NE)	85	3 (3.5)	NR (NE, NE)	3.754 (1.057, 13.330)	0.0277
Docetaxel	56	5 (8.9)	NR (NE, NE)	53	3 (5.7)	NR (3.5, NE)	1.307 (0.309, 5.532)	0.7149
Interaction								0.2975

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble Talking

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	5 (11.6)	NR (NE, NE)	42	1 (2.4)	NR (NE, NE)	3.708 (0.430, 31.997)	0.2017
1	96	12 (12.5)	NR (NE, NE)	96	5 (5.2)	NR (NE, NE)	2.337 (0.823, 6.638)	0.0999
Interaction								0.6602
Region #1								
Asia	103	13 (12.6)	NR (NE, NE)	105	4 (3.8)	NR (NE, NE)	2.876 (0.934, 8.852)	0.0539
Europe/North America	36	4 (11.1)	NR (NE, NE)	33	2 (6.1)	NR (2.9, NE)	1.790 (0.327, 9.807)	0.4960
Interaction								0.6309

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble Talking

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	10 (12.8)	NR (NE, NE)	80	3 (3.8)	NR (NE, NE)	3.336 (0.918, 12.127)	0.0518
Japan	25	3 (12.0)	NR (7.0, NE)	25	1 (4.0)	NR (NE, NE)	1.964 (0.191, 20.233)	0.5642
Europe/North America	36	4 (11.1)	NR (NE, NE)	33	2 (6.1)	NR (2.9, NE)	1.790 (0.327, 9.807)	0.4960
Interaction								0.8499
Race								
Asian and other	105	13 (12.4)	NR (NE, NE)	114	4 (3.5)	NR (NE, NE)	2.989 (0.971, 9.201)	0.0450
White	34	4 (11.8)	NR (NE, NE)	24	2 (8.3)	NR (2.9, NE)	1.538 (0.281, 8.422)	0.6169
Interaction								0.5057

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.2.6.3.1.2.b.s:
Analyses of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble Talking

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	5 (11.1)	NR (NE, NE)	34	0 (0.0)	NR (NE, NE)	22692498.351 (0.000, NE)	0.0537
vCPS < 10%	53	9 (17.0)	NR (NE, NE)	56	2 (3.6)	NR (NE, NE)	4.593 (0.992, 21.259)	0.0318
Missing	41	3 (7.3)	NR (7.0, NE)	48	4 (8.3)	NR (3.5, NE)	0.664 (0.145, 3.037)	0.5952
Interaction								0.2652

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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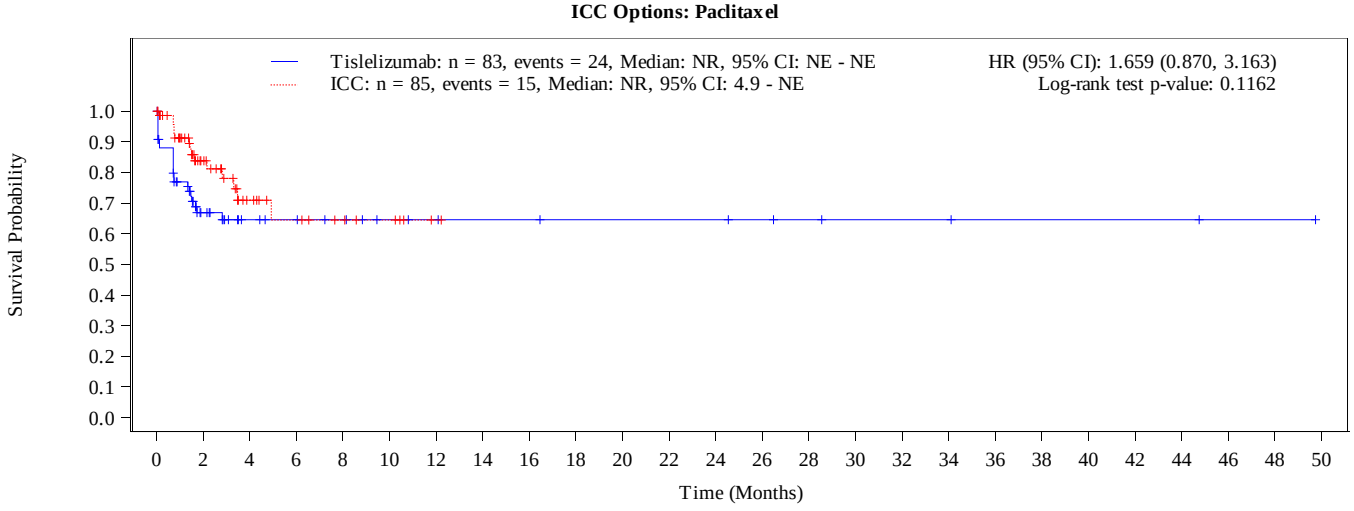
Figure 14.2.7.2.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Pain



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	83	32	16	14	12	9	8	7	7	6	6	6	6	5	4	3	3	3	2	2	2	2	2	1	1	0
ICC	85	34	15	10	7	5	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
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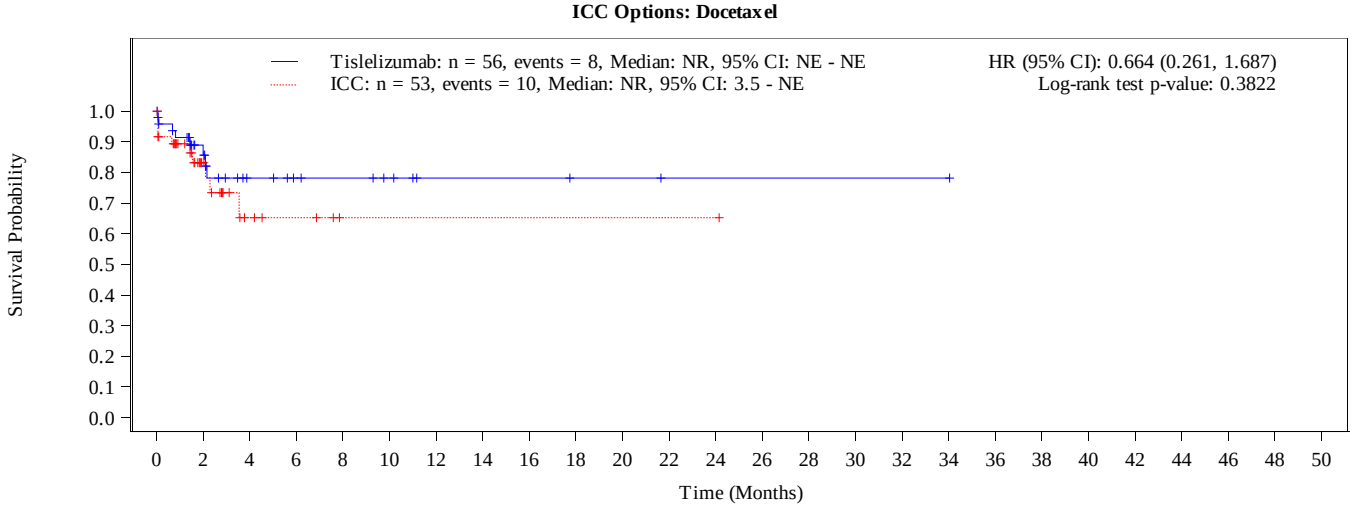
Figure 14.2.7.2.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Pain



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	56	27	12	9	8	6	3	3	3	2	2	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0
ICC	53	18	6	4	1	1	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
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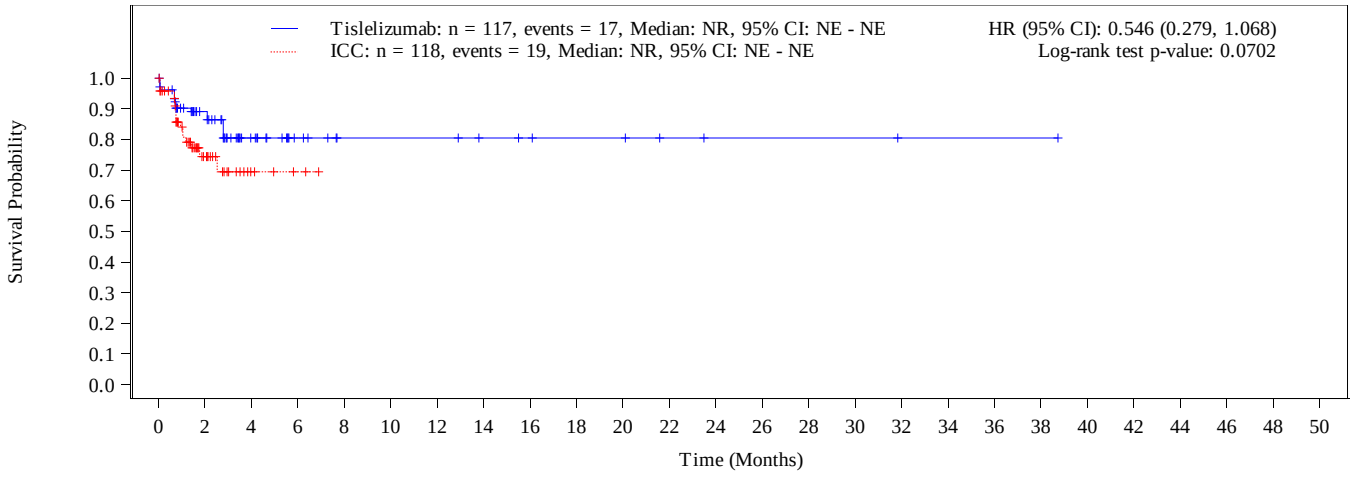
Figure 14.2.7.2.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Pain

ICC Options: Irinotecan



Number of Patients at Risk:

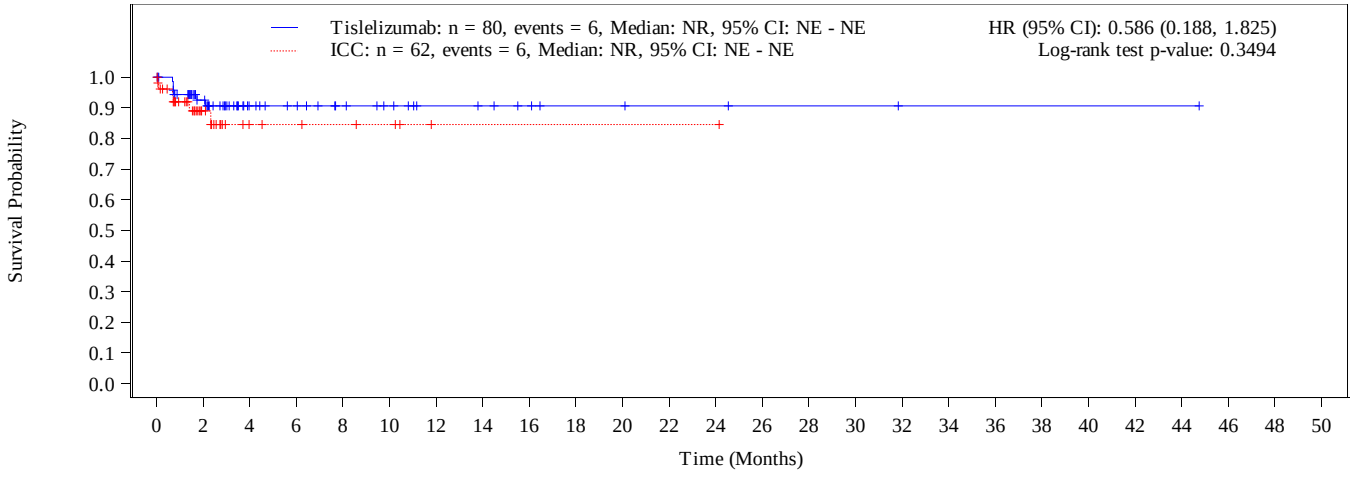
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	117	67	26	15	9	9	9	7	6	5	5	3	2	2	2	2	1	1	1	1	0	0	0	0	0	0
ICC	118	24	5	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 05JUN2024 20:06 f-14-02-07-02-02-s-km-tteqs-subgrp-o18-itt-cl.rtf

Figure 14.2.7.2.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Choked When Swallowing

Baseline PD-L1 Status: vCPS >= 10%



Number of Patients at Risk:

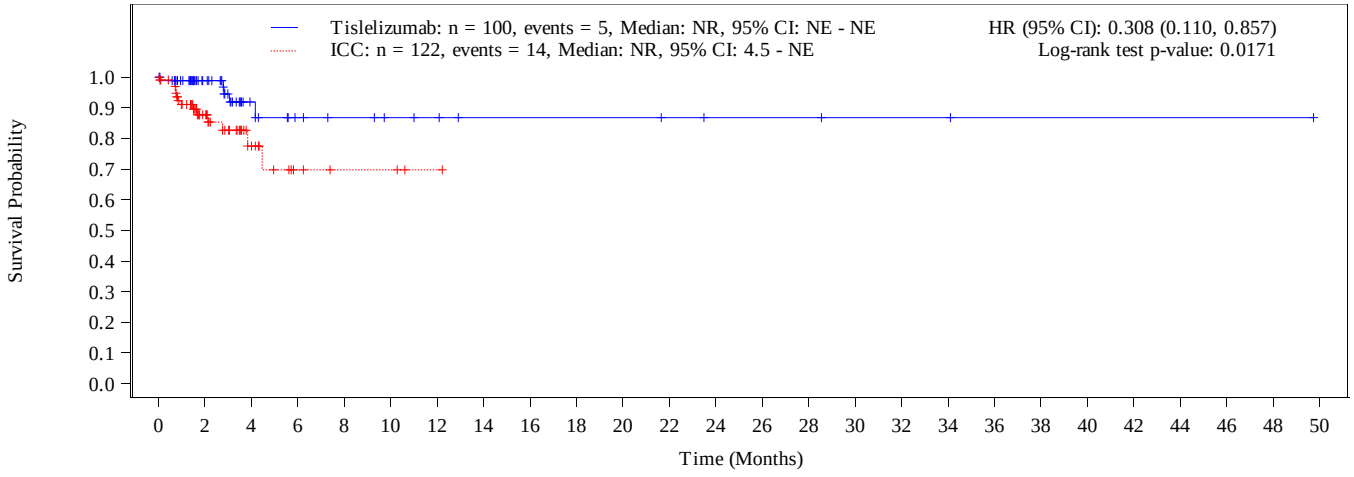
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	80	50	26	22	16	13	9	8	6	4	4	3	3	2	2	2	1	1	1	1	1	1	1	0	0	0
ICC	62	21	7	6	5	4	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 05JUN2024 20:06 f-14-02-07-02-02-s-km-tteqs-subgrp-o18-itt-cl.rtf

Figure 14.2.7.2.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Choked When Swallowing

Baseline PD-L1 Status: vCPS < 10%



Number of Patients at Risk:

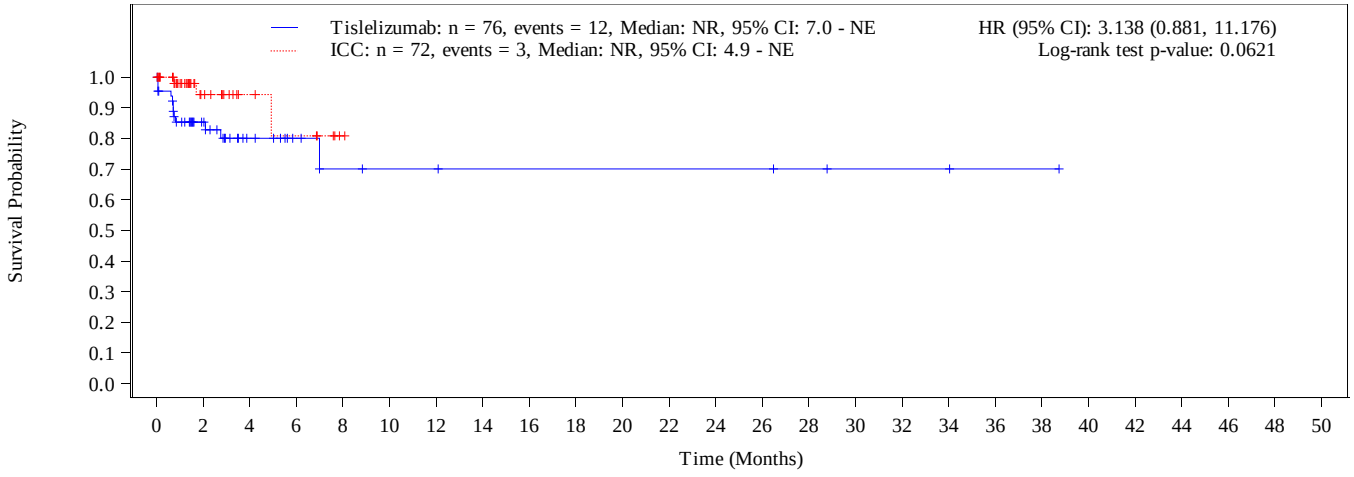
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	100	55	18	12	10	8	7	5	5	5	5	4	3	3	3	2	2	2	1	1	1	1	1	1	1	0
ICC	122	41	14	5	3	3	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 05JUN2024 20:06 f-14-02-07-02-02-s-km-tteqs-subgrp-o18-itt-cl.rtf

Figure 14.2.7.2.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Choked When Swallowing

Baseline PD-L1 Status: Missing



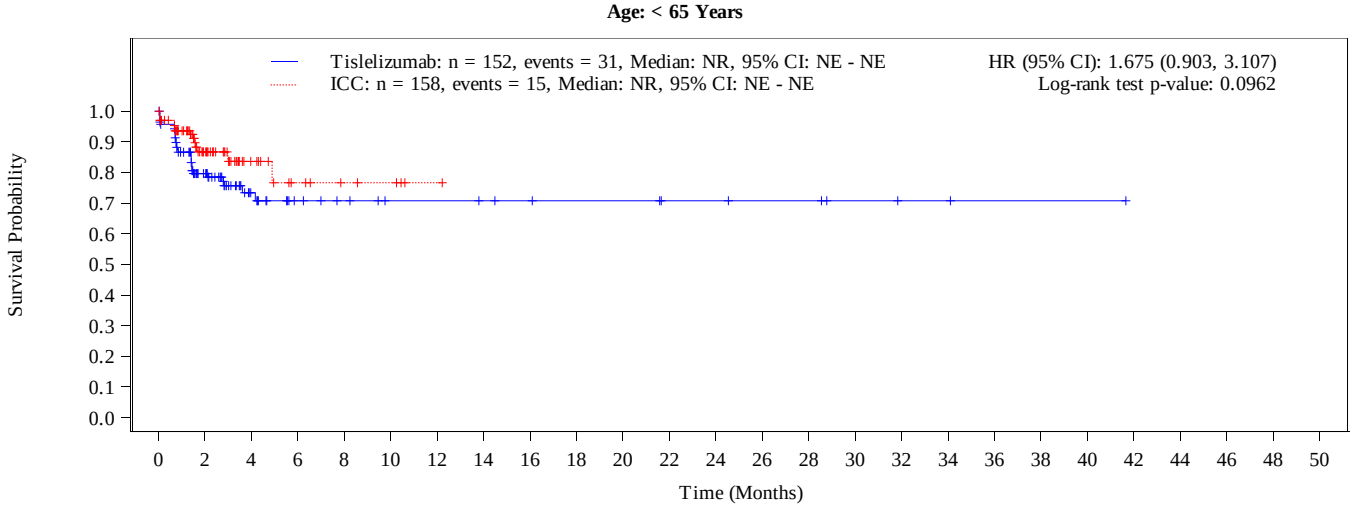
Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	76	35	15	9	6	5	5	4	4	4	4	4	4	4	3	2	2	2	1	1	0	0	0	0	0	0
ICC	72	20	8	6	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 05JUN2024 20:06 f-14-02-07-02-02-s-km-tteqs-subgrp-o18-itt-cl.rtf

Figure 14.2.7.2.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Dry Mouth



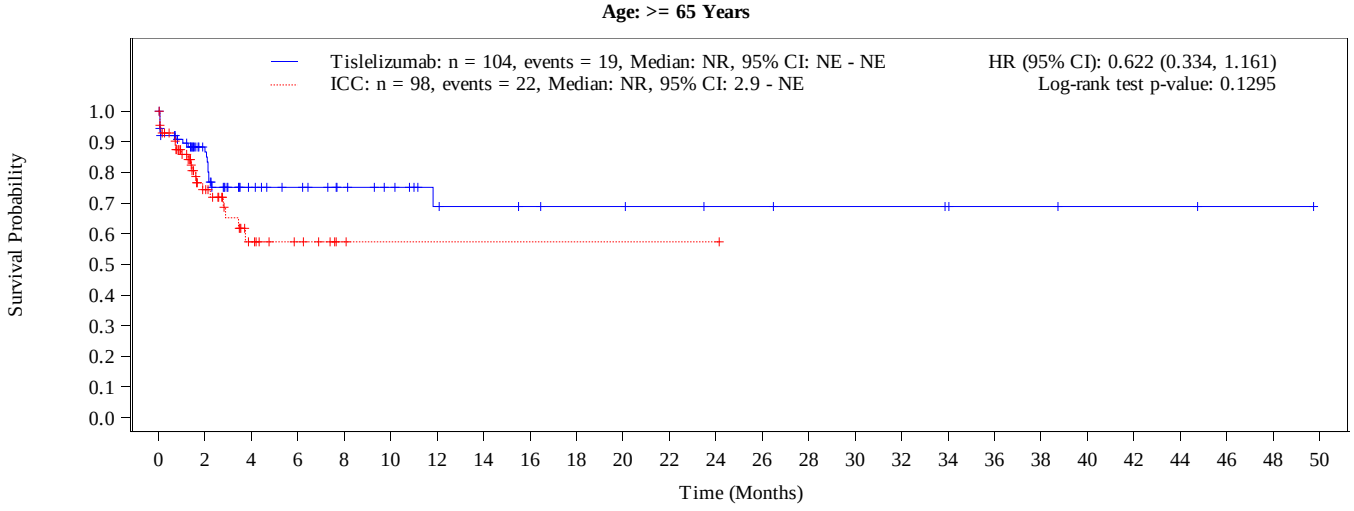
Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	152	72	28	17	14	11	11	10	9	8	8	6	6	5	5	3	2	2	1	1	1	0	0	0	0	0
ICC	158	43	16	8	5	4	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 05JUN2024 20:06 f-14-02-07-02-02-s-km-tteqs-subgrp-o18-itt-cl.rtf

Figure 14.2.7.2.2.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set

Outcome: Dry Mouth

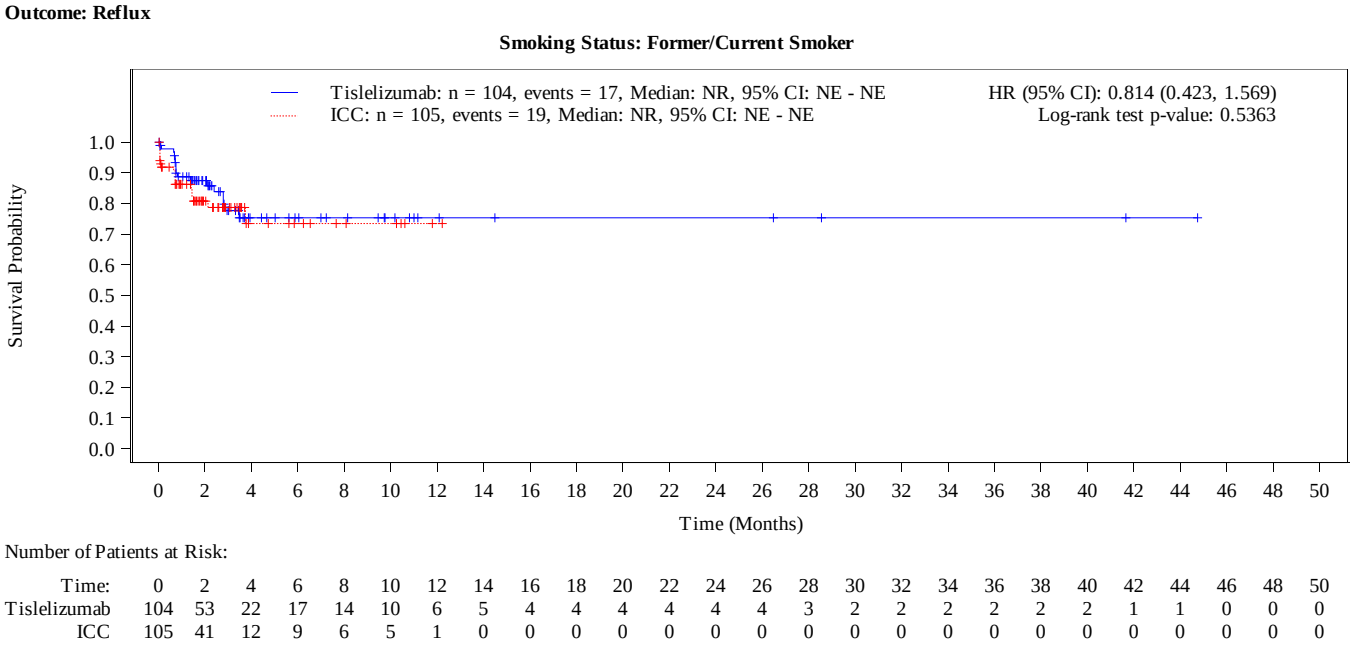


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	104	54	28	24	19	16	11	10	9	8	8	7	6	6	5	5	5	4	3	3	2	2	2	1	1	0
ICC	98	32	12	7	2	1	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

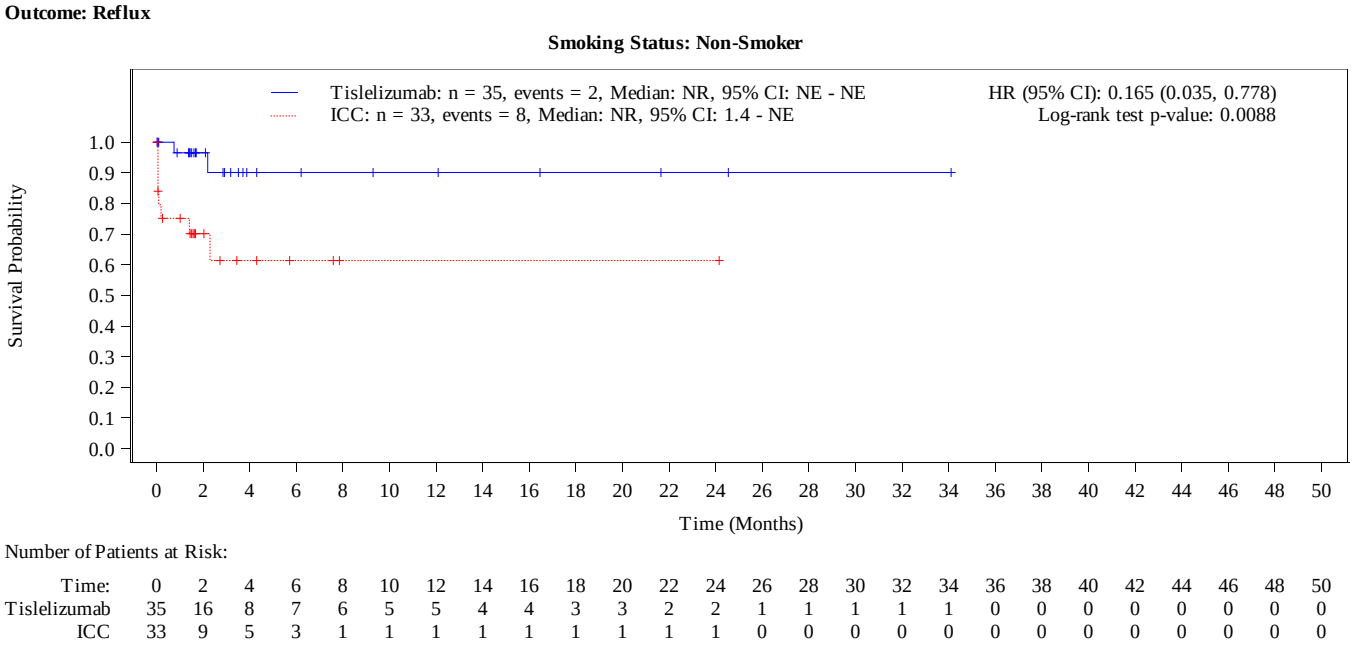
Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 05JUN2024 20:06 f-14-02-07-02-02-s-km-tteqs-subgrp-o18-itt-cl.rtf

Figure 14.2.7.2.2.b.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 05JUN2024 20:06 f-14-02-07-02-02-b-s-km-tteqs-subgrp-o18-itts-cl.rtf

Figure 14.2.7.2.2.b.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

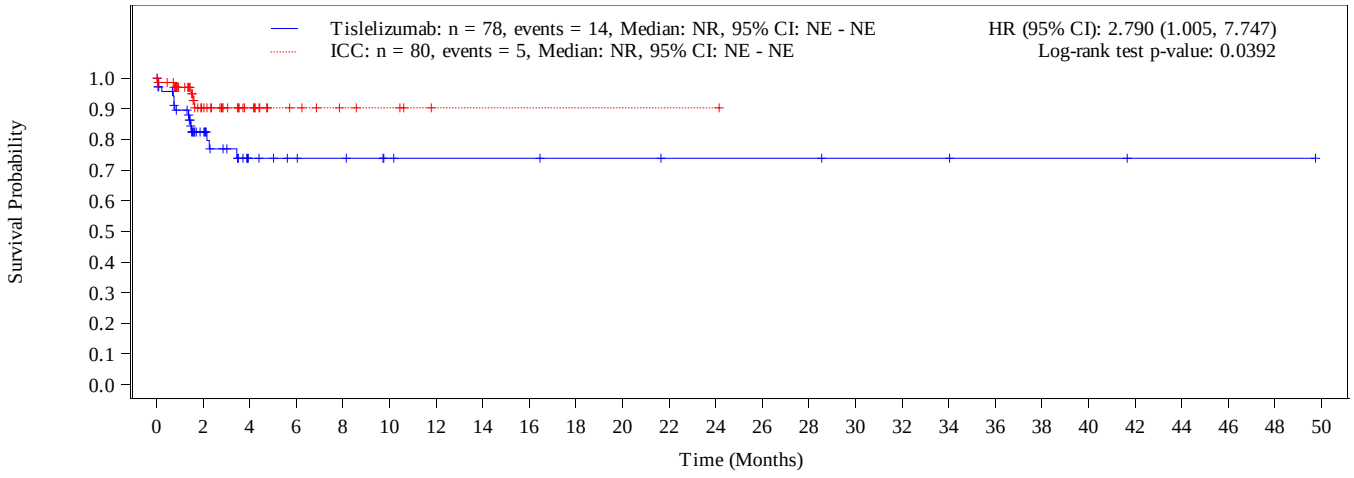
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	35	16	8	7	6	5	5	4	4	3	3	2	2	1	1	1	1	1	0	0	0	0	0	0	0	0
ICC	33	9	5	3	1	1	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 05JUN2024 20:06 f-14-02-07-02-02-b-s-km-tteqs-subgrp-o18-itts-cl.rtf

Figure 14.2.7.2.2.b.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble With Taste

Region #2: Asia (excluding Japan)



Number of Patients at Risk:

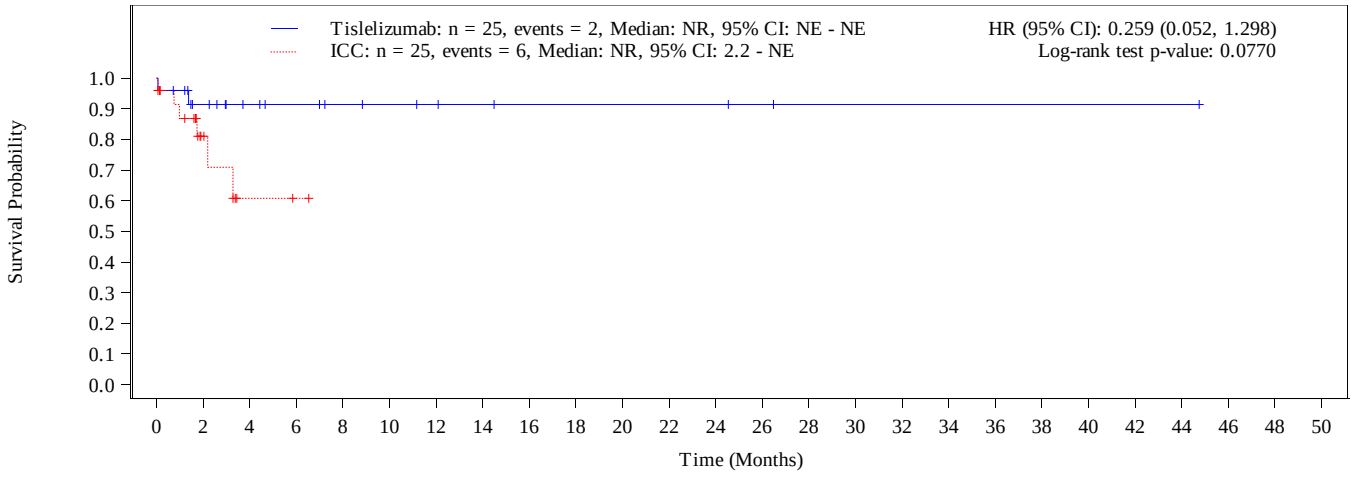
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	78	34	14	11	10	7	6	6	6	5	5	4	4	4	4	3	3	3	2	2	2	1	1	1	1	0
ICC	80	32	16	8	5	4	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 05JUN2024 20:06 f-14-02-07-02-02-b-s-km-tteqs-subgrp-o18-itts-cl.rtf

Figure 14.2.7.2.2.b.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble With Taste

Region #2: Japan



Number of Patients at Risk:

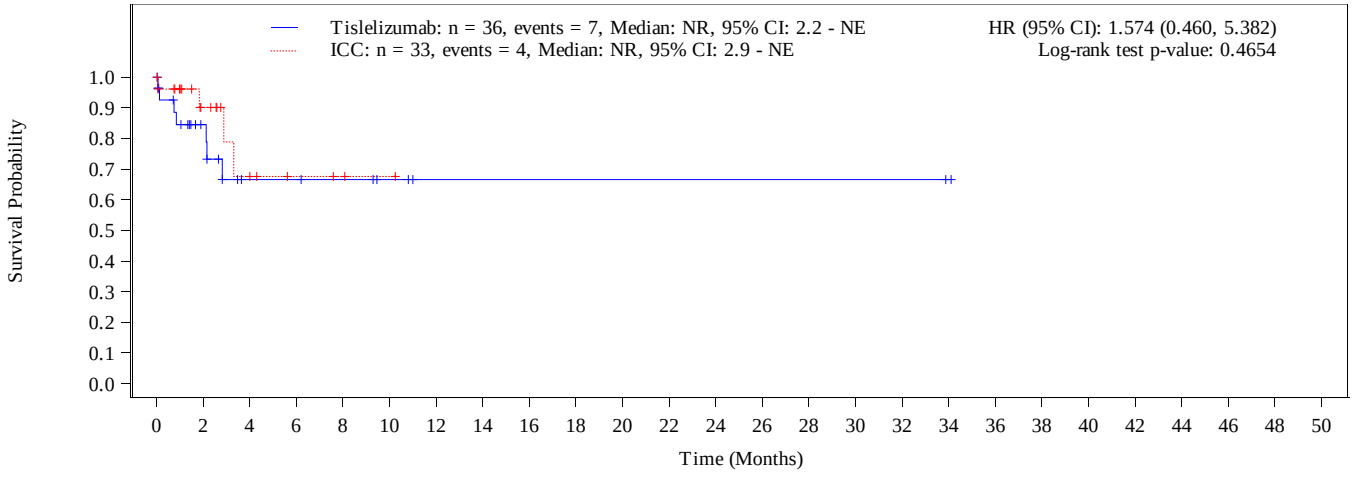
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	25	17	12	10	8	7	6	4	3	3	3	3	3	2	1	1	1	1	1	1	1	1	1	0	0	0
ICC	25	9	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 05JUN2024 20:06 f-14-02-07-02-02-b-s-km-tteqs-subgrp-o18-itts-cl.rtf

Figure 14.2.7.2.2.b.s:
Kaplan-Meier Plot of Time to Deterioration of EORTC QLQ-OES18 - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: Trouble With Taste

Region #2: Europe/North America



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	36	15	7	7	6	4	2	2	2	2	2	2	2	2	2	2	2	1	0	0	0	0	0	0	0	0
ICC	33	13	6	3	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EORTC QLQ-OES18 is defined as the >= 10 points of change from baseline derived score in the worsen direction.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 05JUN2024 20:06 f-14-02-07-02-02-b-s-km-tteqs-subgrp-o18-itts-cl.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: EQ-5D-5L VAS Score

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	242		247	
	Mean (SD)	73.7 (17.05)		72.5 (18.13)	
	Median	80.0		75.0	
	Min, Max	10, 100		10, 100	
Cycle 1	n	140	133	134	130
	Mean (SD)	73.4 (17.90)	0.1 (11.59)	72.9 (17.68)	-0.3 (10.87)
	Median	79.0	0.0	75.0	0.0
	Min, Max	10, 100	-43, 35	10, 100	-30, 42
Cycle 2	n	223	212	173	169
	Mean (SD)	74.0 (18.22)	-1.2 (14.73)	70.3 (18.67)	-2.1 (14.76)
	Median	80.0	0.0	75.0	0.0
	Min, Max	5, 100	-65, 45	10, 100	-65, 49
Cycle 3	n	180	171	90	87
	Mean (SD)	74.5 (17.53)	-1.6 (13.26)	70.9 (18.15)	-1.9 (14.25)
	Median	80.0	0.0	75.0	0.0
	Min, Max	1, 100	-69, 31	0, 100	-49, 30

Source: Listing 16.2.6.6.3. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-05-01-qs-chg-eq5d-itt-cl.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: EQ-5D-5L VAS Score

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	147	139	77	74
	Mean (SD)	77.5 (14.77)	-0.2 (10.91)	70.8 (17.01)	-1.8 (14.17)
	Median	80.0	0.0	76.0	0.0
	Min, Max	19, 100	-28, 30	25, 100	-50, 25
Cycle 5	n	109	104	45	42
	Mean (SD)	78.7 (14.64)	0.3 (13.40)	73.3 (15.53)	-4.2 (17.64)
	Median	81.0	0.0	76.0	-0.5
	Min, Max	40, 100	-44, 34	39, 100	-50, 45
Cycle 6	n	99	94	36	33
	Mean (SD)	78.5 (16.03)	-0.6 (14.81)	73.8 (16.32)	-5.9 (16.34)
	Median	80.0	0.0	80.0	-3.0
	Min, Max	18, 100	-72, 34	40, 100	-50, 20
End of Treatment	n	78	76	83	81
	Mean (SD)	62.9 (21.99)	-10.2 (17.48)	63.8 (19.90)	-9.8 (15.68)
	Median	68.5	-7.0	62.0	-10.0
	Min, Max	10, 100	-60, 28	3, 100	-50, 31

Source: Listing 16.2.6.6.3. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-05-01-qs-chg-eq5d-itt-cl.rtf

Table 14.2.6.5.1:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set

Parameter: EQ-5D-5L VAS Score

		Tislelizumab (N = 256)		ICC (N = 256)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	117	113	97	95
	Mean (SD)	66.6 (21.70)	-8.8 (18.82)	65.8 (21.15)	-8.3 (16.64)
	Median	70.0	-6.0	70.0	-10.0
	Min, Max	1, 100	-69, 36	0, 100	-59, 30
Worst Post-Baseline Value	n	245	231	228	221
	Mean (SD)	62.3 (21.45)	-11.9 (16.62)	61.5 (20.35)	-10.8 (16.47)
	Median	67.0	-10.0	64.5	-10.0
	Min, Max	1, 100	-72, 28	0, 100	-65, 32

Source: Listing 16.2.6.6.3. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-05-01-qs-chg-eq5d-itt-cl.rtf

Table 14.2.6.5.1.b:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: EQ-5D-5L VAS Score

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Baseline	n	128		134	
	Mean (SD)	72.3 (17.25)		72.0 (18.80)	
	Median	76.5		75.0	
	Min, Max	10, 100		10, 100	
Cycle 1	n	83	78	83	82
	Mean (SD)	72.3 (19.36)	0.3 (12.13)	71.5 (18.96)	-0.7 (11.18)
	Median	75.0	0.0	75.0	0.0
	Min, Max	10, 100	-43, 35	10, 100	-30, 32
Cycle 2	n	124	114	96	95
	Mean (SD)	72.6 (18.85)	-1.1 (16.70)	69.2 (20.14)	-2.9 (15.29)
	Median	80.0	0.0	75.0	0.0
	Min, Max	5, 100	-65, 45	10, 100	-65, 30
Cycle 3	n	98	89	57	56
	Mean (SD)	71.9 (19.34)	-2.0 (15.22)	68.4 (19.48)	-4.1 (15.28)
	Median	76.5	0.0	70.0	-5.0
	Min, Max	1, 100	-69, 30	0, 100	-49, 30

Source: Listing 16.2.6.6.3. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-05-01-b-qs-chg-eq5d-itts-cl.rtf

Table 14.2.6.5.1.b:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: EQ-5D-5L VAS Score

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Cycle 4	n	77	69	52	51
	Mean (SD)	75.6 (16.27)	0.6 (11.85)	68.4 (18.00)	-3.9 (15.45)
	Median	80.0	0.0	71.5	0.0
	Min, Max	19, 100	-28, 29	25, 100	-50, 25
Cycle 5	n	57	52	32	31
	Mean (SD)	75.9 (15.56)	-0.7 (15.52)	71.1 (16.41)	-4.5 (19.59)
	Median	80.0	0.0	74.0	0.0
	Min, Max	40, 100	-44, 34	39, 100	-50, 45
Cycle 6	n	55	50	25	24
	Mean (SD)	76.9 (18.49)	-0.9 (18.22)	72.9 (17.83)	-6.9 (18.83)
	Median	83.0	0.5	80.0	-2.5
	Min, Max	18, 100	-72, 34	40, 100	-50, 20
End of Treatment	n	42	40	46	45
	Mean (SD)	60.9 (22.04)	-11.1 (19.20)	63.1 (20.70)	-10.4 (16.44)
	Median	64.0	-10.0	62.0	-9.0
	Min, Max	20, 97	-60, 28	3, 100	-50, 31

Source: Listing 16.2.6.6.3. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-05-01-b-qs-chg-eq5d-itts-cl.rtf

Table 14.2.6.5.1.b:
Summary of EQ-5D-VAS Score by Visit: Observed and Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

Parameter: EQ-5D-5L VAS Score

		Tislelizumab (N = 139)		ICC (N = 138)	
Visit		**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
Safety Follow-Up	n	71	67	62	61
	Mean (SD)	62.5 (22.61)	-9.7 (21.65)	65.0 (22.28)	-8.9 (16.97)
	Median	69.0	-6.0	70.0	-10.0
	Min, Max	1, 100	-69, 36	0, 100	-59, 25
Worst Post-Baseline Value	n	136	125	129	126
	Mean (SD)	59.0 (21.83)	-13.9 (18.24)	59.4 (21.89)	-12.4 (17.75)
	Median	60.5	-10.0	60.0	-10.0
	Min, Max	1, 100	-72, 28	0, 100	-65, 32

Source: Listing 16.2.6.6.3. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Only patients with data at both baseline and each post-baseline visit are included in the summary statistics for change from baseline.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-qs-chg.sas 05JUN2024 17:44 t-14-02-06-05-01-b-qs-chg-eq5d-itts-cl.rtf

Table 14.2.6.5.1.1:
EQ-5D VAS: MMRM on Change from Baseline
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)					
	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
EQ-5D VAS									
Cycle 4	139		-0.15 (0.97)	74		-2.88 (1.25)	2.73 (-0.28, 5.75)	0.24 (-0.02, 0.50)	0.0755
Cycle 6	94		-1.86 (1.31)	33		-6.31 (1.95)	4.46 (-0.09, 9.01)	0.31 (-0.01, 0.63)	0.0549
Overall Treatment Effect	228	73.73 (17.05)	-0.70 (0.81)	208	72.50 (18.13)	-3.33 (0.97)	2.63 (0.29, 4.97)	0.26 (0.03, 0.49)	0.0278

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.

Only patients with baseline and postbaseline value are included in analysis.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Positive changes are favorable.

[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Positive changes are favorable.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-05-01-01-eff-mmrmqs-eq5-itt-cl.rtf

Table 14.2.6.5.1.1.b:
EQ-5D VAS: MMRM on Change from Baseline
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)					
	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Total No. of Patients	Mean at Baseline (SD) [a]	Mean Change from Baseline (SE) [b]	Difference in Mean Change from Baseline (95% CI) [c]	Hedges'g (95% CI) [d]	2-sided p-value [e]
EQ-5D VAS									
Cycle 4	69		0.04 (1.48)	51		-5.05 (1.70)	5.09 (0.73, 9.44)	0.38 (0.05, 0.71)	0.0225
Cycle 6	50		-2.26 (2.11)	24		-8.57 (2.75)	6.31 (-0.50, 13.13)	0.35 (-0.03, 0.74)	0.0691
Overall Treatment Effect	123	72.27 (17.25)	-0.81 (1.24)	120	71.99 (18.80)	-4.76 (1.39)	3.96 (0.39, 7.52)	0.33 (0.03, 0.63)	0.0298

Source: ADSL, ADQS. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

Only patients with baseline and postbaseline value are included in analysis.

The mixed effect model with repeated measures uses the post-baseline score as the response variable, and treatment, visit, treatment-by-visit interaction, baseline score, baseline ECOG status and ICC options as covariates, and an unstructured covariance structure for repeated measures on patient level.

[a] Sample mean and SD at baseline based on the patients with baseline value.

[b] Modelled mean change from baseline for treatment arm. Positive changes are favorable.

[c] Modelled mean change from baseline of tislelizumab arm minus that of ICC arm. Positive changes are favorable.

[d] Hedges'g was calculated as estimated difference in mean changes divided by modelled standard deviation multiplied by a correction factor.

[e] P-value was calculated based on testing whether treatment effect is zero or not.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-mmrmqs.sas 05JUN2024 19:58 t-14-02-06-05-01-01-b-eff-mmrmqs-eq5-itts-cl.rtf

Table 14.2.6.5.1.2:
Analyses of Time to Deterioration of EQ-5D-VAS
ITT Analysis Set

	Tislelizumab (N = 256)			ICC (N = 256)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
EQ-5D VAS Score	256	31 (12.1)	NR (NE, NE)	256	27 (10.5)	NR (NE, NE)	0.917 (0.544, 1.546)	0.7459

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-tte-qlq.sas 05JUN2024 19:37 t-14-02-06-05-01-02-eff-tte-qlq-eq5-itt-cl.rtf

Table 14.2.6.5.1.2.b:
Analysis of Time to Deterioration of EQ-5D-VAS
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 138)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
EQ-5D VAS Score	139	17 (12.2)	NR (NE, NE)	138	20 (14.5)	NR (NE, NE)	0.761 (0.398, 1.458)	0.4082

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.

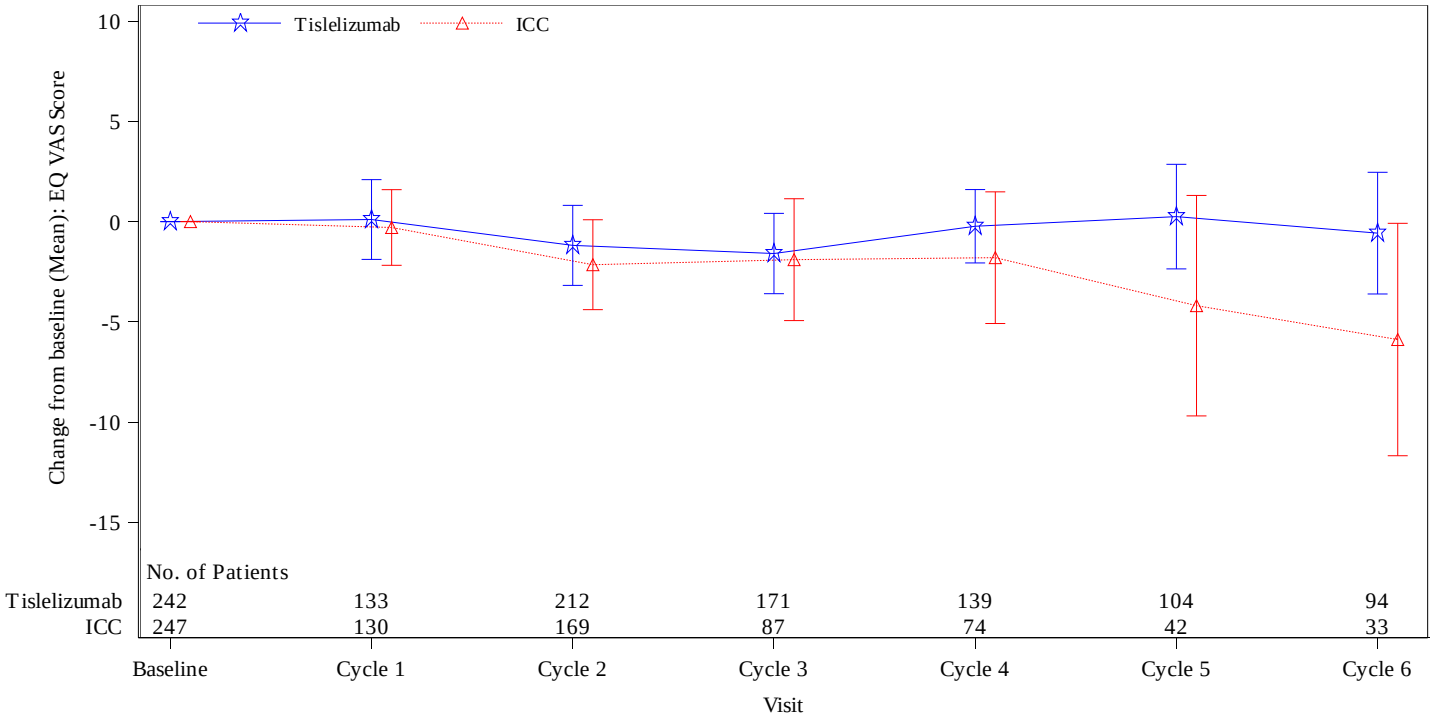
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

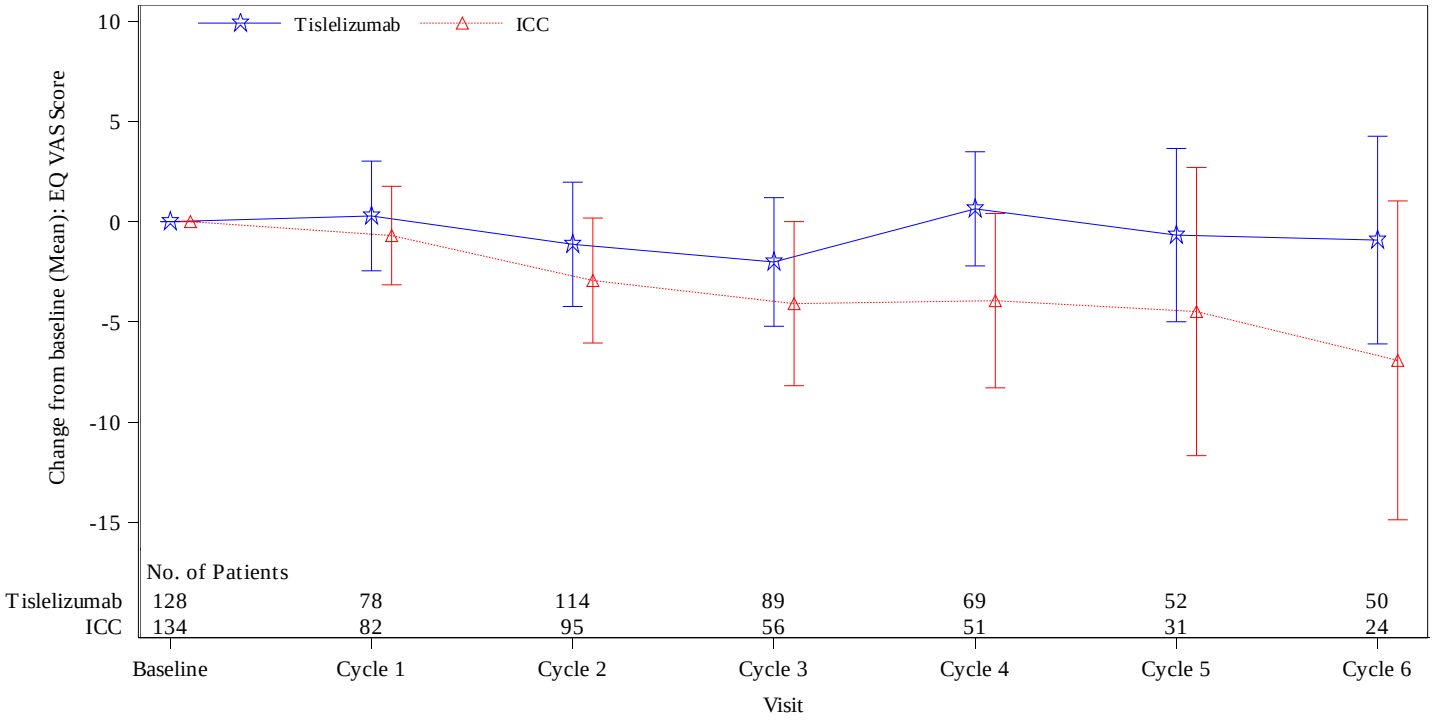
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-tte-qlq.sas 05JUN2024 19:37 t-14-02-06-05-01-02-b-eff-tte-qlq-eq5-itts-cl.rtf

Figure 14.2.7.4:
Summary of EQ-5D-VAS Scores by Visit
ITT Analysis Set



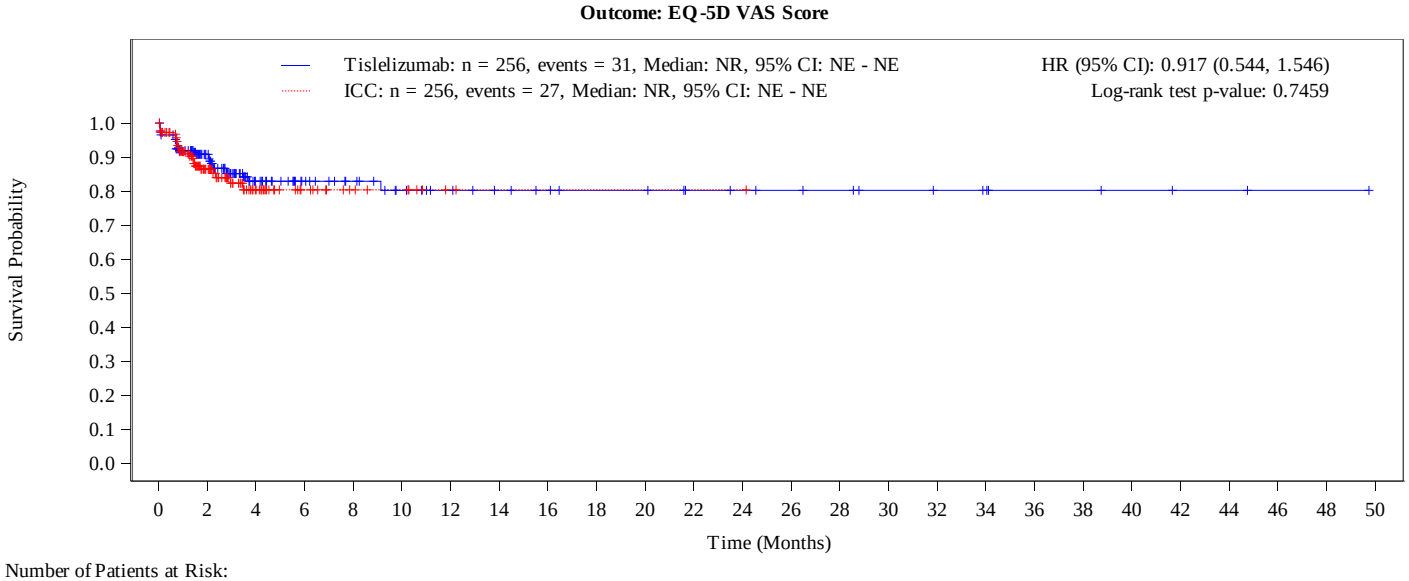
Source: Listing 16.2.6.6.3. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan.
Datapoints represent means and 95% CI.
Increases in scores are improvements.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-series.sas 05JUN2024 17:48 f-14-02-07-04-series-eq5d-itt-cl.rtf

Figure 14.2.7.4.b:
Summary of EQ-5D-VAS Scores by Visit
ITT Analysis Set - Subpopulation without Irinotecan



Source: Listing 16.2.6.6.3. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Datapoints represent means and 95% CI.
Increases in scores are improvements.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-series.sas 05JUN2024 17:48 f-14-02-07-04-b-series-eq5d-itts-cl.rtf

Figure 14.2.7.4.2:
Kaplan-Meier Plot of Time to Deterioration of EQ-5D-VAS
ITT Analysis Set

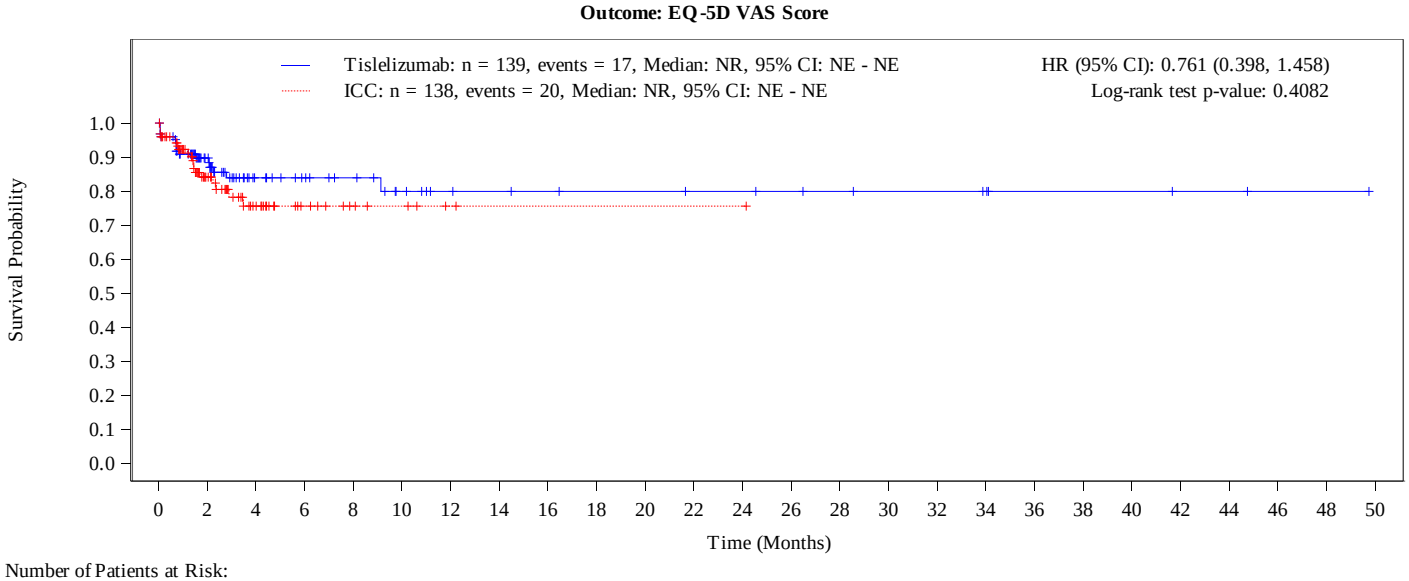


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	256	137	58	41	34	27	23	20	18	16	16	13	12	11	10	8	7	6	4	4	3	2	2	1	1	0
ICC	256	81	32	16	9	7	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-04-02-km-qs-eq5-itt-cl.rtf

Figure 14.2.7.4.2.b:
Kaplan-Meier Plot of Time to Deterioration of EQ-5D-VAS
ITT Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	67	33	27	23	17	13	12	11	10	10	9	9	8	7	6	6	5	3	3	3	2	2	1	1	0
ICC	138	52	24	12	7	5	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.
Two-sided p-value was estimated from log rank test stratified by ECOG performance status and ICC option, for descriptive purpose only.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-qs.sas 05JUN2024 19:59 f-14-02-07-04-02-b-km-qs-eq5-itts-cl.rtf

Table 14.2.6.5.1.2.s:
Analyses of Time to Deterioration of EQ-5D-VAS - Subgroup Analysis
ITT Analysis Set

Outcome: EQ-5D VAS Score

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	20 (13.2)	NR (NE, NE)	158	14 (8.9)	NR (NE, NE)	1.134 (0.570, 2.255)	0.7181
>= 65 Years	104	11 (10.6)	NR (NE, NE)	98	13 (13.3)	NR (NE, NE)	0.599 (0.267, 1.343)	0.2073
Interaction								0.2779
Gender								
Male	217	27 (12.4)	NR (NE, NE)	215	24 (11.2)	NR (NE, NE)	0.873 (0.502, 1.519)	0.6281
Female	39	4 (10.3)	NR (NE, NE)	41	3 (7.3)	NR (3.5, NE)	0.784 (0.171, 3.604)	0.7530
Interaction								0.8243

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 05JUN2024 19:38 t-14-02-06-05-01-02-s-eff-tteqs-subgrp-eq5-itt-cl.rtf

Table 14.2.6.5.1.2.s:
Analyses of Time to Deterioration of EQ-5D-VAS - Subgroup Analysis
ITT Analysis Set

Outcome: EQ-5D VAS Score

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	188	24 (12.8)	NR (NE, NE)	192	23 (12.0)	NR (NE, NE)	0.801 (0.450, 1.425)	0.4471
Non-Smoker	68	7 (10.3)	NR (NE, NE)	63	4 (6.3)	NR (NE, NE)	1.248 (0.362, 4.301)	0.7252
Interaction								0.5451
ICC Options								
Paclitaxel	83	9 (10.8)	NR (NE, NE)	85	13 (15.3)	NR (NE, NE)	0.606 (0.257, 1.427)	0.2446
Docetaxel	56	8 (14.3)	NR (NE, NE)	53	7 (13.2)	NR (NE, NE)	0.967 (0.350, 2.674)	0.9489
Irinotecan	117	14 (12.0)	NR (NE, NE)	118	7 (5.9)	NR (NE, NE)	1.282 (0.510, 3.218)	0.5957
Interaction								0.5253

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 05JUN2024 19:38 t-14-02-06-05-01-02-s-eff-tteqs-subgrp-eq5-itt-cl.rtf

Table 14.2.6.5.1.2.s:
Analyses of Time to Deterioration of EQ-5D-VAS - Subgroup Analysis
ITT Analysis Set

Outcome: EQ-5D VAS Score

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	64	9 (14.1)	NR (NE, NE)	63	7 (11.1)	NR (NE, NE)	0.954 (0.351, 2.590)	0.9255
1	192	22 (11.5)	NR (NE, NE)	193	20 (10.4)	NR (NE, NE)	0.831 (0.452, 1.528)	0.5487
Interaction								0.7649
Region #1								
Asia	201	24 (11.9)	NR (NE, NE)	203	23 (11.3)	NR (NE, NE)	0.799 (0.449, 1.421)	0.4408
Europe/North America	55	7 (12.7)	NR (9.1, NE)	53	4 (7.5)	NR (NE, NE)	1.323 (0.385, 4.548)	0.6555
Interaction								0.3698

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 05JUN2024 19:38 t-14-02-06-05-01-02-s-eff-tteqs-subgrp-eq5-itt-cl.rtf

Table 14.2.6.5.1.2.s:
Analyses of Time to Deterioration of EQ-5D-VAS - Subgroup Analysis
ITT Analysis Set

Outcome: EQ-5D VAS Score

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	20 (11.4)	NR (NE, NE)	178	15 (8.4)	NR (NE, NE)	1.033 (0.527, 2.025)	0.9252
Japan	25	4 (16.0)	NR (NE, NE)	25	8 (32.0)	NR (1.5, NE)	0.387 (0.115, 1.305)	0.1066
Europe/North America	55	7 (12.7)	NR (9.1, NE)	53	4 (7.5)	NR (NE, NE)	1.323 (0.385, 4.548)	0.6555
Interaction								0.2021
Race								
Asian and other	203	24 (11.8)	NR (NE, NE)	212	23 (10.8)	NR (NE, NE)	0.820 (0.461, 1.459)	0.4977
White	53	7 (13.2)	NR (9.1, NE)	44	4 (9.1)	NR (NE, NE)	1.211 (0.353, 4.156)	0.7608
Interaction								0.4829

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 05JUN2024 19:38 t-14-02-06-05-01-02-s-eff-tteqs-subgrp-eq5-itt-cl.rtf

Table 14.2.6.5.1.2.s:
Analyses of Time to Deterioration of EQ-5D-VAS - Subgroup Analysis
ITT Analysis Set

Outcome: EQ-5D VAS Score

	Tislelizumab (N = 256)			ICC (N = 256)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	11 (13.8)	NR (NE, NE)	62	5 (8.1)	NR (NE, NE)	1.158 (0.398, 3.371)	0.7873
vCPS < 10%	100	13 (13.0)	NR (NE, NE)	122	11 (9.0)	NR (NE, NE)	1.174 (0.524, 2.627)	0.6948
Missing	76	7 (9.2)	NR (NE, NE)	72	11 (15.3)	NR (NE, NE)	0.462 (0.178, 1.199)	0.1013
Interaction								0.2270

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 05JUN2024 19:38 t-14-02-06-05-01-02-s-eff-tteqs-subgrp-eq5-itt-cl.rtf

Table 14.2.6.5.1.2.b.s:
Analysis of Time to Deterioration of EQ-5D-VAS - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: EQ-5D VAS Score

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	11 (14.5)	NR (9.1, NE)	76	8 (10.5)	NR (NE, NE)	1.239 (0.497, 3.090)	0.6426
>= 65 Years	63	6 (9.5)	NR (NE, NE)	62	12 (19.4)	NR (2.9, NE)	0.403 (0.151, 1.079)	0.0604
Interaction								0.0943
Gender								
Male	118	16 (13.6)	NR (NE, NE)	111	17 (15.3)	NR (NE, NE)	0.780 (0.392, 1.551)	0.4755
Female	21	1 (4.8)	NR (NE, NE)	27	3 (11.1)	NR (2.4, NE)	0.267 (0.026, 2.735)	0.2380
Interaction								0.5133

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-eff-tteqs-subgrp.sas 05JUN2024 19:38 t-14-02-06-05-01-02-b-s-eff-tteqs-subgrp-eq5-itts-cl.rtf

Table 14.2.6.5.1.2.b.s:
Analysis of Time to Deterioration of EQ-5D-VAS - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: EQ-5D VAS Score

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	14 (13.5)	NR (NE, NE)	105	18 (17.1)	NR (NE, NE)	0.695 (0.344, 1.405)	0.3061
Non-Smoker	35	3 (8.6)	NR (NE, NE)	33	2 (6.1)	NR (NE, NE)	1.149 (0.192, 6.882)	0.8786
Interaction								0.6714
ICC Options								
Paclitaxel	83	9 (10.8)	NR (NE, NE)	85	13 (15.3)	NR (NE, NE)	0.606 (0.257, 1.427)	0.2446
Docetaxel	56	8 (14.3)	NR (NE, NE)	53	7 (13.2)	NR (NE, NE)	0.967 (0.350, 2.674)	0.9489
Interaction								0.5329

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.5.1.2.b.s:
Analysis of Time to Deterioration of EQ-5D-VAS - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: EQ-5D VAS Score

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	5 (11.6)	NR (NE, NE)	42	5 (11.9)	NR (NE, NE)	0.777 (0.221, 2.730)	0.6922
1	96	12 (12.5)	NR (NE, NE)	96	15 (15.6)	NR (NE, NE)	0.739 (0.346, 1.580)	0.4316
Interaction								0.9248
Region #1								
Asia	103	14 (13.6)	NR (NE, NE)	105	17 (16.2)	NR (NE, NE)	0.743 (0.366, 1.509)	0.4064
Europe/North America	36	3 (8.3)	NR (9.1, NE)	33	3 (9.1)	NR (2.9, NE)	0.603 (0.115, 3.159)	0.5453
Interaction								0.8638

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.5.1.2.b.s:
Analysis of Time to Deterioration of EQ-5D-VAS - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: EQ-5D VAS Score

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	10 (12.8)	NR (NE, NE)	80	9 (11.3)	NR (NE, NE)	1.079 (0.438, 2.655)	0.8684
Japan	25	4 (16.0)	NR (NE, NE)	25	8 (32.0)	NR (1.5, NE)	0.387 (0.115, 1.305)	0.1066
Europe/North America	36	3 (8.3)	NR (9.1, NE)	33	3 (9.1)	NR (2.9, NE)	0.603 (0.115, 3.159)	0.5453
Interaction								0.3405
Race								
Asian and other	105	14 (13.3)	NR (NE, NE)	114	17 (14.9)	NR (NE, NE)	0.777 (0.383, 1.578)	0.4805
White	34	3 (8.8)	NR (9.1, NE)	24	3 (12.5)	NR (2.4, NE)	0.532 (0.102, 2.766)	0.4466
Interaction								0.9469

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.2.6.5.1.2.b.s:
Analysis of Time to Deterioration of EQ-5D-VAS - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan

Outcome: EQ-5D VAS Score

	Tislelizumab (N = 139)			ICC (N = 138)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	5 (11.1)	NR (NE, NE)	34	4 (11.8)	NR (3.5, NE)	0.793 (0.210, 2.995)	0.7318
vCPS < 10%	53	7 (13.2)	NR (NE, NE)	56	8 (14.3)	NR (NE, NE)	0.827 (0.300, 2.283)	0.7131
Missing	41	5 (12.2)	NR (NE, NE)	48	8 (16.7)	NR (2.2, NE)	0.671 (0.219, 2.054)	0.4776
Interaction								0.9418

Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

The deterioration of EQ-5D VAS is defined as the >= 15 points of change from baseline derived score in the worsen direction.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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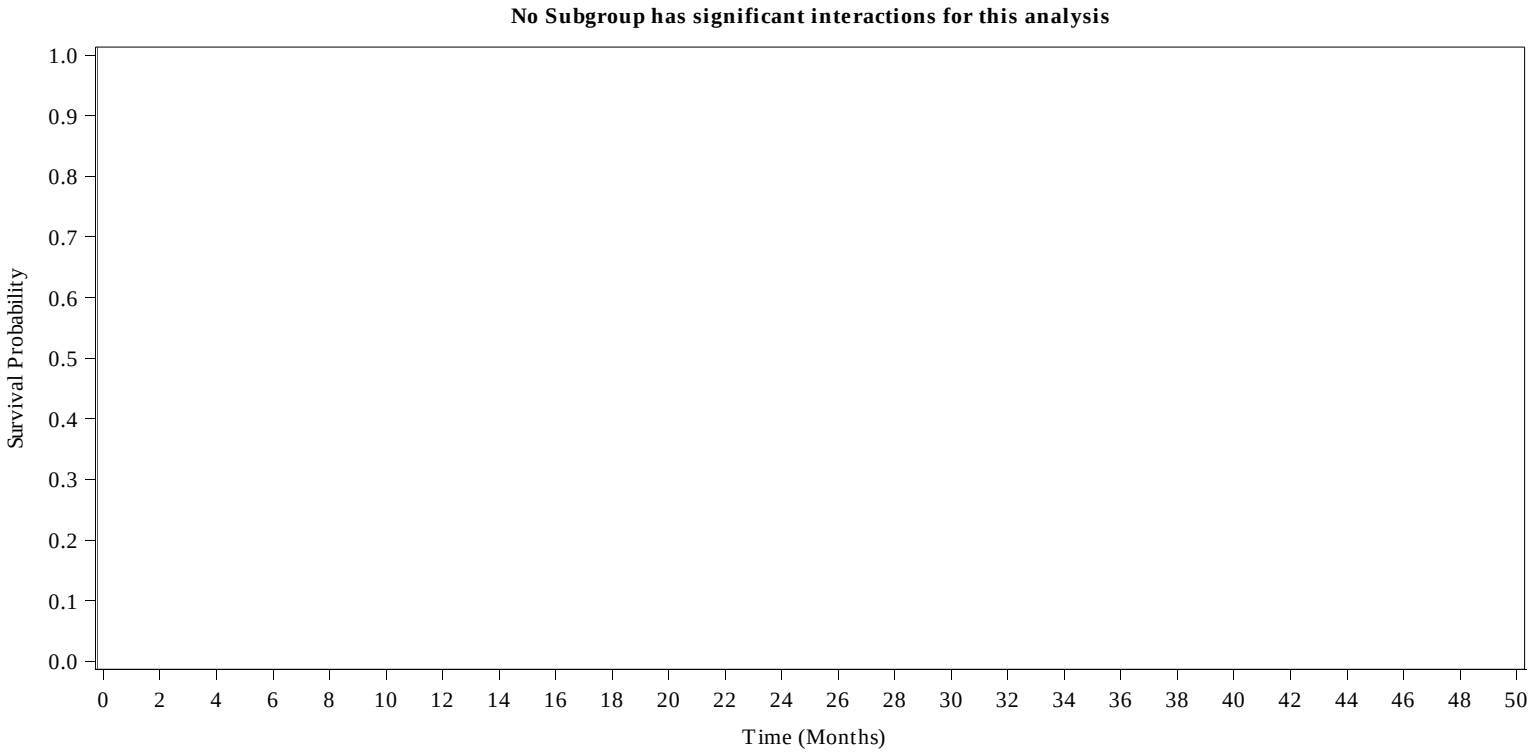
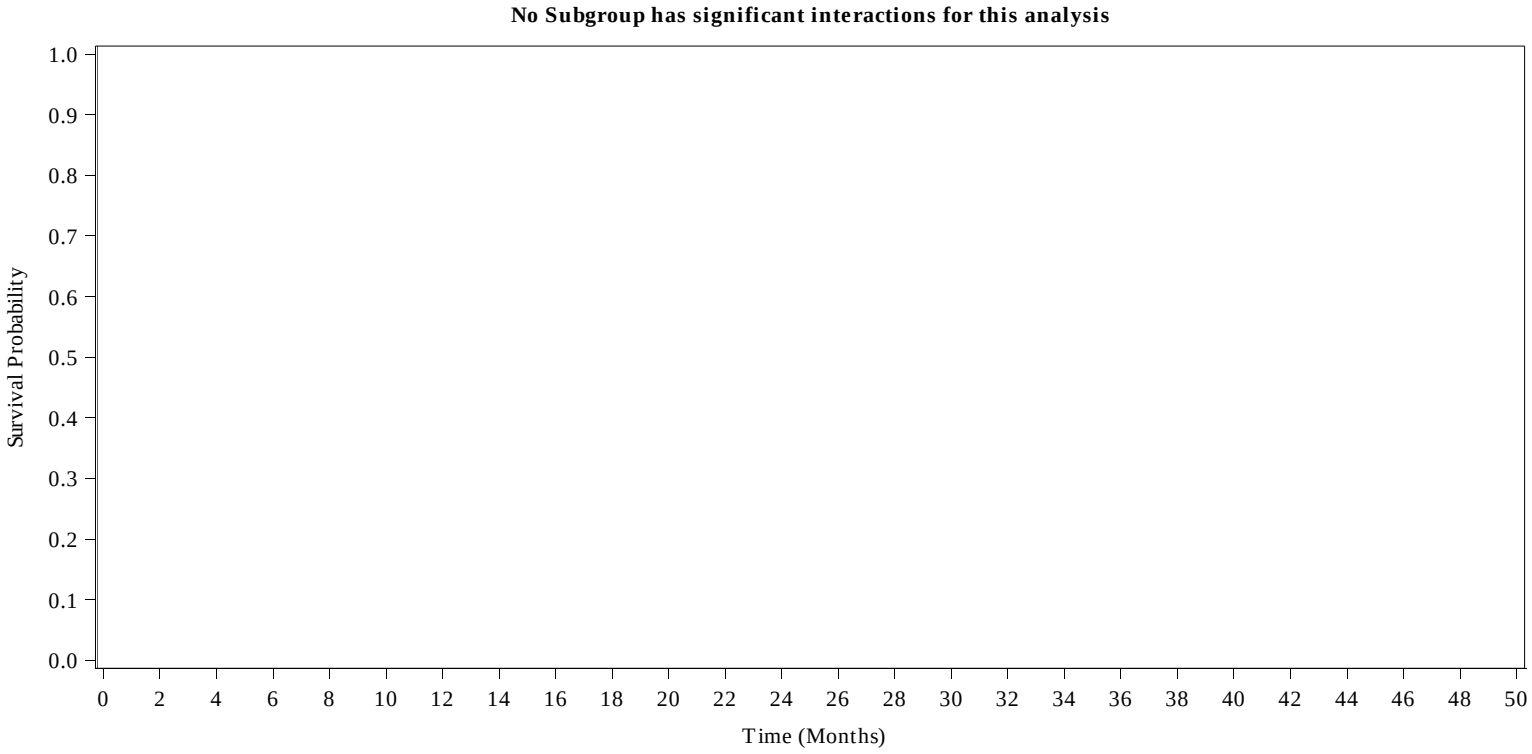
Figure 14.2.7.4.2.s:
Kaplan-Meier Plot of Time to Deterioration of EQ-5D-VAS - Subgroup Analysis
ITT Analysis Set



Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 05JUN2024 20:06 f-14-02-07-04-02-s-km-tteqs-subgrp-eq5-itt-cl.rtf

Figure 14.2.7.4.2.b.s:
Kaplan-Meier Plot of Time to Deterioration of EQ-5D-VAS - Subgroup Analysis
ITT Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEQS1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
The Kaplan-Meier plots for individual subgroups are only presented for subgroup analyses with a statistically significant interaction term (p-value < 0.05). If any subgroups are not displayed, the respective criteria for subgroup analyses are not met.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteqs-subgrp.sas 05JUN2024 20:06 f-14-02-07-04-02-b-s-km-tteqs-subgrp-eq5-itts-cl.rtf

Table 14.2.8.1.b:
Post-Treatment Subsequent Anti-Cancer Therapies
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)	ICC (N = 138)
Patients With Any Subsequent Anti-Cancer Therapy, n (%)	80 (57.6)	85 (61.6)
Procedure, Radiotherapy or Surgery	29 (20.9)	29 (21.0)
Systemic Therapy	71 (51.1)	76 (55.1)
Immunotherapy	10 (7.2)	34 (24.6)
Time to First Post-Treatment Anti-Cancer Therapy (months)		
n	80	85
Mean (SD)	0.56 (0.905)	1.07 (1.855)
Median	0.26	0.53
Q1, Q3	0.13, 0.66	0.20, 0.95
Min, Max	-0.7, 6.0	-0.3, 12.6
Time to First Post-Treatment Immunotherapy (months)		
n	10	34
Mean (SD)	8.82 (5.840)	2.62 (3.134)
Median	6.93	0.90
Q1, Q3	3.68, 13.57	0.53, 4.70
Min, Max	3.1, 19.6	0.0, 12.6

Source: Listing 16.2.4.10,16.2.4.11. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.

Percentages were based on N.

Time to first subsequent anti-cancer therapy is defined for patients with the use of subsequent anti-cancer therapy as the time from end of study treatment to first dose of subsequent anti-cancer therapy. There were 3 patients started new anti-cancer therapy before the treatment discontinuation without informing the investigator.

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Table 14.2.8.1.b:
Post-Treatment Subsequent Anti-Cancer Therapies
ITT Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)	ICC (N = 138)
Post-Treatment Systemic Therapy Duration (months)		
n	71	76
Mean (SD)	7.16 (8.476)	6.94 (10.475)
Median	4.34	2.23
Q1, Q3	2.20, 9.23	0.85, 7.38
Min, Max	0.0, 40.5	0.0, 48.6
Post-Treatment Immunotherapy Duration (months)		
n	10	34
Mean (SD)	0.53 (0.460)	6.72 (9.787)
Median	0.59	2.91
Q1, Q3	0.03, 0.95	0.53, 5.65
Min, Max	0.0, 1.1	0.0, 32.1

Source: Listing 16.2.4.10,16.2.4.11. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Time to first subsequent anti-cancer therapy is defined for patients with the use of subsequent anti-cancer therapy as the time from end of study treatment to first dose of subsequent anti-cancer therapy. There were 3 patients started new anti-cancer therapy before the treatment discontinuation without informing the investigator.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-subanti.sas 05JUN2024 17:45 t-14-02-08-01-b-subanti-itts-cl.rtf

Table 14.2.8.3.b:
Summary of Post-Treatment Systemic Therapies and Immunotherapies
ITT Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 138) n (%)
Systemic Therapy	71 (51.1)	76 (55.1)
Taxanes	47 (33.8)	15 (10.9)
Paclitaxel	34 (24.5)	8 (5.8)
Docetaxel	15 (10.8)	5 (3.6)
Paclitaxel Liposome	1 (0.7)	0 (0.0)
Paclitaxel Nanoparticle Albumin-Bound	1 (0.7)	3 (2.2)
Pyrimidine Analogues	33 (23.7)	27 (19.6)
Fluorouracil	18 (12.9)	11 (8.0)
Gimeracil;oteracil Potassium;tegafur	10 (7.2)	8 (5.8)
Capecitabine	4 (2.9)	1 (0.7)
Gemcitabine Hydrochloride	3 (2.2)	1 (0.7)
Gemcitabine	2 (1.4)	5 (3.6)
Tegafur	2 (1.4)	3 (2.2)
Gimeracil;oteracil;tegafur	1 (0.7)	0 (0.0)
Tegafur;uracil	1 (0.7)	0 (0.0)
Tipiracil Hydrochloride;trifluridine	0 (0.0)	1 (0.7)

Source: Listing 16.2.4.10,16.2.4.11. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.2.8.3.b:
Summary of Post-Treatment Systemic Therapies and Immunotherapies
ITT Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 138) n (%)
Platinum Compounds	25 (18.0)	24 (17.4)
Cisplatin	17 (12.2)	18 (13.0)
Carboplatin	4 (2.9)	1 (0.7)
Nedaplatin	3 (2.2)	1 (0.7)
Oxaliplatin	2 (1.4)	4 (2.9)
Lobaplatin	1 (0.7)	0 (0.0)
Topoisomerase 1 (Top1) Inhibitors	16 (11.5)	15 (10.9)
Irinotecan	15 (10.8)	12 (8.7)
Irinotecan Hydrochloride	1 (0.7)	3 (2.2)

Source: Listing 16.2.4.10,16.2.4.11. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-postsys.sas 05JUN2024 17:48 t-14-02-08-03-b-postsys-itts-cl.rtf

Table 14.2.8.3.b:
Summary of Post-Treatment Systemic Therapies and Immunotherapies
ITT Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 138) n (%)
Pd-1/Pdl-1 (Programmed Cell Death Protein 1/Death Ligand 1) Inhibitors	9 (6.5)	32 (23.2)
Nivolumab	6 (4.3)	15 (10.9)
Camrelizumab	2 (1.4)	3 (2.2)
Durvalumab	1 (0.7)	0 (0.0)
Atezolizumab	0 (0.0)	1 (0.7)
Avelumab	0 (0.0)	1 (0.7)
Envafolimab	0 (0.0)	1 (0.7)
Ezabenlimab	0 (0.0)	2 (1.4)
Geptanolimab	0 (0.0)	2 (1.4)
Pembrolizumab	0 (0.0)	2 (1.4)
Sct I10a	0 (0.0)	1 (0.7)
Sintilimab	0 (0.0)	4 (2.9)
Tislelizumab	0 (0.0)	1 (0.7)
Toripalimab	0 (0.0)	1 (0.7)

Source: Listing 16.2.4.10,16.2.4.11. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-postsys.sas 05JUN2024 17:48 t-14-02-08-03-b-postsys-itts-cl.rtf

Table 14.2.8.3.b:
Summary of Post-Treatment Systemic Therapies and Immunotherapies
ITT Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 138) n (%)
Detoxifying Agents For Antineoplastic Treatment	8 (5.8)	7 (5.1)
Calcium Folinate	2 (1.4)	1 (0.7)
Calcium Levofolinate	2 (1.4)	2 (1.4)
Folinic Acid	2 (1.4)	3 (2.2)
Gimeracil	1 (0.7)	0 (0.0)
Levofolinic Acid	1 (0.7)	1 (0.7)
Oteracil Potassium	1 (0.7)	0 (0.0)
Vascular Endothelial Growth Factor Receptor (Vegfr) Tyrosine Kinase Inhibitors	7 (5.0)	5 (3.6)
Rivoceranib Mesylate	5 (3.6)	4 (2.9)
Rivoceranib	2 (1.4)	1 (0.7)
Folic Acid Analogues	5 (3.6)	3 (2.2)
Methotrexate	3 (2.2)	1 (0.7)
Raltitrexed	2 (1.4)	0 (0.0)
Methotrexate Sodium	0 (0.0)	1 (0.7)
Pemetrexed Disodium	0 (0.0)	1 (0.7)

Source: Listing 16.2.4.10,16.2.4.11. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-postsys.sas 05JUN2024 17:48 t-14-02-08-03-b-postsys-itts-cl.rtf

Table 14.2.8.3.b:
Summary of Post-Treatment Systemic Therapies and Immunotherapies
ITT Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 138) n (%)
Other Protein Kinase Inhibitors	5 (3.6)	13 (9.4)
Catequentinib Hydrochloride	5 (3.6)	9 (6.5)
Catequentinib	1 (0.7)	2 (1.4)
Regorafenib	0 (0.0)	1 (0.7)
Simurosertib	0 (0.0)	1 (0.7)
Vinca Alkaloids And Analogues	5 (3.6)	6 (4.3)
Vinorelbine	2 (1.4)	3 (2.2)
Vinorelbine Tartrate	2 (1.4)	3 (2.2)
Vincristine Sulfate	1 (0.7)	0 (0.0)
Other Antineoplastic Agents	4 (2.9)	3 (2.2)
Endostatin	3 (2.2)	2 (1.4)
Lenalidomide	1 (0.7)	0 (0.0)
Other Antineoplastic Agents	0 (0.0)	1 (0.7)

Source: Listing 16.2.4.10,16.2.4.11. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-postsys.sas 05JUN2024 17:48 t-14-02-08-03-b-postsys-itts-cl.rtf

Table 14.2.8.3.b:
Summary of Post-Treatment Systemic Therapies and Immunotherapies
ITT Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 138) n (%)
Anthracyclines And Related Substances	3 (2.2)	2 (1.4)
Doxorubicin	1 (0.7)	0 (0.0)
Epirubicin	1 (0.7)	2 (1.4)
Epirubicin Hydrochloride	1 (0.7)	0 (0.0)
Antineoplastic Agents	2 (1.4)	0 (0.0)
Antineoplastic Agents	2 (1.4)	0 (0.0)
Herbal Immunomodulators	2 (1.4)	0 (0.0)
Astragalus Mongholicus Root;oxymatrine;panax Ginseng Dry Extract	2 (1.4)	0 (0.0)
Plant Alkaloids And Other Natural Products	2 (1.4)	0 (0.0)
Brucea Javanica Oil	1 (0.7)	0 (0.0)
Brucea Javanica Oil;glycerol;lecithin	1 (0.7)	0 (0.0)
All Other Therapeutic Products	1 (0.7)	1 (0.7)
All Other Therapeutic Products	1 (0.7)	1 (0.7)

Source: Listing 16.2.4.10,16.2.4.11. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-postsys.sas 05JUN2024 17:48 t-14-02-08-03-b-postsys-itts-cl.rtf

Table 14.2.8.3.b:
Summary of Post-Treatment Systemic Therapies and Immunotherapies
ITT Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 138) n (%)
Cyclin-Dependent Kinase (Cdk) Inhibitors	1 (0.7)	0 (0.0)
Palbociclib	1 (0.7)	0 (0.0)
Egfr (Epidermal Growth Factor Receptor) Inhibitors	1 (0.7)	2 (1.4)
Cetuximab	1 (0.7)	1 (0.7)
Nimotuzumab	0 (0.0)	1 (0.7)
Epidermal Growth Factor Receptor (Egfr) Tyrosine Kinase Inhibitors	1 (0.7)	2 (1.4)
Afatinib	1 (0.7)	0 (0.0)
Afatinib Dimaleate	0 (0.0)	1 (0.7)
Erlotinib	0 (0.0)	1 (0.7)
Immunostimulants	1 (0.7)	0 (0.0)
Immunotherapy	1 (0.7)	0 (0.0)
Other Cytotoxic Antibiotics	1 (0.7)	1 (0.7)
Bleomycin	1 (0.7)	0 (0.0)
Mitomycin	0 (0.0)	1 (0.7)

Source: Listing 16.2.4.10,16.2.4.11. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
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Table 14.2.8.3.b:
Summary of Post-Treatment Systemic Therapies and Immunotherapies
ITT Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 138) n (%)
Other Immunostimulants	1 (0.7)	1 (0.7)
D-Ribose;peptides Nos	1 (0.7)	0 (0.0)
Ribonucleic Acid	1 (0.7)	0 (0.0)
Thymostimulin	1 (0.7)	0 (0.0)
Ubenimex	0 (0.0)	1 (0.7)
Other Plant Alkaloids And Natural Products	1 (0.7)	0 (0.0)
Cinobufagin	1 (0.7)	0 (0.0)
Podophyllotoxin Derivatives	1 (0.7)	3 (2.2)
Etoposide	1 (0.7)	3 (2.2)
Unspecified Herbal And Traditional Medicine	1 (0.7)	3 (2.2)
Unspecified Herbal And Traditional Medicine	1 (0.7)	3 (2.2)
Vegf/Vegfr (Vascular Endothelial Growth Factor) Inhibitors	1 (0.7)	1 (0.7)
Bevacizumab	1 (0.7)	1 (0.7)

Source: Listing 16.2.4.10,16.2.4.11. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-postsys.sas 05JUN2024 17:48 t-14-02-08-03-b-postsys-itts-cl.rtf

Table 14.2.8.3.b:
Summary of Post-Treatment Systemic Therapies and Immunotherapies
ITT Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 138) n (%)
Herbal Anticancer Remedies	0 (0.0)	3 (2.2)
Agrimonia Pilosa Herb;alum;citrus Aurantium Unripe Fruit;curcuma Spp. Root Tuber;flying Squirrel Feces;potassium Nitrate;strychnos Nux-Vomica Seed;toxicodendron Vernicifluum Resin	0 (0.0)	1 (0.7)
Astragalus Mongholicus Root;eleutherococcus Senticosus Root With Rhizome;mylabris Spp.;panax Ginseng Root	0 (0.0)	1 (0.7)
Marsdenia Tenacissima Stem	0 (0.0)	1 (0.7)
Monoclonal Antibodies And Antibody Drug Conjugates	0 (0.0)	2 (1.4)
Antineoplastic Monoclonal Antibodies	0 (0.0)	2 (1.4)
Nitrogen Mustard Analogues	0 (0.0)	2 (1.4)
Cyclophosphamide	0 (0.0)	2 (1.4)
Other Monoclonal Antibodies And Antibody Drug Conjugates	0 (0.0)	3 (2.2)
Miptenalimab	0 (0.0)	2 (1.4)
Simlukafusp Alfa	0 (0.0)	1 (0.7)

Source: Listing 16.2.4.10,16.2.4.11. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-postsys.sas 05JUN2024 17:48 t-14-02-08-03-b-postsys-itts-cl.rtf

Table 14.2.8.3.b:
Summary of Post-Treatment Systemic Therapies and Immunotherapies
ITT Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 138) n (%)
Immunotherapy	10 (7.2)	34 (24.6)
Pd-1/Pdl-1 (Programmed Cell Death Protein 1/Death Ligand 1) Inhibitors	9 (6.5)	32 (23.2)
Nivolumab	6 (4.3)	15 (10.9)
Camrelizumab	2 (1.4)	3 (2.2)
Durvalumab	1 (0.7)	0 (0.0)
Atezolizumab	0 (0.0)	1 (0.7)
Avelumab	0 (0.0)	1 (0.7)
Envafolimab	0 (0.0)	1 (0.7)
Ezabenlimab	0 (0.0)	2 (1.4)
Geptanolimab	0 (0.0)	2 (1.4)
Pembrolizumab	0 (0.0)	2 (1.4)
Sct I10a	0 (0.0)	1 (0.7)
Sintilimab	0 (0.0)	4 (2.9)
Tislelizumab	0 (0.0)	1 (0.7)
Toripalimab	0 (0.0)	1 (0.7)
Immunostimulants	1 (0.7)	0 (0.0)
Immunotherapy	1 (0.7)	0 (0.0)

Source: Listing 16.2.4.10,16.2.4.11. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-postsys.sas 05JUN2024 17:48 t-14-02-08-03-b-postsys-itts-cl.rtf

Table 14.2.8.3.b:
Summary of Post-Treatment Systemic Therapies and Immunotherapies
ITT Analysis Set - Subpopulation without Irinotecan

Anatomical Therapeutic Chemical WHO Drug Dictionary Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 138) n (%)
Monoclonal Antibodies And Antibody Drug Conjugates	0 (0.0)	2 (1.4)
Antineoplastic Monoclonal Antibodies	0 (0.0)	2 (1.4)
Other Monoclonal Antibodies And Antibody Drug Conjugates	0 (0.0)	3 (2.2)
Miptenalimab	0 (0.0)	2 (1.4)
Simlukafusp Alfa	0 (0.0)	1 (0.7)

Source: Listing 16.2.4.10,16.2.4.11. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel.
Percentages were based on N.
Patients with two or more medications within a class level and preferred term were counted only once within that class level and preferred term.
Medication terms were coded using World Health Organization Drug Dictionary Global-B3.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-postsys.sas 05JUN2024 17:48 t-14-02-08-03-b-postsys-itts-cl.rtf

Table 14.3.1.1.1.b:
Study Medication Administration - Tislelizumab
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)
Duration of Exposure (Days)	
n	139
Mean (SD)	191.7 (270.97)
Median	84.0
Q1, Q3	43.0, 229.0
Min, Max	10, 1513

Source: Listing 16.2.5.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Percentages were based on N.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/cycle) is defined as total dose (mg) / duration of exposure (day) * cycle length in days.

[c] RDI is defined as the ratio of the actual dose intensity (mg/cycle) and the planned dose intensity (mg/cycle) = dose intensity / (200 mg/cycle). The planned dose intensity is the total planned dose in a cycle. For a patient in the tislelizumab arm, the planned dose intensity is 200 mg once every three weeks.

[d] A patient was counted only once within each category but may be counted in multiple categories.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-ex-tis.sas 05JUN2024 17:44 t-14-03-01-01-01-b-ex-tis-safetys-cl.rtf

Table 14.3.1.1.1.b:
Study Medication Administration - Tislelizumab
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)
Duration of Exposure, n (%)	
<1 month	12 (8.6)
>=1 to <3 month	69 (49.6)
>=3 to <6 month	18 (12.9)
>=6 to <12 month	23 (16.5)
>=12 to <18 month	6 (4.3)
>=18 to <24 month	2 (1.4)
>=24 to <30 month	3 (2.2)
>=30 to <36 month	3 (2.2)
>=36 month	3 (2.2)

Source: Listing 16.2.5.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Percentages were based on N.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/cycle) is defined as total dose (mg) / duration of exposure (day) * cycle length in days.

[c] RDI is defined as the ratio of the actual dose intensity (mg/cycle) and the planned dose intensity (mg/cycle) = dose intensity / (200 mg/cycle). The planned dose intensity is the total planned dose in a cycle. For a patient in the tislelizumab arm, the planned dose intensity is 200 mg once every three weeks.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.1.b:
Study Medication Administration - Tislelizumab
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)
Number of Cycles Received, n (%)	
1	12 (8.6)
2	28 (20.1)
3	22 (15.8)
4	19 (13.7)
5	4 (2.9)
6	11 (7.9)
7	2 (1.4)
8	1 (0.7)
9	1 (0.7)
10	4 (2.9)
>10	35 (25.2)

Source: Listing 16.2.5.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Percentages were based on N.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/cycle) is defined as total dose (mg) / duration of exposure (day) * cycle length in days.

[c] RDI is defined as the ratio of the actual dose intensity (mg/cycle) and the planned dose intensity (mg/cycle) = dose intensity / (200 mg/cycle). The planned dose intensity is the total planned dose in a cycle. For a patient in the tislelizumab arm, the planned dose intensity is 200 mg once every three weeks.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.1.b:
Study Medication Administration - Tislelizumab
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)
Number of Cycles Received, n (%)	
1-3	62 (44.6)
4-6	34 (24.5)
7-9	4 (2.9)
10-12	10 (7.2)
13-18	13 (9.4)
19-24	4 (2.9)
25-30	3 (2.2)
31-36	1 (0.7)
>36	8 (5.8)

Source: Listing 16.2.5.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Percentages were based on N.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/cycle) is defined as total dose (mg) / duration of exposure (day) * cycle length in days.

[c] RDI is defined as the ratio of the actual dose intensity (mg/cycle) and the planned dose intensity (mg/cycle) = dose intensity / (200 mg/cycle). The planned dose intensity is the total planned dose in a cycle. For a patient in the tislelizumab arm, the planned dose intensity is 200 mg once every three weeks.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.1.b:
Study Medication Administration - Tislelizumab
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)
Number of Treatment Cycles	
n	139
Mean (SD)	8.9 (12.52)
Median	4.0
Q1, Q3	2.0, 11.0
Min, Max	1, 72
Cumulative Total Dose (mg) per Patient [a]	
n	139
Mean (SD)	1776.98 (2504.151)
Median	800.00
Q1, Q3	400.00, 2200.00
Min, Max	200.0, 14400.0

Source: Listing 16.2.5.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Percentages were based on N.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/cycle) is defined as total dose (mg) / duration of exposure (day) * cycle length in days.

[c] RDI is defined as the ratio of the actual dose intensity (mg/cycle) and the planned dose intensity (mg/cycle) = dose intensity / (200 mg/cycle). The planned dose intensity is the total planned dose in a cycle. For a patient in the tislelizumab arm, the planned dose intensity is 200 mg once every three weeks.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.1.b:
Study Medication Administration - Tislelizumab
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)
Actual Dose Intensity (mg/cycle) per Patient [b]	
n	139
Mean (SD)	198.04 (21.732)
Median	200.00
Q1, Q3	195.35, 200.00
Min, Max	133.3, 420.0
Relative Dose Intensity (%) per Patient [c]	
n	139
Mean (SD)	99.02 (10.866)
Median	100.00
Q1, Q3	97.67, 100.00
Min, Max	66.7, 210.0

Source: Listing 16.2.5.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Percentages were based on N.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/cycle) is defined as total dose (mg) / duration of exposure (day) * cycle length in days.

[c] RDI is defined as the ratio of the actual dose intensity (mg/cycle) and the planned dose intensity (mg/cycle) = dose intensity / (200 mg/cycle). The planned dose intensity is the total planned dose in a cycle. For a patient in the tislelizumab arm, the planned dose intensity is 200 mg once every three weeks.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.1.b:
Study Medication Administration - Tislelizumab
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)
Patients with Any Dose Modification, n (%) [d]	45 (32.4)
Dose Delay	45 (32.4)
Adverse Event	24 (17.3)
Other	28 (20.1)
COVID-19	6 (4.3)
Infusion Interrupted	0 (0.0)
Adverse Event	0 (0.0)
Other	0 (0.0)
COVID-19	0 (0.0)

Source: Listing 16.2.5.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Percentages were based on N.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/cycle) is defined as total dose (mg) / duration of exposure (day) * cycle length in days.

[c] RDI is defined as the ratio of the actual dose intensity (mg/cycle) and the planned dose intensity (mg/cycle) = dose intensity / (200 mg/cycle). The planned dose intensity is the total planned dose in a cycle. For a patient in the tislelizumab arm, the planned dose intensity is 200 mg once every three weeks.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.2.b:
Study Medication Administration - Investigator Chosen Chemotherapy (ICC)
Safety Analysis Set - Subpopulation without Irinotecan

	Paclitaxel			Docetaxel			
	Paclitaxel Grp1 (N = 62)	Paclitaxel Grp2 (N = 17)	Overall (N = 79)	Docetaxel Grp1 (N = 44)	Docetaxel Grp2 (N = 6)	Overall (N = 50)	Overall (N = 129)
Duration of Exposure (Days)							
n	62	17	79	44	6	50	129
Mean (SD)	94.9 (80.28)	89.9 (89.70)	93.8 (81.83)	91.0 (117.58)	69.8 (26.81)	88.5 (110.70)	91.8 (93.69)
Median	63.0	49.0	59.0	45.0	66.5	47.5	50.0
Q1, Q3	42.0, 126.0	37.0, 91.0	42.0, 126.0	41.5, 95.0	49.0, 87.0	42.0, 92.0	42.0, 108.0
Min, Max	7, 357	21, 357	7, 357	7, 731	42, 108	7, 731	7, 731

Source: Listing 16.2.5.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Percentages were based on N. Paclitaxel Grp1: 135-175mg/m^2 IV on Day 1, given every 21 days. Paclitaxel may also be given in doses of 80-100mg/m^2 IV on a weekly schedule; Paclitaxel Grp2--Paclitaxel (Japan): 100 mg/m^2 IV on Day 1, 8, 15, 22, 29, and 36, followed by one week of rest. Docetaxel Grp1: 75 mg/m^2 IV on Day 1, given every 21 days; Docetaxel Grp2--70 mg/m^2 IV on Day 1, given every 21 days for Japan patients.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/ m^2/cycle) = (total dose received / BSA) / Duration of Treatment in cycle * cycle length in days. Baseline weights are used to derive BSA, unless the change of the BSA at the visit are at least 10% or greater than the baseline (increased or decreased).

[c] Relative dose intensity (RDI) is defined as the ratio of the actual dose intensity (mg/ m^2/cycle) and the planned dose intensity (mg/ m^2/cycle). The planned dose intensity is the total planned dose in a cycle.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.2.b:
Study Medication Administration - Investigator Chosen Chemotherapy (ICC)
Safety Analysis Set - Subpopulation without Irinotecan

	Paclitaxel			Docetaxel			
	Paclitaxel Grp1 (N = 62)	Paclitaxel Grp2 (N = 17)	Overall (N = 79)	Docetaxel Grp1 (N = 44)	Docetaxel Grp2 (N = 6)	Overall (N = 50)	Overall (N = 129)
Duration of Exposure, n (%)							
<1 month	9 (14.5)	1 (5.9)	10 (12.7)	9 (20.5)	0 (0.0)	9 (18.0)	19 (14.7)
>=1 to <3 month	30 (48.4)	12 (70.6)	42 (53.2)	23 (52.3)	5 (83.3)	28 (56.0)	70 (54.3)
>=3 to <6 month	14 (22.6)	2 (11.8)	16 (20.3)	6 (13.6)	1 (16.7)	7 (14.0)	23 (17.8)
>=6 to <12 month	9 (14.5)	2 (11.8)	11 (13.9)	5 (11.4)	0 (0.0)	5 (10.0)	16 (12.4)
>=12 to <18 month	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
>=18 to <24 month	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
>=24 to <30 month	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (2.0)	1 (0.8)

Source: Listing 16.2.5.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Percentages were based on N. Paclitaxel Grp1: 135-175mg/m^2 IV on Day 1, given every 21 days. Paclitaxel may also be given in doses of 80-100mg/m^2 IV on a weekly schedule; Paclitaxel Grp2--Paclitaxel (Japan): 100 mg/m^2 IV on Day 1, 8, 15, 22, 29, and 36, followed by one week of rest. Docetaxel Grp1: 75 mg/m^2 IV on Day 1, given every 21 days; Docetaxel Grp2--70 mg/m^2 IV on Day 1, given every 21 days for Japan patients.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/ m^2/cycle) = (total dose received / BSA) / Duration of Treatment in cycle * cycle length in days. Baseline weights are used to derive BSA, unless the change of the BSA at the visit are at least 10% or greater than the baseline (increased or decreased).

[c] Relative dose intensity (RDI) is defined as the ratio of the actual dose intensity (mg/ m^2/cycle) and the planned dose intensity (mg/ m^2/cycle). The planned dose intensity is the total planned dose in a cycle.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.2.b:
Study Medication Administration - Investigator Chosen Chemotherapy (ICC)
Safety Analysis Set - Subpopulation without Irinotecan

	Paclitaxel			Docetaxel			
	Paclitaxel Grp1 (N = 62)	Paclitaxel Grp2 (N = 17)	Overall (N = 79)	Docetaxel Grp1 (N = 44)	Docetaxel Grp2 (N = 6)	Overall (N = 50)	Overall (N = 129)
>=30 to <36 month	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
>=36 month	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Number of Cycles Received							
n	62	17	79	44	6	50	129
Mean (SD)	4.0 (3.20)	2.1 (1.82)	3.6 (3.06)	4.3 (5.43)	3.2 (1.33)	4.2 (5.12)	3.8 (3.97)
Median	3.0	1.0	2.0	2.0	3.0	2.0	2.0
Q1, Q3	2.0, 5.0	1.0, 2.0	1.0, 4.0	2.0, 4.5	2.0, 4.0	2.0, 4.0	2.0, 4.0
Min, Max	1, 14	1, 7	1, 14	1, 34	2, 5	1, 34	1, 34

Source: Listing 16.2.5.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Percentages were based on N. Paclitaxel Grp1: 135-175mg/m^2 IV on Day 1, given every 21 days. Paclitaxel may also be given in doses of 80-100mg/m^2 IV on a weekly schedule; Paclitaxel Grp2--Paclitaxel (Japan): 100 mg/m^2 IV on Day 1, 8, 15, 22, 29, and 36, followed by one week of rest. Docetaxel Grp1: 75 mg/m^2 IV on Day 1, given every 21 days; Docetaxel Grp2--70 mg/m^2 IV on Day 1, given every 21 days for Japan patients.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/ m^2/cycle) = (total dose received / BSA) / Duration of Treatment in cycle * cycle length in days. Baseline weights are used to derive BSA, unless the change of the BSA at the visit are at least 10% or greater than the baseline (increased or decreased).

[c] Relative dose intensity (RDI) is defined as the ratio of the actual dose intensity (mg/ m^2/cycle) and the planned dose intensity (mg/ m^2/cycle). The planned dose intensity is the total planned dose in a cycle.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.2.b:
Study Medication Administration - Investigator Chosen Chemotherapy (ICC)
Safety Analysis Set - Subpopulation without Irinotecan

	Paclitaxel			Docetaxel			
	Paclitaxel Grp1 (N = 62)	Paclitaxel Grp2 (N = 17)	Overall (N = 79)	Docetaxel Grp1 (N = 44)	Docetaxel Grp2 (N = 6)	Overall (N = 50)	Overall (N = 129)
Number of Cycles Received, n (%)							
1	9 (14.5)	11 (64.7)	20 (25.3)	7 (15.9)	0 (0.0)	7 (14.0)	27 (20.9)
2	19 (30.6)	2 (11.8)	21 (26.6)	18 (40.9)	3 (50.0)	21 (42.0)	42 (32.6)
3	6 (9.7)	0 (0.0)	6 (7.6)	3 (6.8)	0 (0.0)	3 (6.0)	9 (7.0)
4	11 (17.7)	2 (11.8)	13 (16.5)	5 (11.4)	2 (33.3)	7 (14.0)	20 (15.5)
5	2 (3.2)	1 (5.9)	3 (3.8)	2 (4.5)	1 (16.7)	3 (6.0)	6 (4.7)
6	5 (8.1)	0 (0.0)	5 (6.3)	1 (2.3)	0 (0.0)	1 (2.0)	6 (4.7)
7	2 (3.2)	1 (5.9)	3 (3.8)	0 (0.0)	0 (0.0)	0 (0.0)	3 (2.3)

Source: Listing 16.2.5.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Percentages were based on N. Paclitaxel Grp1: 135-175mg/m^2 IV on Day 1, given every 21 days. Paclitaxel may also be given in doses of 80-100mg/m^2 IV on a weekly schedule; Paclitaxel Grp2--Paclitaxel (Japan): 100 mg/m^2 IV on Day 1, 8, 15, 22, 29, and 36, followed by one week of rest. Docetaxel Grp1: 75 mg/m^2 IV on Day 1, given every 21 days; Docetaxel Grp2--70 mg/m^2 IV on Day 1, given every 21 days for Japan patients.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/ m^2/cycle) = (total dose received / BSA) / Duration of Treatment in cycle * cycle length in days. Baseline weights are used to derive BSA, unless the change of the BSA at the visit are at least 10% or greater than the baseline (increased or decreased).

[c] Relative dose intensity (RDI) is defined as the ratio of the actual dose intensity (mg/ m^2/cycle) and the planned dose intensity (mg/ m^2/cycle). The planned dose intensity is the total planned dose in a cycle.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.2.b:
Study Medication Administration - Investigator Chosen Chemotherapy (ICC)
Safety Analysis Set - Subpopulation without Irinotecan

	Paclitaxel			Docetaxel			
	Paclitaxel Grp1 (N = 62)	Paclitaxel Grp2 (N = 17)	Overall (N = 79)	Docetaxel Grp1 (N = 44)	Docetaxel Grp2 (N = 6)	Overall (N = 50)	Overall (N = 129)
8	2 (3.2)	0 (0.0)	2 (2.5)	2 (4.5)	0 (0.0)	2 (4.0)	4 (3.1)
9	1 (1.6)	0 (0.0)	1 (1.3)	1 (2.3)	0 (0.0)	1 (2.0)	2 (1.6)
10	1 (1.6)	0 (0.0)	1 (1.3)	2 (4.5)	0 (0.0)	2 (4.0)	3 (2.3)
>10	4 (6.5)	0 (0.0)	4 (5.1)	3 (6.8)	0 (0.0)	3 (6.0)	7 (5.4)

Source: Listing 16.2.5.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Percentages were based on N. Paclitaxel Grp1: 135-175mg/m^2 IV on Day 1, given every 21 days. Paclitaxel may also be given in doses of 80-100mg/m^2 IV on a weekly schedule; Paclitaxel Grp2--Paclitaxel (Japan): 100 mg/m^2 IV on Day 1, 8, 15, 22, 29, and 36, followed by one week of rest. Docetaxel Grp1: 75 mg/m^2 IV on Day 1, given every 21 days; Docetaxel Grp2--70 mg/m^2 IV on Day 1, given every 21 days for Japan patients.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/ m^2/cycle) = (total dose received / BSA) / Duration of Treatment in cycle * cycle length in days. Baseline weights are used to derive BSA, unless the change of the BSA at the visit are at least 10% or greater than the baseline (increased or decreased).

[c] Relative dose intensity (RDI) is defined as the ratio of the actual dose intensity (mg/ m^2/cycle) and the planned dose intensity (mg/ m^2/cycle). The planned dose intensity is the total planned dose in a cycle.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.2.b:
Study Medication Administration - Investigator Chosen Chemotherapy (ICC)
Safety Analysis Set - Subpopulation without Irinotecan

	Paclitaxel			Docetaxel			
	Paclitaxel Grp1 (N = 62)	Paclitaxel Grp2 (N = 17)	Overall (N = 79)	Docetaxel Grp1 (N = 44)	Docetaxel Grp2 (N = 6)	Overall (N = 50)	Overall (N = 129)
Number of Cycles Received, n (%)							
1-3	34 (54.8)	13 (76.5)	47 (59.5)	28 (63.6)	3 (50.0)	31 (62.0)	78 (60.5)
4-6	18 (29.0)	3 (17.6)	21 (26.6)	8 (18.2)	3 (50.0)	11 (22.0)	32 (24.8)
7-9	5 (8.1)	1 (5.9)	6 (7.6)	3 (6.8)	0 (0.0)	3 (6.0)	9 (7.0)
10-12	3 (4.8)	0 (0.0)	3 (3.8)	4 (9.1)	0 (0.0)	4 (8.0)	7 (5.4)
13-18	2 (3.2)	0 (0.0)	2 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)
19-24	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
25-30	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Source: Listing 16.2.5.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Percentages were based on N. Paclitaxel Grp1: 135-175mg/m^2 IV on Day 1, given every 21 days. Paclitaxel may also be given in doses of 80-100mg/m^2 IV on a weekly schedule; Paclitaxel Grp2--Paclitaxel (Japan): 100 mg/m^2 IV on Day 1, 8, 15, 22, 29, and 36, followed by one week of rest. Docetaxel Grp1: 75 mg/m^2 IV on Day 1, given every 21 days; Docetaxel Grp2--70 mg/m^2 IV on Day 1, given every 21 days for Japan patients.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/ m^2/cycle) = (total dose received / BSA) / Duration of Treatment in cycle * cycle length in days. Baseline weights are used to derive BSA, unless the change of the BSA at the visit are at least 10% or greater than the baseline (increased or decreased).

[c] Relative dose intensity (RDI) is defined as the ratio of the actual dose intensity (mg/ m^2/cycle) and the planned dose intensity (mg/ m^2/cycle). The planned dose intensity is the total planned dose in a cycle.

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Table 14.3.1.1.2.b:
Study Medication Administration - Investigator Chosen Chemotherapy (ICC)
Safety Analysis Set - Subpopulation without Irinotecan

	Paclitaxel			Docetaxel			
	Paclitaxel Grp1 (N = 62)	Paclitaxel Grp2 (N = 17)	Overall (N = 79)	Docetaxel Grp1 (N = 44)	Docetaxel Grp2 (N = 6)	Overall (N = 50)	Overall (N = 129)
31-36	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (2.0)	1 (0.8)
>36	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Source: Listing 16.2.5.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Percentages were based on N. Paclitaxel Grp1: 135-175mg/m^2 IV on Day 1, given every 21 days. Paclitaxel may also be given in doses of 80-100mg/m^2 IV on a weekly schedule; Paclitaxel Grp2--Paclitaxel (Japan): 100 mg/m^2 IV on Day 1, 8, 15, 22, 29, and 36, followed by one week of rest. Docetaxel Grp1: 75 mg/m^2 IV on Day 1, given every 21 days; Docetaxel Grp2--70 mg/m^2 IV on Day 1, given every 21 days for Japan patients.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/ m^2/cycle) = (total dose received / BSA) / Duration of Treatment in cycle * cycle length in days. Baseline weights are used to derive BSA, unless the change of the BSA at the visit are at least 10% or greater than the baseline (increased or decreased).

[c] Relative dose intensity (RDI) is defined as the ratio of the actual dose intensity (mg/ m^2/cycle) and the planned dose intensity (mg/ m^2/cycle). The planned dose intensity is the total planned dose in a cycle.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.2.b:
Study Medication Administration - Investigator Chosen Chemotherapy (ICC)
Safety Analysis Set - Subpopulation without Irinotecan

	Paclitaxel			Docetaxel			
	Paclitaxel Grp1 (N = 62)	Paclitaxel Grp2 (N = 17)	Overall (N = 79)	Docetaxel Grp1 (N = 44)	Docetaxel Grp2 (N = 6)	Overall (N = 50)	Overall (N = 129)
Cumulative Total Dose (mg/m^2) per Patient [a]							
n	62	17	79	44	6	50	
Mean (SD)	705.89 (537.063)	713.20 (668.246)	707.46 (563.189)	304.40 (341.437)	208.37 (85.386)	292.87 (322.555)	
Median	564.40	415.83	540.54	150.96	198.53	150.96	
Q1, Q3	347.00, 865.74	314.83, 731.13	322.55, 865.74	143.55, 333.20	133.93, 258.37	141.99, 299.22	
Min, Max	79.7, 2175.3	210.4, 2675.2	79.7, 2675.2	72.7, 2020.5	128.3, 332.5	72.7, 2020.5	

Source: Listing 16.2.5.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Percentages were based on N. Paclitaxel Grp1: 135-175mg/m^2 IV on Day 1, given every 21 days. Paclitaxel may also be given in doses of 80-100mg/m^2 IV on a weekly schedule; Paclitaxel Grp2--Paclitaxel (Japan): 100 mg/m^2 IV on Day 1, 8, 15, 22, 29, and 36, followed by one week of rest. Docetaxel Grp1: 75 mg/m^2 IV on Day 1, given every 21 days; Docetaxel Grp2--70 mg/m^2 IV on Day 1, given every 21 days for Japan patients.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/ m^2/cycle) = (total dose received / BSA) / Duration of Treatment in cycle * cycle length in days. Baseline weights are used to derive BSA, unless the change of the BSA at the visit are at least 10% or greater than the baseline (increased or decreased).

[c] Relative dose intensity (RDI) is defined as the ratio of the actual dose intensity (mg/ m^2/cycle) and the planned dose intensity (mg/ m^2/cycle). The planned dose intensity is the total planned dose in a cycle.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.2.b:
Study Medication Administration - Investigator Chosen Chemotherapy (ICC)
Safety Analysis Set - Subpopulation without Irinotecan

	Paclitaxel			Docetaxel			
	Paclitaxel Grp1 (N = 62)	Paclitaxel Grp2 (N = 17)	Overall (N = 79)	Docetaxel Grp1 (N = 44)	Docetaxel Grp2 (N = 6)	Overall (N = 50)	Overall (N = 129)
Actual Dose Intensity (mg/m^2/cycle) per Patient [b]							
n	62	17		44	6		
Mean (SD)	170.55 (42.141)	417.24 (79.515)		78.08 (25.893)	62.37 (5.732)		
Median	166.95	421.48		73.69	63.08		
Q1, Q3	137.53, 194.95	367.18, 447.24		70.26, 75.40	57.40, 64.66		
Min, Max	91.8, 289.8	264.2, 572.1		50.0, 219.3	55.0, 71.0		

Source: Listing 16.2.5.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Percentages were based on N. Paclitaxel Grp1: 135-175mg/m^2 IV on Day 1, given every 21 days. Paclitaxel may also be given in doses of 80-100mg/m^2 IV on a weekly schedule; Paclitaxel Grp2--Paclitaxel (Japan): 100 mg/m^2 IV on Day 1, 8, 15, 22, 29, and 36, followed by one week of rest. Docetaxel Grp1: 75 mg/m^2 IV on Day 1, given every 21 days; Docetaxel Grp2--70 mg/m^2 IV on Day 1, given every 21 days for Japan patients.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/ m^2/cycle) = (total dose received / BSA) / Duration of Treatment in cycle * cycle length in days. Baseline weights are used to derive BSA, unless the change of the BSA at the visit are at least 10% or greater than the baseline (increased or decreased).

[c] Relative dose intensity (RDI) is defined as the ratio of the actual dose intensity (mg/ m^2/cycle) and the planned dose intensity (mg/ m^2/cycle). The planned dose intensity is the total planned dose in a cycle.

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Table 14.3.1.1.2.b:
Study Medication Administration - Investigator Chosen Chemotherapy (ICC)
Safety Analysis Set - Subpopulation without Irinotecan

	Paclitaxel			Docetaxel			
	Paclitaxel Grp1 (N = 62)	Paclitaxel Grp2 (N = 17)	Overall (N = 79)	Docetaxel Grp1 (N = 44)	Docetaxel Grp2 (N = 6)	Overall (N = 50)	Overall (N = 129)
Relative Dose Intensity (%) per Patient [c]							
n	62	17	79	44	6	50	129
Mean (SD)	84.96 (17.668)	69.54 (13.252)	81.64 (17.911)	104.11 (34.524)	89.10 (8.189)	102.31 (32.819)	89.65 (26.645)
Median	87.31	70.25	82.83	98.25	90.12	97.65	92.54
Q1, Q3	71.71, 100.00	61.20, 74.54	67.51, 100.00	93.68, 100.53	82.00, 92.37	92.27, 100.51	75.56, 100.00
Min, Max	37.6, 126.0	44.0, 95.4	37.6, 126.0	66.7, 292.4	78.6, 101.4	66.7, 292.4	37.6, 292.4

Source: Listing 16.2.5.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Percentages were based on N. Paclitaxel Grp1: 135-175mg/m^2 IV on Day 1, given every 21 days. Paclitaxel may also be given in doses of 80-100mg/m^2 IV on a weekly schedule; Paclitaxel Grp2--Paclitaxel (Japan): 100 mg/m^2 IV on Day 1, 8, 15, 22, 29, and 36, followed by one week of rest. Docetaxel Grp1: 75 mg/m^2 IV on Day 1, given every 21 days; Docetaxel Grp2--70 mg/m^2 IV on Day 1, given every 21 days for Japan patients.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/ m^2/cycle) = (total dose received / BSA) / Duration of Treatment in cycle * cycle length in days. Baseline weights are used to derive BSA, unless the change of the BSA at the visit are at least 10% or greater than the baseline (increased or decreased).

[c] Relative dose intensity (RDI) is defined as the ratio of the actual dose intensity (mg/ m^2/cycle) and the planned dose intensity (mg/ m^2/cycle). The planned dose intensity is the total planned dose in a cycle.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.2.b:
Study Medication Administration - Investigator Chosen Chemotherapy (ICC)
Safety Analysis Set - Subpopulation without Irinotecan

	Paclitaxel			Docetaxel			
	Paclitaxel Grp1 (N = 62)	Paclitaxel Grp2 (N = 17)	Overall (N = 79)	Docetaxel Grp1 (N = 44)	Docetaxel Grp2 (N = 6)	Overall (N = 50)	Overall (N = 129)
Patients with Any Dose Modification, n (%) [d]	38 (61.3)	15 (88.2)	53 (67.1)	17 (38.6)	4 (66.7)	21 (42.0)	74 (57.4)
Dose Reduction	19 (30.6)	10 (58.8)	29 (36.7)	8 (18.2)	4 (66.7)	12 (24.0)	41 (31.8)
Adverse Event	18 (29.0)	5 (29.4)	23 (29.1)	8 (18.2)	4 (66.7)	12 (24.0)	35 (27.1)

Source: Listing 16.2.5.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Percentages were based on N. Paclitaxel Grp1: 135-175mg/m^2 IV on Day 1, given every 21 days. Paclitaxel may also be given in doses of 80-100mg/m^2 IV on a weekly schedule; Paclitaxel Grp2--Paclitaxel (Japan): 100 mg/m^2 IV on Day 1, 8, 15, 22, 29, and 36, followed by one week of rest. Docetaxel Grp1: 75 mg/m^2 IV on Day 1, given every 21 days; Docetaxel Grp2--70 mg/m^2 IV on Day 1, given every 21 days for Japan patients.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/ m^2/cycle) = (total dose received / BSA) / Duration of Treatment in cycle * cycle length in days. Baseline weights are used to derive BSA, unless the change of the BSA at the visit are at least 10% or greater than the baseline (increased or decreased).

[c] Relative dose intensity (RDI) is defined as the ratio of the actual dose intensity (mg/ m^2/cycle) and the planned dose intensity (mg/ m^2/cycle). The planned dose intensity is the total planned dose in a cycle.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.2.b:
Study Medication Administration - Investigator Chosen Chemotherapy (ICC)
Safety Analysis Set - Subpopulation without Irinotecan

	Paclitaxel			Docetaxel			
	Paclitaxel Grp1 (N = 62)	Paclitaxel Grp2 (N = 17)	Overall (N = 79)	Docetaxel Grp1 (N = 44)	Docetaxel Grp2 (N = 6)	Overall (N = 50)	Overall (N = 129)
Dose Delay	26 (41.9)	15 (88.2)	41 (51.9)	15 (34.1)	2 (33.3)	17 (34.0)	58 (45.0)
Adverse Event	21 (33.9)	14 (82.4)	35 (44.3)	8 (18.2)	2 (33.3)	10 (20.0)	45 (34.9)
Other	10 (16.1)	3 (17.6)	13 (16.5)	4 (9.1)	0 (0.0)	4 (8.0)	17 (13.2)
COVID-19	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (2.0)	1 (0.8)

Source: Listing 16.2.5.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Percentages were based on N. Paclitaxel Grp1: 135-175mg/m^2 IV on Day 1, given every 21 days. Paclitaxel may also be given in doses of 80-100mg/m^2 IV on a weekly schedule; Paclitaxel Grp2--Paclitaxel (Japan): 100 mg/m^2 IV on Day 1, 8, 15, 22, 29, and 36, followed by one week of rest. Docetaxel Grp1: 75 mg/m^2 IV on Day 1, given every 21 days; Docetaxel Grp2--70 mg/m^2 IV on Day 1, given every 21 days for Japan patients.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/ m^2/cycle) = (total dose received / BSA) / Duration of Treatment in cycle * cycle length in days. Baseline weights are used to derive BSA, unless the change of the BSA at the visit are at least 10% or greater than the baseline (increased or decreased).

[c] Relative dose intensity (RDI) is defined as the ratio of the actual dose intensity (mg/ m^2/cycle) and the planned dose intensity (mg/ m^2/cycle). The planned dose intensity is the total planned dose in a cycle.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.1.2.b:
Study Medication Administration - Investigator Chosen Chemotherapy (ICC)
Safety Analysis Set - Subpopulation without Irinotecan

	Paclitaxel			Docetaxel			
	Paclitaxel Grp1 (N = 62)	Paclitaxel Grp2 (N = 17)	Overall (N = 79)	Docetaxel Grp1 (N = 44)	Docetaxel Grp2 (N = 6)	Overall (N = 50)	Overall (N = 129)
Infusion Interrupted	7 (11.3)	0 (0.0)	7 (8.9)	1 (2.3)	0 (0.0)	1 (2.0)	8 (6.2)
Adverse Event	4 (6.5)	0 (0.0)	4 (5.1)	1 (2.3)	0 (0.0)	1 (2.0)	5 (3.9)
Other	3 (4.8)	0 (0.0)	3 (3.8)	0 (0.0)	0 (0.0)	0 (0.0)	3 (2.3)
COVID-19	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Source: Listing 16.2.5.2. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Percentages were based on N. Paclitaxel Grp1: 135-175mg/m^2 IV on Day 1, given every 21 days. Paclitaxel may also be given in doses of 80-100mg/m^2 IV on a weekly schedule; Paclitaxel Grp2--Paclitaxel (Japan): 100 mg/m^2 IV on Day 1, 8, 15, 22, 29, and 36, followed by one week of rest. Docetaxel Grp1: 75 mg/m^2 IV on Day 1, given every 21 days; Docetaxel Grp2--70 mg/m^2 IV on Day 1, given every 21 days for Japan patients.

Duration of exposure is based on minimum of (death date, last dose date, cut-off date) and cycle length, i.e., cycle length is depending on the planned frequency of study drug (Tislelizumab or each ICC options per protocol). For the patients with death occurred prior to end of planned cycle, the actual dose intensity (based on duration of exposure) will be higher than planned dose intensity (based on cycles in study treatment), thus these patients may have relative dose intensity (RDI) higher than 100%.

[a] Cumulative total dose (mg) per subject will be computed as the sum of all the doses received in each cycle for each study drug.

[b] Actual dose intensity (mg/ m^2/cycle) = (total dose received / BSA) / Duration of Treatment in cycle * cycle length in days. Baseline weights are used to derive BSA, unless the change of the BSA at the visit are at least 10% or greater than the baseline (increased or decreased).

[c] Relative dose intensity (RDI) is defined as the ratio of the actual dose intensity (mg/ m^2/cycle) and the planned dose intensity (mg/ m^2/cycle). The planned dose intensity is the total planned dose in a cycle.

[d] A patient was counted only once within each category but may be counted in multiple categories.

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Table 14.3.1.2.1.1:
Time to Treatment-Emergent Adverse Events
Safety Analysis Set

	Tislelizumab (N = 255)			ICC (N = 240)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Any TEAE	255	245 (96.1)	0.3 (0.3, 0.5)	240	236 (98.3)	0.1 (0.1, 0.1)	0.440 (0.361, 0.535)	<0.0001
TEAE >= Grade 3	255	123 (48.2)	6.2 (3.6, 10.1)	240	163 (67.9)	0.9 (0.5, 1.0)	0.364 (0.283, 0.468)	<0.0001
Serious TEAE	255	109 (42.7)	9.0 (5.6, 14.0)	240	106 (44.2)	4.2 (2.8, 8.6)	0.623 (0.470, 0.827)	0.0009
TEAE Leading to Treatment Discontinuation	255	49 (19.2)	NR (14.0, NE)	240	64 (26.7)	7.9 (6.1, NE)	0.432 (0.290, 0.642)	<0.0001

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.1.1.b:
Time to Treatment-Emergent Adverse Events
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 129)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Any TEAE	139	135 (97.1)	0.3 (0.3, 0.5)	129	126 (97.7)	0.1 (0.1, 0.2)	0.511 (0.393, 0.664)	<0.0001
TEAE >= Grade 3	139	68 (48.9)	6.9 (3.1, 10.8)	129	88 (68.2)	0.9 (0.5, 1.2)	0.379 (0.269, 0.532)	<0.0001
Serious TEAE	139	64 (46.0)	9.0 (4.0, 14.0)	129	55 (42.6)	6.1 (3.0, 8.6)	0.707 (0.482, 1.038)	0.0738
TEAE Leading to Treatment Discontinuation	139	25 (18.0)	NR (14.0, NE)	129	28 (21.7)	NR (6.5, NE)	0.544 (0.306, 0.966)	0.0351

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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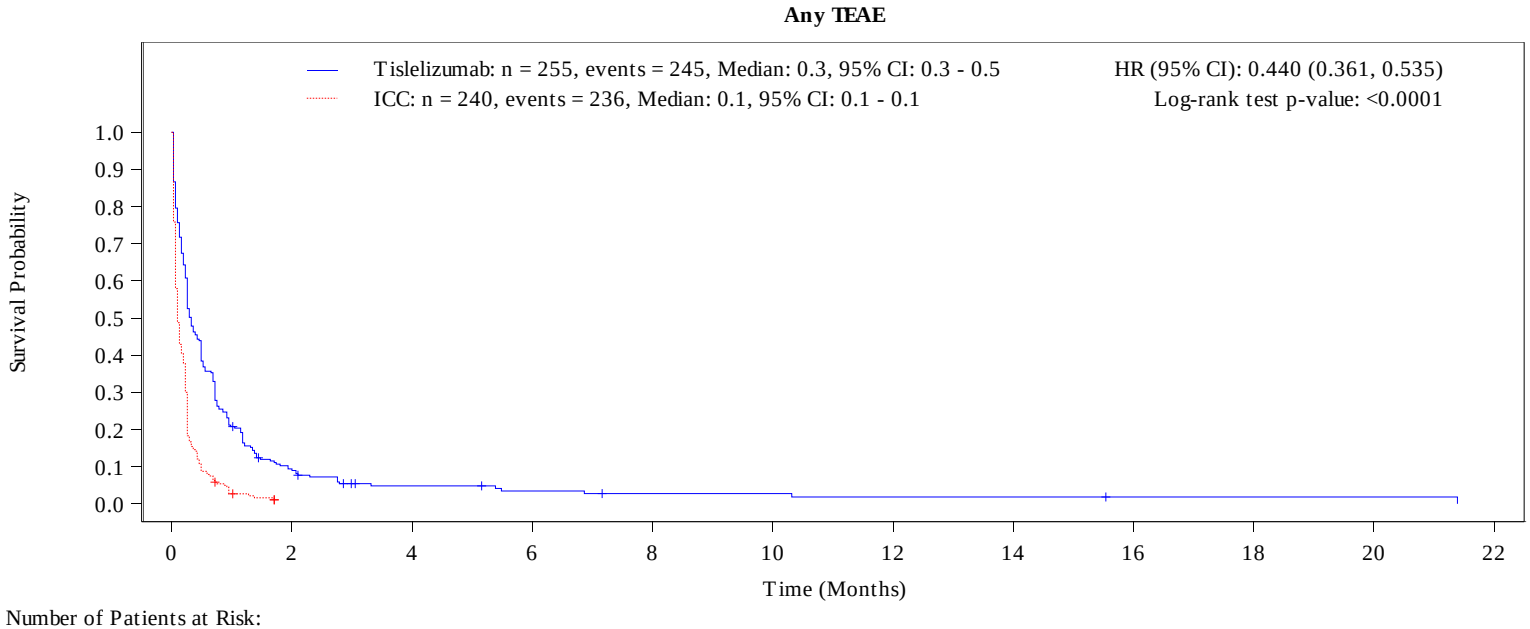
Figure 14.3.1.1:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	255	22	8	5	3	3	2	2	1	1	1	0
ICC	240	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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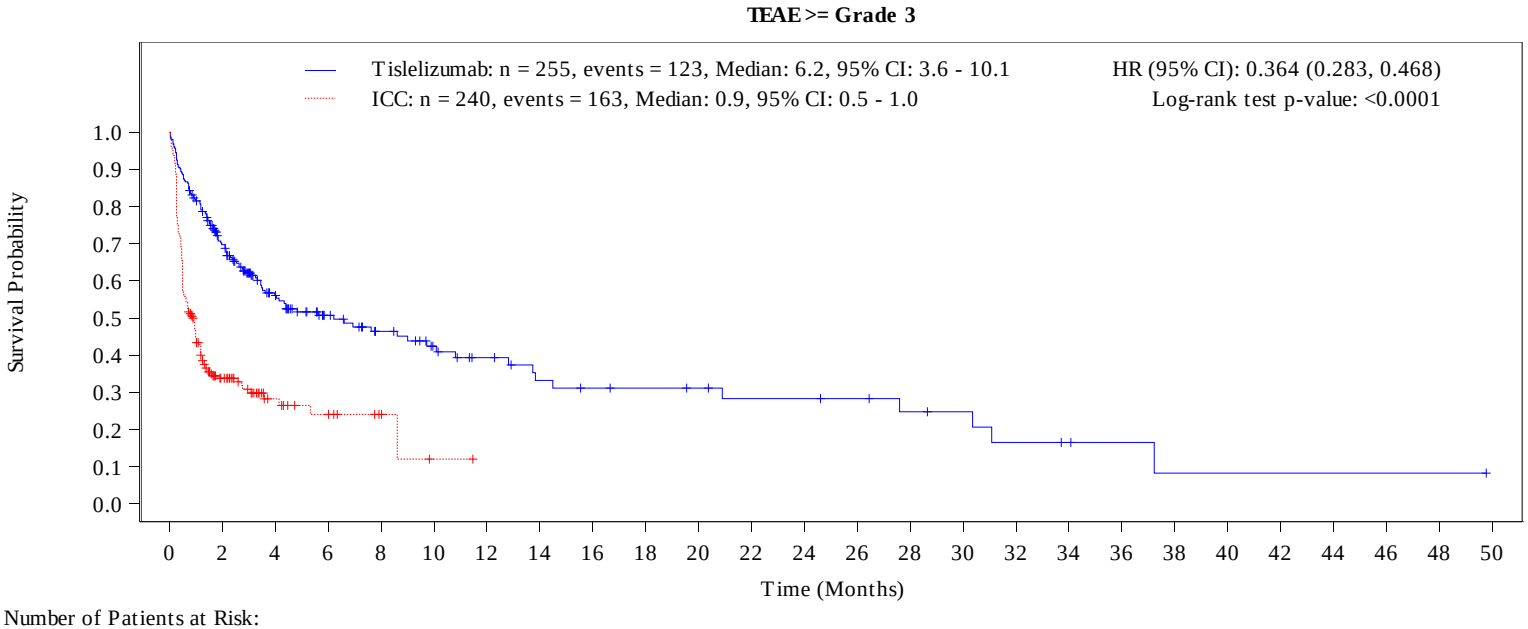
Figure 14.3.1.1:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events
Safety Analysis Set

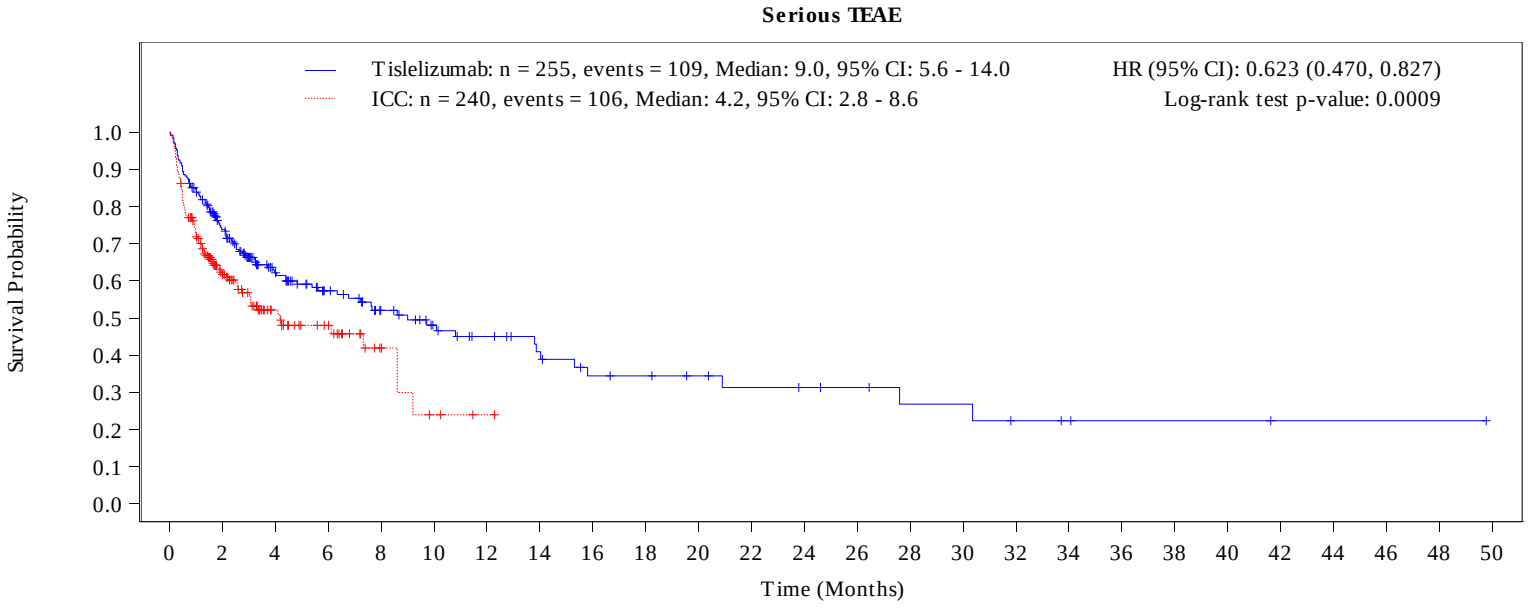


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	143	79	50	38	28	21	16	14	13	12	10	10	9	7	6	4	3	2	1	1	1	1	1	1	0
ICC	240	49	16	10	5	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteae.sas 13AUG2024 18:49 f-14-03-01-01-km-tteae-safety-cl.rtf

Figure 14.3.1.1:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	154	85	59	43	32	25	20	15	14	12	10	9	8	6	6	4	3	2	2	2	1	1	1	1	0
ICC	240	92	38	22	8	3	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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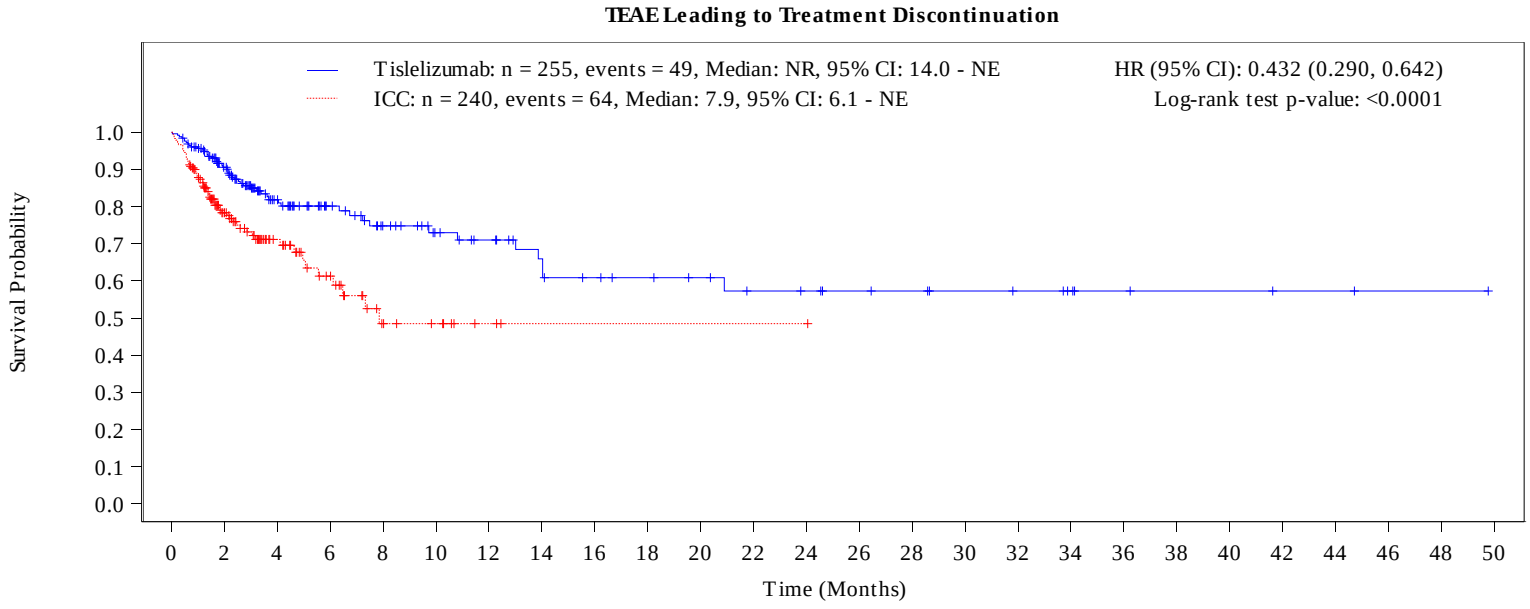
Figure 14.3.1.1:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	172	97	64	49	38	32	26	22	20	18	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	106	45	26	11	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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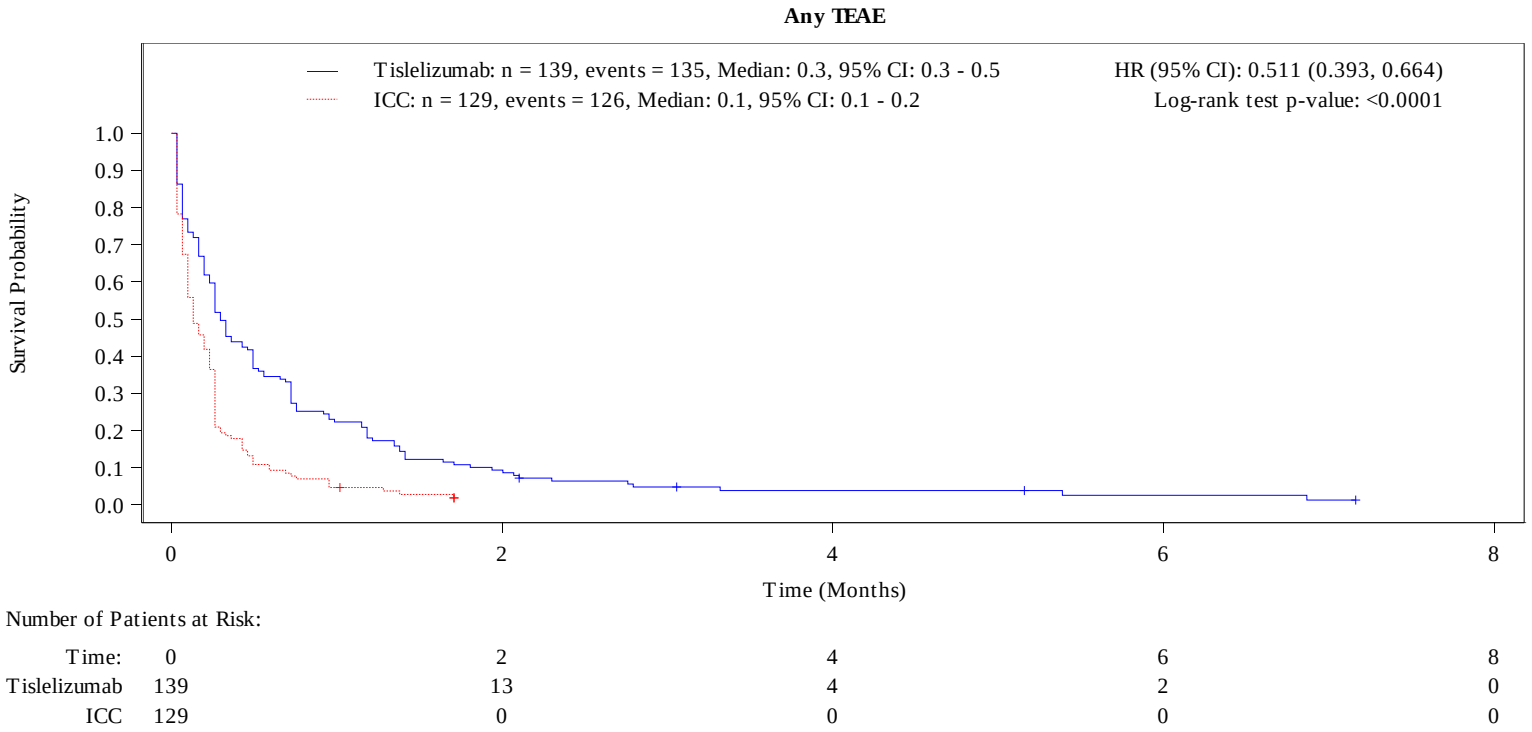
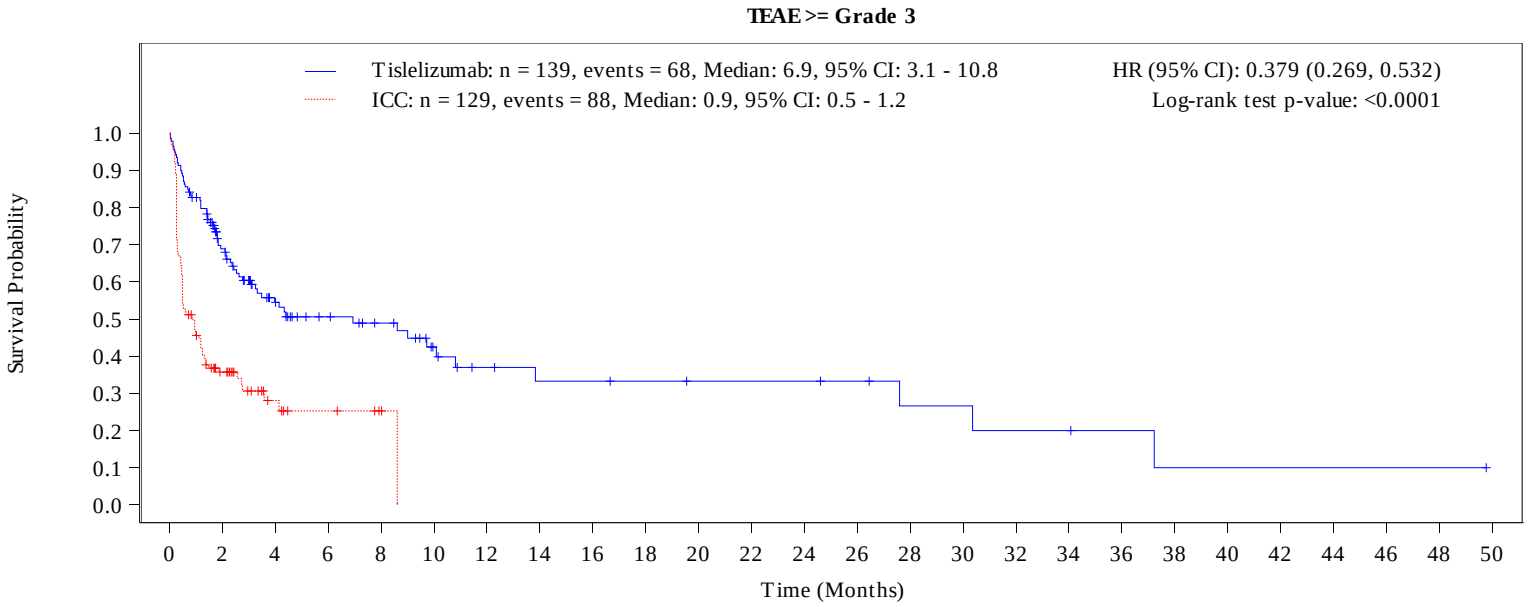
Figure 14.3.1.1.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteae.sas 13AUG2024 18:49 f-14-03-01-01-b-km-tteae-safetys-cl.rtf

Figure 14.3.1.1.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events
Safety Analysis Set - Subpopulation without Irinotecan

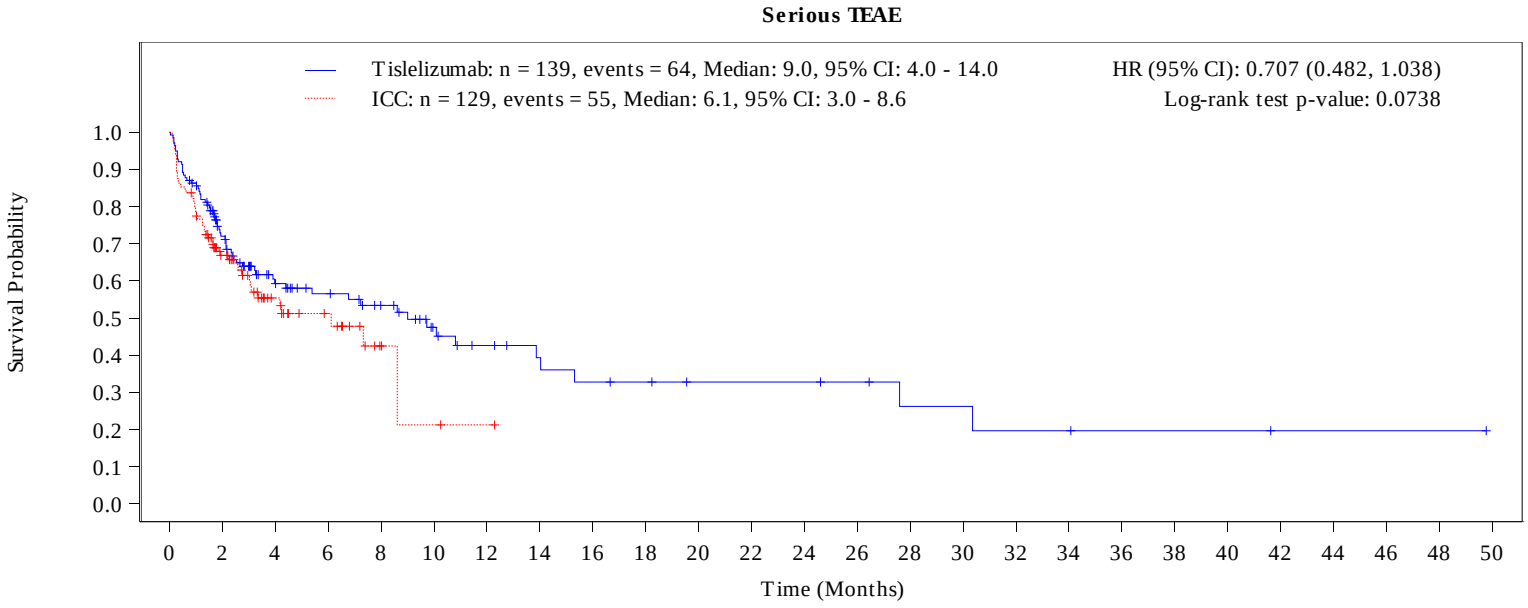


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	75	43	31	25	16	11	9	9	8	7	7	7	6	4	4	3	3	2	1	1	1	1	1	1	0
ICC	129	33	10	6	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteae.sas 13AUG2024 18:49 f-14-03-01-01-b-km-tteae-safetys-cl.rtf

Figure 14.3.1.1.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events
Safety Analysis Set - Subpopulation without Irinotecan

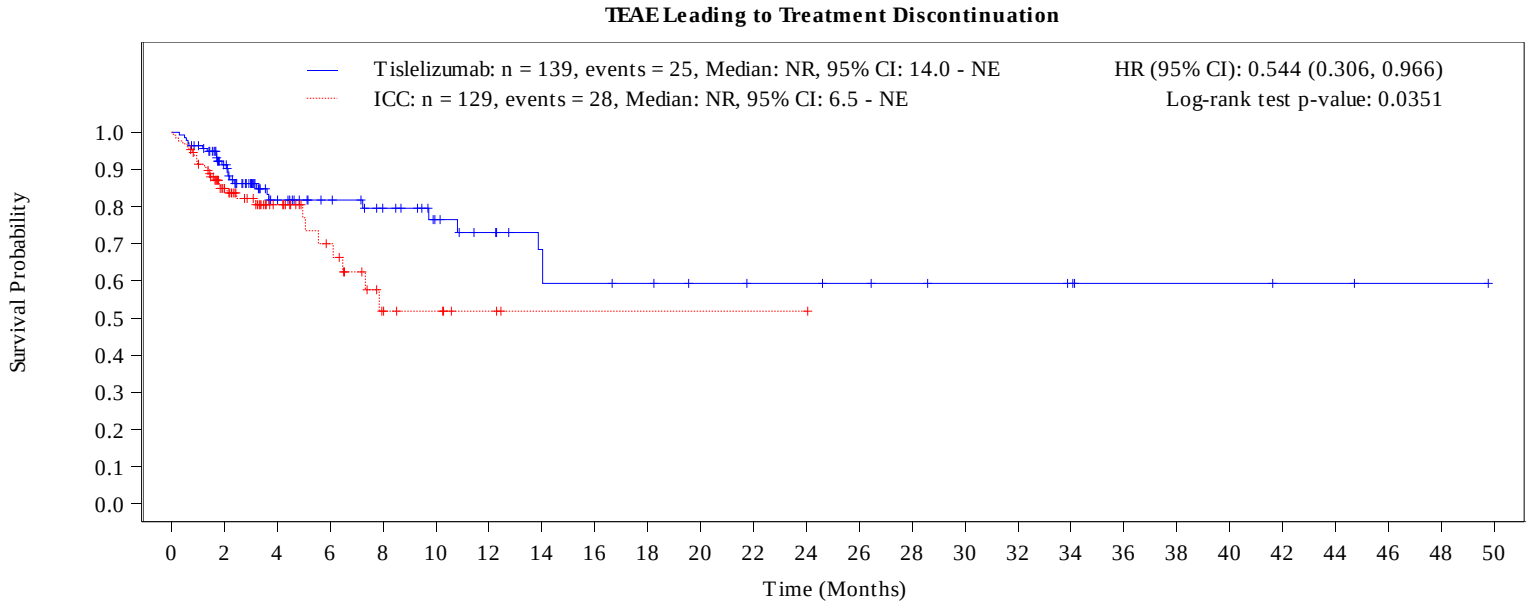


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	82	49	38	30	20	15	12	10	9	7	7	7	6	4	4	3	3	2	2	2	1	1	1	1	0
ICC	129	62	27	15	5	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteae.sas 13AUG2024 18:49 f-14-03-01-01-b-km-tteae-safetys-cl.rtf

Figure 14.3.1.1.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	93	52	40	32	23	19	15	13	12	10	9	9	8	7	6	6	5	3	3	3	2	2	1	1	0
ICC	129	71	33	19	8	6	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteae.sas 13AUG2024 18:49 f-14-03-01-01-b-km-tteae-safetys-cl.rtf

Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Any TEAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	150 (98.7)	0.3 (0.3, 0.4)	146	143 (97.9)	0.1 (0.1, 0.1)	0.480 (0.376, 0.613)	<0.0001
>= 65 Years	103	95 (92.2)	0.4 (0.3, 0.5)	94	93 (98.9)	0.1 (0.1, 0.2)	0.419 (0.308, 0.570)	<0.0001
Interaction								0.4512
Gender								
Male	216	207 (95.8)	0.3 (0.3, 0.5)	204	201 (98.5)	0.1 (0.1, 0.2)	0.442 (0.359, 0.545)	<0.0001
Female	39	38 (97.4)	0.2 (0.2, 0.4)	36	35 (97.2)	0.1 (0.1, 0.2)	0.525 (0.323, 0.852)	0.0046
Interaction								0.5502

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Any TEAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	179 (95.7)	0.3 (0.3, 0.5)	183	179 (97.8)	0.1 (0.1, 0.1)	0.478 (0.384, 0.596)	<0.0001
Non-Smoker	68	66 (97.1)	0.4 (0.2, 0.6)	57	57 (100.0)	0.1 (0.1, 0.2)	0.346 (0.229, 0.523)	<0.0001
Interaction								0.9247
ICC Options								
Paclitaxel	83	80 (96.4)	0.3 (0.2, 0.5)	79	78 (98.7)	0.2 (0.1, 0.3)	0.555 (0.400, 0.772)	0.0002
Docetaxel	56	55 (98.2)	0.3 (0.2, 0.5)	50	48 (96.0)	0.1 (0.1, 0.2)	0.483 (0.319, 0.733)	0.0002
Irinotecan	116	110 (94.8)	0.4 (0.3, 0.5)	111	110 (99.1)	0.1 (0.1, 0.1)	0.365 (0.272, 0.490)	<0.0001
Interaction								0.1216

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Any TEAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	60 (95.2)	0.5 (0.3, 0.7)	57	55 (96.5)	0.2 (0.1, 0.3)	0.543 (0.370, 0.797)	0.0008
1	192	185 (96.4)	0.3 (0.3, 0.4)	183	181 (98.9)	0.1 (0.1, 0.1)	0.422 (0.337, 0.528)	<0.0001
Interaction								0.2228
Region #1								
Asia	201	193 (96.0)	0.4 (0.3, 0.5)	191	189 (99.0)	0.1 (0.1, 0.1)	0.373 (0.300, 0.464)	<0.0001
Europe/North America	54	52 (96.3)	0.1 (0.1, 0.2)	49	47 (95.9)	0.2 (0.1, 0.3)	0.889 (0.593, 1.333)	0.5348
Interaction								0.0017

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Any TEAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	169 (96.0)	0.3 (0.3, 0.5)	168	167 (99.4)	0.1 (0.1, 0.1)	0.353 (0.279, 0.447)	<0.0001
Japan	25	24 (96.0)	0.6 (0.4, 1.1)	23	22 (95.7)	0.2 (0.1, 0.3)	0.452 (0.246, 0.832)	0.0074
Europe/North America	54	52 (96.3)	0.1 (0.1, 0.2)	49	47 (95.9)	0.2 (0.1, 0.3)	0.889 (0.593, 1.333)	0.5348
Interaction								0.0029
Race								
Asian and other	203	195 (96.1)	0.4 (0.3, 0.5)	198	195 (98.5)	0.1 (0.1, 0.1)	0.399 (0.322, 0.494)	<0.0001
White	52	50 (96.2)	0.1 (0.1, 0.2)	42	41 (97.6)	0.1 (0.1, 0.3)	0.774 (0.505, 1.186)	0.1931
Interaction								0.0394

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Any TEAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	77 (96.3)	0.3 (0.3, 0.5)	60	58 (96.7)	0.1 (0.1, 0.2)	0.455 (0.316, 0.654)	<0.0001
vCPS < 10%	100	95 (95.0)	0.2 (0.2, 0.3)	119	117 (98.3)	0.1 (0.1, 0.2)	0.573 (0.431, 0.760)	<0.0001
Missing	75	73 (97.3)	0.5 (0.3, 0.7)	61	61 (100.0)	0.1 (0.1, 0.2)	0.335 (0.229, 0.489)	<0.0001
Interaction								0.2633

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	75 (49.3)	5.6 (2.8, 12.8)	146	95 (65.1)	1.0 (0.5, 1.2)	0.393 (0.285, 0.542)	<0.0001
>= 65 Years	103	48 (46.6)	6.6 (3.5, 13.7)	94	68 (72.3)	0.7 (0.5, 1.2)	0.337 (0.228, 0.500)	<0.0001
Interaction								0.3530
Gender								
Male	216	105 (48.6)	6.6 (4.0, 10.8)	204	138 (67.6)	0.9 (0.5, 1.0)	0.366 (0.279, 0.480)	<0.0001
Female	39	18 (46.2)	3.5 (1.7, NE)	36	25 (69.4)	0.9 (0.5, 1.4)	0.391 (0.209, 0.730)	0.0021
Interaction								0.9477

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	91 (48.7)	6.6 (3.6, 10.8)	183	124 (67.8)	0.9 (0.5, 1.2)	0.359 (0.269, 0.478)	<0.0001
Non-Smoker	68	32 (47.1)	6.2 (2.1, 20.9)	57	39 (68.4)	1.0 (0.5, 1.3)	0.402 (0.245, 0.659)	0.0002
Interaction								0.7649
ICC Options								
Paclitaxel	83	40 (48.2)	10.8 (2.5, 30.4)	79	53 (67.1)	1.2 (0.5, 1.9)	0.418 (0.271, 0.646)	<0.0001
Docetaxel	56	28 (50.0)	6.9 (2.4, 9.7)	50	35 (70.0)	0.3 (0.3, 1.0)	0.313 (0.181, 0.541)	<0.0001
Irinotecan	116	55 (47.4)	6.2 (3.5, 13.7)	111	75 (67.6)	0.9 (0.6, 1.0)	0.354 (0.244, 0.514)	<0.0001
Interaction								0.7792

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	22 (34.9)	13.8 (6.9, NE)	57	33 (57.9)	1.2 (0.5, NE)	0.299 (0.166, 0.539)	<0.0001
1	192	101 (52.6)	3.6 (2.8, 6.6)	183	130 (71.0)	0.7 (0.5, 1.0)	0.382 (0.290, 0.503)	<0.0001
Interaction								0.5796
Region #1								
Asia	201	93 (46.3)	7.6 (4.3, 10.8)	191	128 (67.0)	0.7 (0.5, 1.0)	0.323 (0.242, 0.431)	<0.0001
Europe/North America	54	30 (55.6)	2.5 (1.7, NE)	49	35 (71.4)	1.2 (0.5, 2.6)	0.567 (0.346, 0.929)	0.0216
Interaction								0.1019

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	81 (46.0)	6.9 (4.0, 10.8)	168	112 (66.7)	0.8 (0.5, 1.0)	0.327 (0.240, 0.445)	<0.0001
Japan	25	12 (48.0)	10.1 (1.9, NE)	23	16 (69.6)	0.5 (0.3, 1.3)	0.298 (0.129, 0.688)	0.0023
Europe/North America	54	30 (55.6)	2.5 (1.7, NE)	49	35 (71.4)	1.2 (0.5, 2.6)	0.567 (0.346, 0.929)	0.0216
Interaction								0.2361
Race								
Asian and other	203	94 (46.3)	7.6 (4.1, 10.8)	198	132 (66.7)	0.7 (0.5, 1.0)	0.331 (0.249, 0.441)	<0.0001
White	52	29 (55.8)	2.5 (1.7, NE)	42	31 (73.8)	1.2 (0.5, 2.6)	0.538 (0.322, 0.897)	0.0152
Interaction								0.1793

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	38 (47.5)	6.6 (3.4, 14.5)	60	44 (73.3)	1.0 (0.5, 1.3)	0.259 (0.161, 0.417)	<0.0001
vCPS < 10%	100	55 (55.0)	4.0 (2.1, 9.0)	119	84 (70.6)	0.7 (0.5, 1.0)	0.426 (0.298, 0.608)	<0.0001
Missing	75	30 (40.0)	13.7 (3.5, NE)	61	35 (57.4)	1.2 (0.5, 5.3)	0.426 (0.255, 0.711)	0.0006
Interaction								0.4936

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Serious TEAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	70 (46.1)	7.2 (3.7, 13.9)	146	63 (43.2)	4.2 (2.0, NE)	0.721 (0.508, 1.024)	0.0658
>= 65 Years	103	39 (37.9)	13.8 (6.8, NE)	94	43 (45.7)	4.1 (2.6, NE)	0.527 (0.332, 0.837)	0.0057
Interaction								0.2524
Gender								
Male	216	95 (44.0)	8.6 (5.4, 13.9)	204	92 (45.1)	4.1 (2.6, 8.6)	0.646 (0.480, 0.870)	0.0037
Female	39	14 (35.9)	15.3 (4.4, NE)	36	14 (38.9)	8.6 (1.9, NE)	0.652 (0.301, 1.412)	0.2732
Interaction								0.8577

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Serious TEAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	84 (44.9)	8.6 (4.4, 13.9)	183	81 (44.3)	4.2 (2.8, 8.6)	0.665 (0.484, 0.915)	0.0113
Non-Smoker	68	25 (36.8)	20.9 (6.3, NE)	57	25 (43.9)	7.3 (1.8, NE)	0.594 (0.336, 1.052)	0.0698
Interaction								0.4588
ICC Options								
Paclitaxel	83	33 (39.8)	15.3 (7.2, NE)	79	30 (38.0)	8.6 (3.4, NE)	0.800 (0.476, 1.345)	0.3974
Docetaxel	56	31 (55.4)	4.4 (2.1, 9.0)	50	25 (50.0)	3.1 (1.3, 7.3)	0.640 (0.367, 1.116)	0.1100
Irinotecan	116	45 (38.8)	7.7 (4.8, 20.9)	111	51 (45.9)	3.1 (1.6, NE)	0.536 (0.353, 0.813)	0.0028
Interaction								0.4150

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Serious TEAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	23 (36.5)	13.9 (7.2, NE)	57	18 (31.6)	8.6 (4.2, NE)	0.676 (0.351, 1.302)	0.2382
1	192	86 (44.8)	7.6 (3.9, 13.8)	183	88 (48.1)	3.0 (1.9, 6.1)	0.631 (0.464, 0.859)	0.0030
Interaction								0.4204
Region #1								
Asia	201	86 (42.8)	9.0 (5.6, 13.9)	191	82 (42.9)	4.2 (2.2, NE)	0.629 (0.458, 0.863)	0.0036
Europe/North America	54	23 (42.6)	15.3 (2.6, NE)	49	24 (49.0)	6.1 (2.5, 9.2)	0.714 (0.398, 1.281)	0.2544
Interaction								0.7588

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Serious TEAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	76 (43.2)	7.7 (4.0, 13.8)	168	72 (42.9)	4.2 (2.2, NE)	0.645 (0.461, 0.902)	0.0096
Japan	25	10 (40.0)	13.9 (6.8, NE)	23	10 (43.5)	NR (1.1, NE)	0.511 (0.197, 1.327)	0.1596
Europe/North America	54	23 (42.6)	15.3 (2.6, NE)	49	24 (49.0)	6.1 (2.5, 9.2)	0.714 (0.398, 1.281)	0.2544
Interaction								0.8991
Race								
Asian and other	203	87 (42.9)	9.0 (5.6, 13.9)	198	84 (42.4)	4.2 (2.6, NE)	0.651 (0.476, 0.890)	0.0066
White	52	22 (42.3)	15.3 (2.6, NE)	42	22 (52.4)	6.1 (2.5, 8.6)	0.649 (0.355, 1.187)	0.1557
Interaction								0.9366

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Serious TEAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	31 (38.8)	13.9 (6.3, 30.4)	60	27 (45.0)	3.1 (1.9, NE)	0.433 (0.247, 0.759)	0.0027
vCPS < 10%	100	49 (49.0)	6.8 (2.9, 10.8)	119	53 (44.5)	4.2 (2.5, NE)	0.843 (0.567, 1.254)	0.3964
Missing	75	29 (38.7)	13.8 (3.3, NE)	61	26 (42.6)	7.3 (1.6, NE)	0.628 (0.363, 1.085)	0.0910
Interaction								0.2655

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

TEAE Leading to Treatment Discontinuation

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	30 (19.7)	20.9 (13.0, NE)	146	33 (22.6)	7.9 (5.0, NE)	0.503 (0.299, 0.848)	0.0086
>= 65 Years	103	19 (18.4)	NR (NE, NE)	94	31 (33.0)	7.3 (5.1, NE)	0.399 (0.221, 0.720)	0.0016
Interaction								0.2494
Gender								
Male	216	42 (19.4)	NR (14.0, NE)	204	55 (27.0)	7.9 (5.6, NE)	0.442 (0.289, 0.676)	0.0001
Female	39	7 (17.9)	NR (7.2, NE)	36	9 (25.0)	NR (2.6, NE)	0.563 (0.207, 1.534)	0.2548
Interaction								0.8441

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

TEAE Leading to Treatment Discontinuation

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	35 (18.7)	NR (14.0, NE)	183	48 (26.2)	NR (6.1, NE)	0.458 (0.290, 0.722)	0.0006
Non-Smoker	68	14 (20.6)	20.9 (7.5, NE)	57	16 (28.1)	7.3 (4.6, NE)	0.484 (0.231, 1.013)	0.0495
Interaction								0.8405
ICC Options								
Paclitaxel	83	11 (13.3)	NR (14.0, NE)	79	19 (24.1)	NR (5.1, NE)	0.365 (0.163, 0.815)	0.0105
Docetaxel	56	14 (25.0)	14.0 (9.7, NE)	50	9 (18.0)	7.3 (5.6, NE)	0.936 (0.397, 2.207)	0.8791
Irinotecan	116	24 (20.7)	NR (13.0, NE)	111	36 (32.4)	4.6 (2.9, NE)	0.359 (0.208, 0.619)	0.0001
Interaction								0.0799

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

TEAE Leading to Treatment Discontinuation

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	9 (14.3)	NR (13.9, NE)	57	14 (24.6)	NR (5.0, NE)	0.284 (0.112, 0.720)	0.0049
1	192	40 (20.8)	NR (14.0, NE)	183	50 (27.3)	7.9 (6.1, NE)	0.515 (0.336, 0.791)	0.0020
Interaction								0.6162
Region #1								
Asia	201	41 (20.4)	NR (13.9, NE)	191	49 (25.7)	NR (6.5, NE)	0.492 (0.319, 0.760)	0.0011
Europe/North America	54	8 (14.8)	NR (NE, NE)	49	15 (30.6)	7.3 (5.0, NE)	0.401 (0.169, 0.949)	0.0313
Interaction								0.5563

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

TEAE Leading to Treatment Discontinuation

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	39 (22.2)	NR (14.0, NE)	168	45 (26.8)	NR (6.5, NE)	0.530 (0.340, 0.826)	0.0044
Japan	25	2 (8.0)	NR (10.8, NE)	23	4 (17.4)	NR (5.1, NE)	0.114 (0.011, 1.160)	0.0366
Europe/North America	54	8 (14.8)	NR (NE, NE)	49	15 (30.6)	7.3 (5.0, NE)	0.401 (0.169, 0.949)	0.0313
Interaction								0.6715
Race								
Asian and other	203	42 (20.7)	NR (13.9, NE)	198	50 (25.3)	NR (6.5, NE)	0.513 (0.334, 0.787)	0.0019
White	52	7 (13.5)	NR (NE, NE)	42	14 (33.3)	6.1 (5.0, NE)	0.333 (0.134, 0.829)	0.0129
Interaction								0.3113

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

TEAE Leading to Treatment Discontinuation

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	15 (18.8)	NR (10.8, NE)	60	19 (31.7)	7.9 (4.6, NE)	0.343 (0.170, 0.692)	0.0018
vCPS < 10%	100	20 (20.0)	14.0 (13.0, NE)	119	28 (23.5)	NR (5.6, NE)	0.559 (0.305, 1.025)	0.0565
Missing	75	14 (18.7)	NR (20.9, NE)	61	17 (27.9)	7.3 (5.1, NE)	0.495 (0.238, 1.027)	0.0540
Interaction								0.4521

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	76 (100.0)	0.3 (0.2, 0.4)	69	67 (97.1)	0.1 (0.1, 0.2)	0.579 (0.410, 0.818)	0.0008
>= 65 Years	63	59 (93.7)	0.4 (0.2, 0.6)	60	59 (98.3)	0.2 (0.1, 0.2)	0.474 (0.322, 0.696)	<0.0001
Interaction								0.3558
Gender								
Male	118	115 (97.5)	0.3 (0.3, 0.5)	106	104 (98.1)	0.1 (0.1, 0.2)	0.526 (0.397, 0.697)	<0.0001
Female	21	20 (95.2)	0.3 (0.2, 0.5)	23	22 (95.7)	0.1 (0.1, 0.2)	0.539 (0.285, 1.018)	0.0423
Interaction								0.9109

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	102 (98.1)	0.3 (0.2, 0.4)	101	98 (97.0)	0.1 (0.1, 0.2)	0.558 (0.417, 0.747)	<0.0001
Non-Smoker	35	33 (94.3)	0.4 (0.2, 0.7)	28	28 (100.0)	0.2 (0.1, 0.3)	0.370 (0.206, 0.667)	0.0003
Interaction								0.7349
ICC Options								
Paclitaxel	83	80 (96.4)	0.3 (0.2, 0.5)	79	78 (98.7)	0.2 (0.1, 0.3)	0.555 (0.400, 0.772)	0.0002
Docetaxel	56	55 (98.2)	0.3 (0.2, 0.5)	50	48 (96.0)	0.1 (0.1, 0.2)	0.483 (0.319, 0.733)	0.0002
Interaction								0.5106

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	40 (93.0)	0.4 (0.3, 0.7)	37	35 (94.6)	0.2 (0.1, 0.3)	0.558 (0.346, 0.899)	0.0095
1	96	95 (99.0)	0.3 (0.2, 0.4)	92	91 (98.9)	0.1 (0.1, 0.2)	0.501 (0.367, 0.683)	<0.0001
Interaction								0.9091
Region #1								
Asia	103	101 (98.1)	0.4 (0.3, 0.5)	99	98 (99.0)	0.1 (0.1, 0.2)	0.432 (0.321, 0.581)	<0.0001
Europe/North America	36	34 (94.4)	0.2 (0.1, 0.2)	30	28 (93.3)	0.2 (0.1, 0.3)	0.943 (0.564, 1.577)	0.8102
Interaction								0.0705

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	77 (98.7)	0.3 (0.3, 0.5)	76	76 (100.0)	0.1 (0.1, 0.2)	0.413 (0.293, 0.584)	<0.0001
Japan	25	24 (96.0)	0.6 (0.4, 1.1)	23	22 (95.7)	0.2 (0.1, 0.3)	0.452 (0.246, 0.832)	0.0074
Europe/North America	36	34 (94.4)	0.2 (0.1, 0.2)	30	28 (93.3)	0.2 (0.1, 0.3)	0.943 (0.564, 1.577)	0.8102
Interaction								0.1493
Race								
Asian and other	105	103 (98.1)	0.4 (0.3, 0.5)	106	104 (98.1)	0.1 (0.1, 0.2)	0.474 (0.355, 0.633)	<0.0001
White	34	32 (94.1)	0.2 (0.1, 0.3)	23	22 (95.7)	0.2 (0.0, 0.3)	0.783 (0.448, 1.369)	0.3484
Interaction								0.5345

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	45 (100.0)	0.3 (0.2, 0.5)	34	33 (97.1)	0.1 (0.1, 0.2)	0.530 (0.331, 0.851)	0.0047
vCPS < 10%	53	50 (94.3)	0.2 (0.1, 0.3)	54	52 (96.3)	0.2 (0.1, 0.3)	0.746 (0.501, 1.112)	0.1240
Missing	41	40 (97.6)	0.5 (0.3, 1.2)	41	41 (100.0)	0.1 (0.1, 0.3)	0.338 (0.208, 0.549)	<0.0001
Interaction								0.1704

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	39 (51.3)	4.3 (2.4, 13.8)	69	48 (69.6)	0.9 (0.5, 1.2)	0.363 (0.231, 0.571)	<0.0001
>= 65 Years	63	29 (46.0)	8.6 (3.1, NE)	60	40 (66.7)	0.9 (0.4, 1.9)	0.392 (0.236, 0.650)	0.0001
Interaction								0.7795
Gender								
Male	118	58 (49.2)	8.6 (3.3, 10.8)	106	74 (69.8)	0.6 (0.5, 1.2)	0.344 (0.238, 0.498)	<0.0001
Female	21	10 (47.6)	3.1 (1.5, NE)	23	14 (60.9)	1.4 (0.5, NE)	0.599 (0.264, 1.356)	0.2110
Interaction								0.3279

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	55 (52.9)	4.4 (2.8, 10.8)	101	71 (70.3)	0.9 (0.5, 1.2)	0.378 (0.260, 0.551)	<0.0001
Non-Smoker	35	13 (37.1)	9.0 (2.1, NE)	28	17 (60.7)	1.0 (0.5, 3.6)	0.393 (0.184, 0.839)	0.0116
Interaction								0.9207
ICC Options								
Paclitaxel	83	40 (48.2)	10.8 (2.5, 30.4)	79	53 (67.1)	1.2 (0.5, 1.9)	0.418 (0.271, 0.646)	<0.0001
Docetaxel	56	28 (50.0)	6.9 (2.4, 9.7)	50	35 (70.0)	0.3 (0.3, 1.0)	0.313 (0.181, 0.541)	<0.0001
Interaction								0.4637

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	16 (37.2)	13.8 (6.9, NE)	37	23 (62.2)	1.1 (0.5, NE)	0.290 (0.143, 0.588)	0.0002
1	96	52 (54.2)	3.1 (2.1, 9.7)	92	65 (70.7)	0.7 (0.5, 1.2)	0.410 (0.279, 0.601)	<0.0001
Interaction								0.5591
Region #1								
Asia	103	49 (47.6)	8.6 (3.3, 13.8)	99	68 (68.7)	0.5 (0.4, 1.2)	0.312 (0.208, 0.467)	<0.0001
Europe/North America	36	19 (52.8)	2.5 (1.5, NE)	30	20 (66.7)	1.5 (0.5, 3.6)	0.640 (0.340, 1.204)	0.1607
Interaction								0.0904

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	37 (47.4)	6.9 (2.8, 10.8)	76	52 (68.4)	0.7 (0.3, 1.2)	0.321 (0.203, 0.508)	<0.0001
Japan	25	12 (48.0)	10.1 (1.9, NE)	23	16 (69.6)	0.5 (0.3, 1.3)	0.298 (0.129, 0.688)	0.0023
Europe/North America	36	19 (52.8)	2.5 (1.5, NE)	30	20 (66.7)	1.5 (0.5, 3.6)	0.640 (0.340, 1.204)	0.1607
Interaction								0.2262
Race								
Asian and other	105	50 (47.6)	8.6 (3.3, 10.8)	106	72 (67.9)	0.6 (0.5, 1.2)	0.327 (0.220, 0.486)	<0.0001
White	34	18 (52.9)	3.1 (1.5, NE)	23	16 (69.6)	1.9 (0.5, 3.6)	0.613 (0.311, 1.207)	0.1512
Interaction								0.1676

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	22 (48.9)	9.7 (3.1, NE)	34	25 (73.5)	1.0 (0.5, 2.8)	0.340 (0.183, 0.630)	0.0003
vCPS < 10%	53	31 (58.5)	4.1 (2.1, 10.8)	54	39 (72.2)	0.5 (0.4, 1.0)	0.340 (0.202, 0.571)	<0.0001
Missing	41	15 (36.6)	8.6 (2.5, NE)	41	24 (58.5)	1.2 (0.3, NE)	0.430 (0.221, 0.836)	0.0090
Interaction								0.9448

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious TEAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	38 (50.0)	7.2 (2.8, 13.9)	69	31 (44.9)	4.2 (1.9, 8.6)	0.786 (0.482, 1.281)	0.3306
>= 65 Years	63	26 (41.3)	10.8 (6.8, NE)	60	24 (40.0)	6.1 (2.8, NE)	0.705 (0.389, 1.276)	0.2446
Interaction								0.7113
Gender								
Male	118	55 (46.6)	9.0 (3.9, 14.0)	106	47 (44.3)	4.2 (2.8, NE)	0.721 (0.481, 1.081)	0.1108
Female	21	9 (42.9)	15.3 (1.7, NE)	23	8 (34.8)	8.6 (1.9, NE)	0.988 (0.361, 2.705)	0.9819
Interaction								0.6744

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious TEAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	52 (50.0)	8.6 (3.9, 14.0)	101	45 (44.6)	4.2 (2.8, 8.6)	0.755 (0.497, 1.146)	0.1842
Non-Smoker	35	12 (34.3)	NR (2.5, NE)	28	10 (35.7)	7.3 (1.9, NE)	0.787 (0.333, 1.863)	0.5846
Interaction								0.8643
ICC Options								
Paclitaxel	83	33 (39.8)	15.3 (7.2, NE)	79	30 (38.0)	8.6 (3.4, NE)	0.800 (0.476, 1.345)	0.3974
Docetaxel	56	31 (55.4)	4.4 (2.1, 9.0)	50	25 (50.0)	3.1 (1.3, 7.3)	0.640 (0.367, 1.116)	0.1100
Interaction								0.9495

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious TEAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	15 (34.9)	13.9 (7.2, NE)	37	11 (29.7)	8.6 (4.2, NE)	0.685 (0.296, 1.585)	0.3726
1	96	49 (51.0)	3.9 (2.3, 10.8)	92	44 (47.8)	3.1 (2.2, NE)	0.768 (0.504, 1.172)	0.2180
Interaction								0.7011
Region #1								
Asia	103	47 (45.6)	9.0 (3.9, 14.0)	99	43 (43.4)	4.2 (2.6, NE)	0.675 (0.437, 1.041)	0.0726
Europe/North America	36	17 (47.2)	7.2 (1.7, NE)	30	12 (40.0)	7.3 (2.8, NE)	1.086 (0.509, 2.315)	0.8306
Interaction								0.2717

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious TEAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	37 (47.4)	8.6 (2.8, 14.0)	76	33 (43.4)	4.2 (2.2, NE)	0.727 (0.446, 1.186)	0.1977
Japan	25	10 (40.0)	13.9 (6.8, NE)	23	10 (43.5)	NR (1.1, NE)	0.511 (0.197, 1.327)	0.1596
Europe/North America	36	17 (47.2)	7.2 (1.7, NE)	30	12 (40.0)	7.3 (2.8, NE)	1.086 (0.509, 2.315)	0.8306
Interaction								0.4796
Race								
Asian and other	105	48 (45.7)	9.0 (3.9, 14.0)	106	45 (42.5)	4.2 (2.6, NE)	0.714 (0.466, 1.094)	0.1192
White	34	16 (47.1)	7.2 (1.7, NE)	23	10 (43.5)	7.3 (2.8, NE)	1.000 (0.446, 2.243)	0.9997
Interaction								0.4577

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious TEAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	19 (42.2)	13.9 (3.3, NE)	34	16 (47.1)	4.2 (1.9, NE)	0.481 (0.231, 1.001)	0.0449
vCPS < 10%	53	28 (52.8)	6.8 (2.4, 14.0)	54	23 (42.6)	6.1 (2.6, NE)	0.893 (0.504, 1.583)	0.6983
Missing	41	17 (41.5)	8.6 (2.3, NE)	41	16 (39.0)	7.3 (1.7, NE)	0.879 (0.439, 1.760)	0.7155
Interaction								0.6286

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE Leading to Treatment Discontinuation

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	14 (18.4)	14.0 (9.7, NE)	69	13 (18.8)	NR (5.6, NE)	0.654 (0.297, 1.439)	0.2875
>= 65 Years	63	11 (17.5)	NR (14.0, NE)	60	15 (25.0)	NR (5.1, NE)	0.506 (0.225, 1.141)	0.0949
Interaction								0.3744
Gender								
Male	118	20 (16.9)	NR (13.9, NE)	106	24 (22.6)	7.9 (6.1, NE)	0.467 (0.248, 0.882)	0.0163
Female	21	5 (23.8)	NR (2.1, NE)	23	4 (17.4)	NR (NE, NE)	1.463 (0.387, 5.528)	0.5725
Interaction								0.3177

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE Leading to Treatment Discontinuation

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	20 (19.2)	NR (13.9, NE)	101	22 (21.8)	NR (6.1, NE)	0.553 (0.290, 1.058)	0.0695
Non-Smoker	35	5 (14.3)	NR (3.7, NE)	28	6 (21.4)	7.3 (5.0, NE)	0.608 (0.185, 2.003)	0.4089
Interaction								0.8663
ICC Options								
Paclitaxel	83	11 (13.3)	NR (14.0, NE)	79	19 (24.1)	NR (5.1, NE)	0.365 (0.163, 0.815)	0.0105
Docetaxel	56	14 (25.0)	14.0 (9.7, NE)	50	9 (18.0)	7.3 (5.6, NE)	0.936 (0.397, 2.207)	0.8791
Interaction								0.0862

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE Leading to Treatment Discontinuation

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	6 (14.0)	NR (13.9, NE)	37	7 (18.9)	NR (5.6, NE)	0.307 (0.084, 1.114)	0.0594
1	96	19 (19.8)	NR (14.0, NE)	92	21 (22.8)	7.9 (6.1, NE)	0.669 (0.355, 1.258)	0.2091
Interaction								0.7722
Region #1								
Asia	103	18 (17.5)	NR (13.9, NE)	99	19 (19.2)	NR (6.5, NE)	0.592 (0.301, 1.163)	0.1238
Europe/North America	36	7 (19.4)	NR (7.2, NE)	30	9 (30.0)	7.3 (5.0, NE)	0.592 (0.219, 1.601)	0.2961
Interaction								0.8865

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE Leading to Treatment Discontinuation

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	16 (20.5)	NR (14.0, NE)	76	15 (19.7)	NR (6.5, NE)	0.765 (0.371, 1.577)	0.4660
Japan	25	2 (8.0)	NR (10.8, NE)	23	4 (17.4)	NR (5.1, NE)	0.114 (0.011, 1.160)	0.0366
Europe/North America	36	7 (19.4)	NR (7.2, NE)	30	9 (30.0)	7.3 (5.0, NE)	0.592 (0.219, 1.601)	0.2961
Interaction								0.5732
Race								
Asian and other	105	19 (18.1)	NR (13.9, NE)	106	20 (18.9)	NR (7.9, NE)	0.635 (0.329, 1.225)	0.1714
White	34	6 (17.6)	NR (7.2, NE)	23	8 (34.8)	6.1 (5.0, NE)	0.472 (0.163, 1.368)	0.1572
Interaction								0.5490

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.1.1.b.s:
Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE Leading to Treatment Discontinuation

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	9 (20.0)	NR (10.8, NE)	34	9 (26.5)	NR (7.9, NE)	0.553 (0.216, 1.417)	0.2107
vCPS < 10%	53	9 (17.0)	NR (14.0, NE)	54	8 (14.8)	NR (5.0, NE)	0.659 (0.235, 1.849)	0.4253
Missing	41	7 (17.1)	NR (NE, NE)	41	11 (26.8)	7.3 (5.1, NE)	0.550 (0.212, 1.427)	0.2126
Interaction								0.7673

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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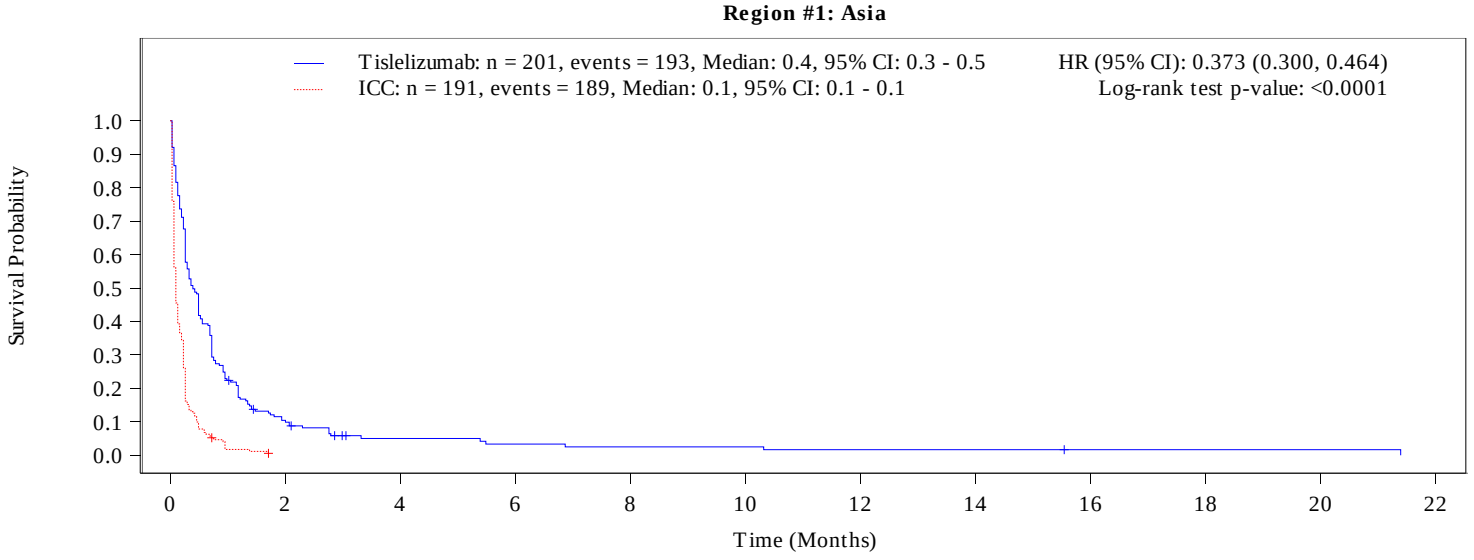
Figure 14.3.1.1.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Any TEAE



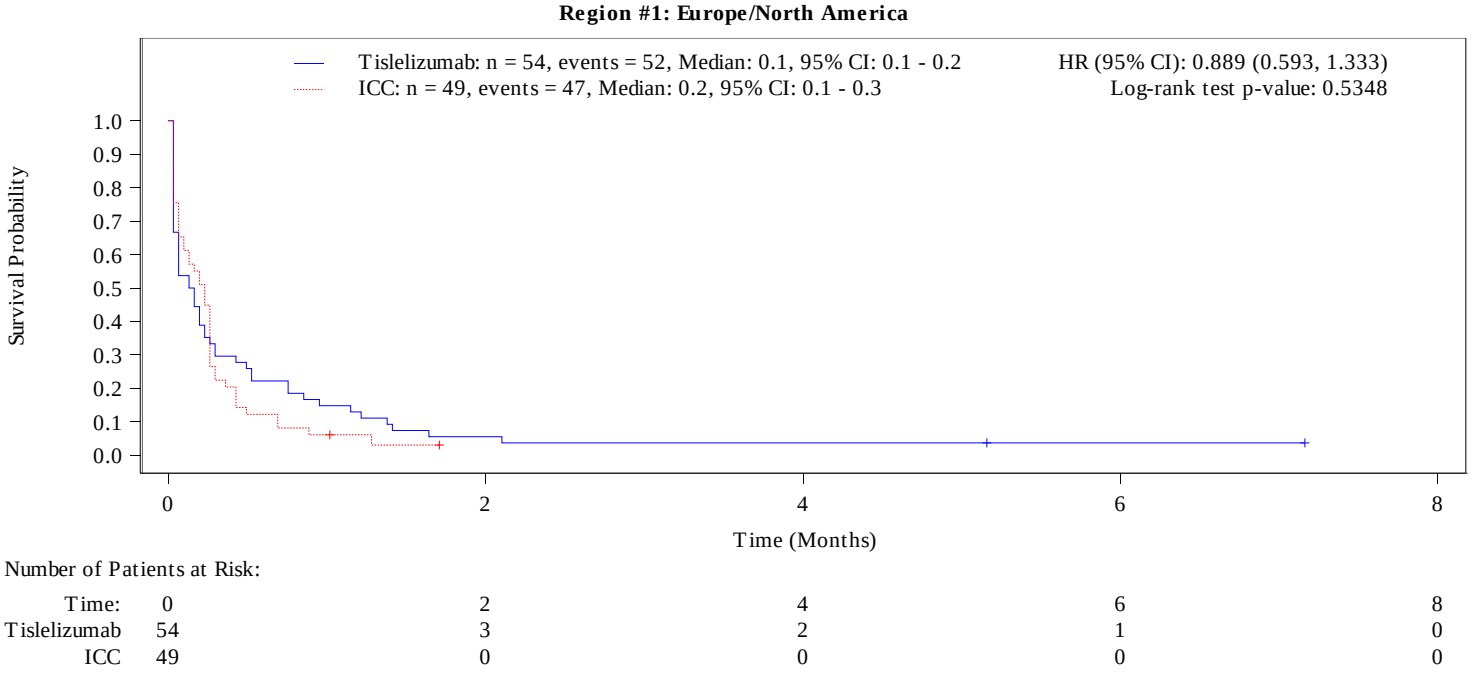
Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	201	19	6	4	3	3	2	2	1	1	1	0
ICC	191	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteae-subgrp.sas 13AUG2024 18:38 f-14-03-01-01-s-km-tteae-subgrp-safety-cl.rtf

Figure 14.3.1.1.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Any TEAE



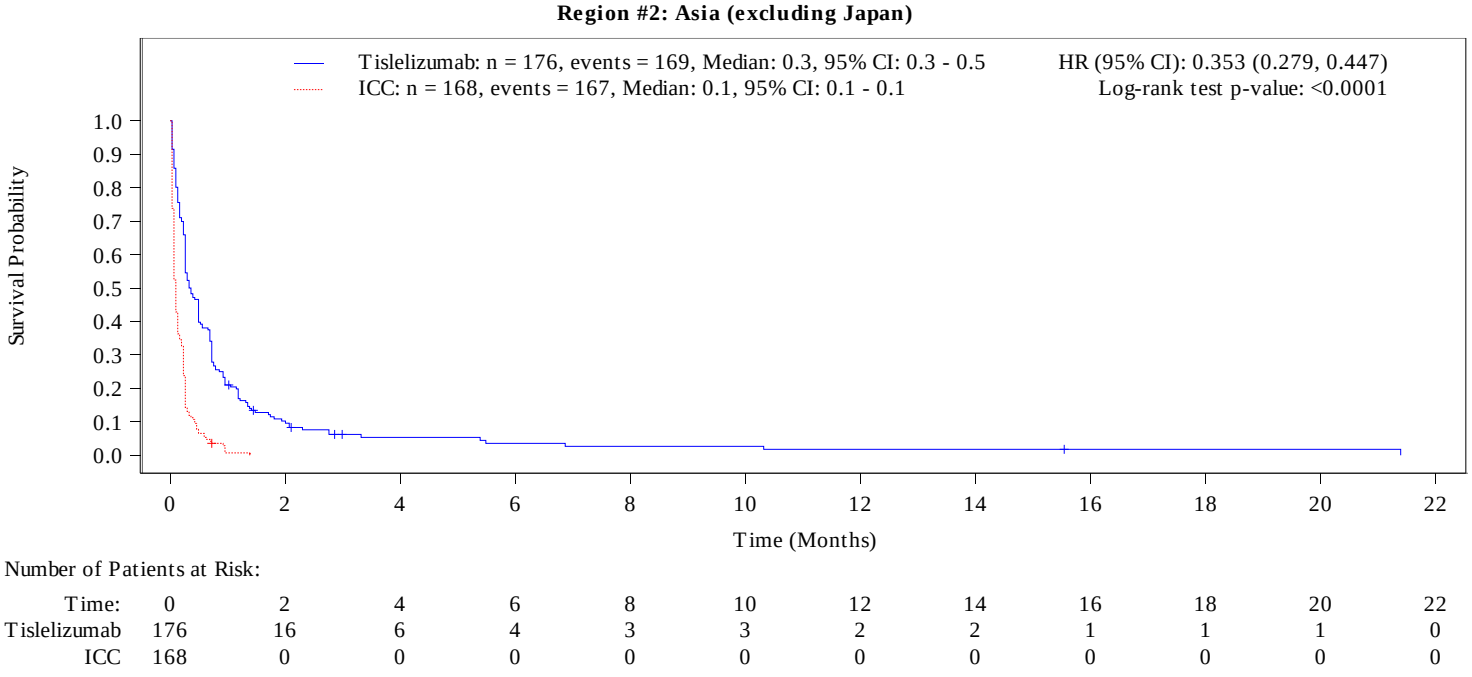
Number of Patients at Risk:

Time:	0	2	4	6	8
Tislelizumab	54	3	2	1	0
ICC	49	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteae-subgrp.sas 13AUG2024 18:38 f-14-03-01-01-s-km-tteae-subgrp-safety-cl.rtf

Figure 14.3.1.1.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Any TEAE



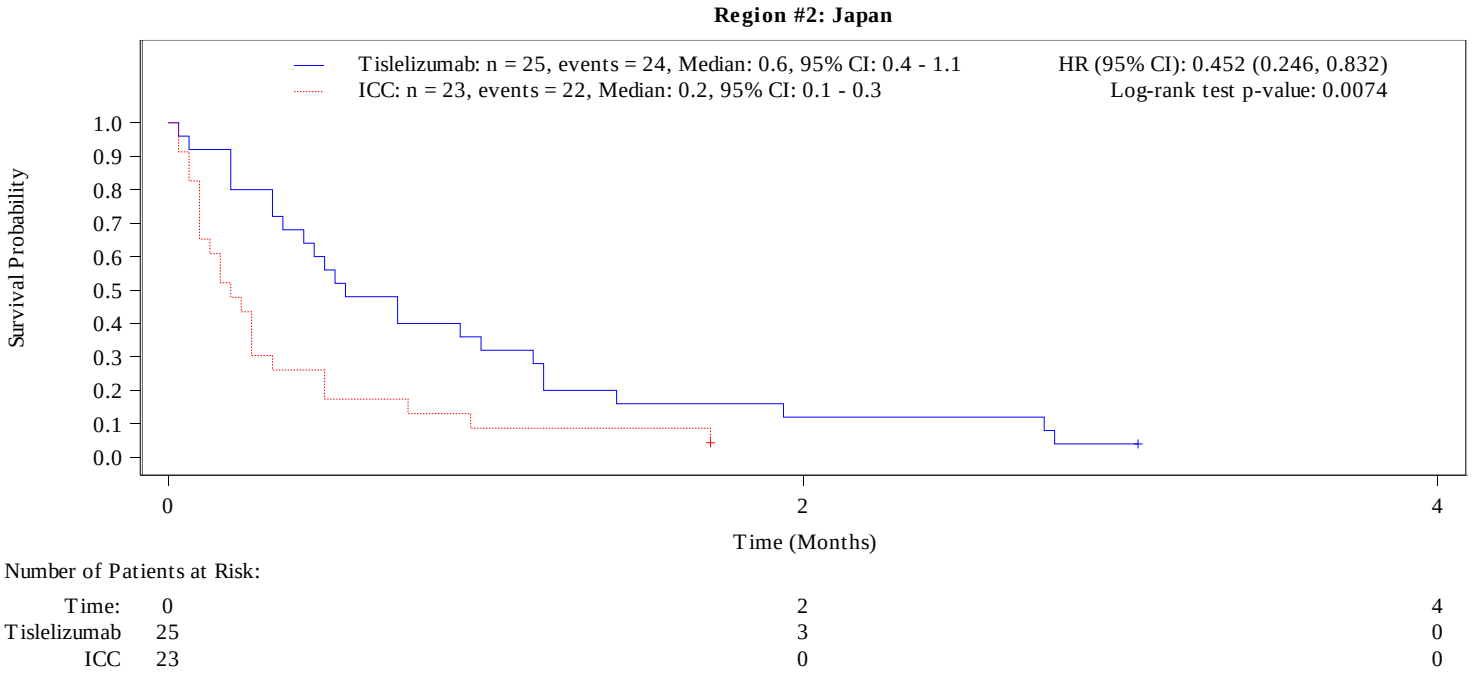
Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22
Tislelizumab	176	16	6	4	3	3	2	2	1	1	1	0
ICC	168	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteae-subgrp.sas 13AUG2024 18:38 f-14-03-01-01-s-km-tteae-subgrp-safety-cl.rtf

Figure 14.3.1.1.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Any TEAE



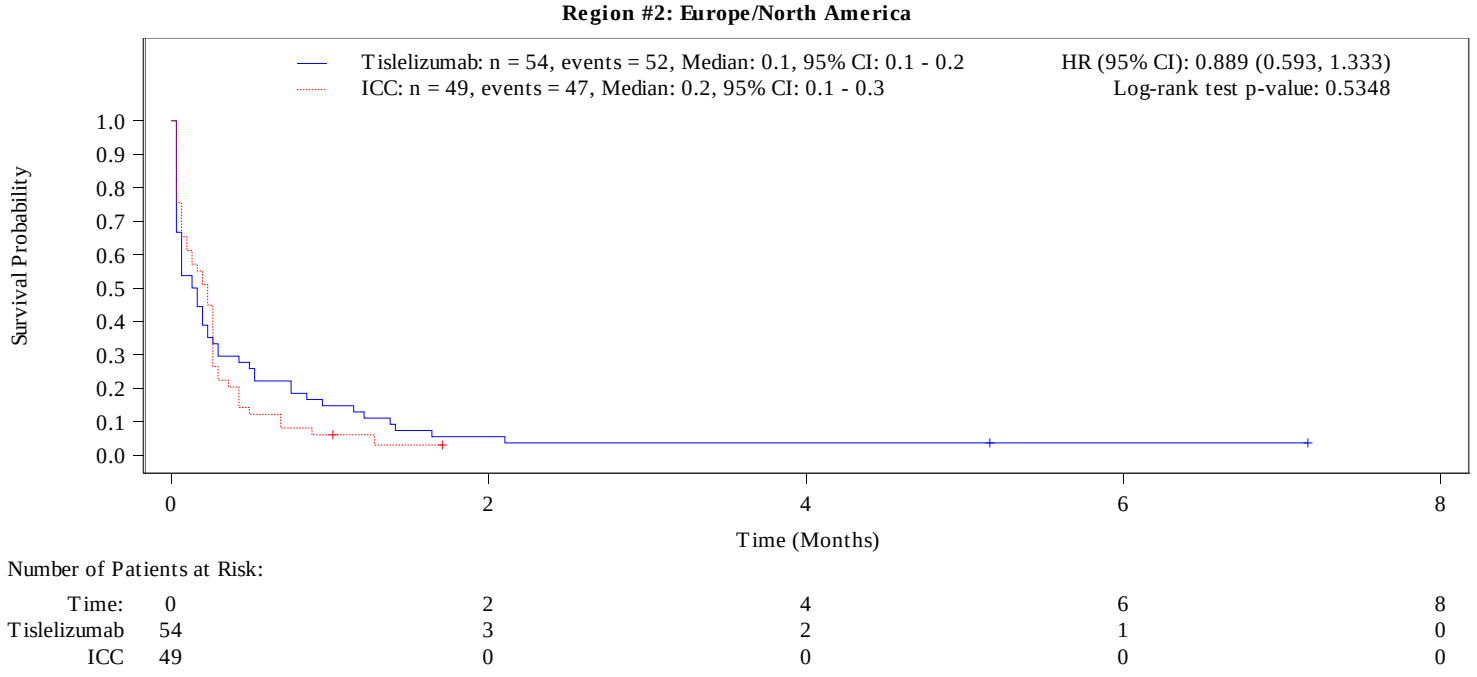
Number of Patients at Risk:

Time:	0	2	4
Tislelizumab	25	3	0
ICC	23	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteae-subgrp.sas 13AUG2024 18:38 f-14-03-01-01-s-km-tteae-subgrp-safety-cl.rtf

Figure 14.3.1.1.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set

Any TEAE

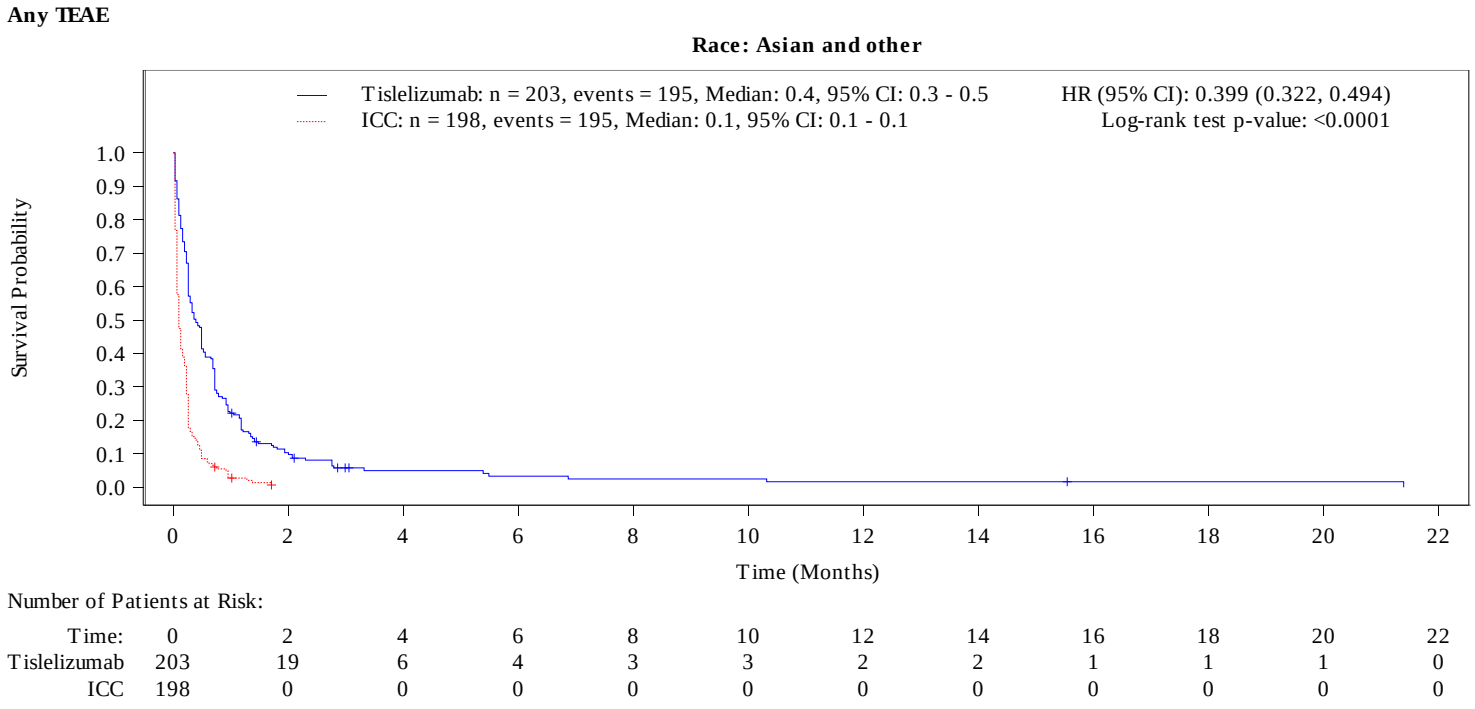


Number of Patients at Risk:

Time:	0	2	4	6	8
Tislelizumab	54	3	2	1	0
ICC	49	0	0	0	0

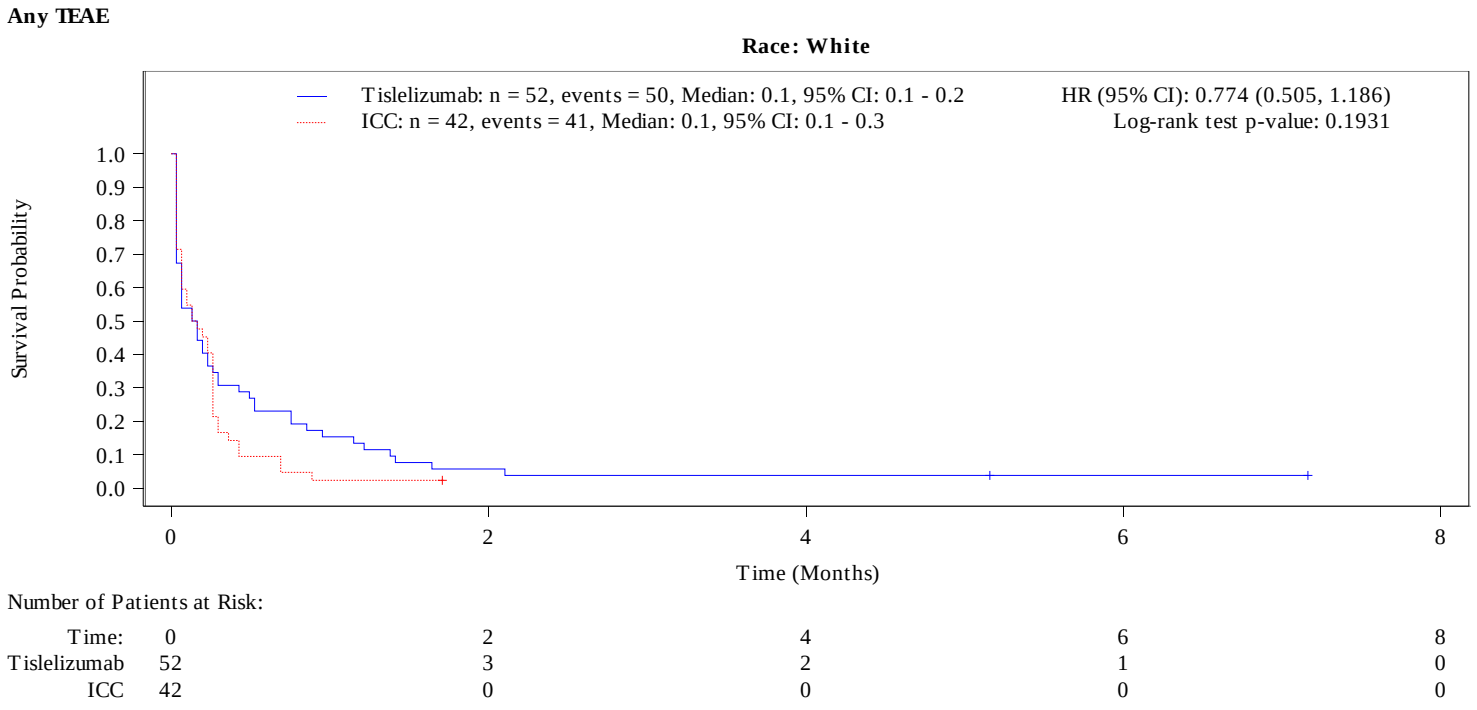
Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteae-subgrp.sas 13AUG2024 18:38 f-14-03-01-01-s-km-tteae-subgrp-safety-cl.rtf

Figure 14.3.1.1.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set



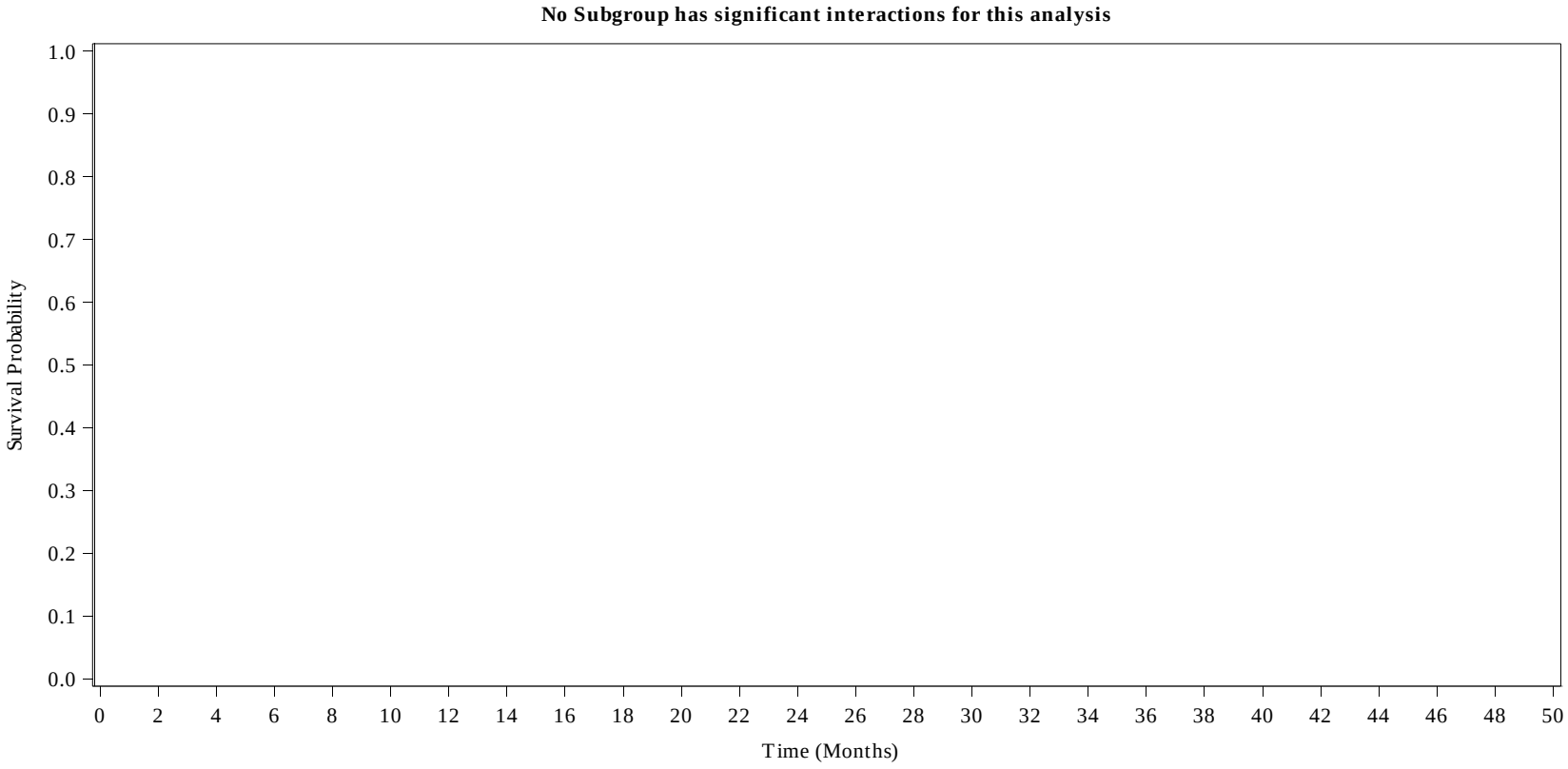
Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteae-subgrp.sas 13AUG2024 18:38 f-14-03-01-01-s-km-tteae-subgrp-safety-cl.rtf

Figure 14.3.1.1.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set



Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteae-subgrp.sas 13AUG2024 18:38 f-14-03-01-01-s-km-tteae-subgrp-safety-cl.rtf

Figure 14.3.1.1.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-tteae-subgrp.sas 13AUG2024 18:38 f-14-03-01-01-b-s-km-tteae-subgrp-safetys-cl.rtf

Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

System Organ Class Preferred Term	Tislelizumab (N = 255) Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	ICC (N = 240) Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Blood and lymphatic system disorders	255	95 (37.3)	12.4 (8.9, 23.6)	240	140 (58.3)	1.0 (0.9, 2.0)	0.386 (0.293, 0.509)	<0.0001
Anaemia	255	80 (31.4)	19.4 (11.0, NE)	240	109 (45.4)	3.7 (2.0, NE)	0.444 (0.327, 0.603)	<0.0001
Febrile neutropenia	255	0 (0.0)	NR (NE, NE)	240	12 (5.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0002
Leukopenia	255	9 (3.5)	NR (NE, NE)	240	30 (12.5)	NR (NE, NE)	0.194 (0.087, 0.430)	<0.0001
Neutropenia	255	2 (0.8)	NR (NE, NE)	240	31 (12.9)	NR (NE, NE)	0.055 (0.013, 0.231)	<0.0001
Thrombocytopenia	255	5 (2.0)	NR (NE, NE)	240	10 (4.2)	NR (NE, NE)	0.338 (0.105, 1.083)	0.0555
Cardiac disorders	255	28 (11.0)	NR (NE, NE)	240	22 (9.2)	NR (NE, NE)	0.859 (0.479, 1.539)	0.6086

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

System Organ Class Preferred Term	Tislelizumab (N = 255) Total No. of Patients	Tislelizumab (N = 255) Patients with events n (%)	Tislelizumab (N = 255) Median time to event (95% CI) [a]	ICC (N = 240) Total No. of Patients	ICC (N = 240) Patients with events n (%)	ICC (N = 240) Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Endocrine disorders	255	43 (16.9)	18.6 (16.1, NE)	240	2 (0.8)	NR (NE, NE)	12.768 (3.062, 53.236)	<0.0001
Hypothyroidism	255	31 (12.2)	NR (18.6, NE)	240	1 (0.4)	NR (NE, NE)	17.068 (2.305, 126.377)	0.0002
Eye disorders	255	19 (7.5)	NR (NE, NE)	240	8 (3.3)	NR (NE, NE)	1.516 (0.642, 3.580)	0.3393

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.
Adverse events were classified based on MedDRA v25.0.
System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.
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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

	Tislelizumab (N = 255)			ICC (N = 240)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Gastrointestinal disorders	255	152 (59.6)	2.9 (1.5, 4.1)	240	172 (71.7)	0.3 (0.3, 0.7)	0.445 (0.352, 0.561)	<0.0001
Abdominal pain	255	18 (7.1)	NR (NE, NE)	240	23 (9.6)	NR (10.8, NE)	0.532 (0.277, 1.020)	0.0535
Abdominal pain upper	255	9 (3.5)	NR (NE, NE)	240	16 (6.7)	NR (NE, NE)	0.420 (0.183, 0.968)	0.0355
Constipation	255	41 (16.1)	NR (30.5, NE)	240	45 (18.8)	NR (NE, NE)	0.651 (0.418, 1.014)	0.0555
Diarrhoea	255	32 (12.5)	NR (NE, NE)	240	76 (31.7)	NR (NE, NE)	0.285 (0.186, 0.437)	<0.0001
Dysphagia	255	30 (11.8)	NR (27.6, NE)	240	20 (8.3)	NR (NE, NE)	0.953 (0.526, 1.725)	0.8739
Gastrooesophageal reflux disease	255	14 (5.5)	NR (NE, NE)	240	12 (5.0)	NR (NE, NE)	0.760 (0.339, 1.705)	0.5041
Nausea	255	37 (14.5)	NR (NE, NE)	240	72 (30.0)	NR (5.1, NE)	0.345 (0.229, 0.521)	<0.0001
Stomatitis	255	9 (3.5)	NR (NE, NE)	240	14 (5.8)	NR (NE, NE)	0.505 (0.217, 1.177)	0.1051
Vomiting	255	27 (10.6)	NR (NE, NE)	240	48 (20.0)	NR (NE, NE)	0.392 (0.241, 0.638)	<0.0001

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

	Tislelizumab (N = 255)			ICC (N = 240)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
General disorders and administration site conditions	255	119 (46.7)	7.0 (3.5, 9.9)	240	149 (62.1)	1.0 (0.8, 1.7)	0.479 (0.370, 0.619)	<0.0001
Asthenia	255	29 (11.4)	37.2 (37.2, NE)	240	37 (15.4)	NR (9.0, NE)	0.548 (0.329, 0.910)	0.0183
Fatigue	255	33 (12.9)	NR (NE, NE)	240	42 (17.5)	NR (NE, NE)	0.631 (0.396, 1.005)	0.0502
Malaise	255	16 (6.3)	NR (NE, NE)	240	36 (15.0)	NR (NE, NE)	0.308 (0.166, 0.569)	<0.0001
Oedema peripheral	255	10 (3.9)	NR (NE, NE)	240	11 (4.6)	NR (10.2, NE)	0.632 (0.257, 1.555)	0.3137
Pyrexia	255	41 (16.1)	NR (NE, NE)	240	34 (14.2)	NR (NE, NE)	0.830 (0.518, 1.330)	0.4372
Hepatobiliary disorders	255	12 (4.7)	NR (NE, NE)	240	7 (2.9)	NR (NE, NE)	1.183 (0.451, 3.102)	0.7316

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

	Tislelizumab (N = 255)			ICC (N = 240)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Infections and infestations	255	80 (31.4)	13.7 (9.5, 27.0)	240	77 (32.1)	8.0 (4.9, NE)	0.699 (0.504, 0.970)	0.0313
Pneumonia	255	38 (14.9)	NR (25.8, NE)	240	27 (11.3)	NR (NE, NE)	0.837 (0.497, 1.409)	0.5013
Upper respiratory tract infection	255	9 (3.5)	NR (NE, NE)	240	11 (4.6)	NR (NE, NE)	0.542 (0.210, 1.401)	0.1993
Injury, poisoning and procedural complications	255	17 (6.7)	NR (NE, NE)	240	7 (2.9)	NR (NE, NE)	1.248 (0.483, 3.223)	0.6471

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

	Tislelizumab (N = 255)			ICC (N = 240)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Investigations	255	133 (52.2)	3.1 (2.2, 6.6)	240	166 (69.2)	0.5 (0.5, 0.7)	0.419 (0.329, 0.533)	<0.0001
Alanine aminotransferase increased	255	33 (12.9)	NR (30.4, NE)	240	19 (7.9)	NR (NE, NE)	1.195 (0.669, 2.136)	0.5457
Aspartate aminotransferase increased	255	37 (14.5)	NR (30.4, NE)	240	11 (4.6)	NR (NE, NE)	2.262 (1.137, 4.500)	0.0168
Blood alkaline phosphatase increased	255	17 (6.7)	NR (NE, NE)	240	5 (2.1)	NR (NE, NE)	2.779 (1.019, 7.577)	0.0369
Blood creatine phosphokinase MB increased	255	11 (4.3)	NR (NE, NE)	240	1 (0.4)	NR (NE, NE)	7.277 (0.922, 57.448)	0.0286
Blood creatine phosphokinase increased	255	10 (3.9)	NR (NE, NE)	240	0 (0.0)	NR (NE, NE)	26494210.890 (0.000, NE)	0.0056
Gamma-glutamyltransferase increased	255	14 (5.5)	NR (NE, NE)	240	8 (3.3)	NR (NE, NE)	1.442 (0.601, 3.462)	0.4095
Lymphocyte count decreased	255	12 (4.7)	NR (NE, NE)	240	22 (9.2)	NR (NE, NE)	0.391 (0.188, 0.814)	0.0092
Neutrophil count decreased	255	6 (2.4)	NR (NE, NE)	240	94 (39.2)	NR (2.8, NE)	0.047 (0.021, 0.107)	<0.0001
Platelet count decreased	255	14 (5.5)	NR (NE, NE)	240	16 (6.7)	NR (NE, NE)	0.595 (0.277, 1.277)	0.1776
Weight decreased	255	62 (24.3)	39.5 (26.9, NE)	240	45 (18.8)	NR (NE, NE)	0.971 (0.654, 1.442)	0.8835
White blood cell count decreased	255	11 (4.3)	NR (NE, NE)	240	99 (41.3)	NR (NE, NE)	0.070 (0.036, 0.134)	<0.0001
White blood cell count increased	255	12 (4.7)	NR (NE, NE)	240	6 (2.5)	NR (NE, NE)	1.536 (0.569, 4.140)	0.3933

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

System Organ Class Preferred Term	Tislelizumab (N = 255) Total No. of Patients	Tislelizumab (N = 255) Patients with events n (%)	Tislelizumab (N = 255) Median time to event (95% CI) [a]	ICC (N = 240) Total No. of Patients	ICC (N = 240) Patients with events n (%)	ICC (N = 240) Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Metabolism and nutrition disorders	255	123 (48.2)	4.9 (3.3, 9.0)	240	141 (58.8)	1.2 (0.8, 2.2)	0.506 (0.392, 0.653)	<0.0001
Decreased appetite	255	42 (16.5)	NR (26.9, NE)	240	84 (35.0)	6.6 (3.7, NE)	0.323 (0.219, 0.476)	<0.0001
Hyperglycaemia	255	17 (6.7)	NR (NE, NE)	240	8 (3.3)	NR (NE, NE)	1.550 (0.654, 3.673)	0.3136
Hyperuricaemia	255	6 (2.4)	NR (NE, NE)	240	11 (4.6)	NR (NE, NE)	0.407 (0.148, 1.121)	0.0726
Hypoalbuminaemia	255	36 (14.1)	NR (30.4, NE)	240	30 (12.5)	NR (NE, NE)	0.894 (0.543, 1.470)	0.6574
Hypocalcaemia	255	8 (3.1)	NR (NE, NE)	240	11 (4.6)	NR (NE, NE)	0.500 (0.192, 1.303)	0.1485
Hypochloraemia	255	6 (2.4)	NR (NE, NE)	240	10 (4.2)	NR (NE, NE)	0.379 (0.128, 1.129)	0.0702
Hypokalaemia	255	22 (8.6)	NR (33.8, NE)	240	22 (9.2)	NR (NE, NE)	0.629 (0.336, 1.176)	0.1428
Hyponatraemia	255	32 (12.5)	NR (NE, NE)	240	33 (13.8)	NR (NE, NE)	0.592 (0.352, 0.994)	0.0431
Hypoproteinaemia	255	13 (5.1)	NR (NE, NE)	240	8 (3.3)	NR (NE, NE)	0.995 (0.396, 2.498)	0.9911

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

	Tislelizumab (N = 255)			ICC (N = 240)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Musculoskeletal and connective tissue disorders	255	70 (27.5)	18.0 (10.7, NE)	240	61 (25.4)	7.3 (6.2, NE)	0.770 (0.539, 1.098)	0.1466
Arthralgia	255	22 (8.6)	NR (29.3, NE)	240	18 (7.5)	NR (NE, NE)	0.896 (0.471, 1.702)	0.7358
Back pain	255	28 (11.0)	NR (25.9, NE)	240	18 (7.5)	NR (NE, NE)	0.999 (0.536, 1.860)	0.9964
Myalgia	255	8 (3.1)	NR (NE, NE)	240	14 (5.8)	NR (NE, NE)	0.373 (0.142, 0.977)	0.0362
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	255	23 (9.0)	NR (NE, NE)	240	8 (3.3)	NR (NE, NE)	2.363 (1.048, 5.330)	0.0327
Cancer pain	255	10 (3.9)	NR (NE, NE)	240	4 (1.7)	NR (NE, NE)	2.014 (0.627, 6.472)	0.2307

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

	Tislelizumab (N = 255)			ICC (N = 240)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Nervous system disorders	255	31 (12.2)	NR (22.6, NE)	240	62 (25.8)	9.7 (7.4, NE)	0.302 (0.192, 0.477)	<0.0001
Dizziness	255	11 (4.3)	NR (NE, NE)	240	19 (7.9)	NR (NE, NE)	0.426 (0.200, 0.908)	0.0231
Peripheral sensory neuropathy	255	2 (0.8)	NR (NE, NE)	240	23 (9.6)	NR (9.7, NE)	0.059 (0.013, 0.258)	<0.0001
Psychiatric disorders	255	28 (11.0)	NR (NE, NE)	240	27 (11.3)	NR (NE, NE)	0.742 (0.430, 1.283)	0.2836
Insomnia	255	21 (8.2)	NR (NE, NE)	240	17 (7.1)	NR (NE, NE)	0.916 (0.473, 1.772)	0.7940
Renal and urinary disorders	255	12 (4.7)	NR (NE, NE)	240	9 (3.8)	NR (NE, NE)	0.683 (0.266, 1.752)	0.4250

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

System Organ Class Preferred Term	Tislelizumab (N = 255) Total No. of Patients	Tislelizumab (N = 255) Patients with events n (%)	Tislelizumab (N = 255) Median time to event (95% CI) [a]	ICC (N = 240) Total No. of Patients	ICC (N = 240) Patients with events n (%)	ICC (N = 240) Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Respiratory, thoracic and mediastinal disorders	255	105 (41.2)	11.3 (4.4, 15.8)	240	79 (32.9)	5.7 (4.0, NE)	1.046 (0.775, 1.412)	0.7679
Cough	255	44 (17.3)	NR (NE, NE)	240	28 (11.7)	NR (NE, NE)	1.276 (0.786, 2.071)	0.3231
Dyspnoea	255	25 (9.8)	NR (NE, NE)	240	19 (7.9)	19.8 (NE, NE)	0.983 (0.532, 1.818)	0.9574
Haemoptysis	255	11 (4.3)	NR (NE, NE)	240	7 (2.9)	NR (NE, NE)	1.180 (0.449, 3.102)	0.7373
Pneumonitis	255	13 (5.1)	NR (32.5, NE)	240	4 (1.7)	NR (NE, NE)	1.535 (0.464, 5.082)	0.4793
Productive cough	255	18 (7.1)	NR (NE, NE)	240	18 (7.5)	NR (NE, NE)	0.715 (0.363, 1.406)	0.3283

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

System Organ Class Preferred Term	Tislelizumab (N = 255) Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	ICC (N = 240) Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Skin and subcutaneous tissue disorders	255	62 (24.3)	30.5 (10.7, NE)	240	67 (27.9)	NR (5.3, NE)	0.678 (0.475, 0.967)	0.0304
Alopecia	255	1 (0.4)	NR (NE, NE)	240	42 (17.5)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Pruritus	255	25 (9.8)	NR (30.5, NE)	240	11 (4.6)	NR (NE, NE)	1.430 (0.681, 3.001)	0.3422
Rash	255	24 (9.4)	36.1 (36.1, NE)	240	10 (4.2)	NR (NE, NE)	1.924 (0.912, 4.061)	0.0798
Vascular disorders	255	28 (11.0)	NR (28.2, NE)	240	17 (7.1)	NR (NE, NE)	1.202 (0.645, 2.240)	0.5598
Hypertension	255	13 (5.1)	NR (NE, NE)	240	6 (2.5)	NR (NE, NE)	1.600 (0.597, 4.293)	0.3442
Hypotension	255	10 (3.9)	NR (NE, NE)	240	6 (2.5)	NR (NE, NE)	1.286 (0.455, 3.633)	0.6343

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1.b:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 129)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Blood and lymphatic system disorders	139	46 (33.1)	NR (21.4, NE)	129	73 (56.6)	1.4 (1.0, 4.1)	0.386 (0.261, 0.568)	<0.0001
Anaemia	139	38 (27.3)	NR (21.4, NE)	129	53 (41.1)	5.1 (2.1, NE)	0.461 (0.297, 0.715)	0.0004
Leukopenia	139	5 (3.6)	NR (NE, NE)	129	12 (9.3)	NR (NE, NE)	0.315 (0.110, 0.901)	0.0226
Neutropenia	139	2 (1.4)	NR (NE, NE)	129	21 (16.3)	NR (NE, NE)	0.079 (0.018, 0.336)	<0.0001
Cardiac disorders	139	18 (12.9)	NR (NE, NE)	129	13 (10.1)	NR (NE, NE)	1.070 (0.517, 2.214)	0.8551
Endocrine disorders	139	27 (19.4)	18.6 (11.6, NE)	129	1 (0.8)	NR (NE, NE)	18.505 (2.490, 137.514)	<0.0001
Hypothyroidism	139	19 (13.7)	29.9 (16.5, NE)	129	0 (0.0)	NR (NE, NE)	23475970.192 (0.000, NE)	0.0006
Eye disorders	139	11 (7.9)	NR (24.1, NE)	129	6 (4.7)	NR (NE, NE)	1.247 (0.442, 3.517)	0.6763

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1.b:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

System Organ Class Preferred Term	Tislelizumab (N = 139) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	ICC (N = 129) Total No. of Patients	 Patients with events n (%)	 Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Gastrointestinal disorders	139	90 (64.7)	2.2 (1.4, 3.3)	129	79 (61.2)	1.1 (0.7, 2.1)	0.716 (0.524, 0.979)	0.0335
Abdominal pain upper	139	3 (2.2)	NR (NE, NE)	129	10 (7.8)	NR (NE, NE)	0.240 (0.066, 0.877)	0.0185
Constipation	139	25 (18.0)	NR (30.5, NE)	129	20 (15.5)	NR (NE, NE)	0.925 (0.502, 1.704)	0.8034
Diarrhoea	139	19 (13.7)	NR (NE, NE)	129	22 (17.1)	NR (NE, NE)	0.698 (0.376, 1.293)	0.2496
Dysphagia	139	18 (12.9)	NR (27.6, NE)	129	13 (10.1)	NR (NE, NE)	1.021 (0.489, 2.129)	0.9568
Nausea	139	23 (16.5)	NR (25.1, NE)	129	19 (14.7)	NR (NE, NE)	0.980 (0.529, 1.818)	0.9500
Stomatitis	139	6 (4.3)	NR (NE, NE)	129	11 (8.5)	NR (NE, NE)	0.406 (0.149, 1.111)	0.0682
Vomiting	139	12 (8.6)	NR (NE, NE)	129	11 (8.5)	NR (NE, NE)	0.930 (0.409, 2.116)	0.8628

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1.b:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 129)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
General disorders and administration site conditions	139	74 (53.2)	6.9 (2.7, 8.5)	129	79 (61.2)	1.3 (0.9, 2.3)	0.547 (0.390, 0.767)	0.0004
Asthenia	139	19 (13.7)	NR (37.2, NE)	129	18 (14.0)	NR (9.0, NE)	0.762 (0.392, 1.480)	0.4207
Fatigue	139	22 (15.8)	NR (NE, NE)	129	25 (19.4)	NR (NE, NE)	0.697 (0.388, 1.254)	0.2248
Malaise	139	11 (7.9)	NR (NE, NE)	129	12 (9.3)	NR (NE, NE)	0.604 (0.255, 1.430)	0.2456
Pyrexia	139	23 (16.5)	NR (NE, NE)	129	20 (15.5)	NR (7.7, NE)	0.778 (0.418, 1.448)	0.4263
Infections and infestations	139	47 (33.8)	10.5 (5.3, NE)	129	48 (37.2)	5.3 (3.1, NE)	0.654 (0.430, 0.996)	0.0462
Pneumonia	139	21 (15.1)	NR (29.9, NE)	129	15 (11.6)	NR (NE, NE)	0.904 (0.454, 1.800)	0.7736
Injury, poisoning and procedural complications	139	13 (9.4)	NR (15.9, NE)	129	5 (3.9)	NR (NE, NE)	1.449 (0.482, 4.358)	0.5069

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1.b:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 129)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Investigations	139	62 (44.6)	7.6 (2.9, 26.9)	129	84 (65.1)	0.5 (0.5, 1.2)	0.366 (0.258, 0.519)	<0.0001
Alanine aminotransferase increased	139	12 (8.6)	NR (30.4, NE)	129	4 (3.1)	NR (NE, NE)	2.305 (0.731, 7.268)	0.1420
Aspartate aminotransferase increased	139	14 (10.1)	NR (30.4, NE)	129	3 (2.3)	NR (NE, NE)	3.604 (1.023, 12.696)	0.0326
Lymphocyte count decreased	139	3 (2.2)	NR (NE, NE)	129	10 (7.8)	NR (NE, NE)	0.255 (0.070, 0.931)	0.0251
Neutrophil count decreased	139	1 (0.7)	NR (NE, NE)	129	55 (42.6)	NR (1.4, NE)	0.013 (0.002, 0.094)	<0.0001
Weight decreased	139	33 (23.7)	39.5 (26.9, NE)	129	16 (12.4)	NR (NE, NE)	1.602 (0.870, 2.949)	0.1252
White blood cell count decreased	139	4 (2.9)	NR (NE, NE)	129	49 (38.0)	NR (NE, NE)	0.057 (0.021, 0.160)	<0.0001

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1.b:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 129)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Metabolism and nutrition disorders	139	63 (45.3)	8.6 (3.7, 13.8)	129	67 (51.9)	2.8 (1.3, 5.7)	0.621 (0.433, 0.890)	0.0079
Decreased appetite	139	29 (20.9)	NR (26.9, NE)	129	39 (30.2)	NR (5.7, NE)	0.524 (0.319, 0.861)	0.0091
Hypoalbuminaemia	139	19 (13.7)	NR (30.4, NE)	129	13 (10.1)	NR (NE, NE)	1.002 (0.483, 2.078)	0.9953
Hypokalaemia	139	8 (5.8)	NR (NE, NE)	129	10 (7.8)	NR (NE, NE)	0.622 (0.244, 1.582)	0.3139
Hyponatraemia	139	12 (8.6)	NR (NE, NE)	129	8 (6.2)	NR (NE, NE)	0.952 (0.374, 2.424)	0.9176

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1.b:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 129)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Musculoskeletal and connective tissue disorders	139	39 (28.1)	18.0 (7.6, NE)	129	40 (31.0)	7.3 (6.2, NE)	0.671 (0.427, 1.054)	0.0802
Arthralgia	139	11 (7.9)	NR (29.3, NE)	129	13 (10.1)	NR (NE, NE)	0.644 (0.281, 1.477)	0.2943
Back pain	139	13 (9.4)	NR (25.9, NE)	129	10 (7.8)	NR (8.6, NE)	0.800 (0.334, 1.917)	0.6154
Myalgia	139	5 (3.6)	NR (NE, NE)	129	14 (10.9)	NR (NE, NE)	0.244 (0.080, 0.748)	0.0074
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	139	14 (10.1)	NR (NE, NE)	129	4 (3.1)	NR (NE, NE)	3.279 (1.077, 9.981)	0.0266
Nervous system disorders	139	21 (15.1)	NR (17.8, NE)	129	42 (32.6)	9.7 (3.5, NE)	0.320 (0.186, 0.550)	<0.0001
Peripheral sensory neuropathy	139	1 (0.7)	NR (NE, NE)	129	22 (17.1)	NR (9.7, NE)	0.029 (0.004, 0.225)	<0.0001

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1.b:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 129)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Psychiatric disorders	139	18 (12.9)	NR (NE, NE)	129	16 (12.4)	NR (NE, NE)	0.888 (0.448, 1.763)	0.7347
Insomnia	139	14 (10.1)	NR (NE, NE)	129	9 (7.0)	NR (NE, NE)	1.243 (0.530, 2.917)	0.6161
Respiratory, thoracic and mediastinal disorders	139	58 (41.7)	8.6 (4.2, 32.5)	129	44 (34.1)	5.7 (3.5, NE)	1.020 (0.681, 1.528)	0.9215
Cough	139	23 (16.5)	NR (16.4, NE)	129	14 (10.9)	NR (NE, NE)	1.237 (0.622, 2.460)	0.5427
Dyspnoea	139	12 (8.6)	NR (NE, NE)	129	14 (10.9)	19.8 (NE, NE)	0.660 (0.297, 1.465)	0.3037
Productive cough	139	8 (5.8)	NR (NE, NE)	129	10 (7.8)	NR (NE, NE)	0.671 (0.263, 1.713)	0.4011

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.2.1.b:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 129)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Skin and subcutaneous tissue disorders	139	38 (27.3)	NR (9.6, NE)	129	49 (38.0)	NR (2.4, NE)	0.592 (0.384, 0.911)	0.0153
Alopecia	139	1 (0.7)	NR (NE, NE)	129	34 (26.4)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Pruritus	139	16 (11.5)	NR (11.8, NE)	129	5 (3.9)	NR (NE, NE)	2.227 (0.797, 6.220)	0.1174
Rash	139	16 (11.5)	NR (NE, NE)	129	7 (5.4)	NR (NE, NE)	1.931 (0.792, 4.710)	0.1397
Vascular disorders	139	21 (15.1)	NR (28.2, NE)	129	13 (10.1)	NR (NE, NE)	1.205 (0.593, 2.450)	0.6046
Hypertension	139	10 (7.2)	NR (NE, NE)	129	6 (4.7)	NR (NE, NE)	1.232 (0.437, 3.472)	0.6912

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

	Tislelizumab (N = 255)			ICC (N = 240)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Blood and lymphatic system disorders	255	18 (7.1)	NR (NE, NE)	240	56 (23.3)	NR (9.2, NE)	0.219 (0.127, 0.380)	<0.0001
Anaemia	255	15 (5.9)	NR (NE, NE)	240	26 (10.8)	NR (NE, NE)	0.415 (0.215, 0.800)	0.0067
Febrile neutropenia	255	0 (0.0)	NR (NE, NE)	240	11 (4.6)	NR (NE, NE)	0.000 (0.000, NE)	0.0003
Leukopenia	255	0 (0.0)	NR (NE, NE)	240	17 (7.1)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Neutropenia	255	1 (0.4)	NR (NE, NE)	240	16 (6.7)	NR (NE, NE)	0.049 (0.006, 0.378)	<0.0001
Gastrointestinal disorders	255	39 (15.3)	NR (27.6, NE)	240	45 (18.8)	NR (8.9, NE)	0.583 (0.374, 0.909)	0.0158
Diarrhoea	255	3 (1.2)	NR (NE, NE)	240	15 (6.3)	NR (NE, NE)	0.166 (0.048, 0.575)	0.0013
Dysphagia	255	17 (6.7)	NR (NE, NE)	240	7 (2.9)	NR (8.9, NE)	1.686 (0.683, 4.165)	0.2525

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

	Tislelizumab (N = 255)			ICC (N = 240)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
General disorders and administration site conditions	255	16 (6.3)	NR (37.2, NE)	240	25 (10.4)	NR (NE, NE)	0.390 (0.197, 0.772)	0.0052
Infections and infestations	255	24 (9.4)	NR (30.4, NE)	240	33 (13.8)	NR (9.2, NE)	0.488 (0.279, 0.852)	0.0101
Pneumonia	255	13 (5.1)	NR (30.4, NE)	240	17 (7.1)	NR (NE, NE)	0.457 (0.209, 0.998)	0.0444
Investigations	255	25 (9.8)	NR (NE, NE)	240	90 (37.5)	NR (4.1, NE)	0.171 (0.107, 0.272)	<0.0001
Lymphocyte count decreased	255	6 (2.4)	NR (NE, NE)	240	18 (7.5)	NR (NE, NE)	0.260 (0.102, 0.664)	0.0025
Neutrophil count decreased	255	0 (0.0)	NR (NE, NE)	240	63 (26.3)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
White blood cell count decreased	255	1 (0.4)	NR (NE, NE)	240	48 (20.0)	NR (NE, NE)	0.017 (0.002, 0.120)	<0.0001

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.3.1:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

	Tislelizumab (N = 255)			ICC (N = 240)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Metabolism and nutrition disorders	255	29 (11.4)	NR (30.8, NE)	240	31 (12.9)	NR (9.6, NE)	0.546 (0.314, 0.949)	0.0294
Decreased appetite	255	2 (0.8)	NR (NE, NE)	240	10 (4.2)	NR (NE, NE)	0.080 (0.010, 0.635)	0.0024
Hyponatraemia	255	14 (5.5)	NR (NE, NE)	240	10 (4.2)	NR (NE, NE)	0.881 (0.374, 2.075)	0.7722
Respiratory, thoracic and mediastinal disorders	255	24 (9.4)	NR (NE, NE)	240	16 (6.7)	NR (8.6, NE)	0.982 (0.509, 1.892)	0.9566

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.3.1.b:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

System Organ Class Preferred Term	Tislelizumab (N = 139) Total No. of Patients	Tislelizumab (N = 139) Patients with events n (%)	Tislelizumab (N = 139) Median time to event (95% CI) [a]	ICC (N = 129) Total No. of Patients	ICC (N = 129) Patients with events n (%)	ICC (N = 129) Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Blood and lymphatic system disorders	139	13 (9.4)	NR (NE, NE)	129	31 (24.0)	NR (NE, NE)	0.300 (0.156, 0.579)	0.0001
Anaemia	139	10 (7.2)	NR (NE, NE)	129	10 (7.8)	NR (NE, NE)	0.806 (0.334, 1.947)	0.6317
Febrile neutropenia	139	0 (0.0)	NR (NE, NE)	129	8 (6.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0014
Leukopenia	139	0 (0.0)	NR (NE, NE)	129	8 (6.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0019
Neutropenia	139	1 (0.7)	NR (NE, NE)	129	12 (9.3)	NR (NE, NE)	0.063 (0.008, 0.491)	0.0005
Gastrointestinal disorders	139	19 (13.7)	NR (27.6, NE)	129	14 (10.9)	NR (8.9, NE)	0.993 (0.490, 2.013)	0.9847
Dysphagia	139	11 (7.9)	NR (27.6, NE)	129	4 (3.1)	NR (8.9, NE)	2.016 (0.628, 6.472)	0.2298
General disorders and administration site conditions	139	12 (8.6)	NR (37.2, NE)	129	11 (8.5)	NR (NE, NE)	0.675 (0.279, 1.637)	0.3819

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.3.1.b:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 129)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Infections and infestations	139	16 (11.5)	NR (30.4, NE)	129	19 (14.7)	NR (NE, NE)	0.621 (0.312, 1.235)	0.1706
Pneumonia	139	8 (5.8)	NR (30.4, NE)	129	11 (8.5)	NR (NE, NE)	0.467 (0.177, 1.233)	0.1162
Investigations	139	12 (8.6)	NR (NE, NE)	129	51 (39.5)	NR (2.4, NE)	0.143 (0.074, 0.276)	<0.0001
Lymphocyte count decreased	139	2 (1.4)	NR (NE, NE)	129	9 (7.0)	NR (NE, NE)	0.186 (0.040, 0.863)	0.0156
Neutrophil count decreased	139	0 (0.0)	NR (NE, NE)	129	38 (29.5)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
White blood cell count decreased	139	0 (0.0)	NR (NE, NE)	129	28 (21.7)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Metabolism and nutrition disorders	139	20 (14.4)	NR (30.8, NE)	129	13 (10.1)	NR (9.6, NE)	0.964 (0.461, 2.014)	0.9224
Hyponatraemia	139	7 (5.0)	NR (NE, NE)	129	4 (3.1)	NR (NE, NE)	1.158 (0.332, 4.045)	0.8177

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.2.3.1.b:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 129)				
System Organ Class Preferred Term	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Respiratory, thoracic and mediastinal disorders	139	15 (10.8)	NR (NE, NE)	129	11 (8.5)	NR (8.6, NE)	1.051 (0.474, 2.328)	0.9030
Vascular disorders	139	8 (5.8)	NR (NE, NE)	129	0 (0.0)	NR (NE, NE)	69810561.547 (0.000, NE)	0.0091

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.4.1.1:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

System Organ Class Preferred Term	Tislelizumab (N = 255) Total No. of Patients	Tislelizumab (N = 255) Patients with events n (%)	Tislelizumab (N = 255) Median time to event (95% CI) [a]	ICC (N = 240) Total No. of Patients	ICC (N = 240) Patients with events n (%)	ICC (N = 240) Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Blood and lymphatic system disorders	255	1 (0.4)	NR (NE, NE)	240	19 (7.9)	NR (NE, NE)	0.046 (0.006, 0.343)	<0.0001
Gastrointestinal disorders	255	37 (14.5)	NR (27.6, NE)	240	30 (12.5)	NR (NE, NE)	0.874 (0.533, 1.433)	0.5930
Dysphagia	255	13 (5.1)	NR (NE, NE)	240	4 (1.7)	NR (NE, NE)	2.491 (0.800, 7.757)	0.1034
General disorders and administration site conditions	255	13 (5.1)	NR (NE, NE)	240	14 (5.8)	NR (NE, NE)	0.731 (0.337, 1.587)	0.4267
Infections and infestations	255	29 (11.4)	NR (30.4, NE)	240	32 (13.3)	NR (9.2, NE)	0.576 (0.337, 0.984)	0.0411
Pneumonia	255	19 (7.5)	NR (30.4, NE)	240	17 (7.1)	NR (NE, NE)	0.666 (0.332, 1.339)	0.2508
Investigations	255	1 (0.4)	NR (NE, NE)	240	13 (5.4)	NR (NE, NE)	0.069 (0.009, 0.529)	0.0006
Neutrophil count decreased	255	0 (0.0)	NR (NE, NE)	240	10 (4.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0008

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.4.1.1:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

System Organ Class Preferred Term	Tislelizumab (N = 255) Total No. of Patients	Tislelizumab (N = 255) Patients with events n (%)	Tislelizumab (N = 255) Median time to event (95% CI) [a]	ICC (N = 240) Total No. of Patients	ICC (N = 240) Patients with events n (%)	ICC (N = 240) Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Metabolism and nutrition disorders	255	10 (3.9)	NR (NE, NE)	240	6 (2.5)	NR (NE, NE)	0.796 (0.259, 2.446)	0.6895
Respiratory, thoracic and mediastinal disorders	255	27 (10.6)	NR (NE, NE)	240	18 (7.5)	NR (NE, NE)	1.026 (0.554, 1.900)	0.9346

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.2.4.1.1.b:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

System Organ Class Preferred Term	Tislelizumab (N = 139) Total No. of Patients	Tislelizumab (N = 139) Patients with events n (%)	Tislelizumab (N = 139) Median time to event (95% CI) [a]	ICC (N = 129) Total No. of Patients	ICC (N = 129) Patients with events n (%)	ICC (N = 129) Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Blood and lymphatic system disorders	139	1 (0.7)	NR (NE, NE)	129	10 (7.8)	NR (NE, NE)	0.084 (0.011, 0.658)	0.0024
Gastrointestinal disorders	139	20 (14.4)	NR (27.6, NE)	129	9 (7.0)	NR (NE, NE)	1.650 (0.741, 3.672)	0.2151
Dysphagia	139	10 (7.2)	NR (27.6, NE)	129	2 (1.6)	NR (NE, NE)	3.836 (0.827, 17.799)	0.0647
General disorders and administration site conditions	139	9 (6.5)	NR (NE, NE)	129	9 (7.0)	NR (NE, NE)	0.768 (0.295, 1.996)	0.5864
Infections and infestations	139	18 (12.9)	NR (30.4, NE)	129	19 (14.7)	NR (NE, NE)	0.654 (0.335, 1.279)	0.2116
Pneumonia	139	11 (7.9)	NR (30.4, NE)	129	10 (7.8)	NR (NE, NE)	0.714 (0.292, 1.745)	0.4576
Metabolism and nutrition disorders	139	8 (5.8)	NR (NE, NE)	129	3 (2.3)	NR (NE, NE)	1.363 (0.331, 5.609)	0.6664
Respiratory, thoracic and mediastinal disorders	139	17 (12.2)	NR (NE, NE)	129	9 (7.0)	NR (8.6, NE)	1.380 (0.605, 3.146)	0.4420

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = treatment-emergent adverse event; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.5.1.b:
Treatment-Emergent Adverse Events (TEAEs) Leading to Treatment Discontinuation by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

System Organ Class Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)
Patients With at Least One TEAE Leading to Treatment Discontinuation	25 (18.0)	28 (21.7)
Respiratory, thoracic and mediastinal disorders	8 (5.8)	5 (3.9)
Immune-mediated lung disease	2 (1.4)	0 (0.0)
Pneumonitis	2 (1.4)	2 (1.6)
Dyspnoea	1 (0.7)	0 (0.0)
Lung disorder	1 (0.7)	0 (0.0)
Pulmonary arterial hypertension	1 (0.7)	0 (0.0)
Pulmonary haemorrhage	1 (0.7)	0 (0.0)
Acquired tracheo-oesophageal fistula	0 (0.0)	1 (0.8)
Haemoptysis	0 (0.0)	1 (0.8)
Pleural effusion	0 (0.0)	1 (0.8)

Source: Listing 16.2.7.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = Treatment-Emergent Adverse Event.
Percentages were based on N.
Patients with multiple events for a given preferred term and system organ class were counted only once for the preferred term and system organ class, respectively.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 25.0.
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Table 14.3.1.5.1.b:
Treatment-Emergent Adverse Events (TEAEs) Leading to Treatment Discontinuation by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

System Organ Class Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)
Infections and infestations	6 (4.3)	5 (3.9)
Pneumonia	4 (2.9)	2 (1.6)
Bronchitis	1 (0.7)	0 (0.0)
Sepsis	1 (0.7)	0 (0.0)
Pneumonia aspiration	0 (0.0)	1 (0.8)
Septic endocarditis	0 (0.0)	1 (0.8)
Septic shock	0 (0.0)	1 (0.8)
Gastrointestinal disorders	4 (2.9)	1 (0.8)
Dysphagia	1 (0.7)	0 (0.0)
Gastrointestinal haemorrhage	1 (0.7)	0 (0.0)
Oesophagomediastinal fistula	1 (0.7)	0 (0.0)
Upper gastrointestinal haemorrhage	1 (0.7)	1 (0.8)

Source: Listing 16.2.7.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = Treatment-Emergent Adverse Event.
Percentages were based on N.
Patients with multiple events for a given preferred term and system organ class were counted only once for the preferred term and system organ class, respectively.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 25.0.
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Table 14.3.1.5.1.b:
Treatment-Emergent Adverse Events (TEAEs) Leading to Treatment Discontinuation by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

System Organ Class Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)
General disorders and administration site conditions	4 (2.9)	6 (4.7)
General physical health deterioration	2 (1.4)	0 (0.0)
Death	1 (0.7)	2 (1.6)
Sudden death	1 (0.7)	1 (0.8)
Asthenia	0 (0.0)	2 (1.6)
Fatigue	0 (0.0)	1 (0.8)
Metabolism and nutrition disorders	2 (1.4)	1 (0.8)
Decreased appetite	1 (0.7)	1 (0.8)
Type 1 diabetes mellitus	1 (0.7)	0 (0.0)
Hepatobiliary disorders	1 (0.7)	0 (0.0)
Biliary obstruction	1 (0.7)	0 (0.0)
Investigations	1 (0.7)	1 (0.8)
Platelet count decreased	1 (0.7)	0 (0.0)
Neutrophil count decreased	0 (0.0)	1 (0.8)

Source: Listing 16.2.7.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = Treatment-Emergent Adverse Event.
Percentages were based on N.
Patients with multiple events for a given preferred term and system organ class were counted only once for the preferred term and system organ class, respectively.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 25.0.
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Table 14.3.1.5.1.b:
Treatment-Emergent Adverse Events (TEAEs) Leading to Treatment Discontinuation by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

System Organ Class Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.7)	1 (0.8)
Tumour fistulisation	1 (0.7)	0 (0.0)
Tumour haemorrhage	0 (0.0)	1 (0.8)
Blood and lymphatic system disorders	0 (0.0)	4 (3.1)
Febrile neutropenia	0 (0.0)	3 (2.3)
Lymphadenopathy	0 (0.0)	1 (0.8)
Cardiac disorders	0 (0.0)	3 (2.3)
Acute left ventricular failure	0 (0.0)	1 (0.8)
Atrial flutter	0 (0.0)	1 (0.8)
Atrioventricular block	0 (0.0)	1 (0.8)
Cardiac arrest	0 (0.0)	1 (0.8)
Musculoskeletal and connective tissue disorders	0 (0.0)	1 (0.8)
Muscle spasms	0 (0.0)	1 (0.8)

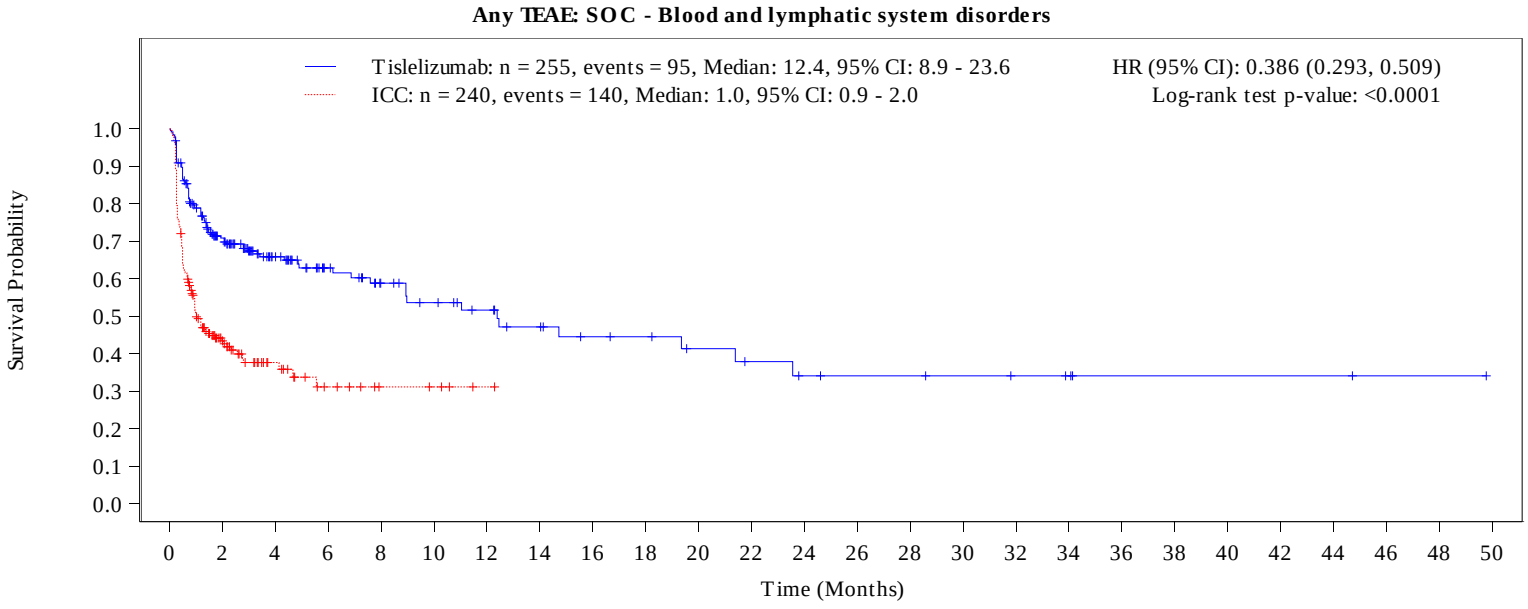
Source: Listing 16.2.7.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = Treatment-Emergent Adverse Event.
Percentages were based on N.
Patients with multiple events for a given preferred term and system organ class were counted only once for the preferred term and system organ class, respectively.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 25.0.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-socpt.sas 05JUN2024 17:45 t-14-03-01-05-01-b-socpt-dis-safetys-cl.rtf

Table 14.3.1.5.1.b:
Treatment-Emergent Adverse Events (TEAEs) Leading to Treatment Discontinuation by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

System Organ Class Preferred Term	Tislelizumab (N = 139) n (%)	ICC (N = 129) n (%)
Nervous system disorders	0 (0.0)	2 (1.6)
Hypoaesthesia	0 (0.0)	1 (0.8)
Peripheral sensory neuropathy	0 (0.0)	1 (0.8)

Source: Listing 16.2.7.1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; TEAE = Treatment-Emergent Adverse Event.
Percentages were based on N.
Patients with multiple events for a given preferred term and system organ class were counted only once for the preferred term and system organ class, respectively.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 25.0.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-socpt.sas 05JUN2024 17:45 t-14-03-01-05-01-b-socpt-dis-safetys-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	134	77	49	36	30	25	20	16	15	12	10	8	7	7	6	5	4	2	2	2	2	2	1	1	0
ICC	240	57	21	10	5	4	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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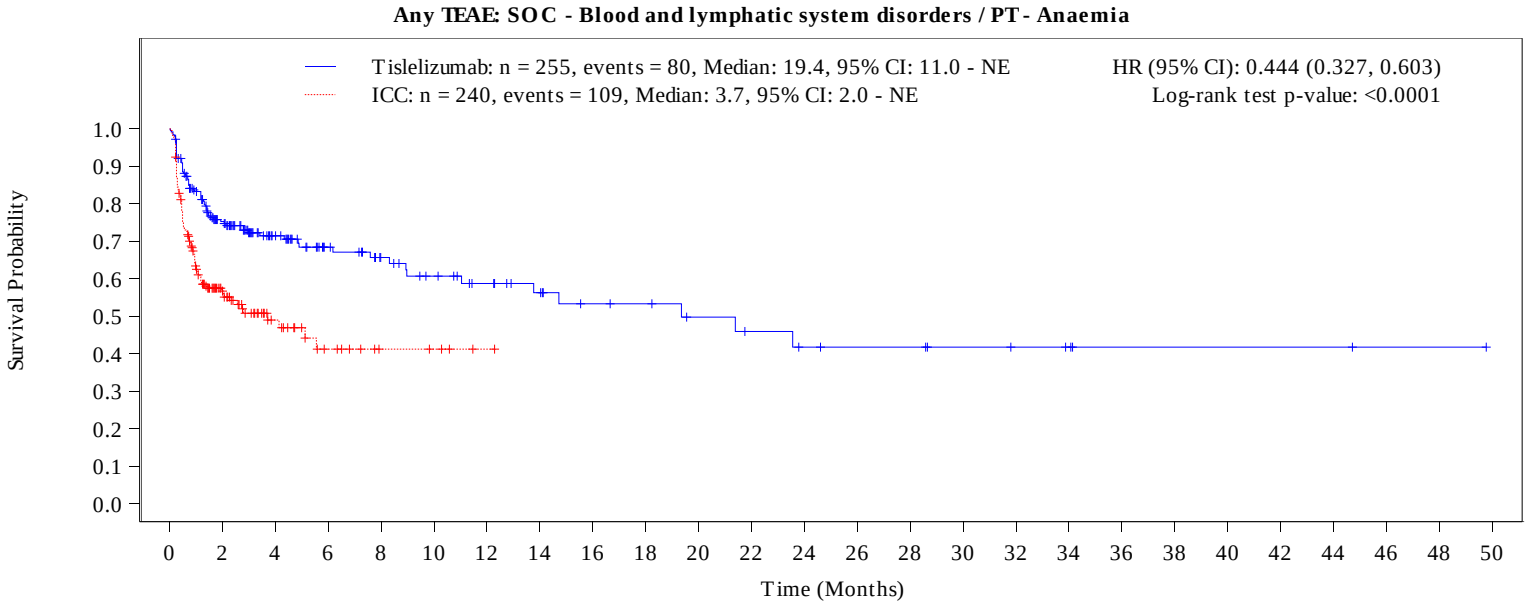
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	141	81	53	41	34	28	23	17	16	13	11	9	8	8	6	5	4	2	2	2	2	2	1	1	0
ICC	240	73	24	11	5	4	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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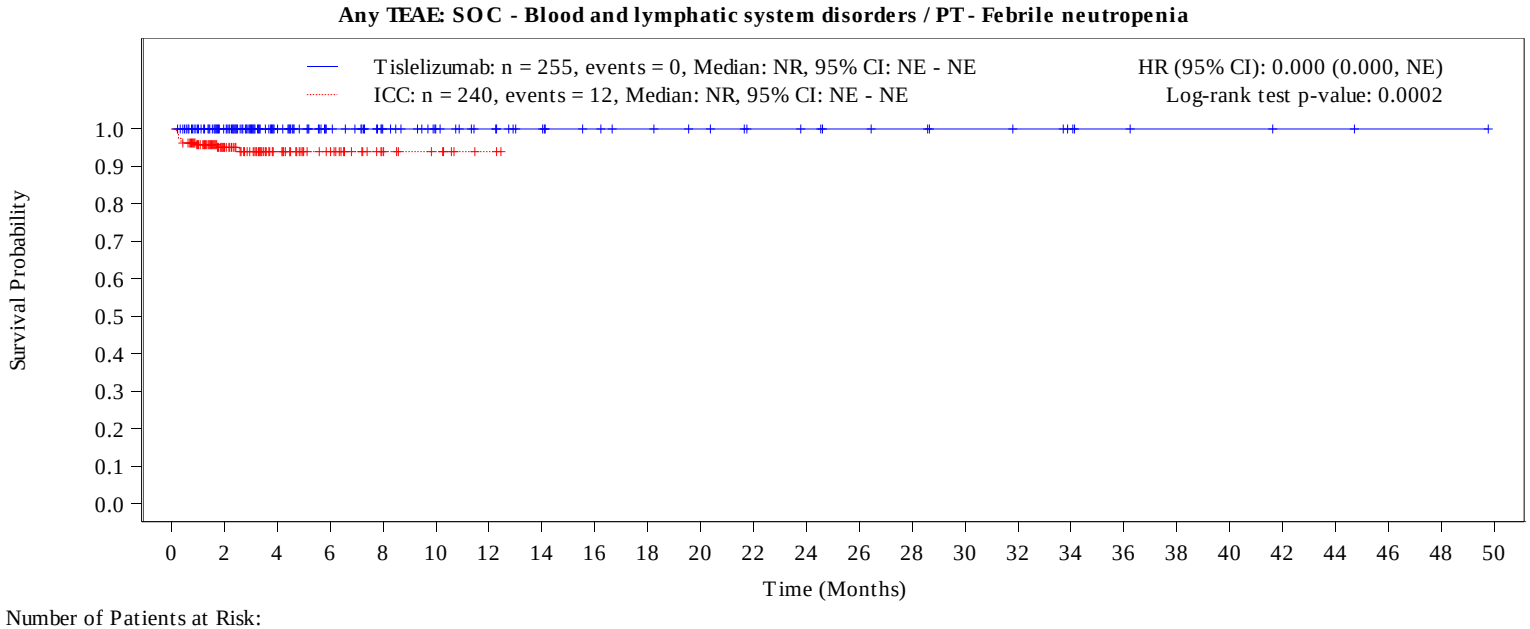
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	175	97	65	49	38	32	27	22	20	18	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	110	44	25	11	7	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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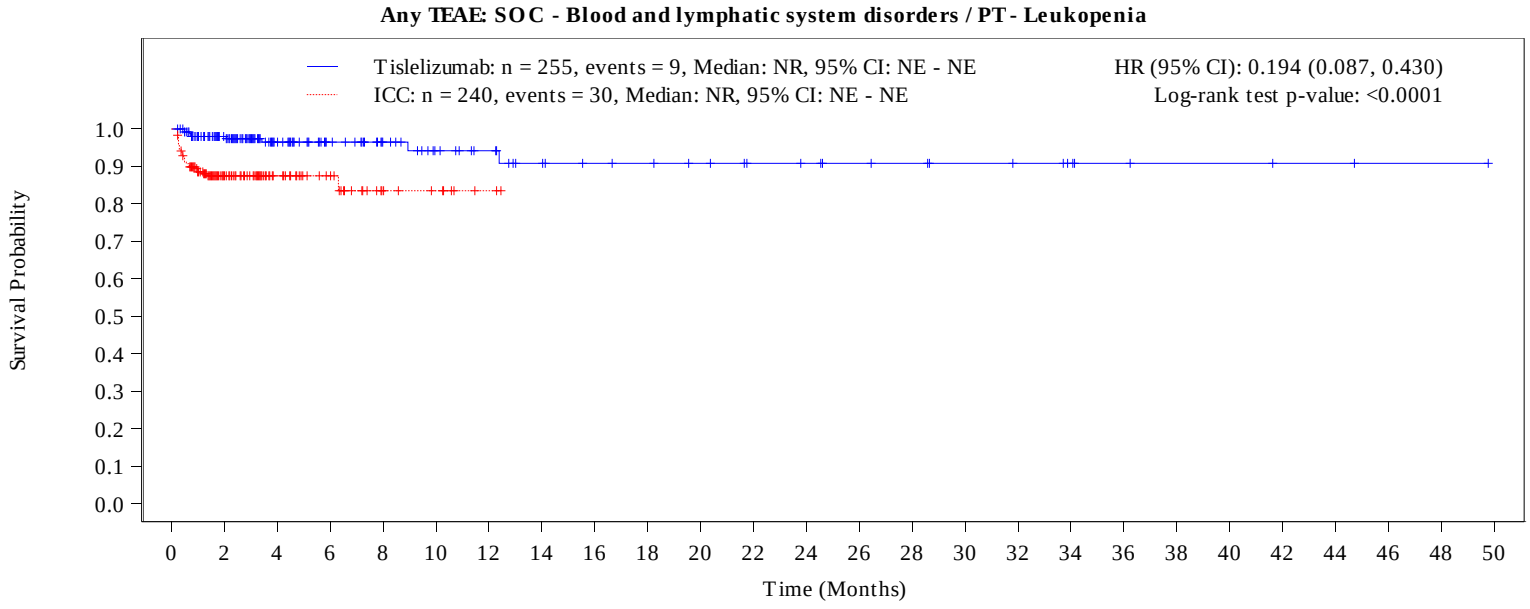
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

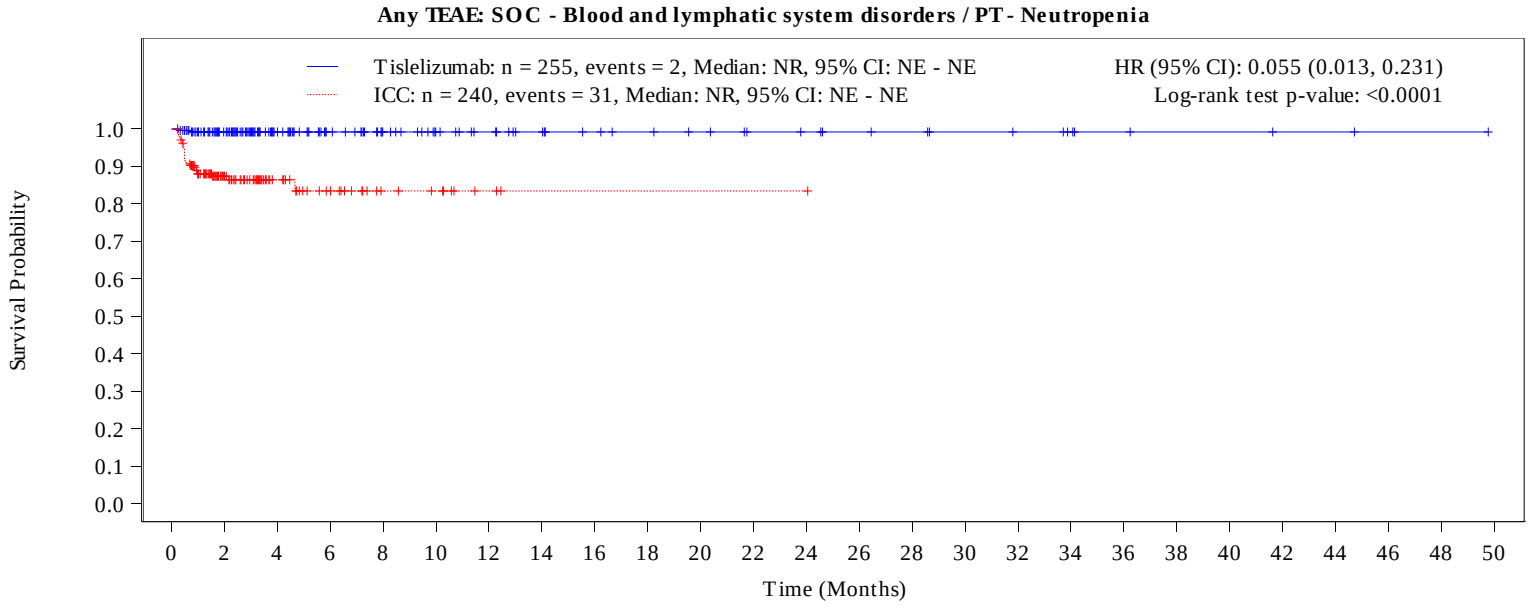


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	171	94	62	46	35	30	24	21	20	18	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	101	40	24	10	7	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

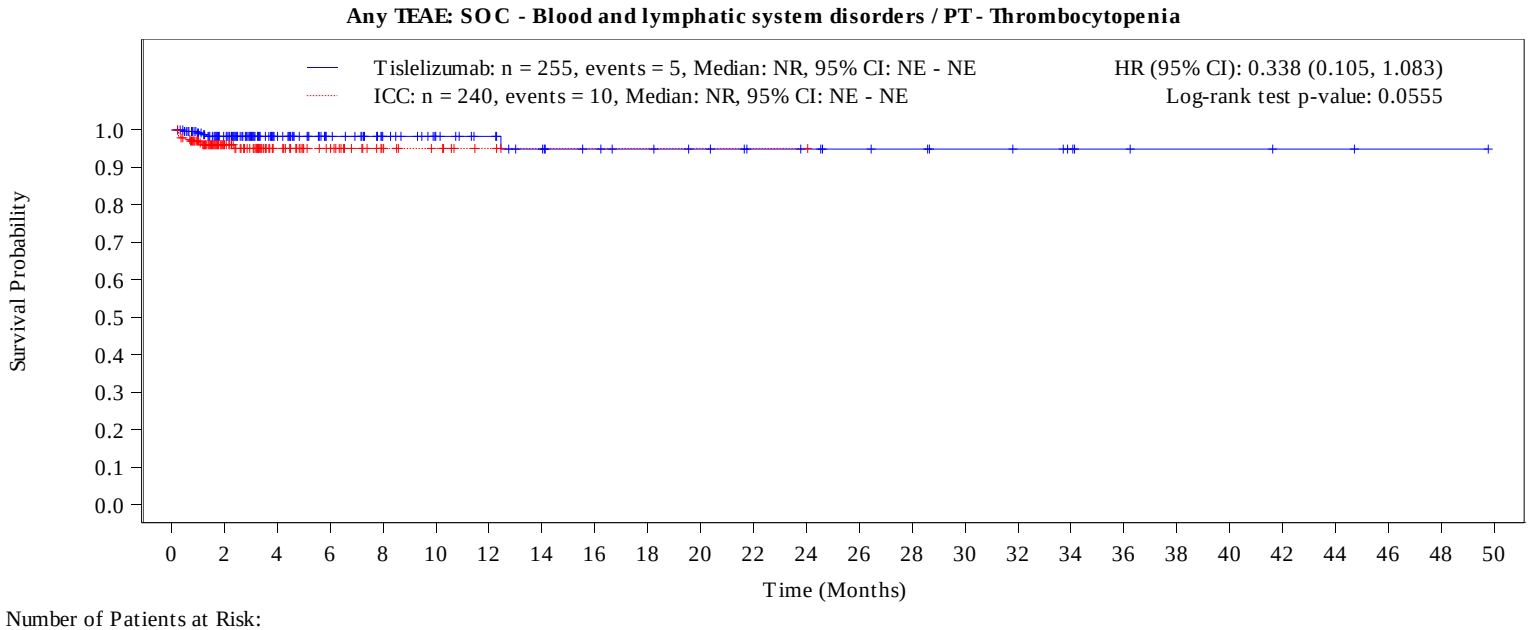


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	174	96	64	48	37	31	26	22	20	18	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	96	35	20	10	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

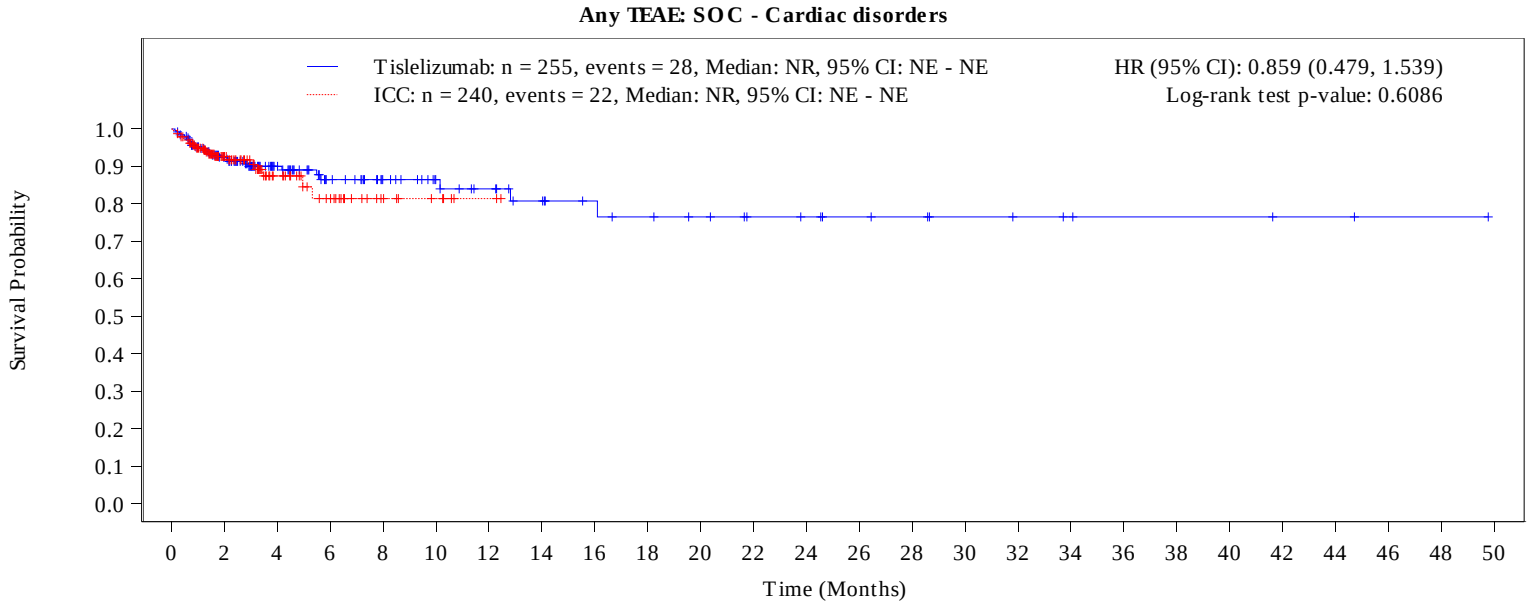


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	172	96	64	48	37	31	26	22	20	18	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	112	44	26	12	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

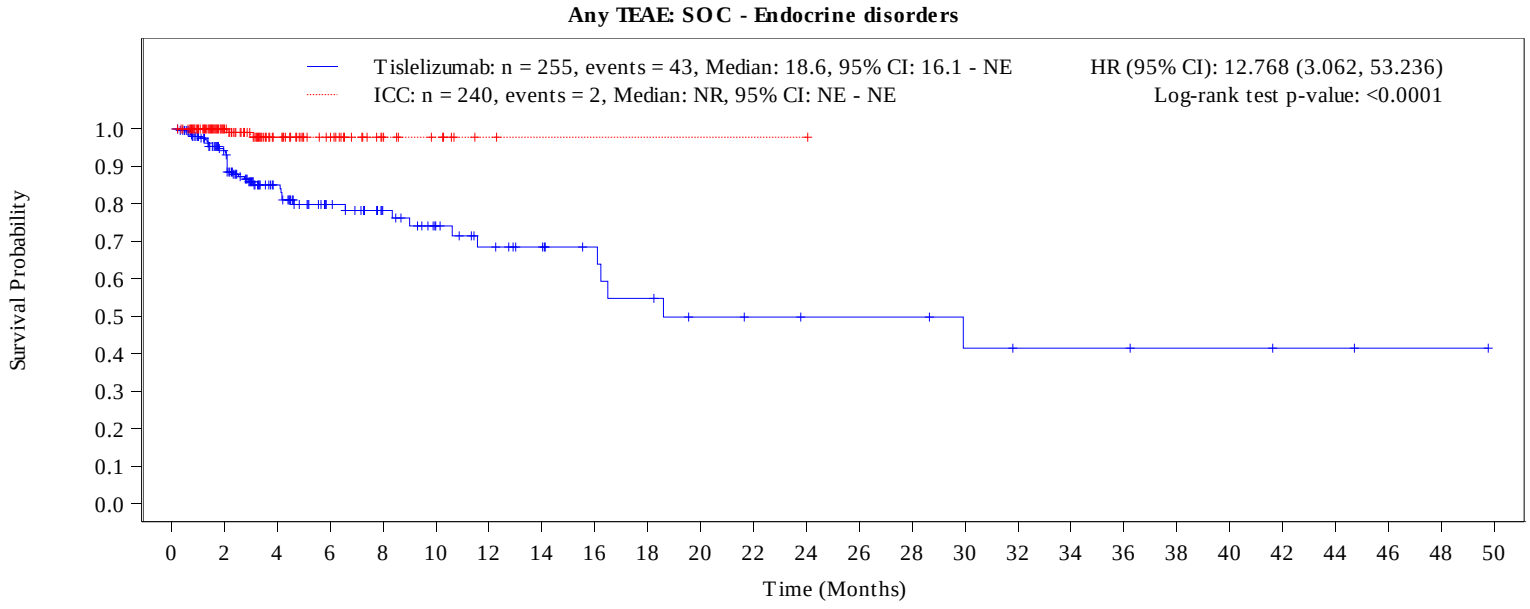


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	167	94	61	46	35	29	24	19	17	15	12	11	9	8	6	5	4	3	3	3	2	2	1	1	0
ICC	240	108	40	22	10	6	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

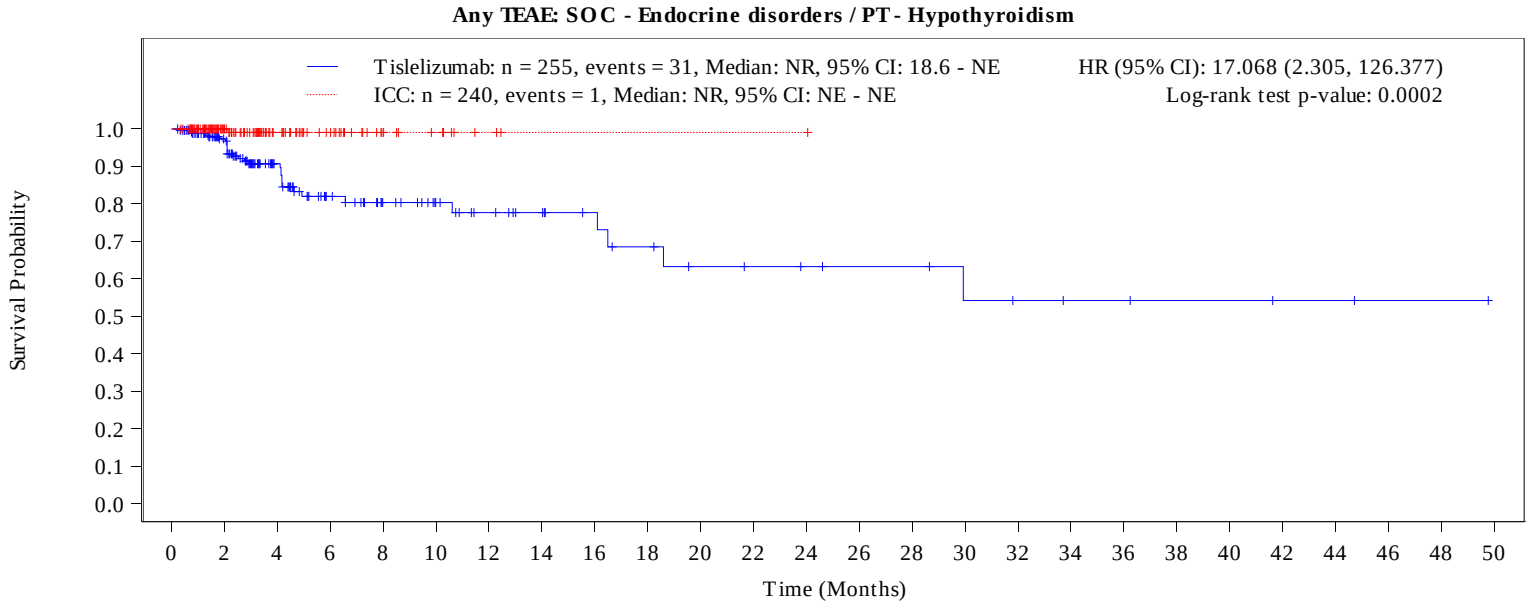


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	166	85	51	39	29	23	19	15	12	9	8	7	7	7	5	4	4	4	3	3	2	2	1	1	0
ICC	240	113	44	25	11	7	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

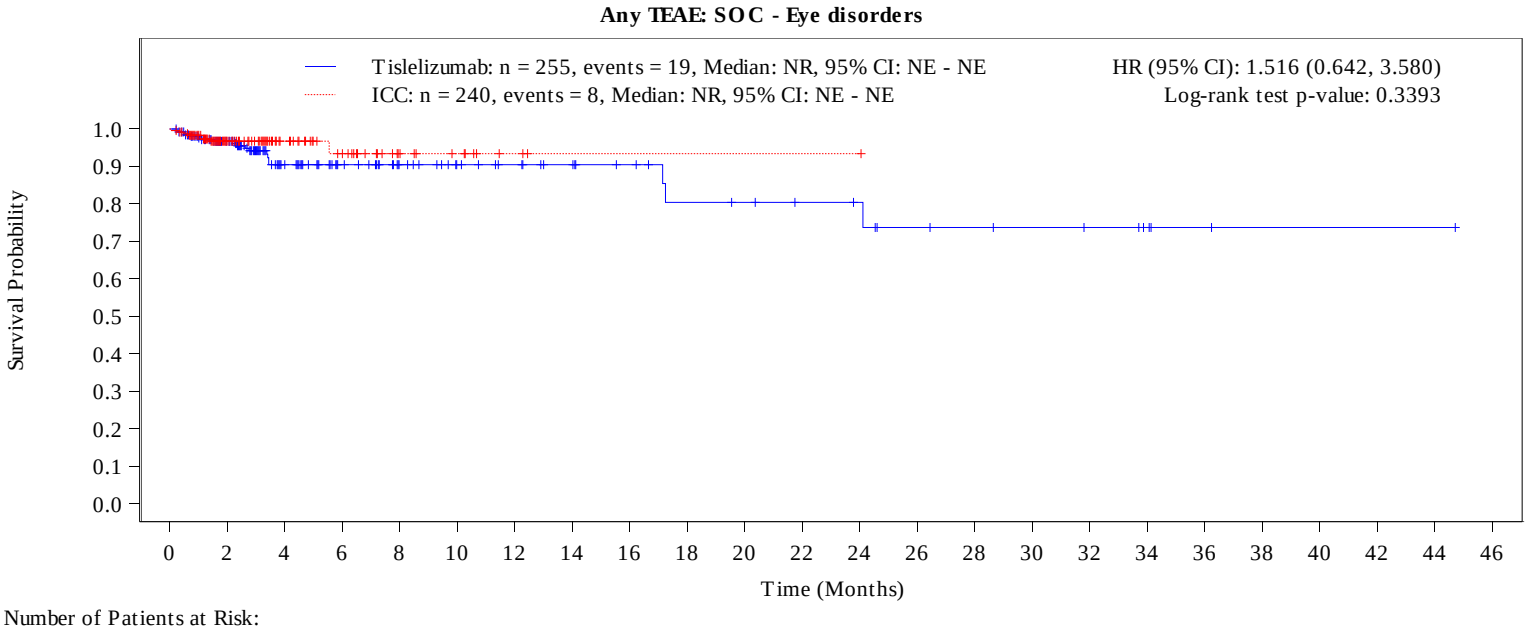


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	171	88	51	39	31	25	21	17	14	11	10	9	8	8	6	5	4	4	3	3	2	2	1	1	0
ICC	240	113	45	26	12	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

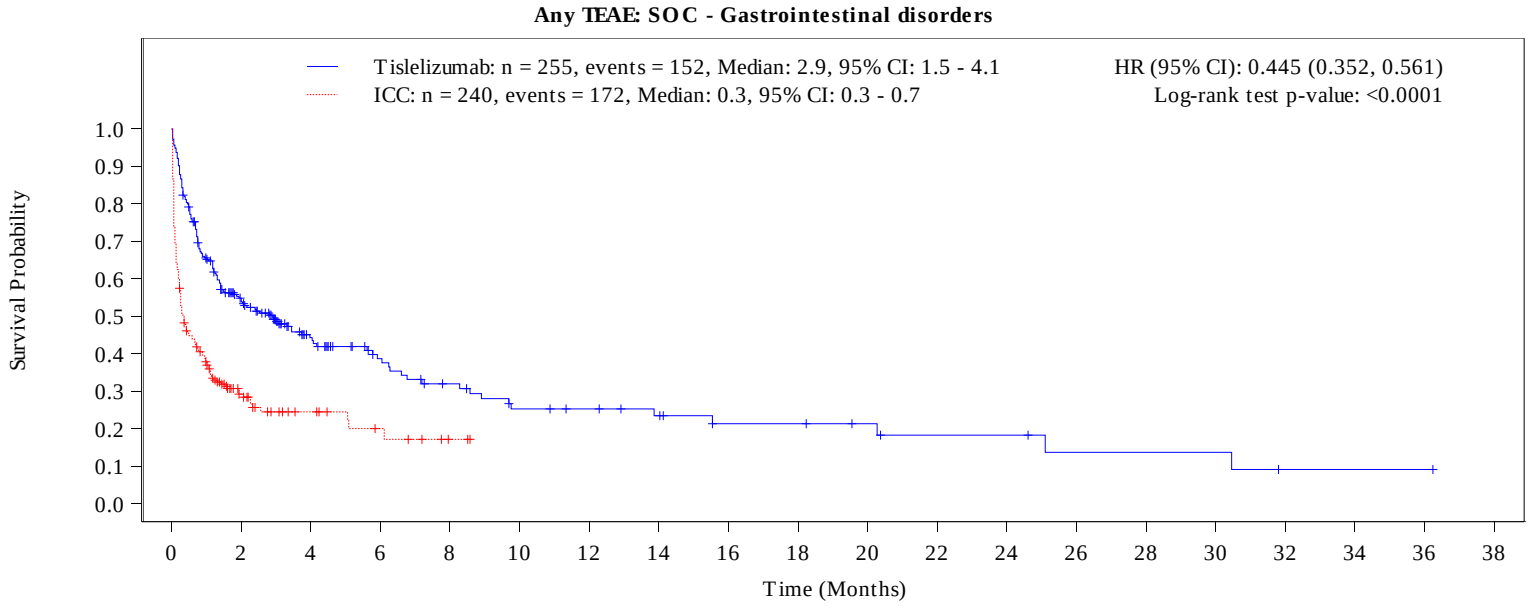


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46
Tislelizumab	255	172	88	60	44	34	29	25	20	16	15	13	12	9	8	7	6	4	2	1	1	1	1	0
ICC	240	109	42	25	12	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

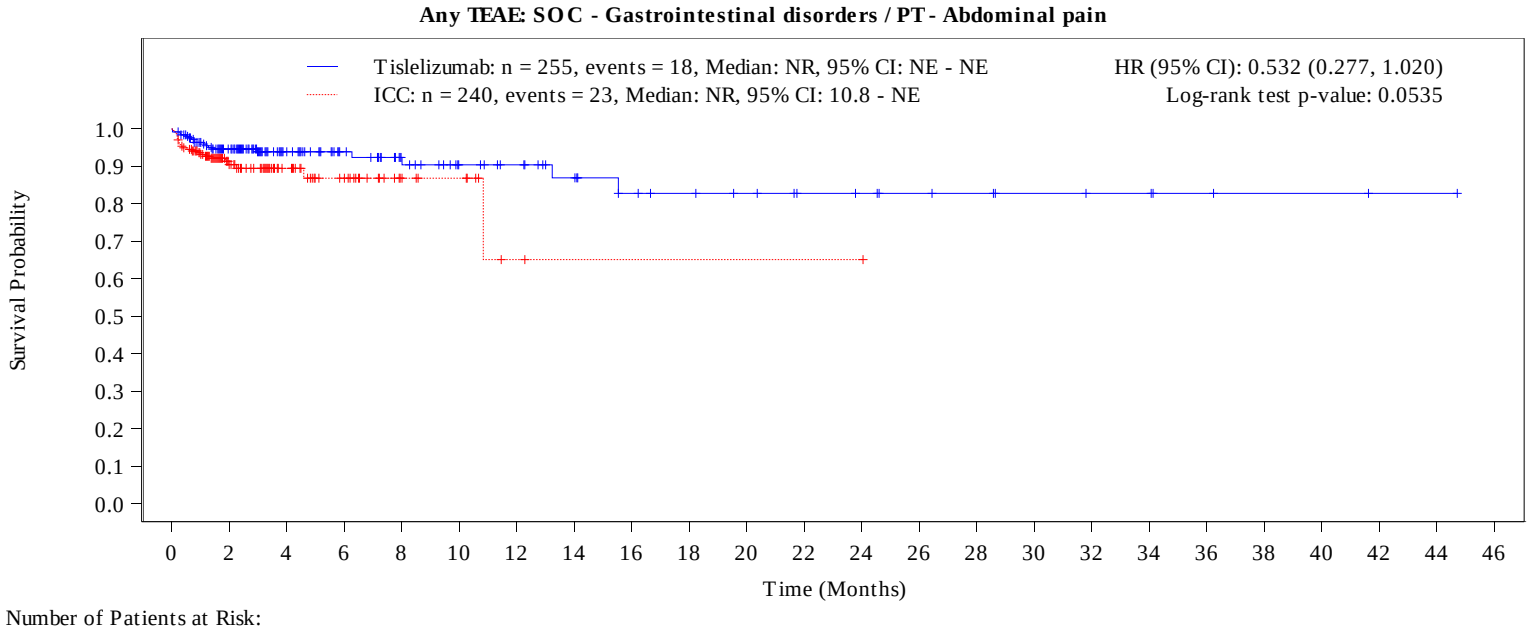


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38
Tislelizumab	255	112	56	35	25	18	16	13	9	9	7	5	5	3	3	3	1	1	1	0
ICC	240	36	15	7	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

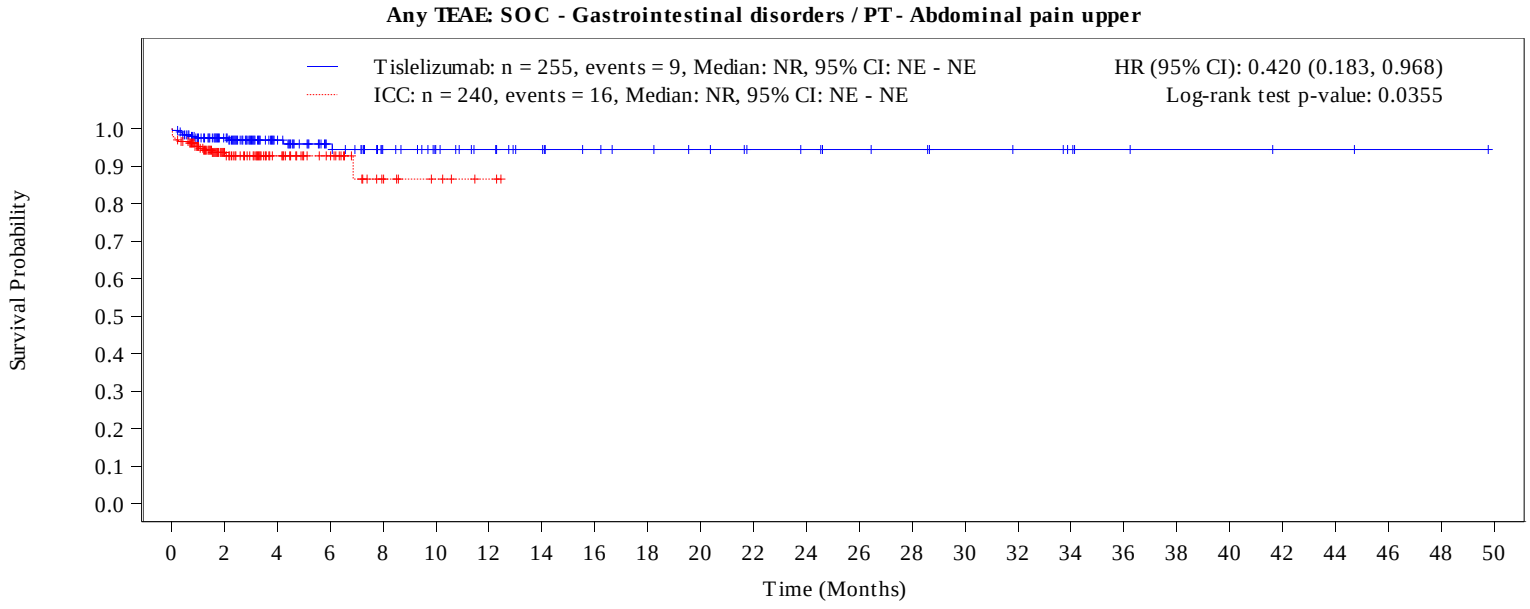


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46
Tislelizumab	255	170	93	63	47	35	31	25	19	17	15	12	11	9	8	6	5	5	3	2	2	1	1	0
ICC	240	103	42	25	11	8	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

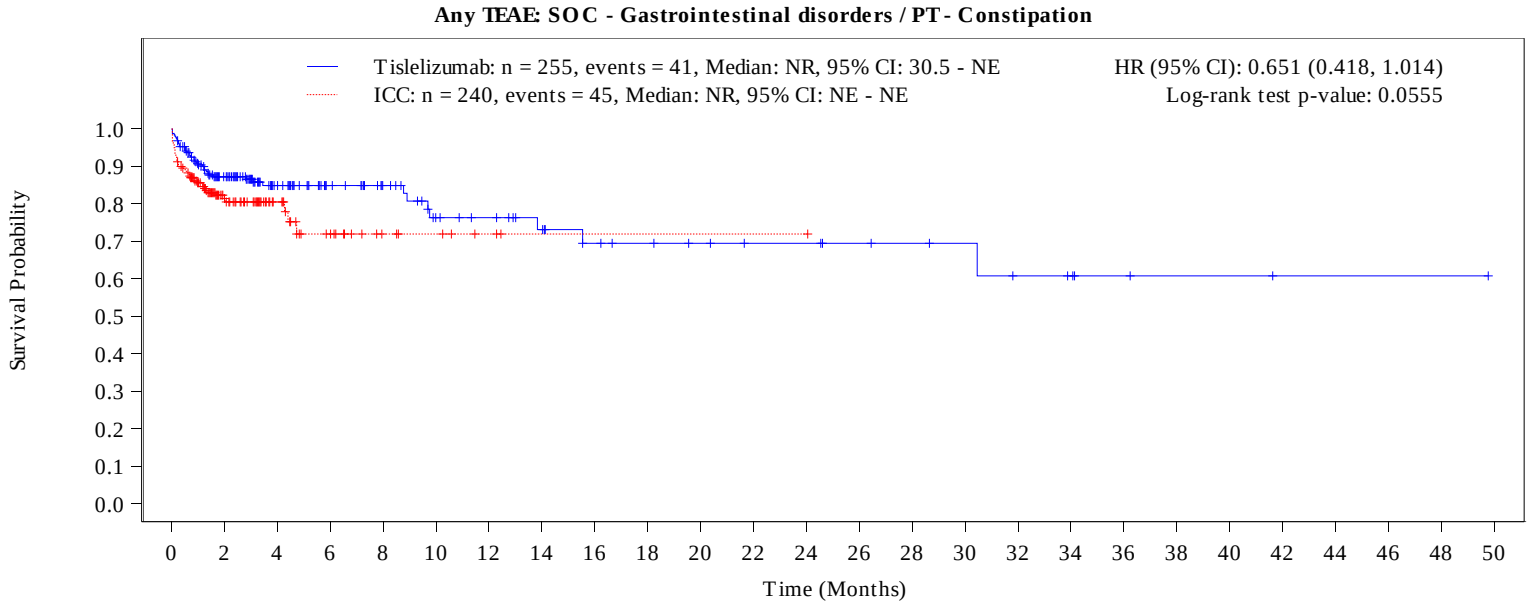


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	171	96	65	48	38	32	27	22	20	18	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	104	41	23	9	5	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

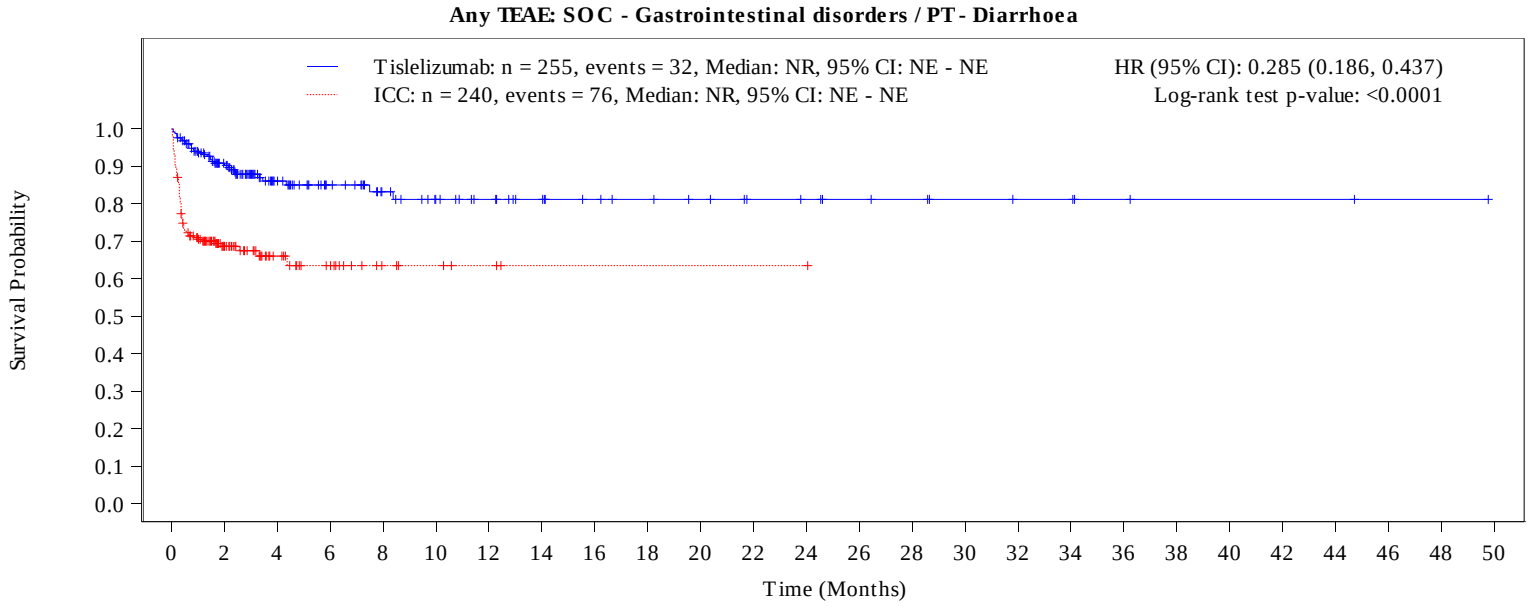


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	157	86	59	45	32	28	23	18	16	14	12	12	10	9	8	6	5	3	2	2	1	1	1	1	0
ICC	240	92	34	17	8	6	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	159	84	56	42	34	29	24	19	17	15	12	11	9	8	6	5	5	3	2	2	2	2	1	1	0
ICC	240	81	29	16	7	5	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

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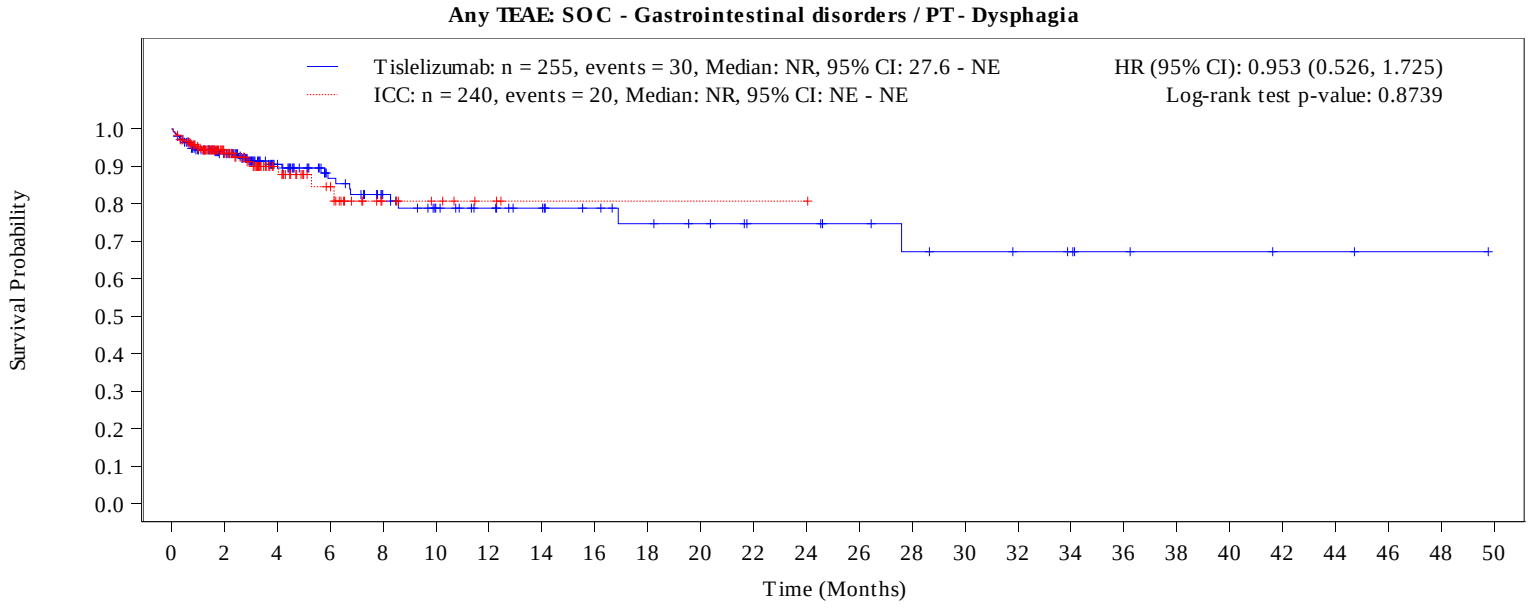
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	168	94	61	47	36	30	26	21	18	16	13	13	11	9	8	7	6	4	3	3	2	2	1	1	0
ICC	240	105	42	23	9	6	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

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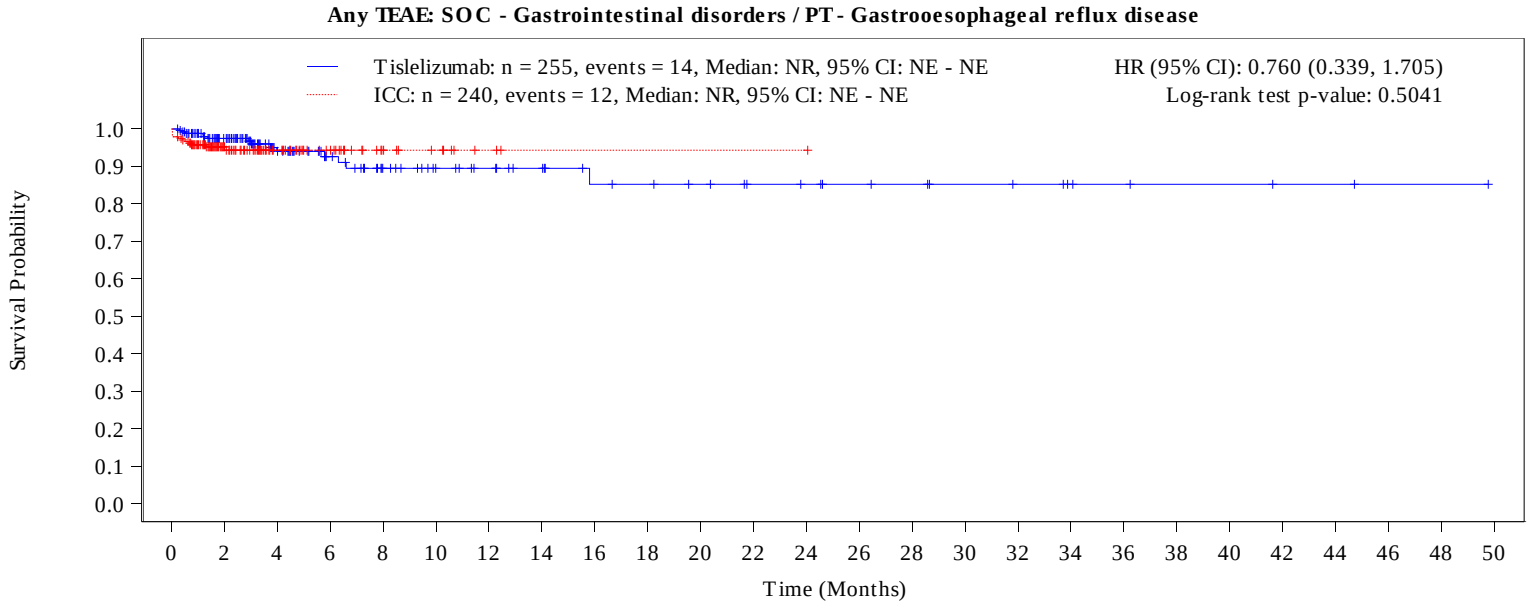
Safety Analysis Set

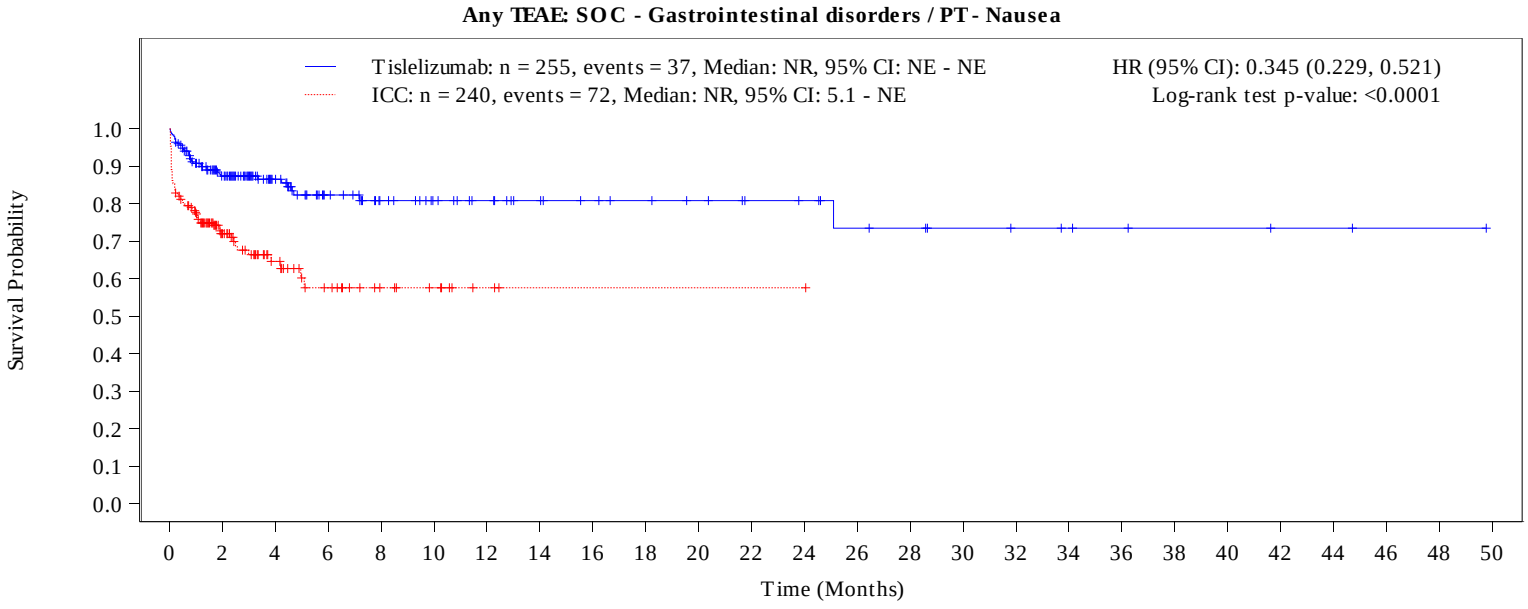


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	170	93	61	45	35	30	26	20	19	17	14	13	11	10	8	7	5	4	3	3	2	2	1	1	0
ICC	240	108	44	25	12	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	159	91	60	45	36	30	25	21	19	17	14	13	10	9	7	6	5	4	3	3	2	2	1	1	0
ICC	240	85	35	19	11	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

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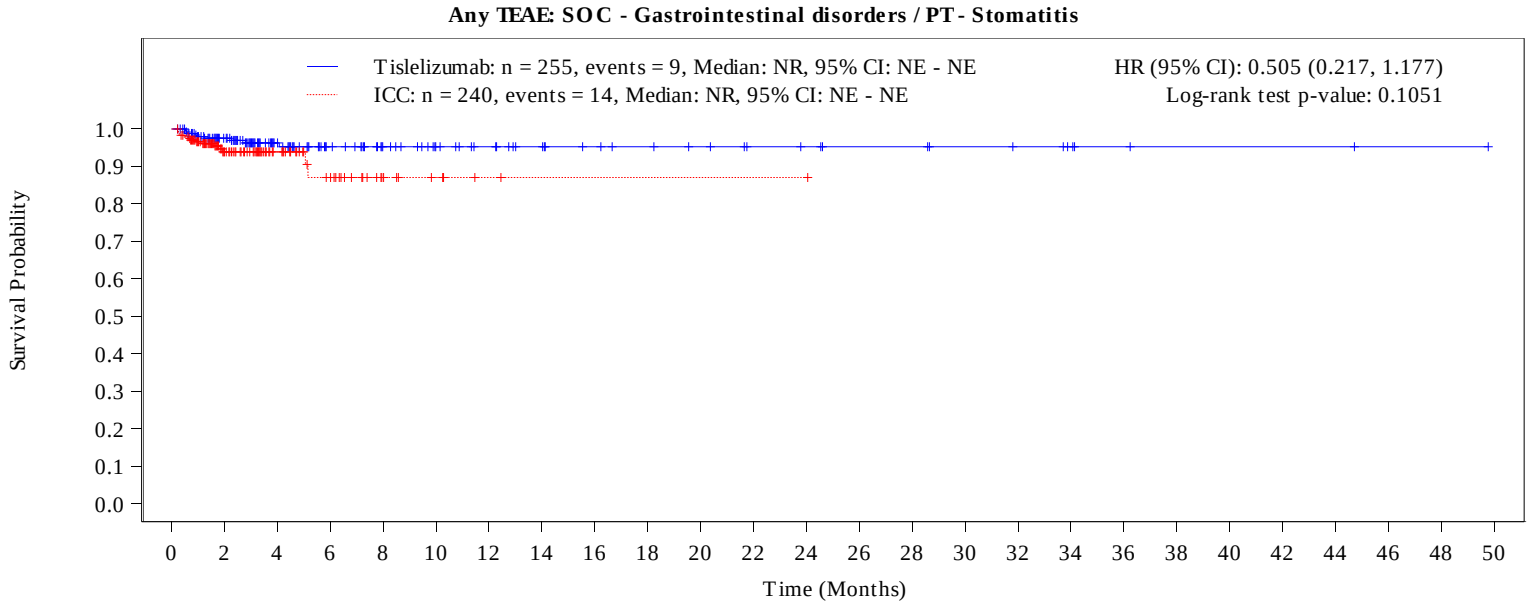
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	171	95	63	47	36	30	25	20	18	16	13	12	10	10	8	7	5	3	2	2	2	2	1	1	0
ICC	240	106	41	22	9	5	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

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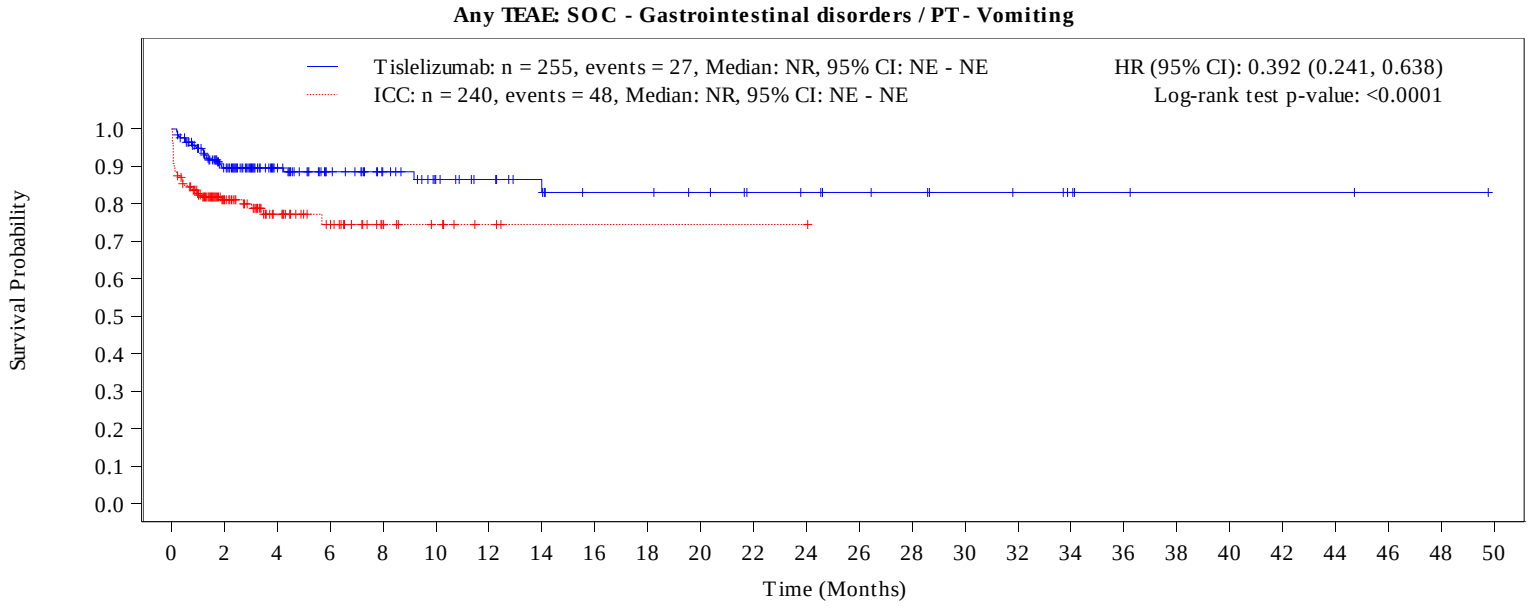
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

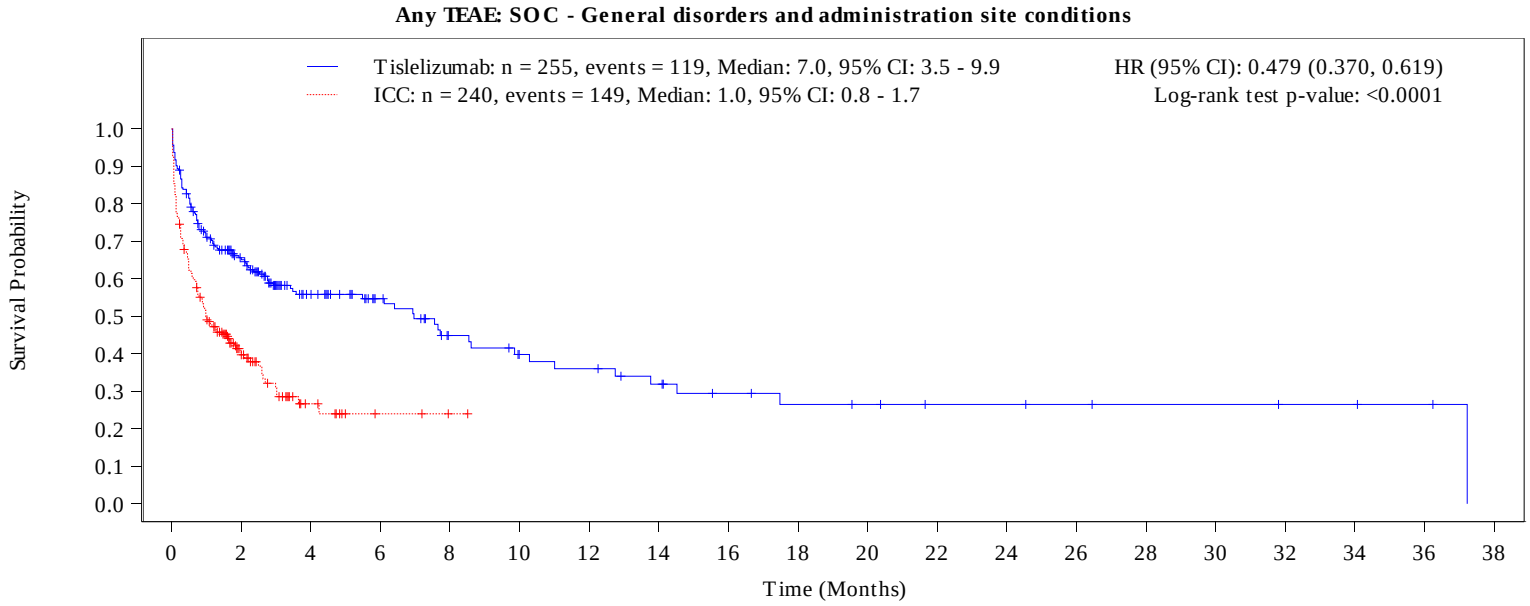


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	162	91	61	47	35	29	24	19	19	17	14	13	11	10	8	7	5	3	2	2	2	2	1	1	0
ICC	240	97	40	24	11	7	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

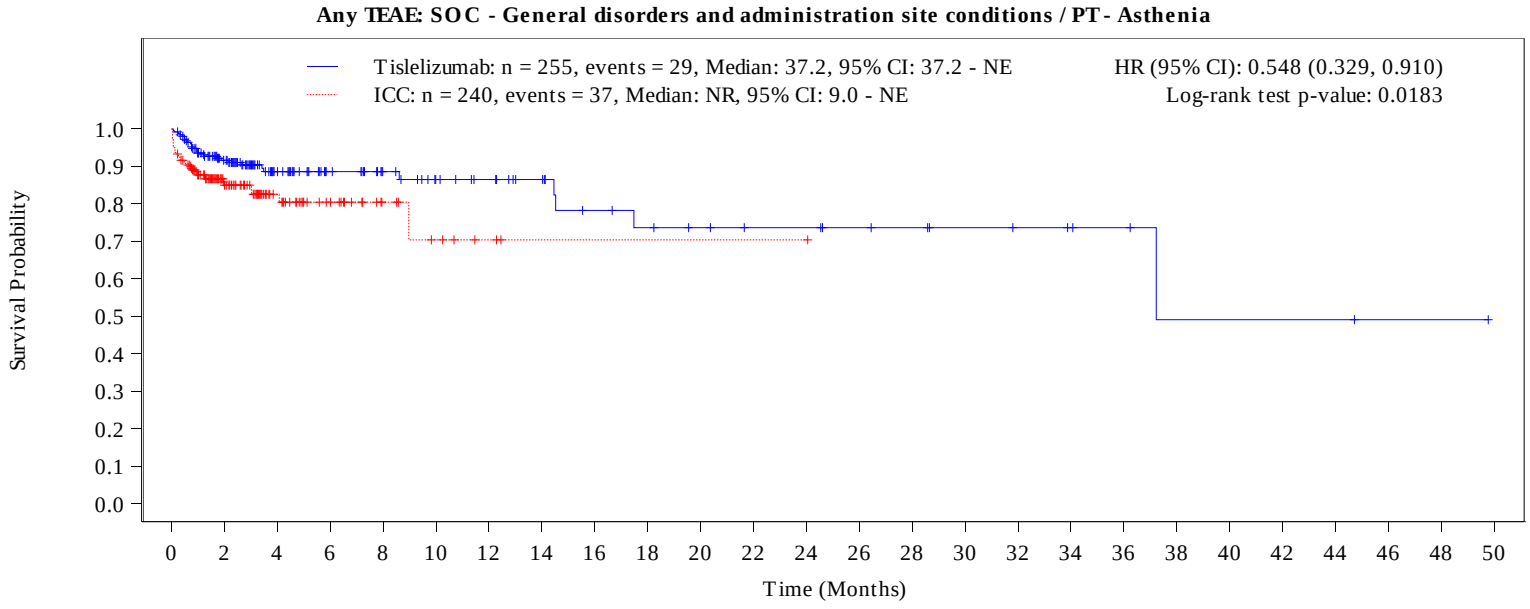


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38
Tislelizumab	255	123	65	42	27	21	19	15	11	9	8	6	6	5	4	4	3	3	2	0
ICC	240	49	11	3	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

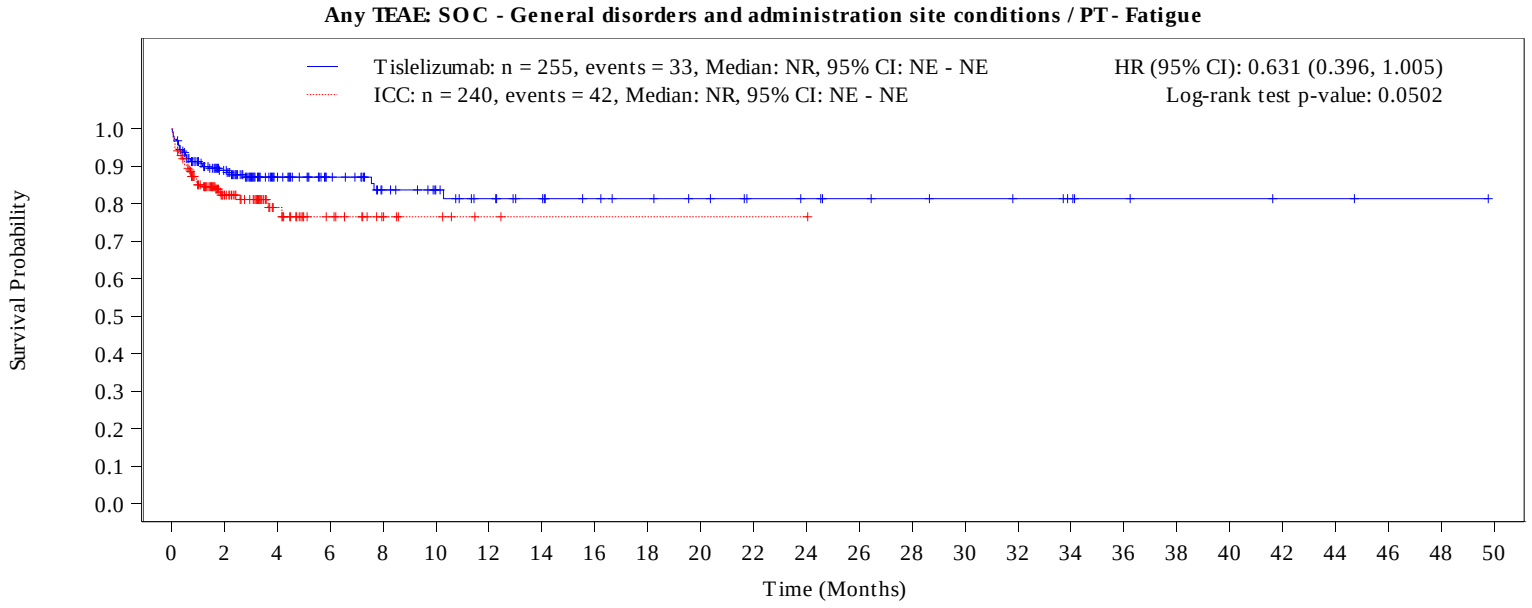


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	163	90	58	44	35	30	25	18	16	14	12	12	10	9	7	6	5	4	2	2	2	2	1	1	0
ICC	240	101	39	21	10	6	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

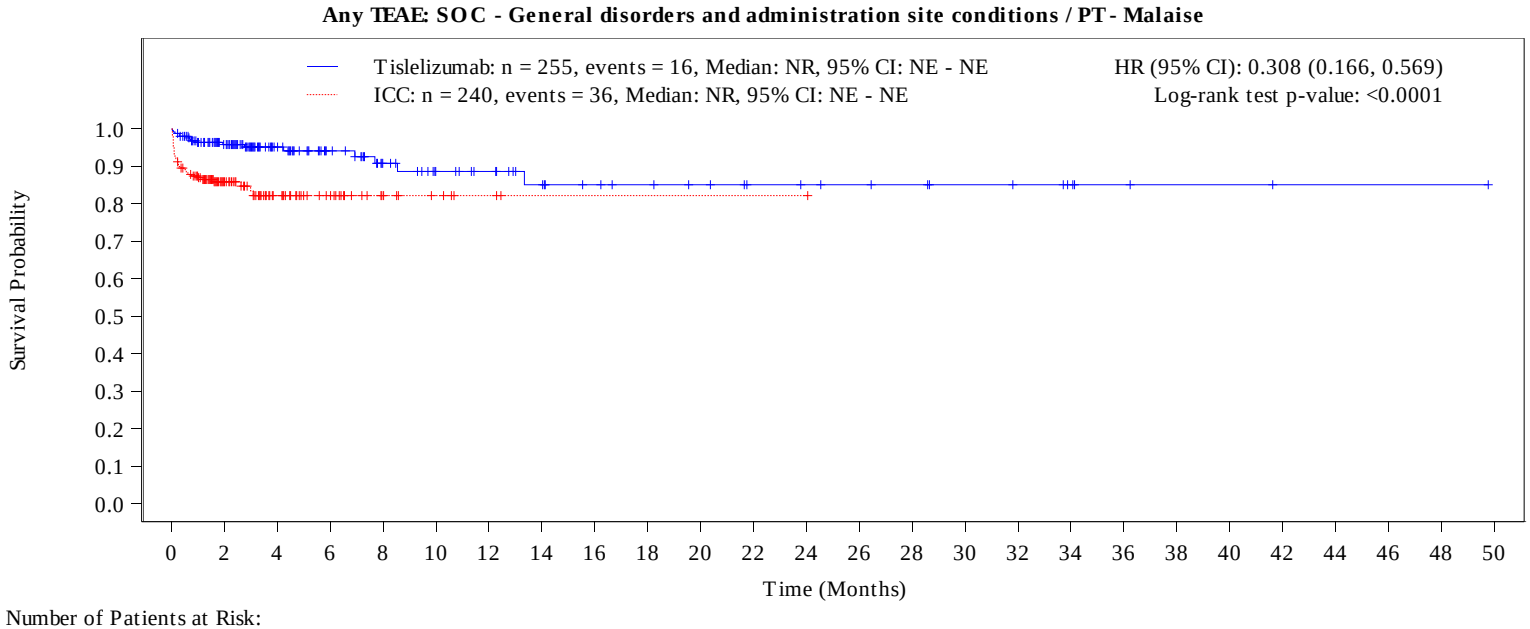


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	158	87	61	44	37	30	26	21	19	17	14	13	11	10	9	8	6	4	3	3	2	2	1	1	0
ICC	240	90	32	16	8	5	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

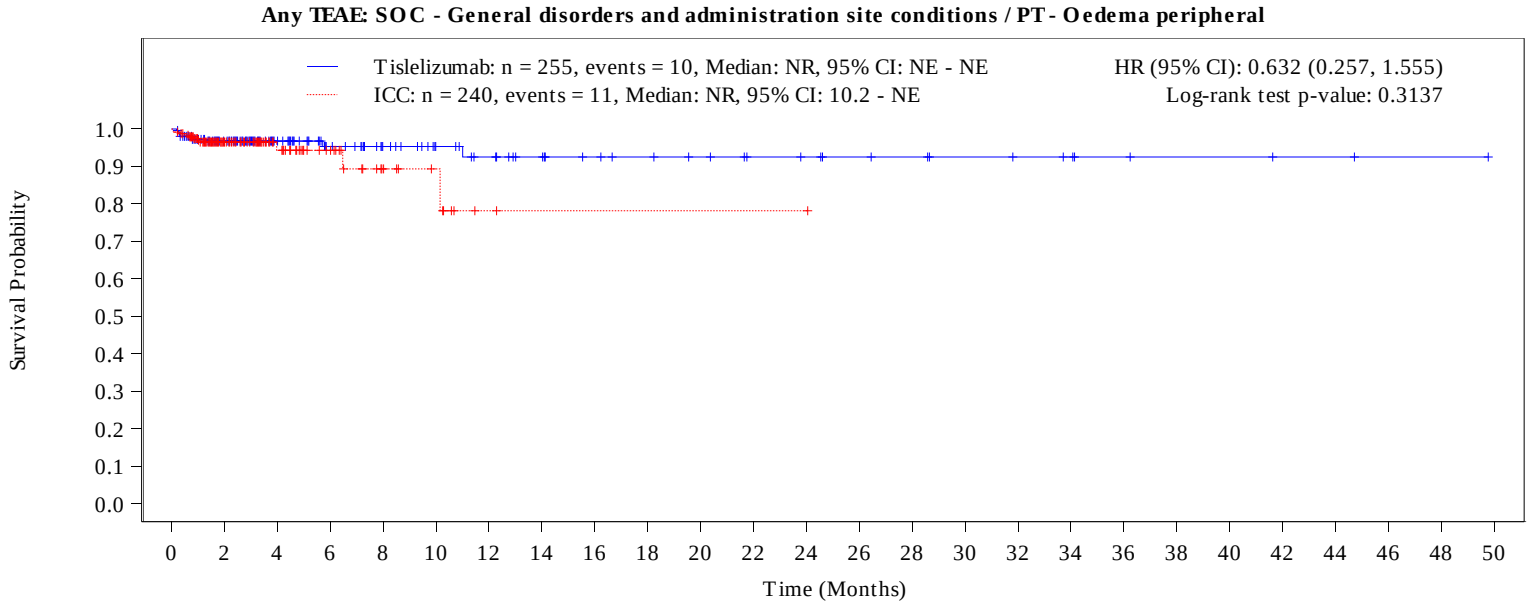


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	168	95	63	45	34	30	24	20	18	16	13	12	11	10	8	7	5	3	2	2	1	1	1	1	0
ICC	240	98	39	22	10	6	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

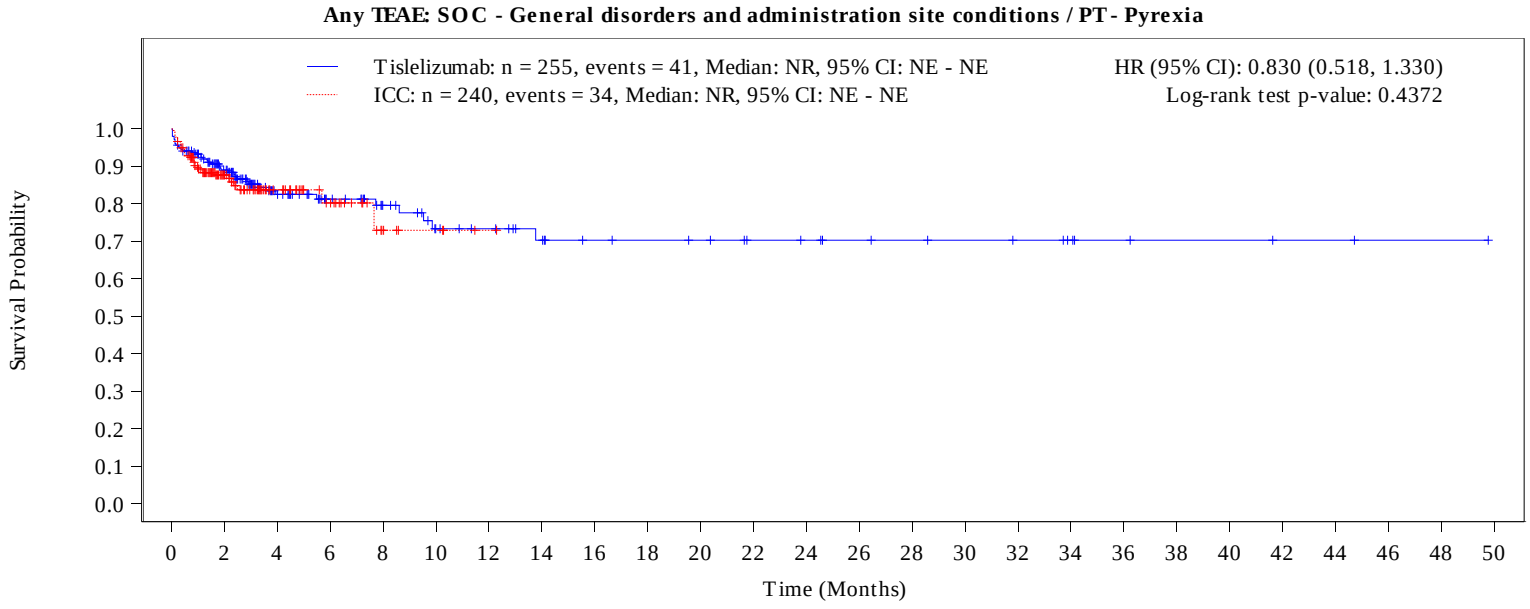


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	170	94	62	47	36	30	25	21	19	17	14	13	11	10	8	7	6	4	3	3	2	2	1	1	0
ICC	240	109	43	24	12	8	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

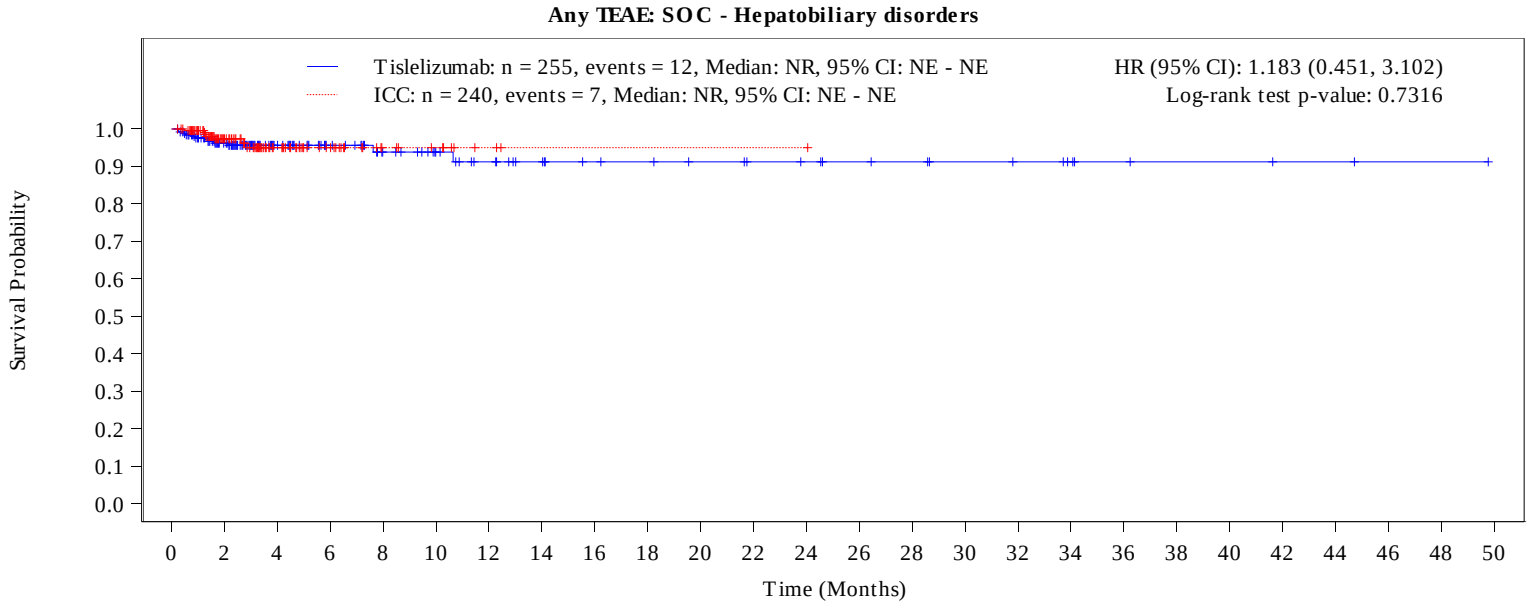


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	159	85	58	43	32	28	23	19	18	17	14	13	11	10	9	8	6	4	3	3	2	2	1	1	0
ICC	240	102	37	21	7	4	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

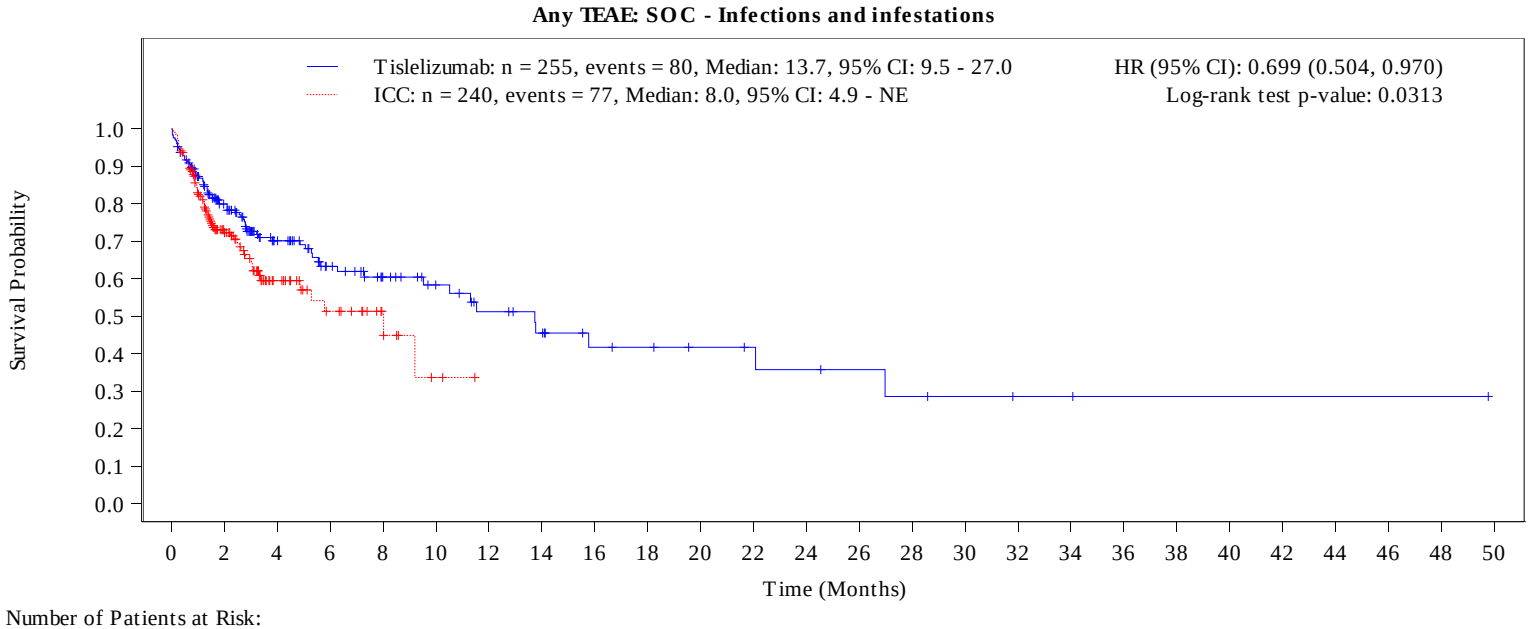


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	170	94	63	47	37	30	25	20	19	17	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	111	42	23	11	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

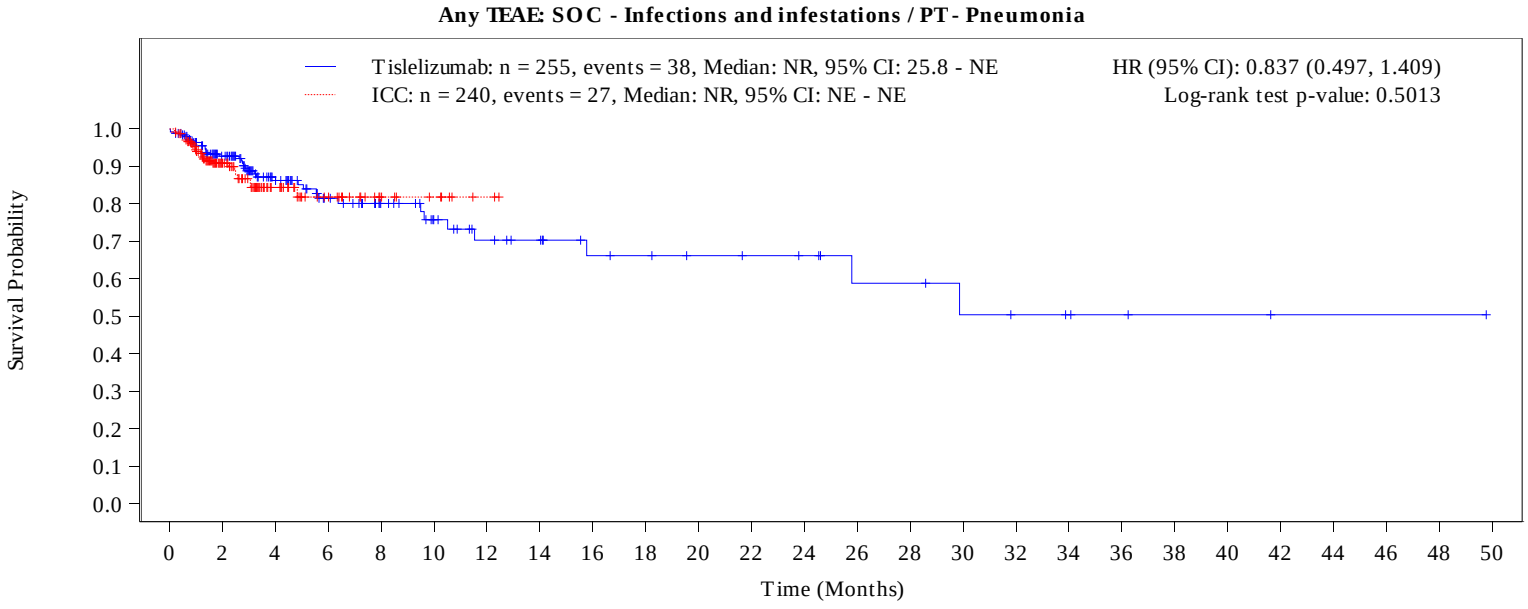


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	144	78	48	35	26	20	16	11	10	8	7	6	5	4	3	2	2	1	1	1	1	1	1	1	0
ICC	240	93	31	17	8	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	166	94	60	44	31	24	21	16	15	13	12	11	8	8	6	5	4	3	2	2	1	1	1	1	0
ICC	240	110	43	23	11	7	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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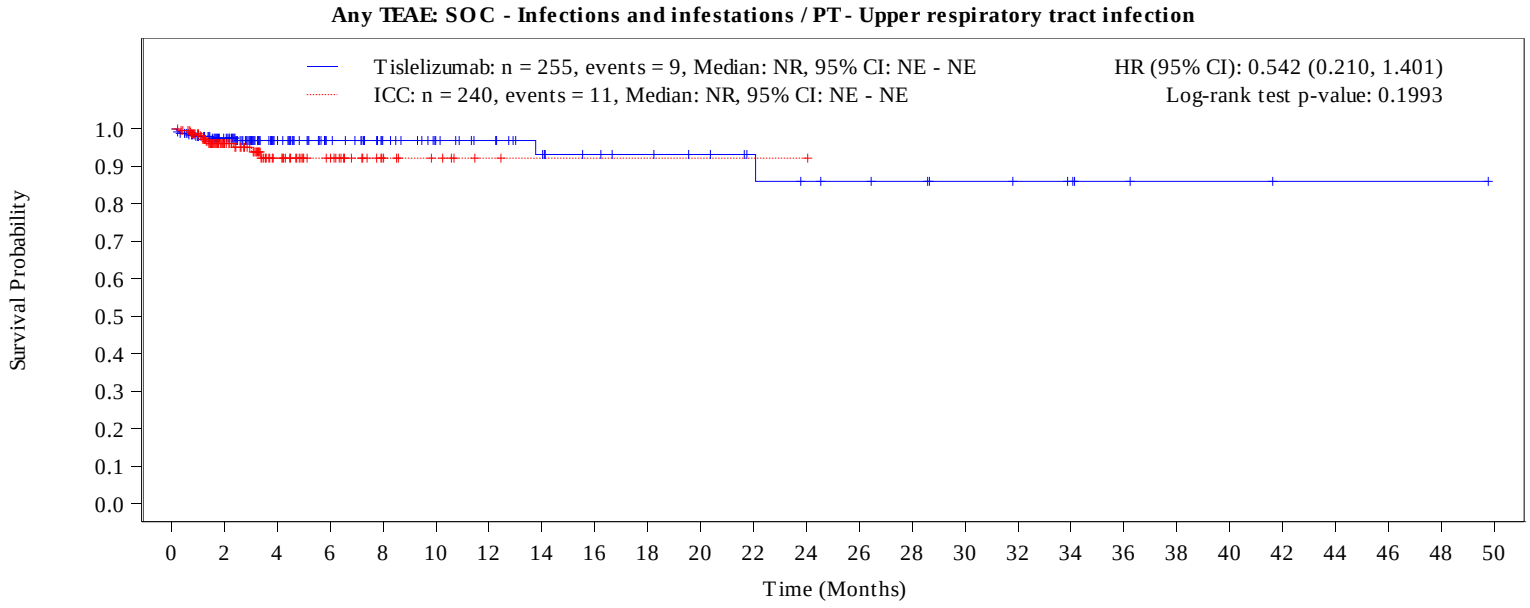
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

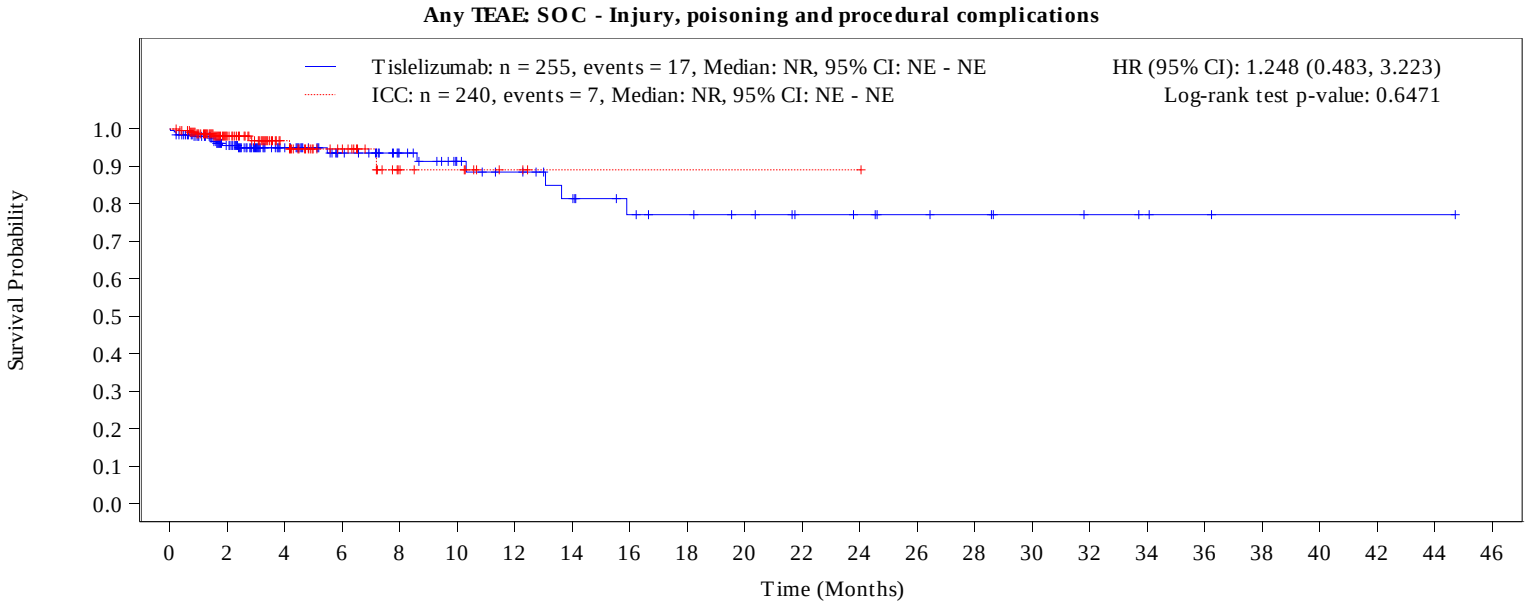


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	171	96	64	48	37	31	25	20	18	16	13	11	10	9	7	6	5	3	2	2	1	1	1	1	0
ICC	240	110	41	24	10	6	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46
Tislelizumab	255	167	93	61	45	33	28	23	18	16	14	11	10	8	7	5	4	3	2	1	1	1	1	0
ICC	240	110	44	24	10	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

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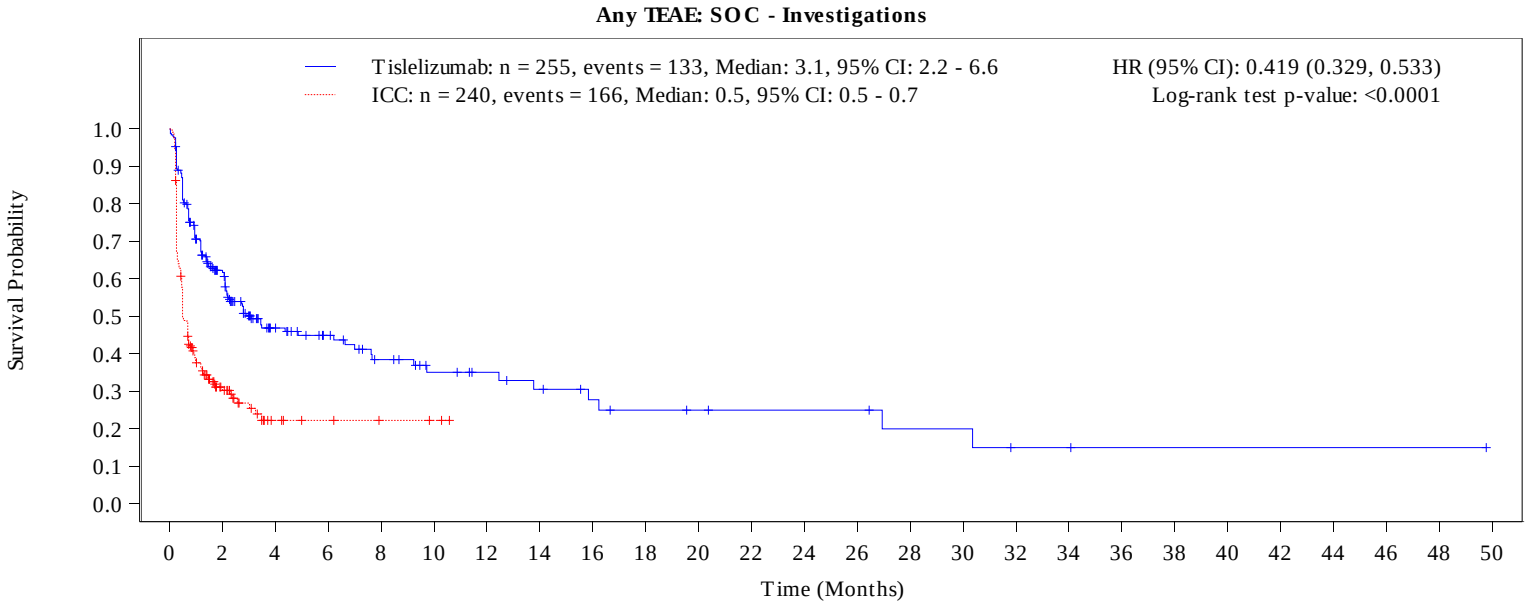
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	114	52	38	27	19	16	13	10	8	7	6	6	6	4	4	2	2	1	1	1	1	1	1	1	0
ICC	240	35	8	5	3	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

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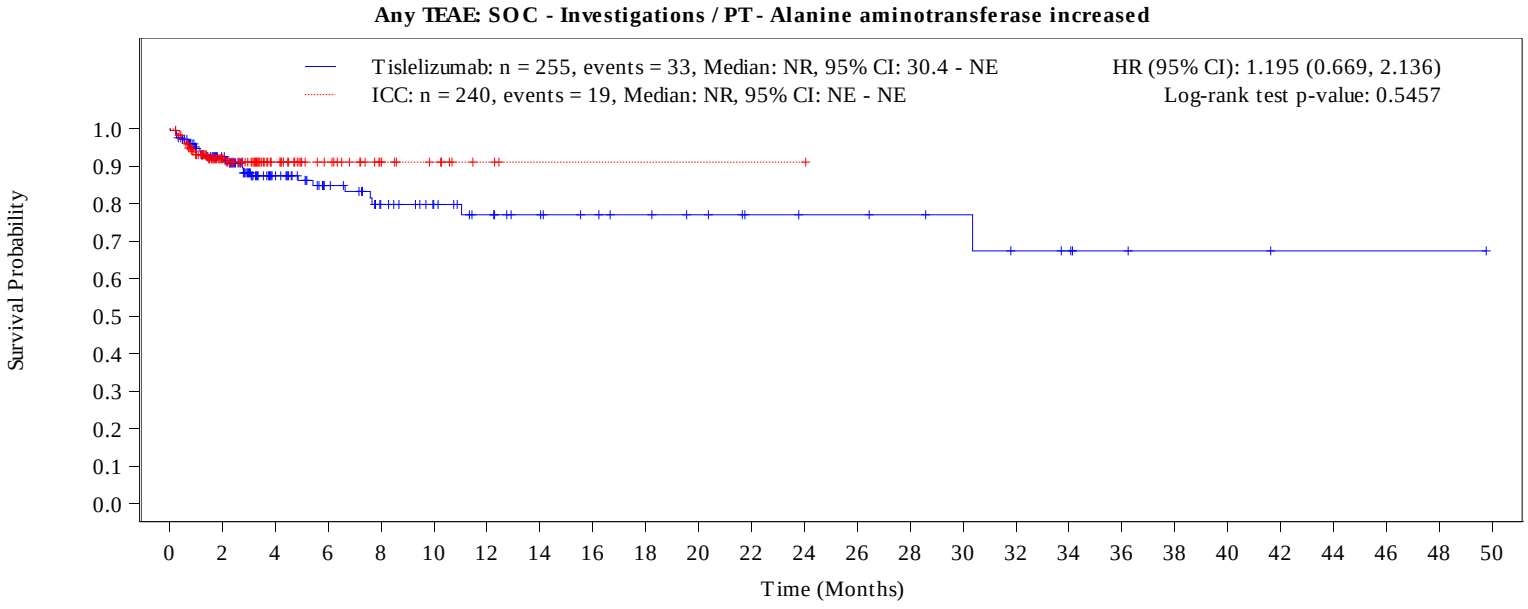
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	166	86	56	41	32	25	21	18	16	14	11	10	10	9	8	6	5	3	2	2	1	1	1	1	0
ICC	240	109	42	23	12	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

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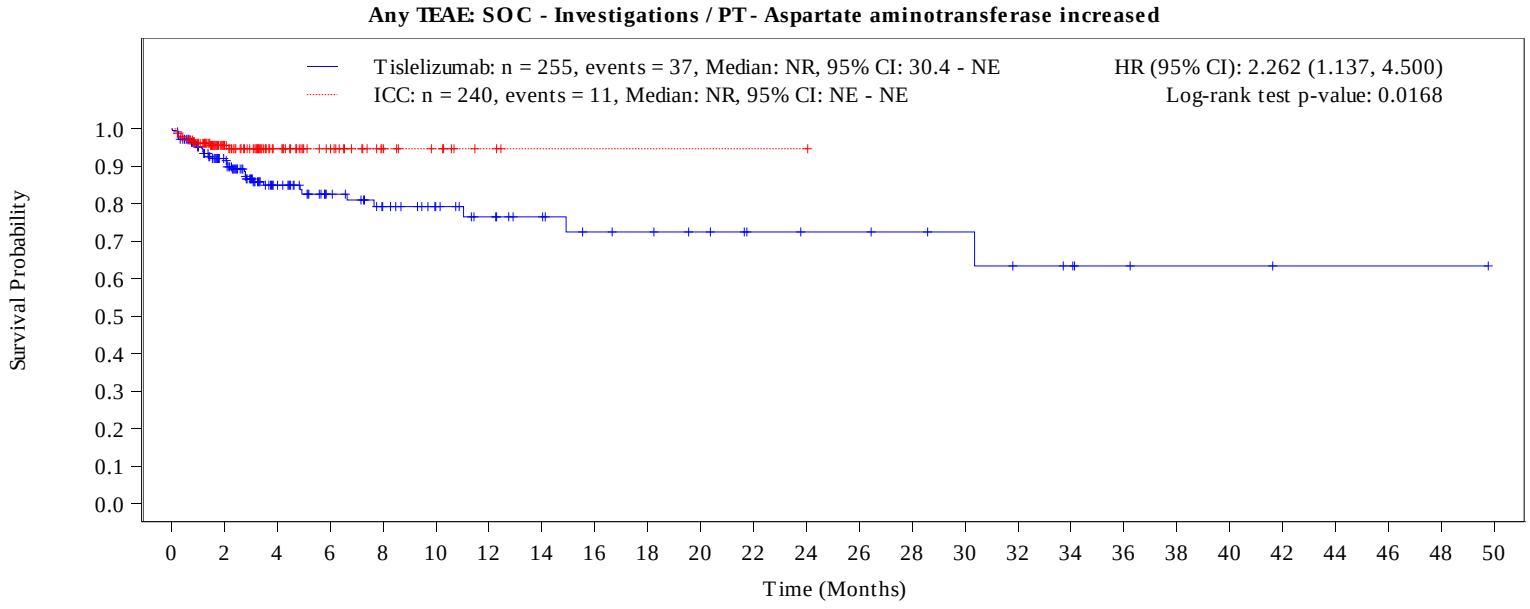
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	166	86	55	42	32	25	21	17	16	14	11	10	10	9	8	6	5	3	2	2	1	1	1	1	0
ICC	240	112	44	25	12	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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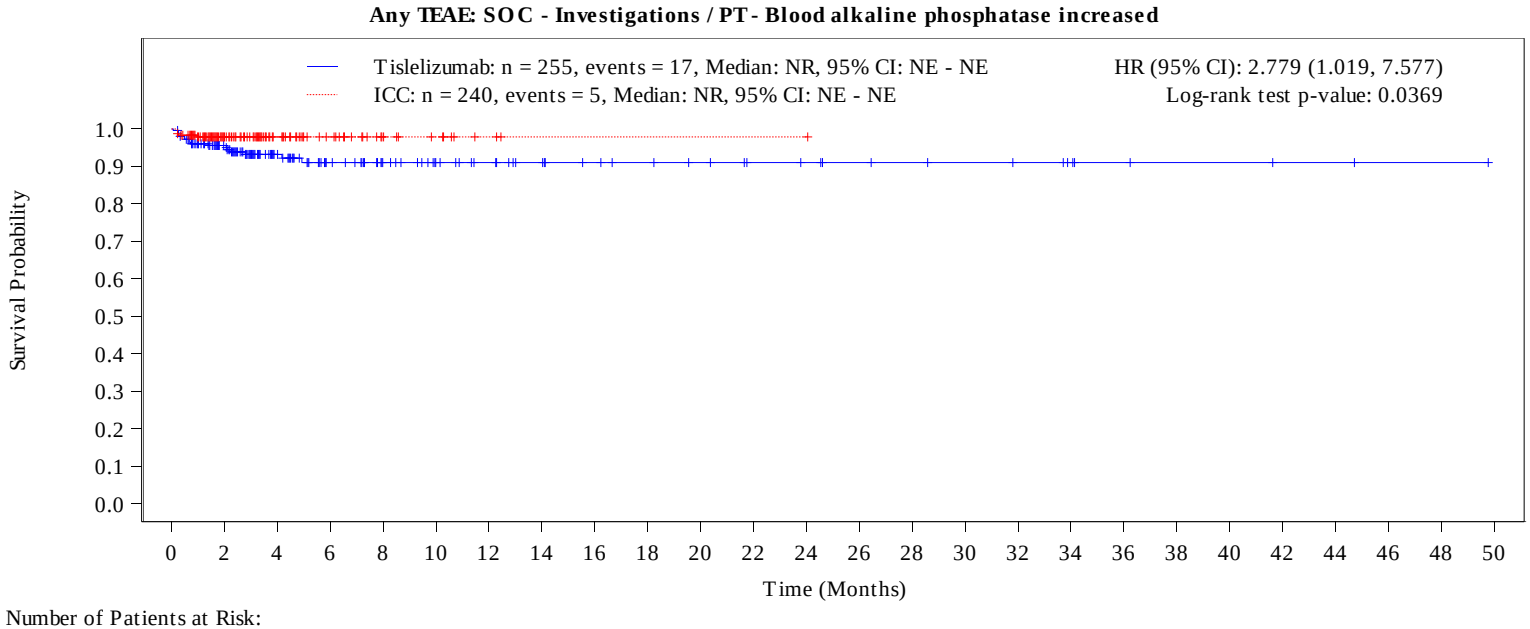
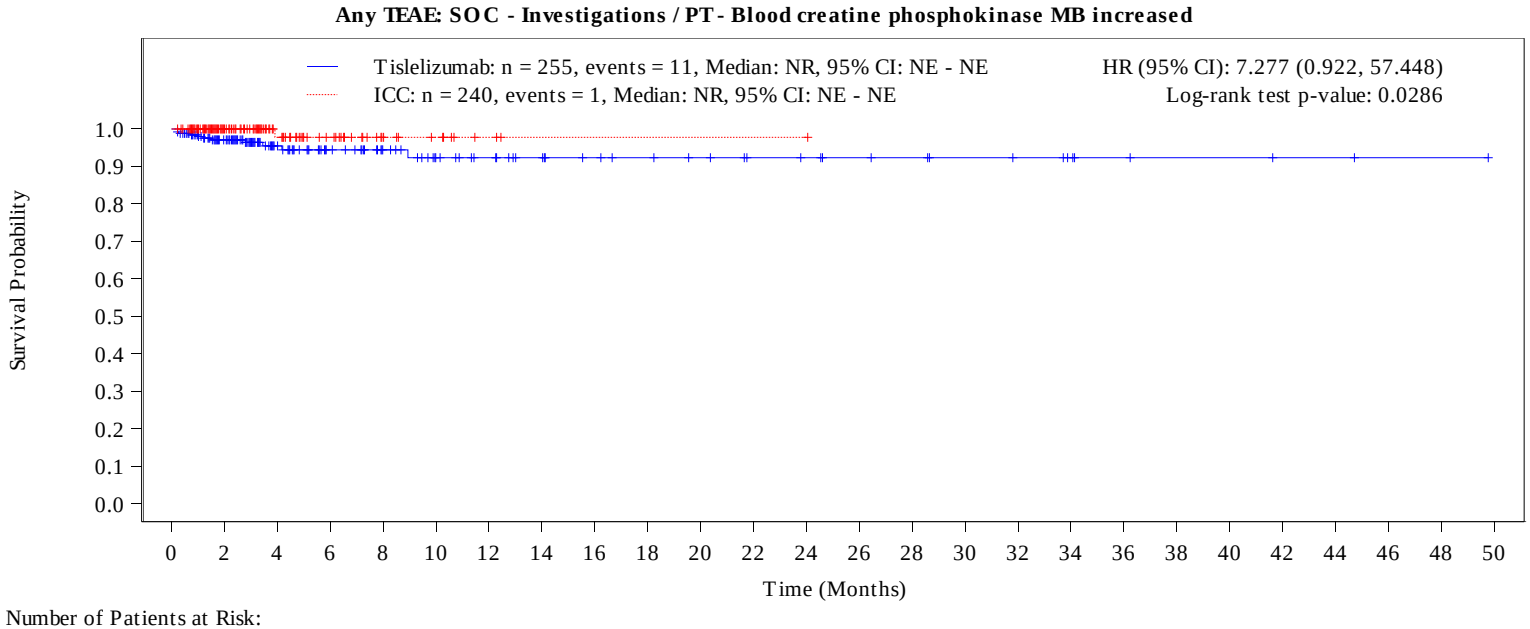


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	169	95	62	47	36	30	25	21	19	17	14	13	11	10	9	8	6	4	3	3	2	2	1	1	0
ICC	240	110	43	24	12	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	170	92	63	48	37	32	27	22	20	18	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	113	44	25	12	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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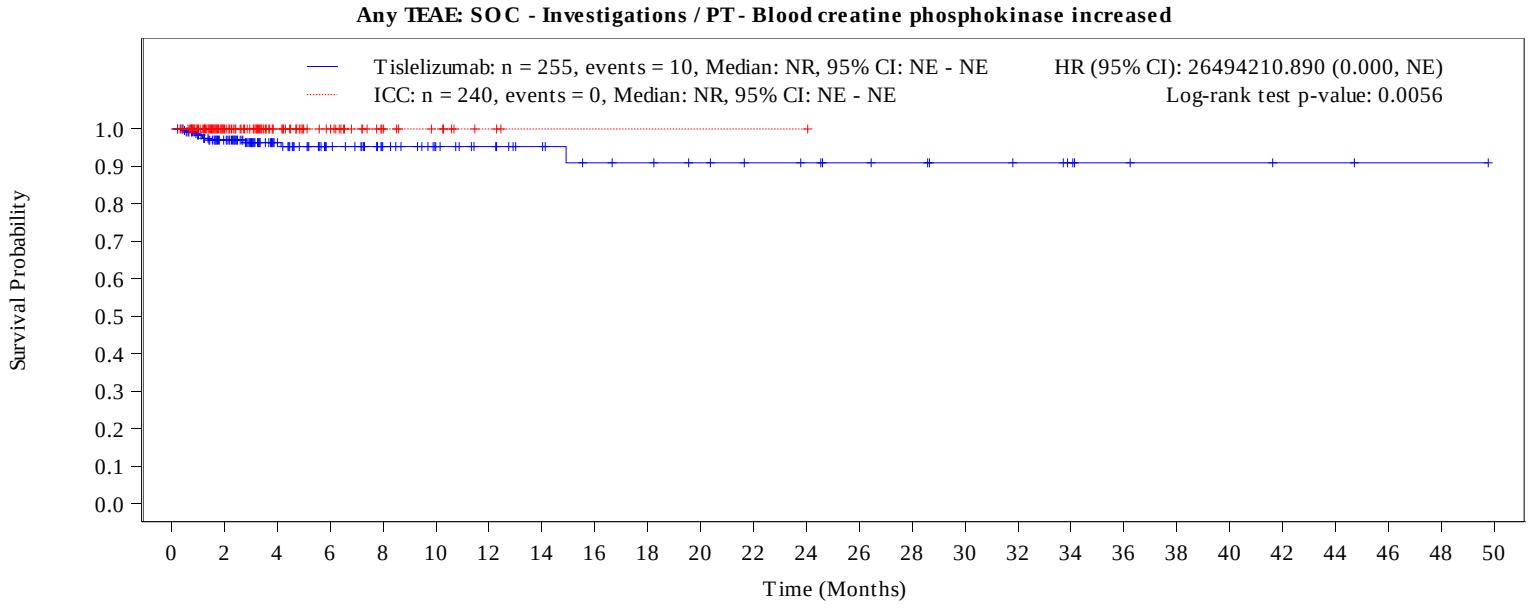
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

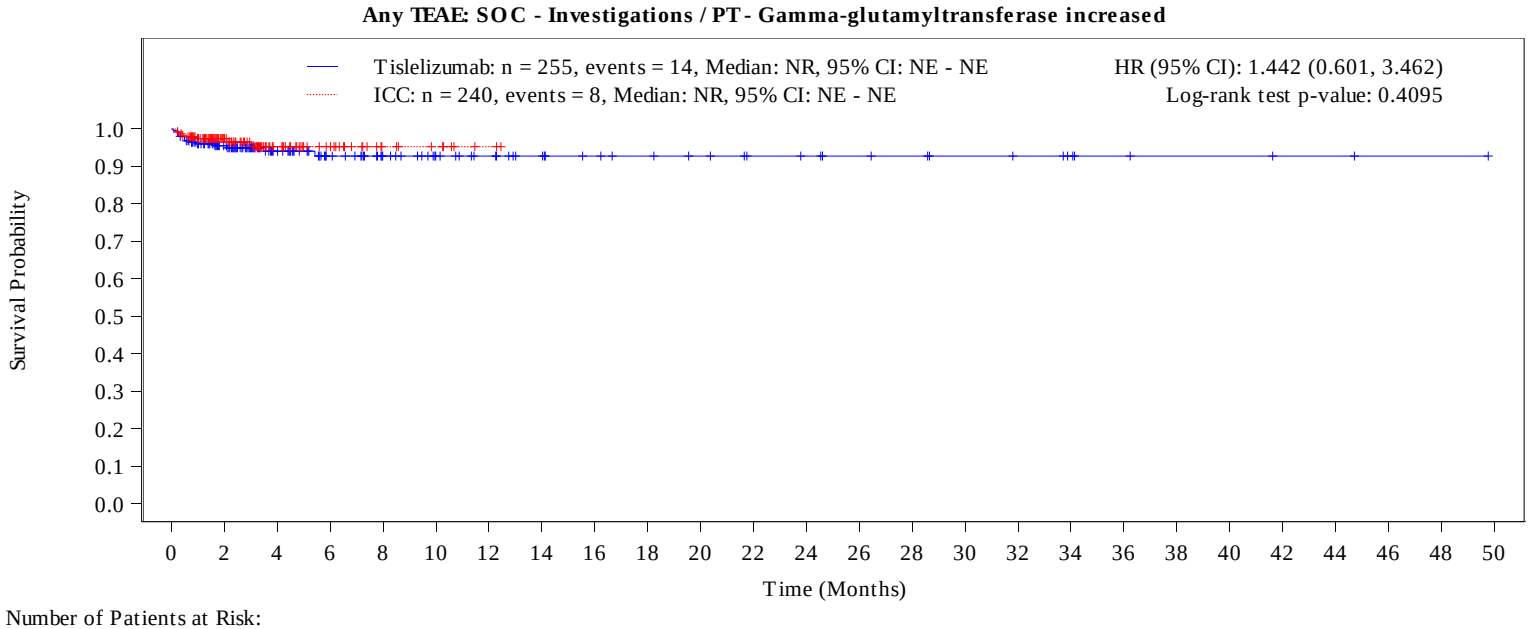


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	170	92	62	47	36	30	25	20	19	17	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	113	45	26	12	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	168	96	64	49	38	32	27	22	20	18	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	111	42	23	10	7	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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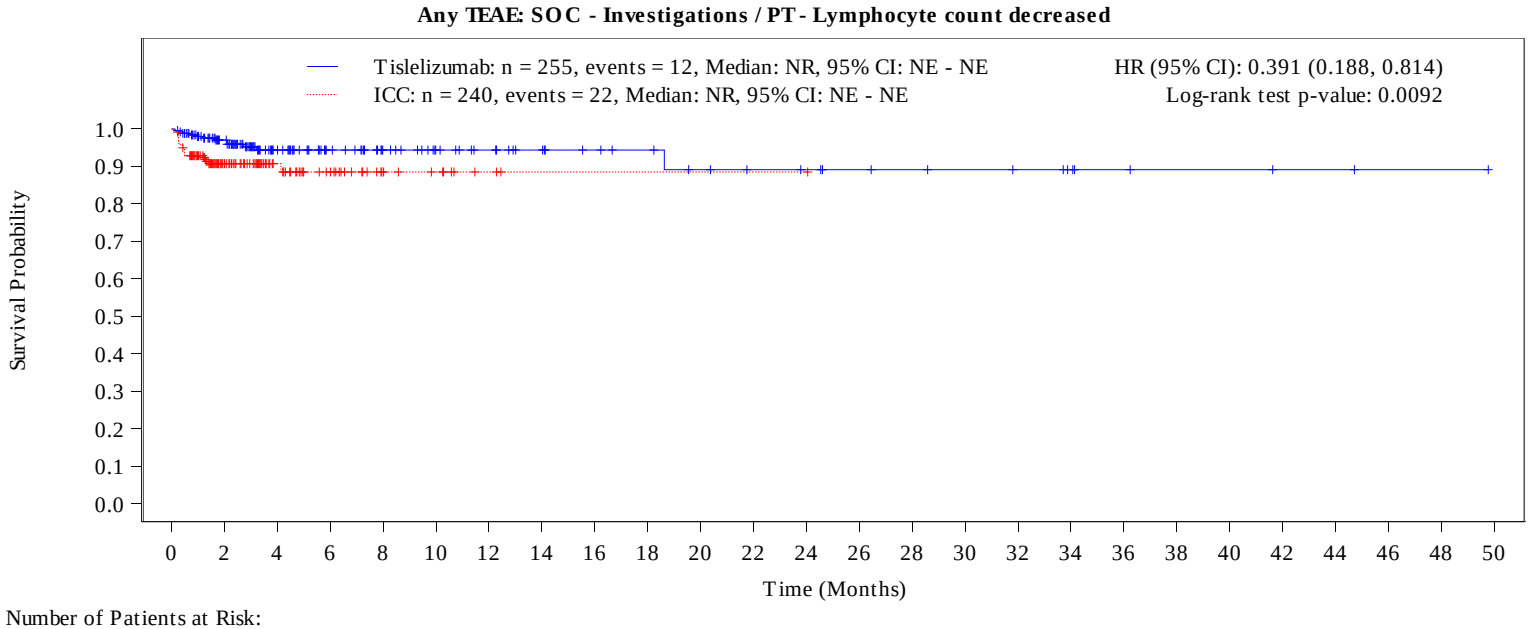
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	171	96	64	48	37	31	26	21	19	16	14	13	11	10	9	8	6	4	3	3	2	2	1	1	0
ICC	240	104	41	24	11	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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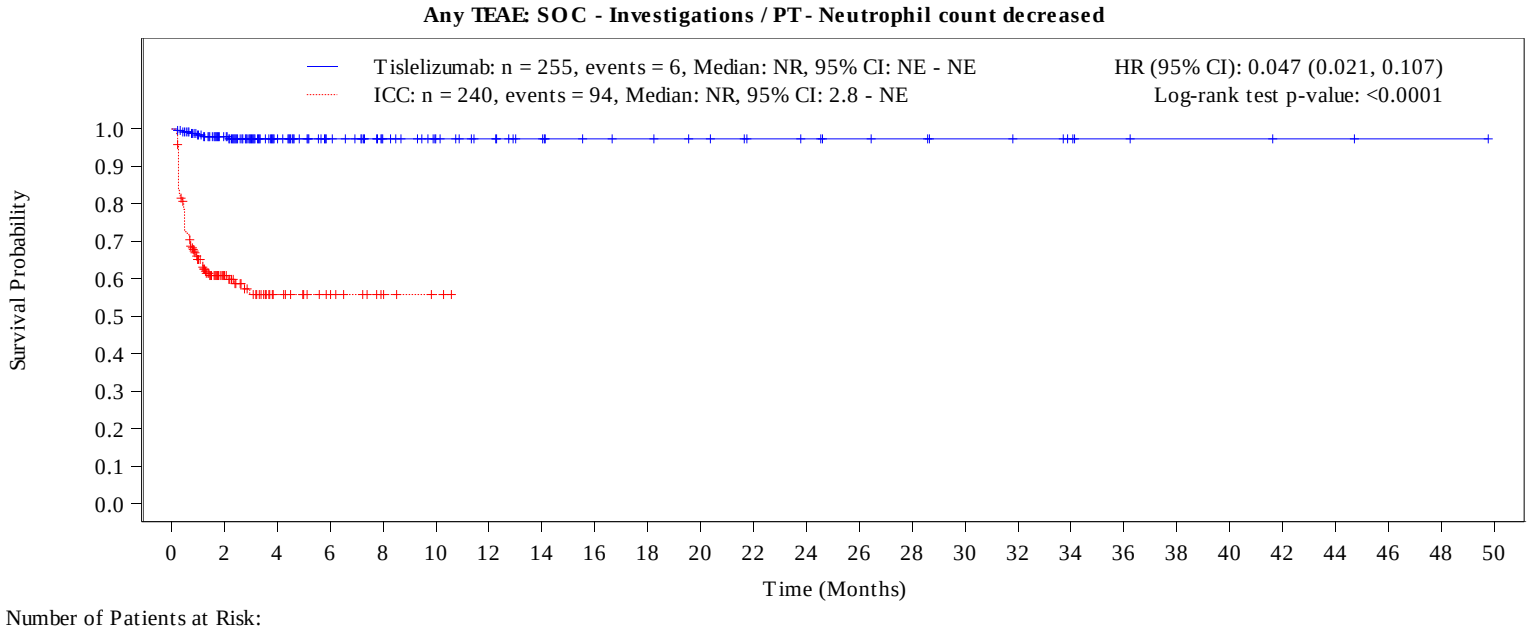
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	170	92	62	48	37	31	26	21	20	18	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	62	20	12	5	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
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unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

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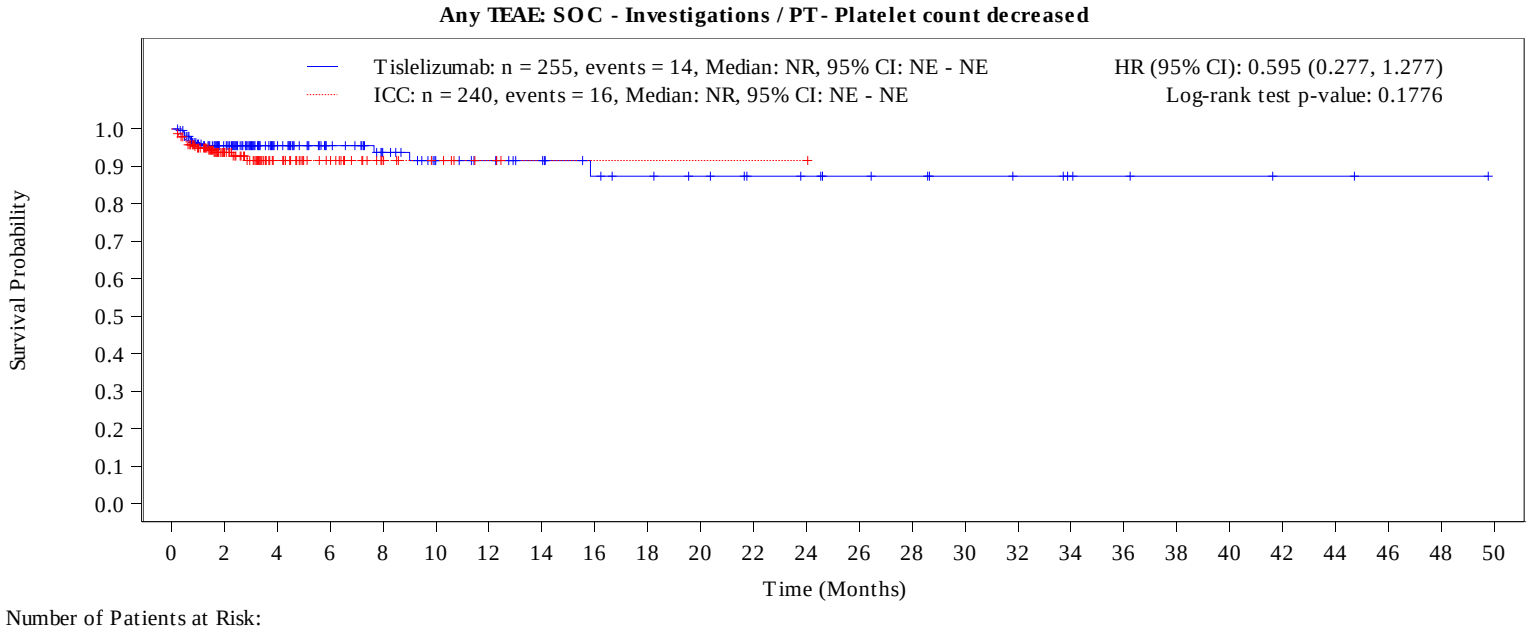

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	169	94	63	47	35	31	26	21	19	17	14	13	11	10	8	7	5	4	3	3	2	2	1	1	0
ICC	240	109	42	24	11	7	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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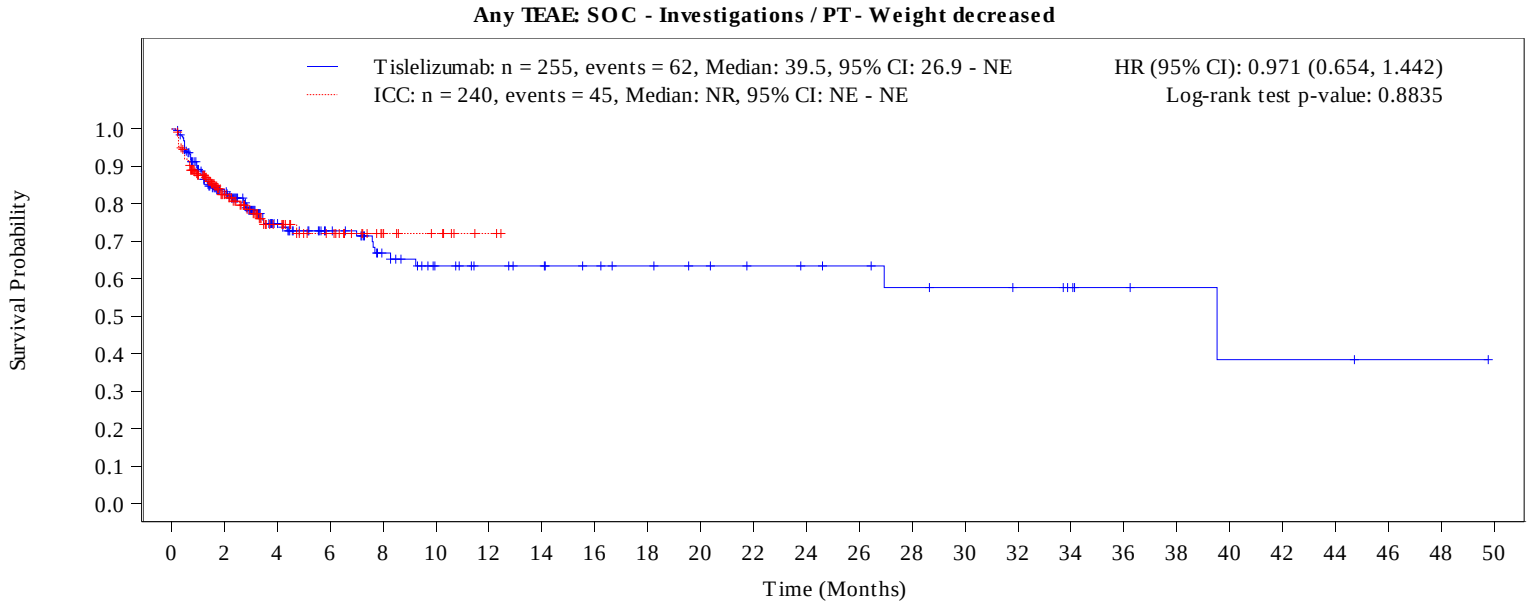
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	151	78	56	41	29	25	23	20	18	16	14	13	12	10	9	8	6	4	3	2	2	2	1	1	0
ICC	240	101	39	23	11	7	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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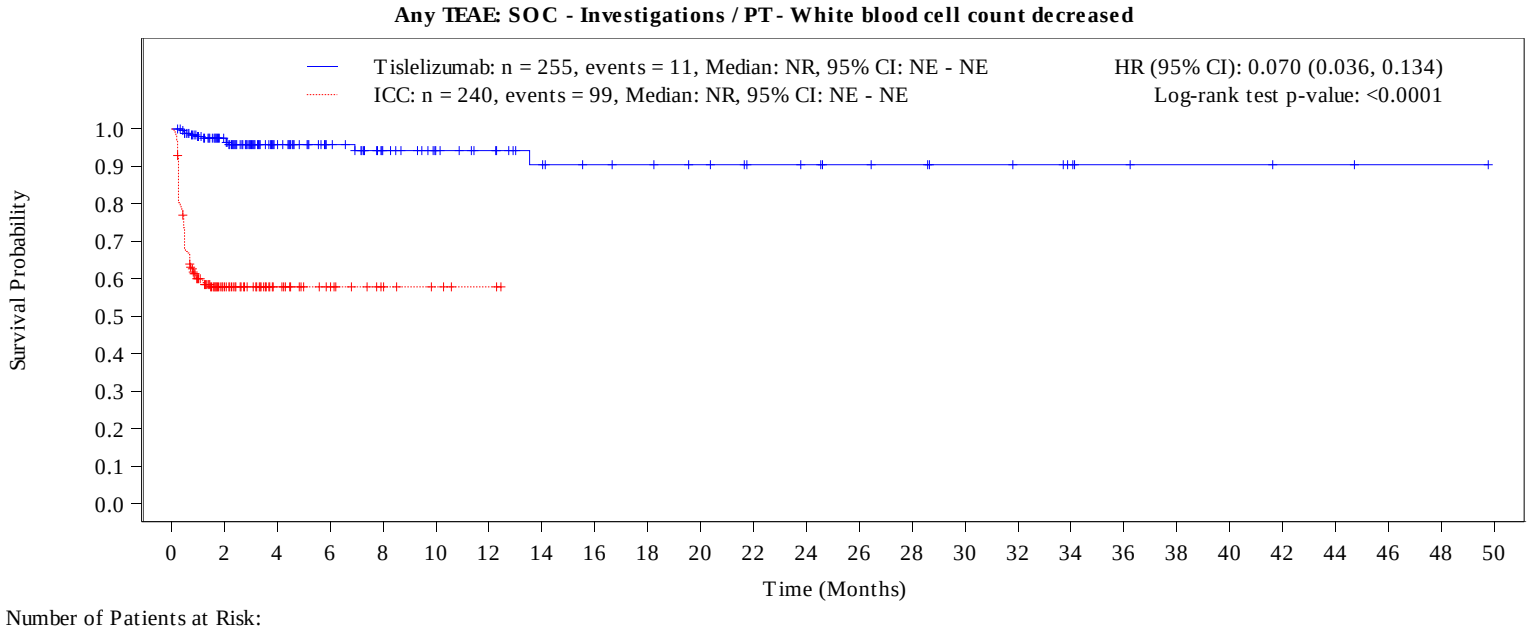
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	171	92	62	46	35	30	24	21	20	18	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	63	24	14	7	4	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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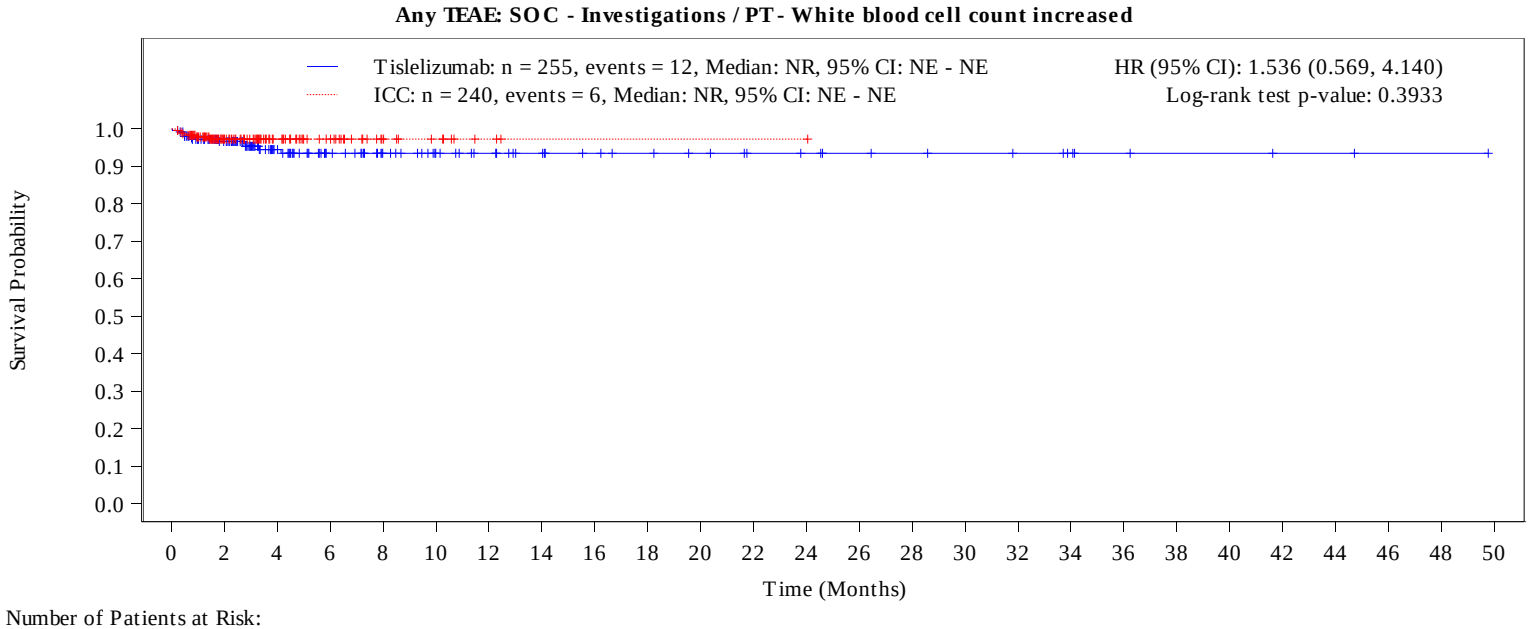
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	174	96	64	48	37	31	26	21	19	17	14	13	11	10	9	8	6	4	3	3	2	2	1	1	0
ICC	240	111	45	26	12	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
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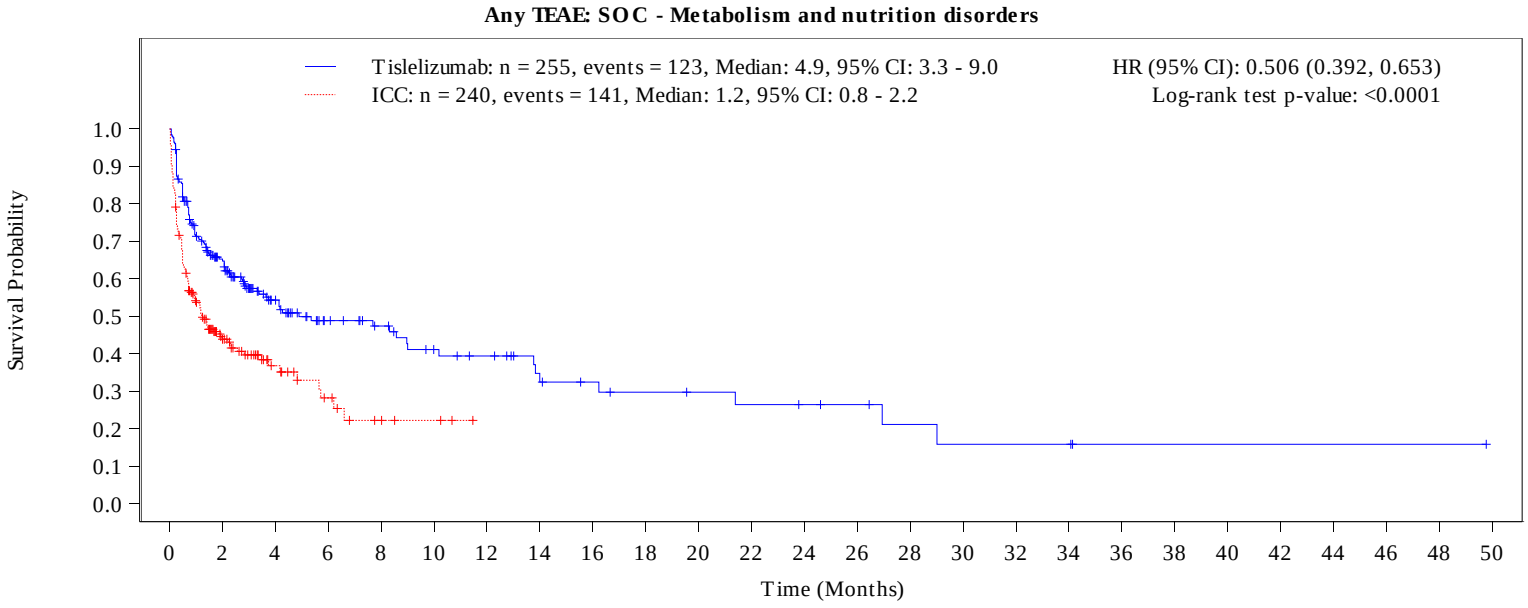

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	125	65	41	32	24	21	14	12	10	9	8	7	6	4	3	3	3	1	1	1	1	1	1	1	0
ICC	240	62	22	11	5	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
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unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

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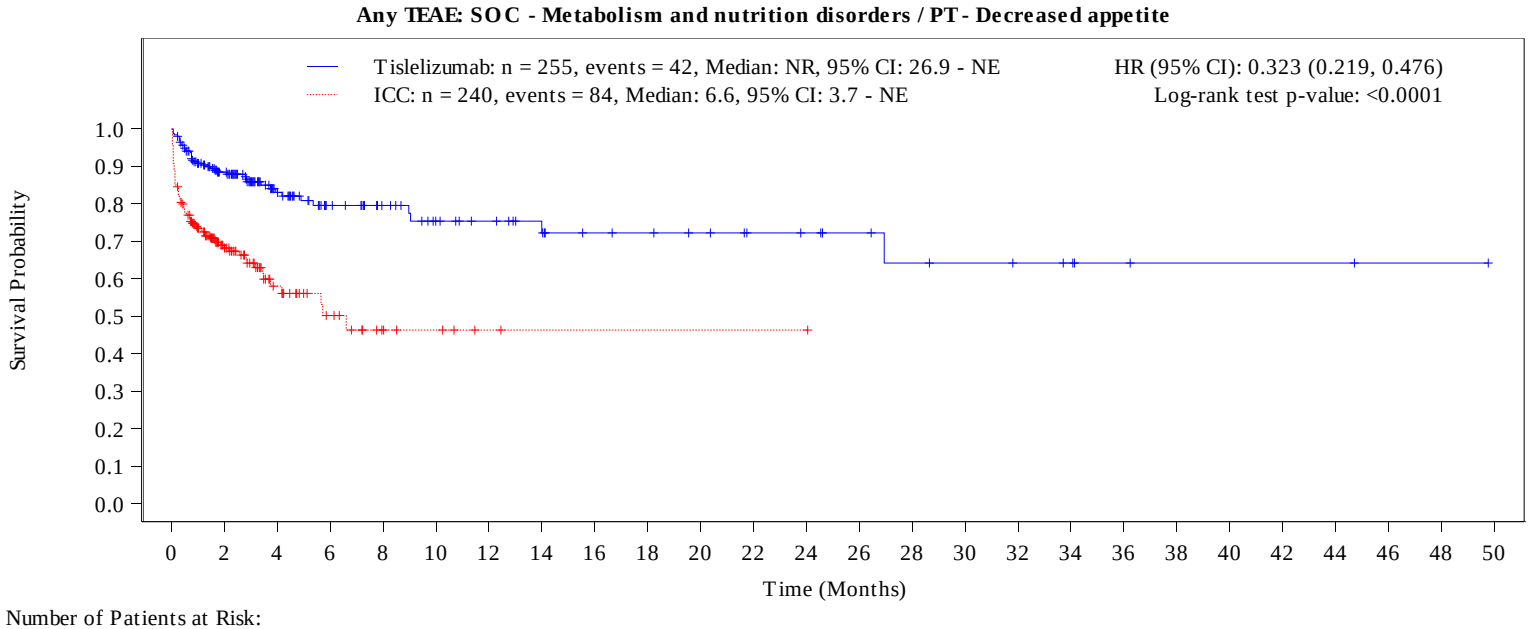
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	157	84	54	41	32	28	23	19	18	16	13	12	10	8	7	6	5	3	2	2	2	2	1	1	0
ICC	240	87	30	15	7	5	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
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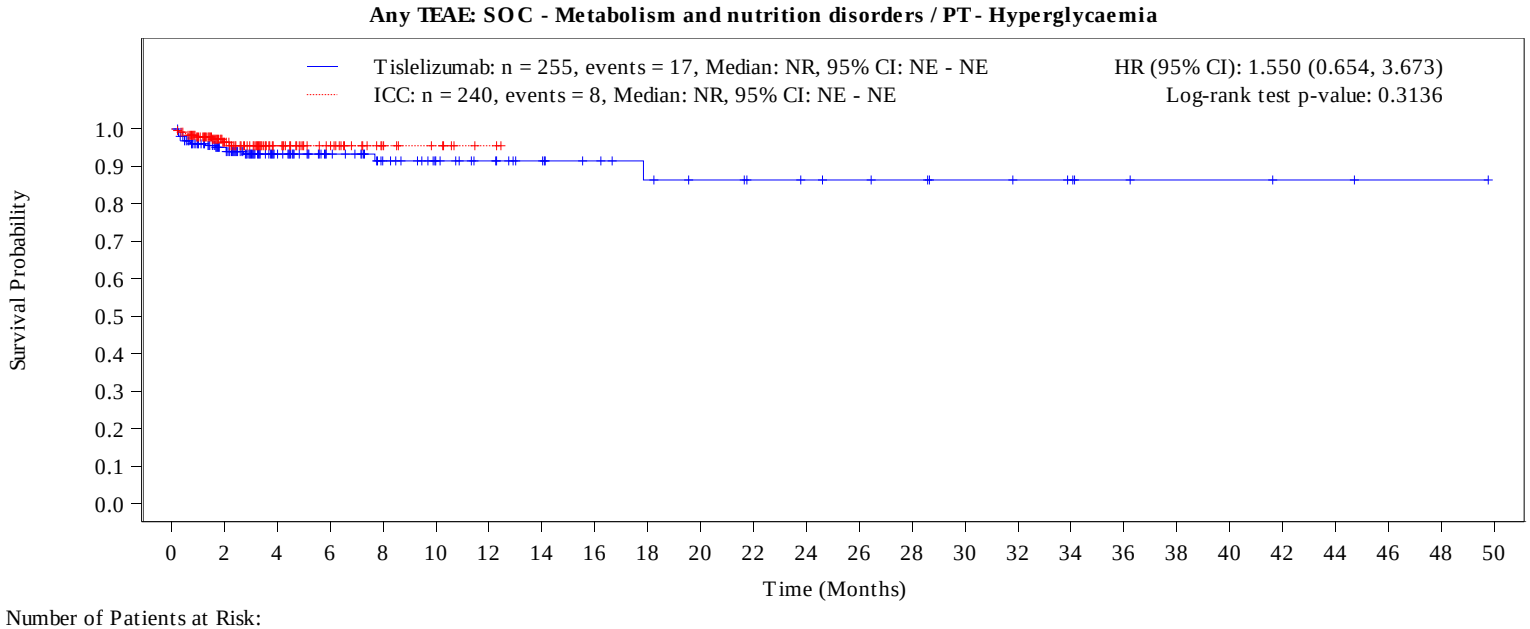
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	169	91	60	46	36	30	25	20	17	15	13	12	11	10	8	7	6	4	3	3	2	2	1	1	0
ICC	240	109	44	25	11	7	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
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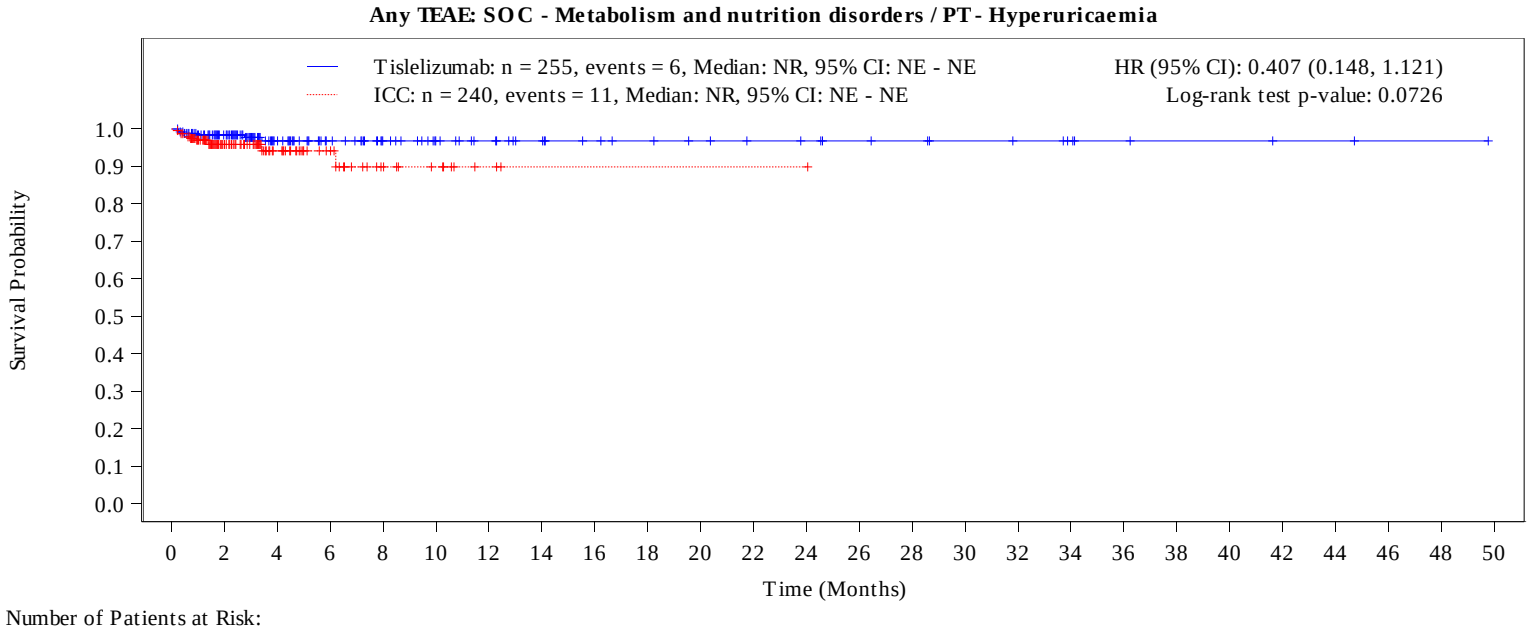

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	175	95	64	48	37	31	26	21	19	17	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	108	42	24	12	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
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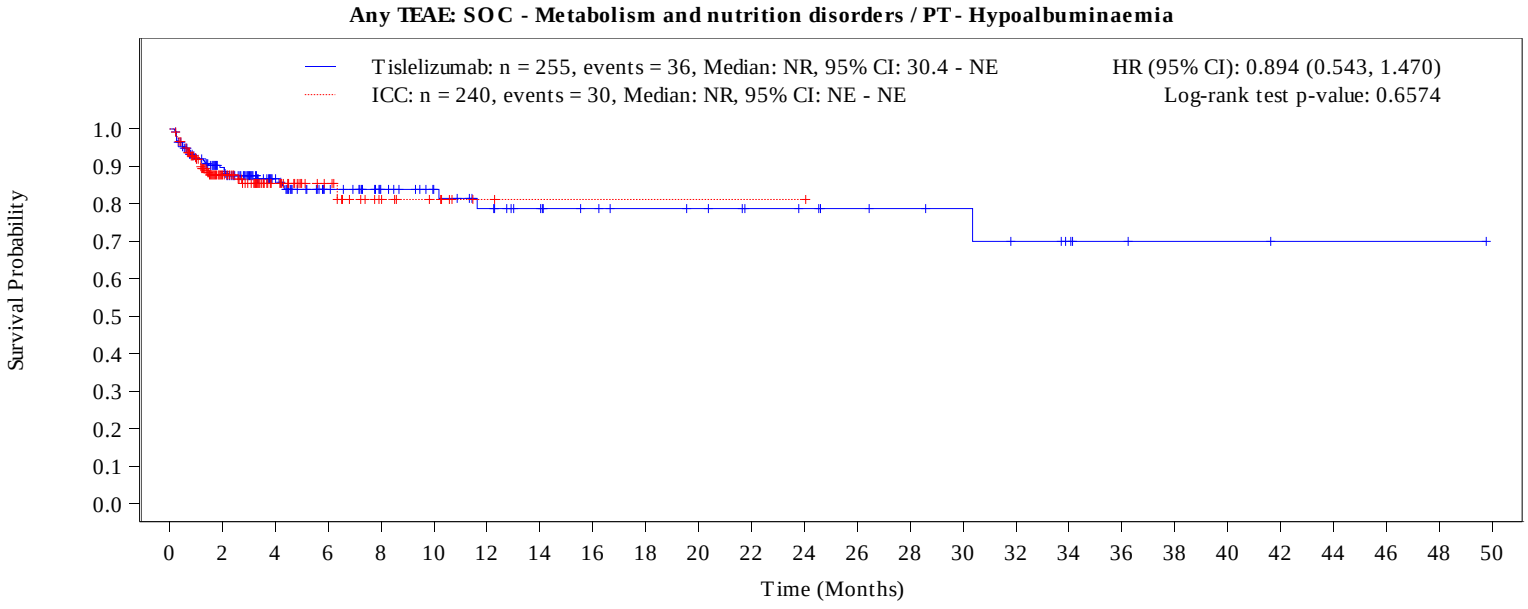

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	165	93	61	45	35	29	24	20	18	17	14	13	11	10	9	7	5	3	2	2	1	1	1	1	0
ICC	240	102	41	22	11	7	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
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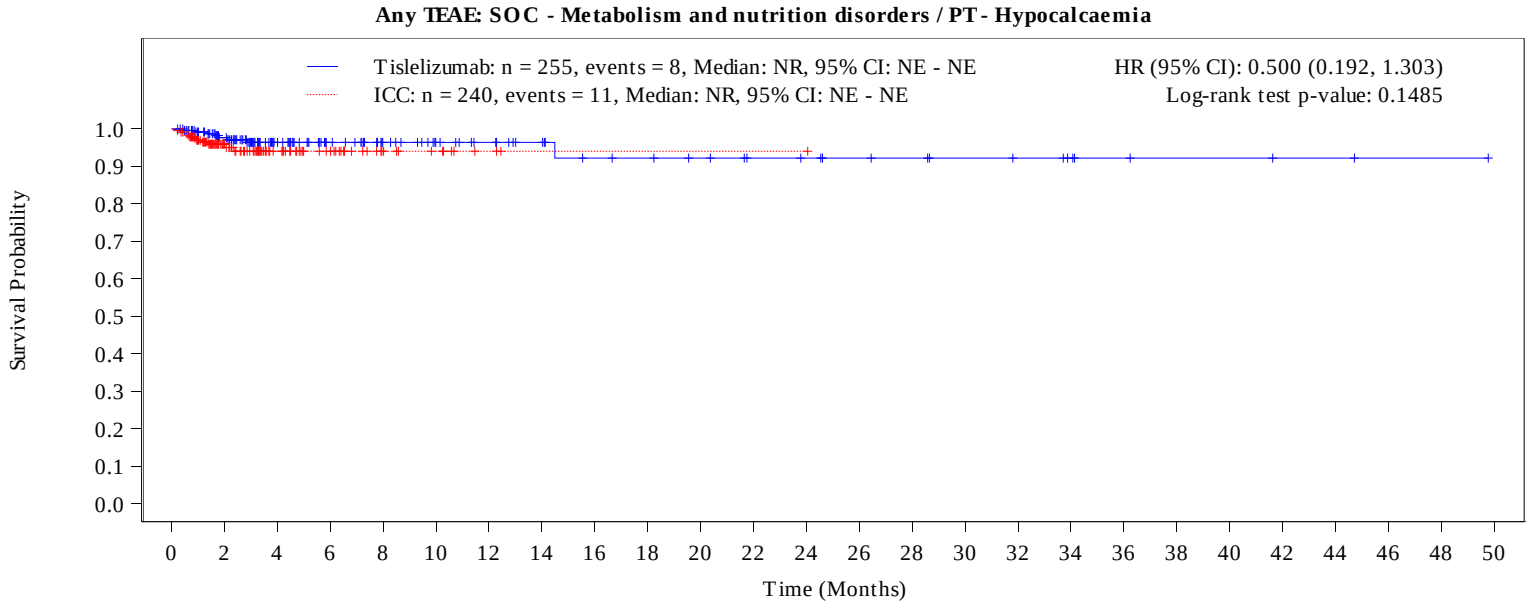
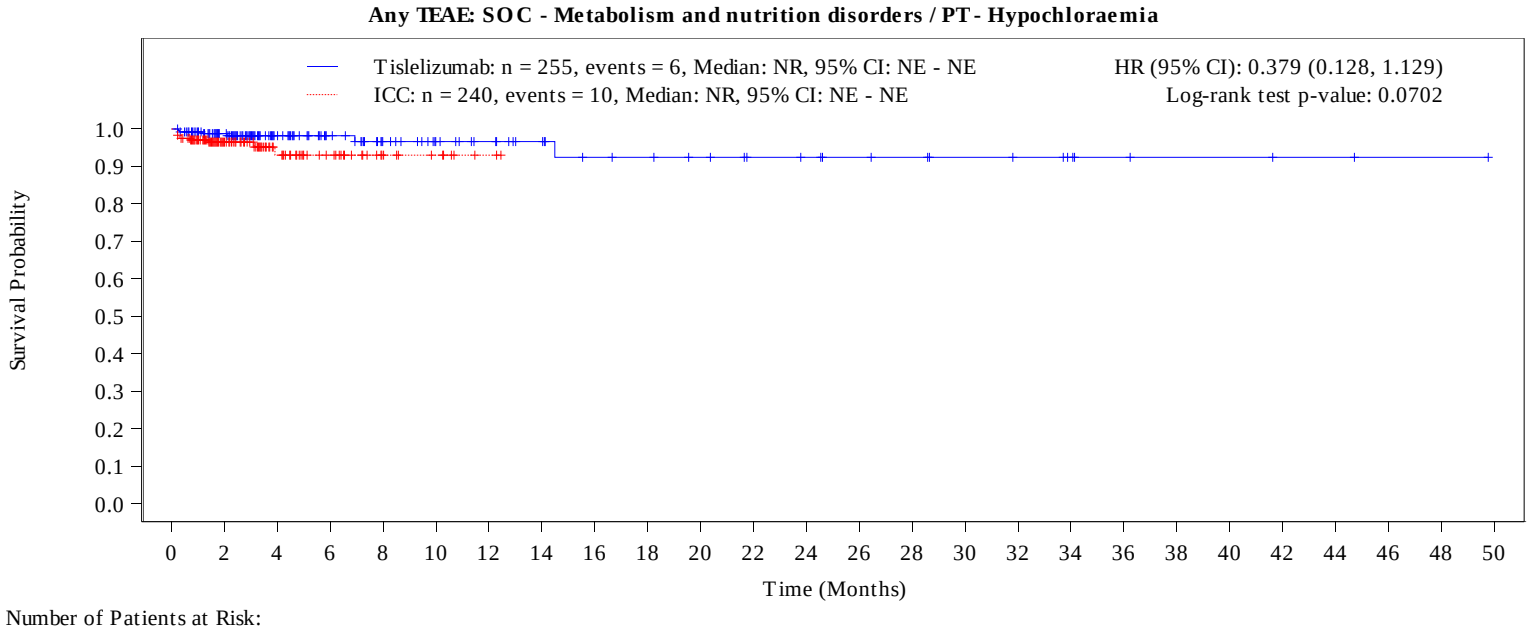


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	172	97	65	49	38	32	27	21	20	18	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	109	43	25	12	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	174	97	65	48	37	31	26	21	20	18	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	110	43	24	11	7	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
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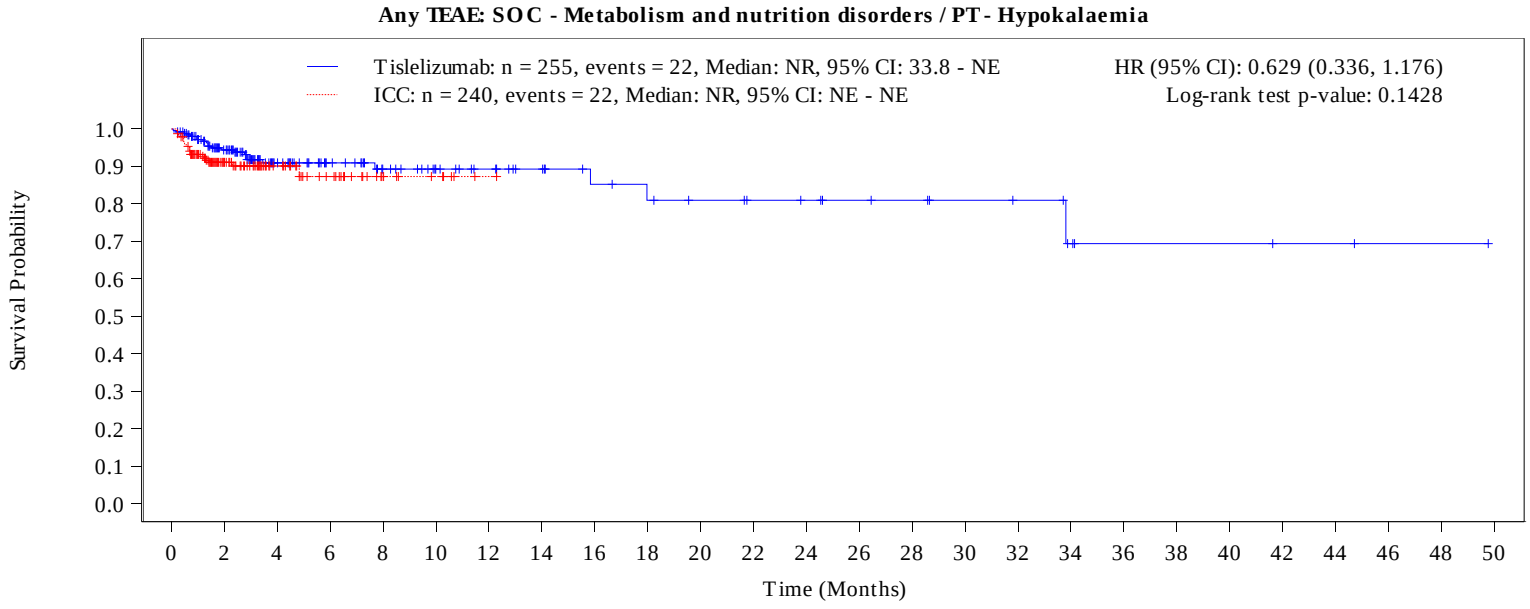
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	169	96	65	49	38	32	27	21	19	17	15	14	12	11	9	8	5	3	3	3	2	2	1	1	0
ICC	240	106	41	23	10	6	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
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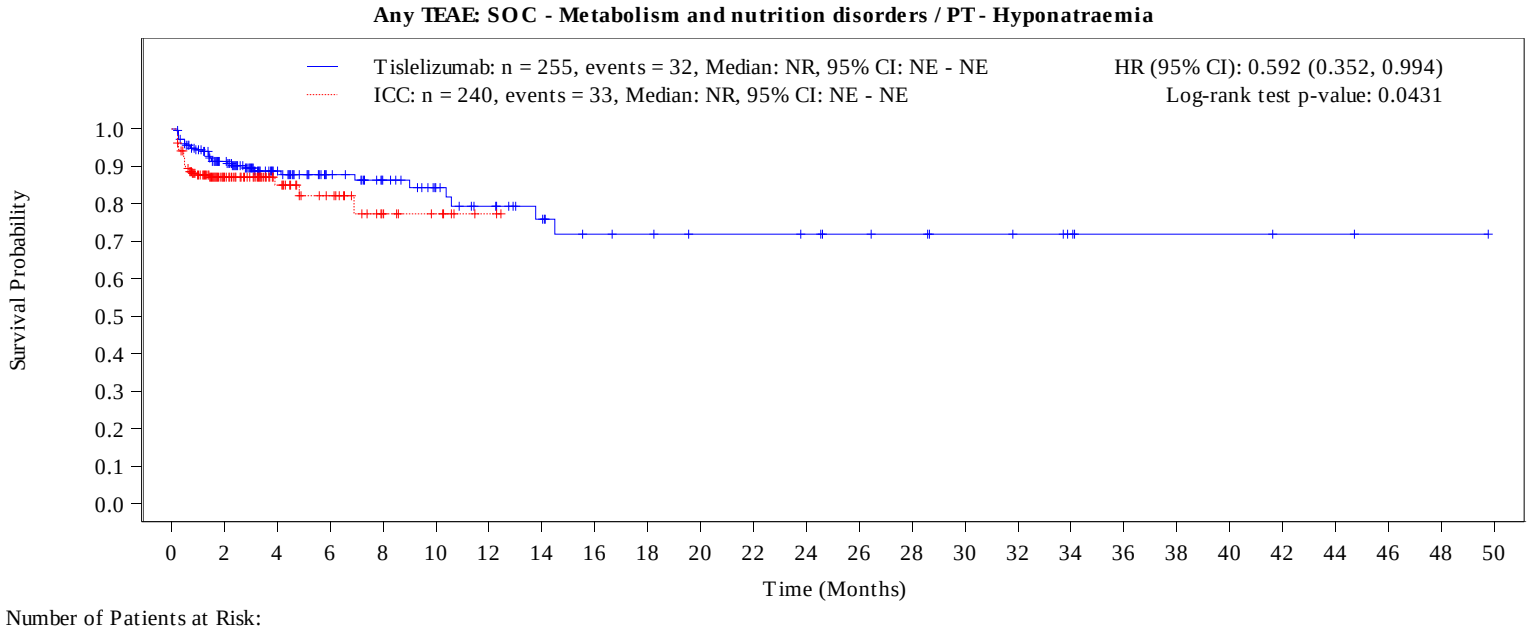
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	166	93	62	47	35	28	22	17	16	14	14	13	11	10	8	7	5	3	3	3	2	2	1	1	0
ICC	240	103	40	23	11	7	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
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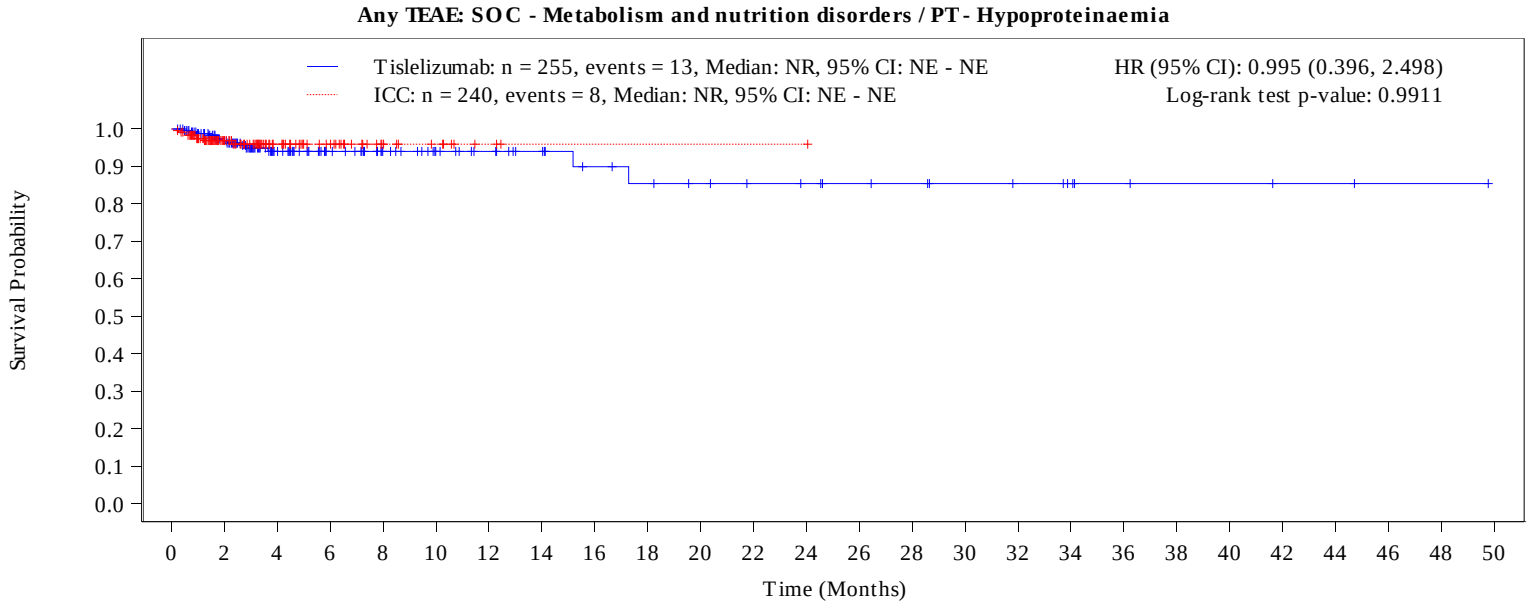
Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	174	96	65	49	38	32	27	21	19	17	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	112	44	26	12	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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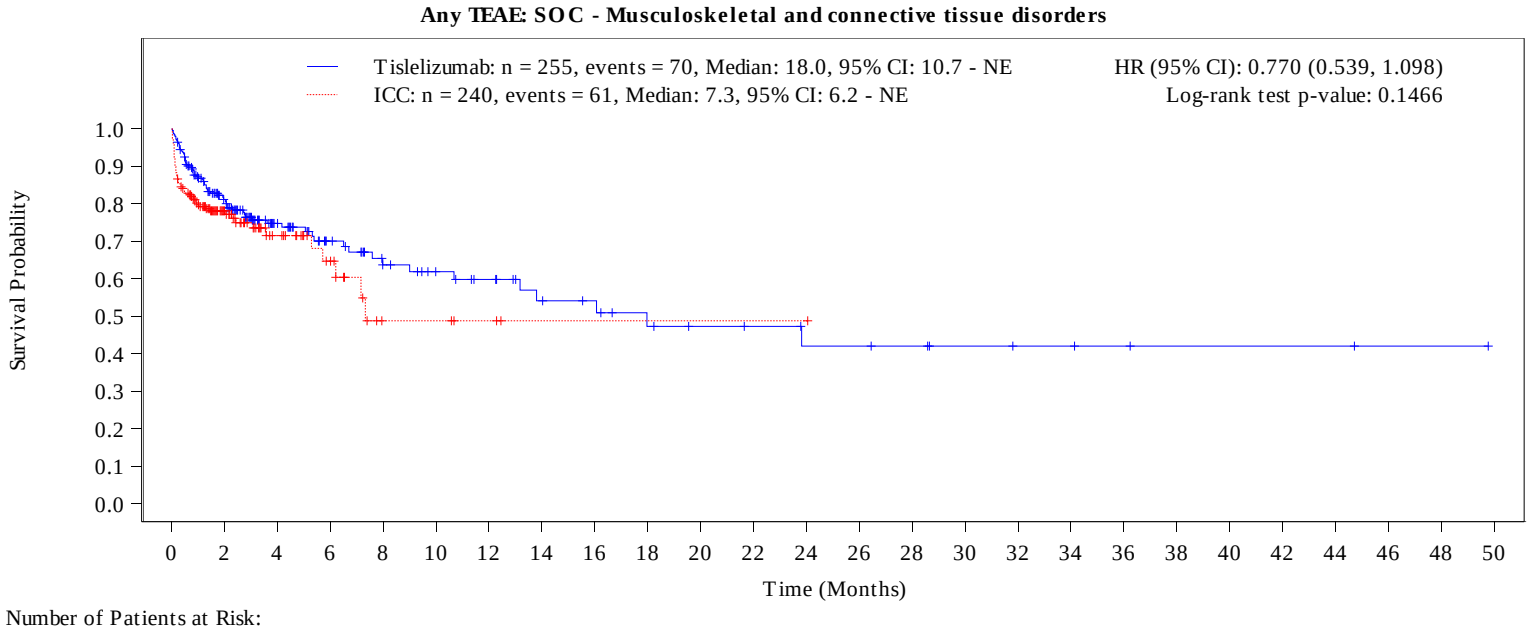

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	145	76	49	36	30	25	19	17	13	11	10	8	8	7	5	4	4	3	2	2	2	2	1	1	0
ICC	240	86	30	17	5	5	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
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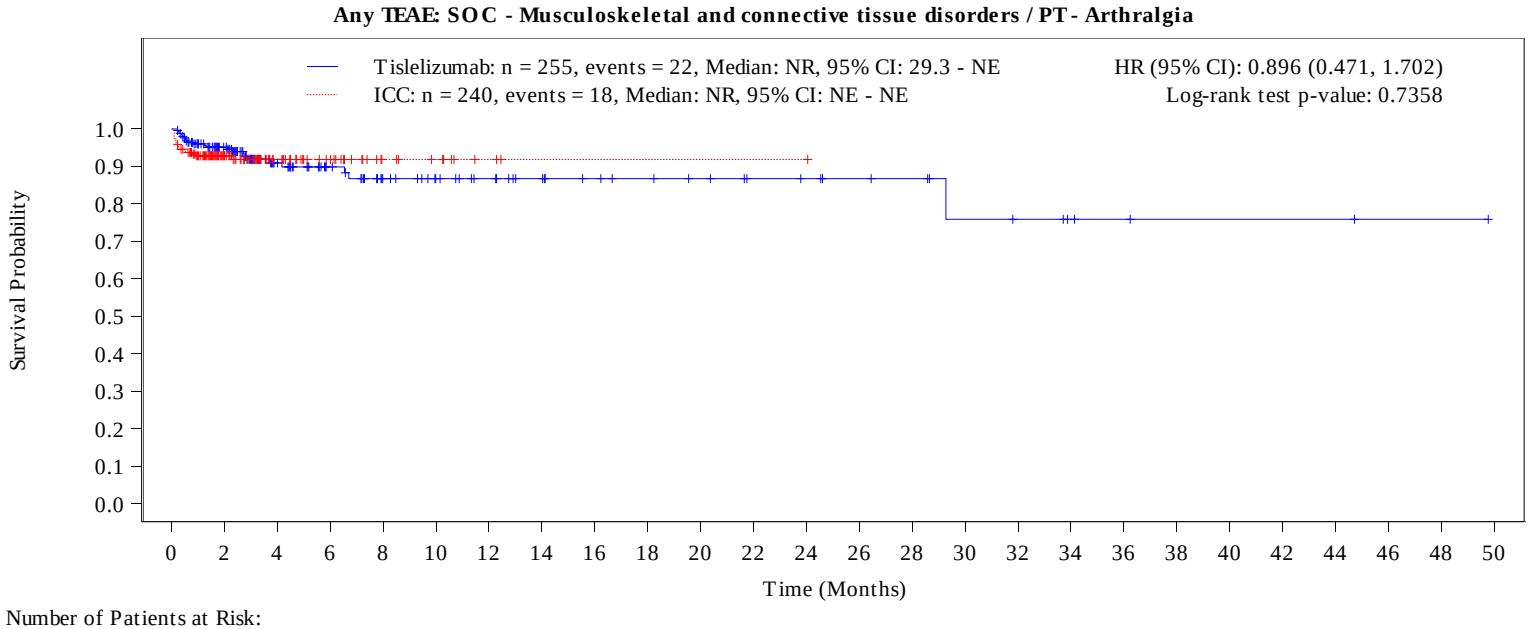

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	168	86	59	44	36	30	25	21	19	17	14	13	11	10	7	6	4	3	2	2	2	2	1	1	0
ICC	240	107	42	24	11	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

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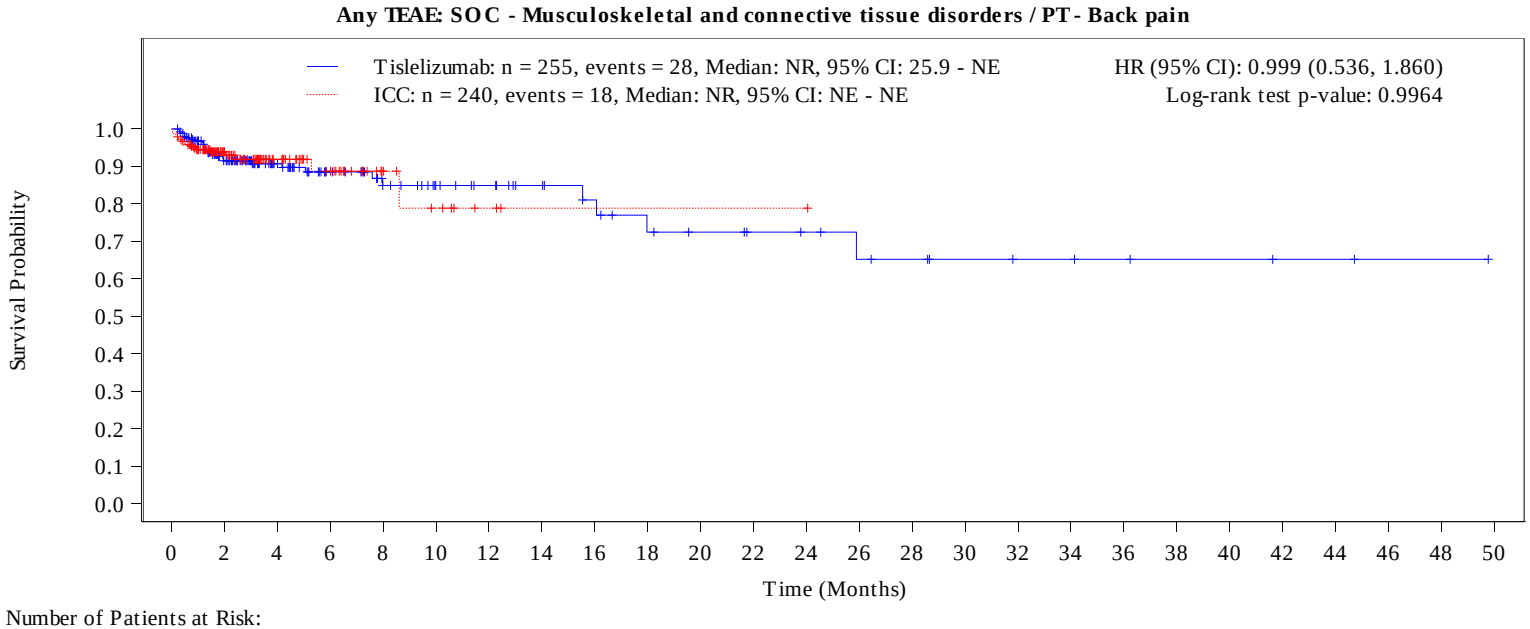
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	160	91	60	44	35	30	25	20	16	14	12	11	9	8	6	5	5	4	3	3	2	2	1	1	0
ICC	240	106	43	25	11	7	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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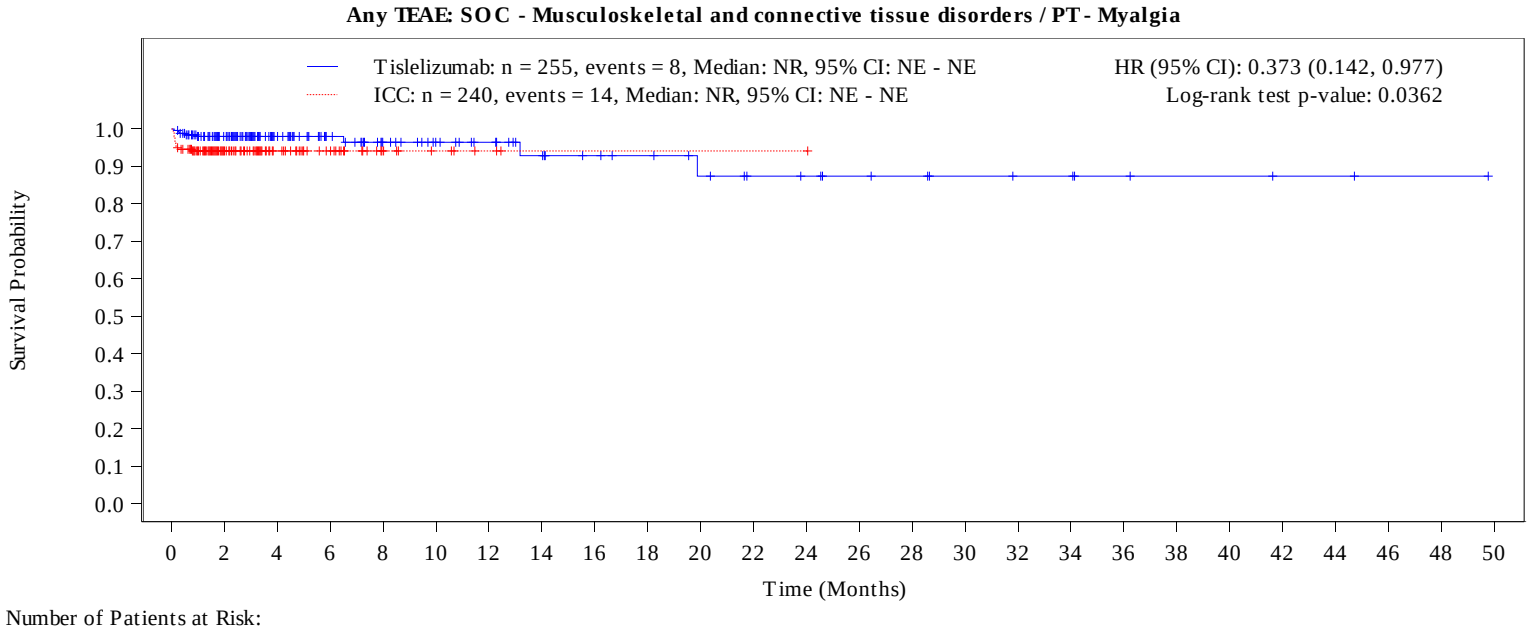
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	172	95	64	48	38	32	26	21	19	16	13	12	10	9	7	6	6	4	3	3	2	2	1	1	0
ICC	240	105	38	23	10	6	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
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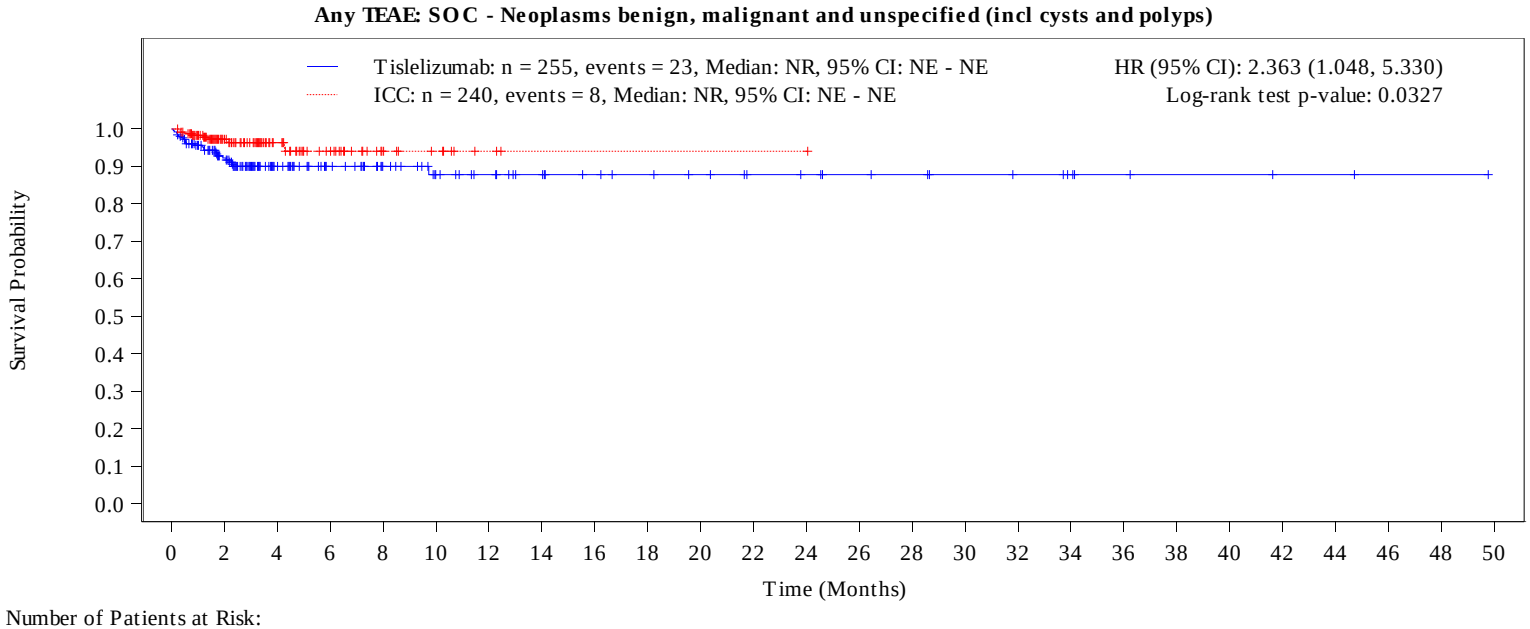
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	168	93	63	48	37	32	27	22	20	18	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	113	45	26	12	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
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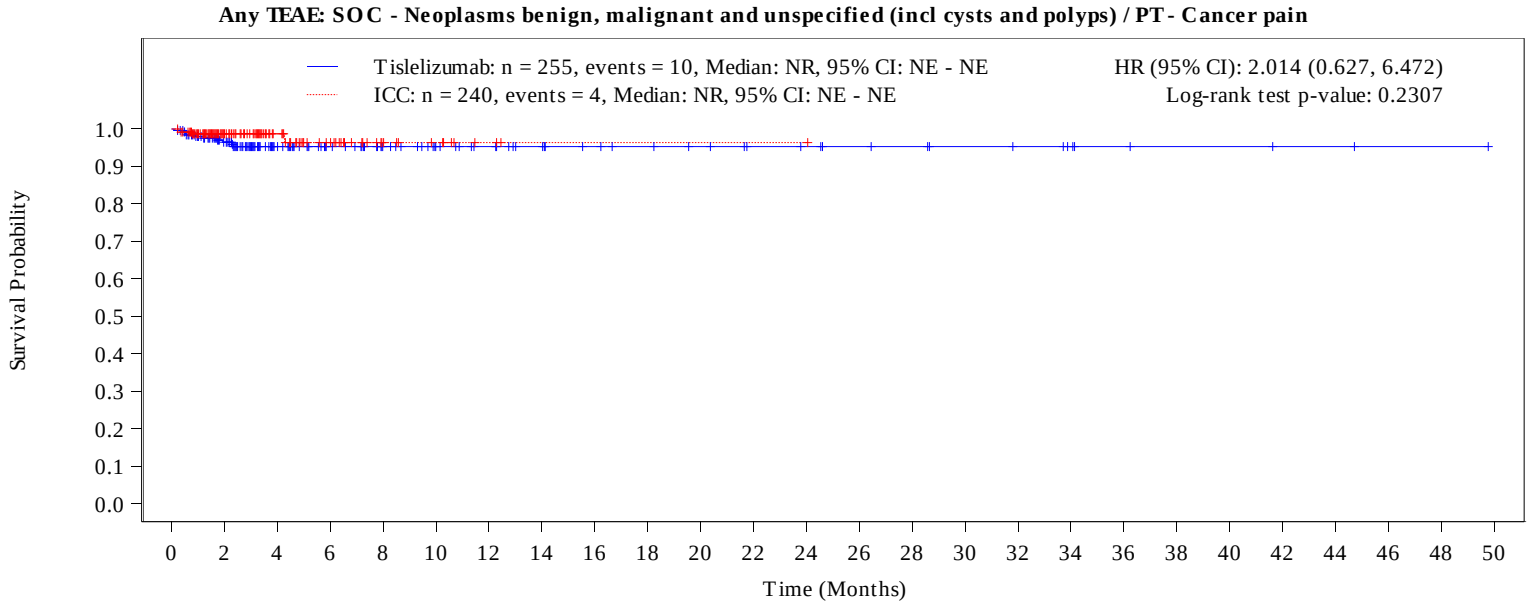

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	171	95	65	49	38	32	27	22	20	18	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	113	45	26	12	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
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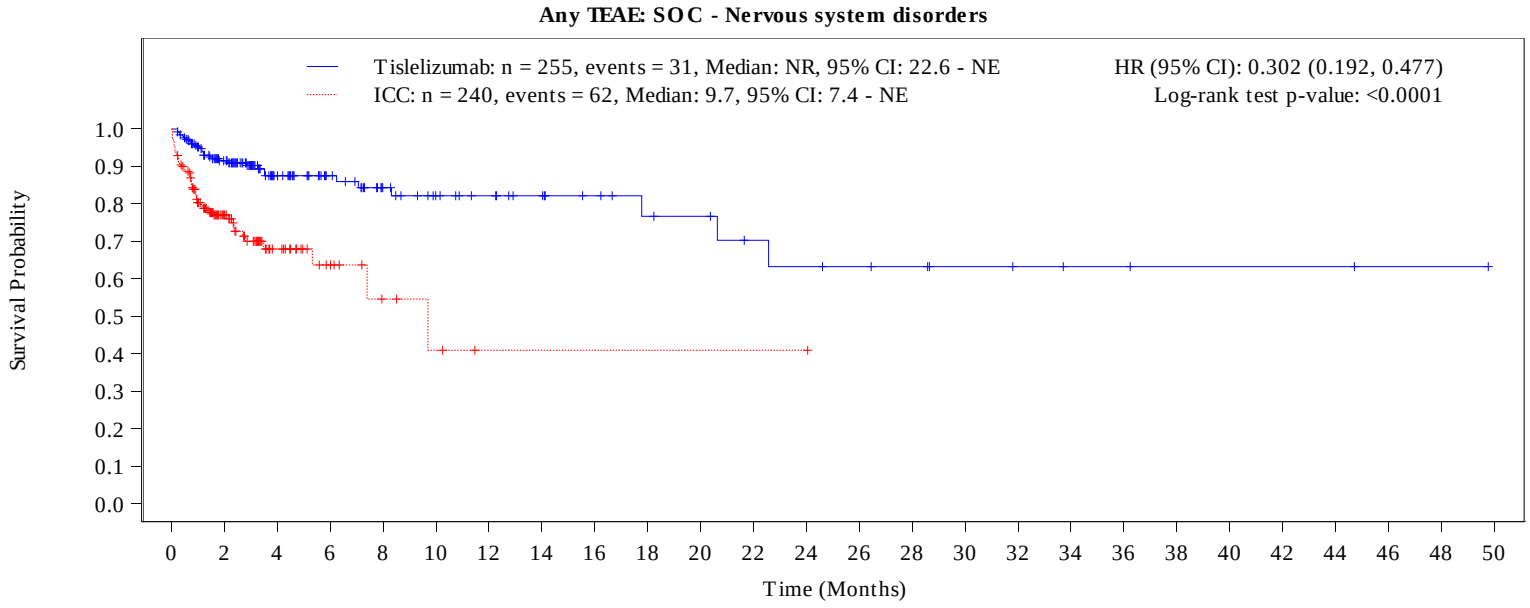
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	162	86	57	40	31	26	22	17	14	13	10	9	8	7	5	4	3	3	2	2	2	2	1	1	0
ICC	240	81	27	11	5	3	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
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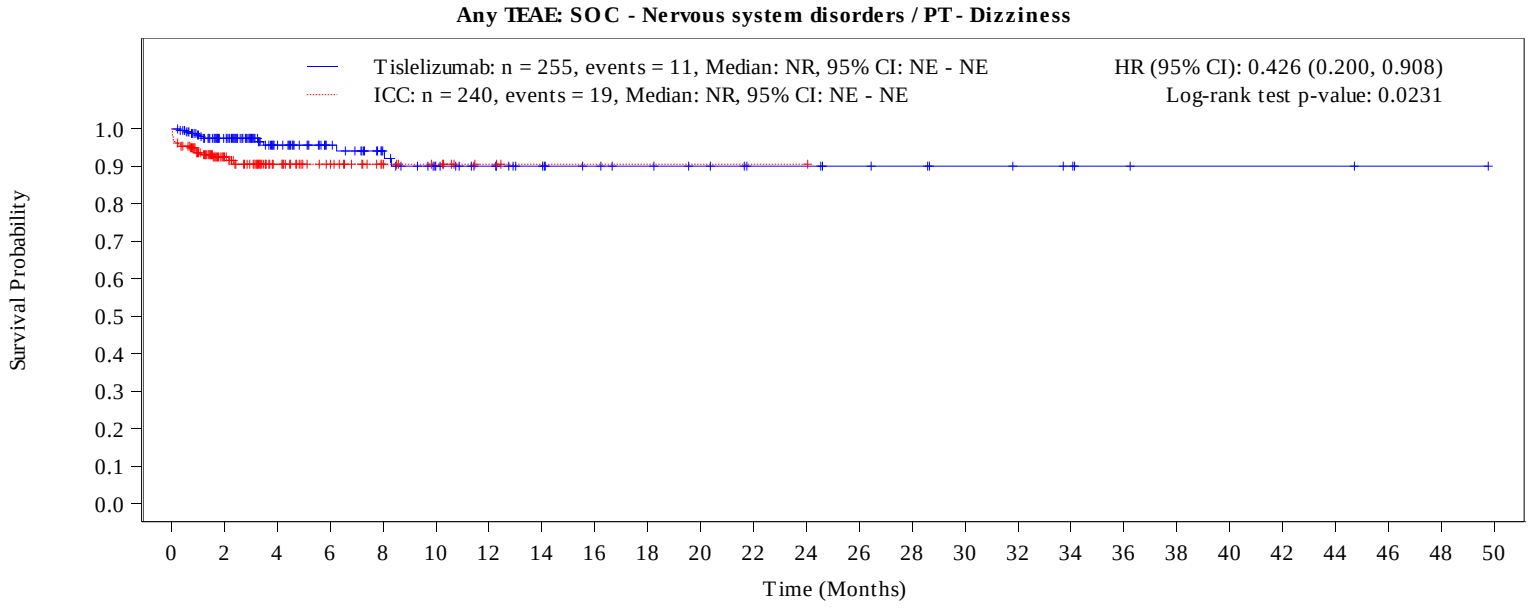

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ICC	240	105	41	24	12	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
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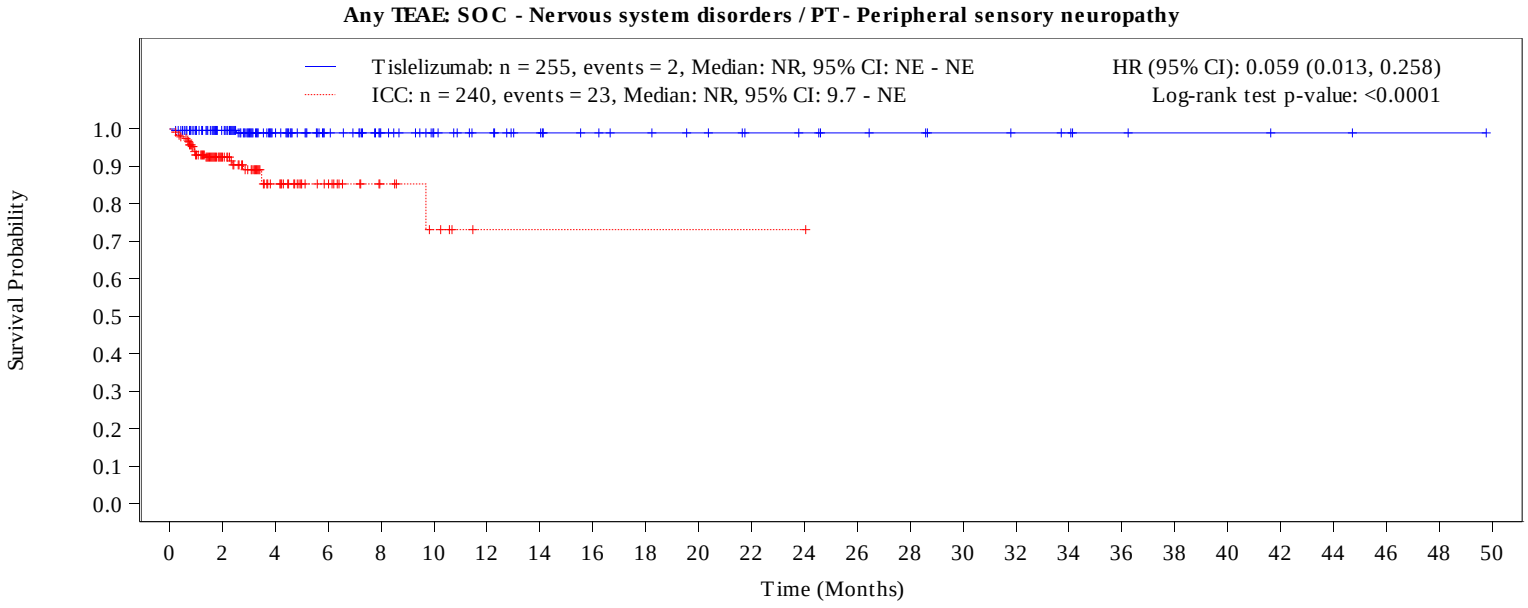

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	174	95	64	48	37	31	26	21	19	17	14	13	11	10	8	7	6	4	3	3	2	2	1	1	0
ICC	240	101	37	19	9	5	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
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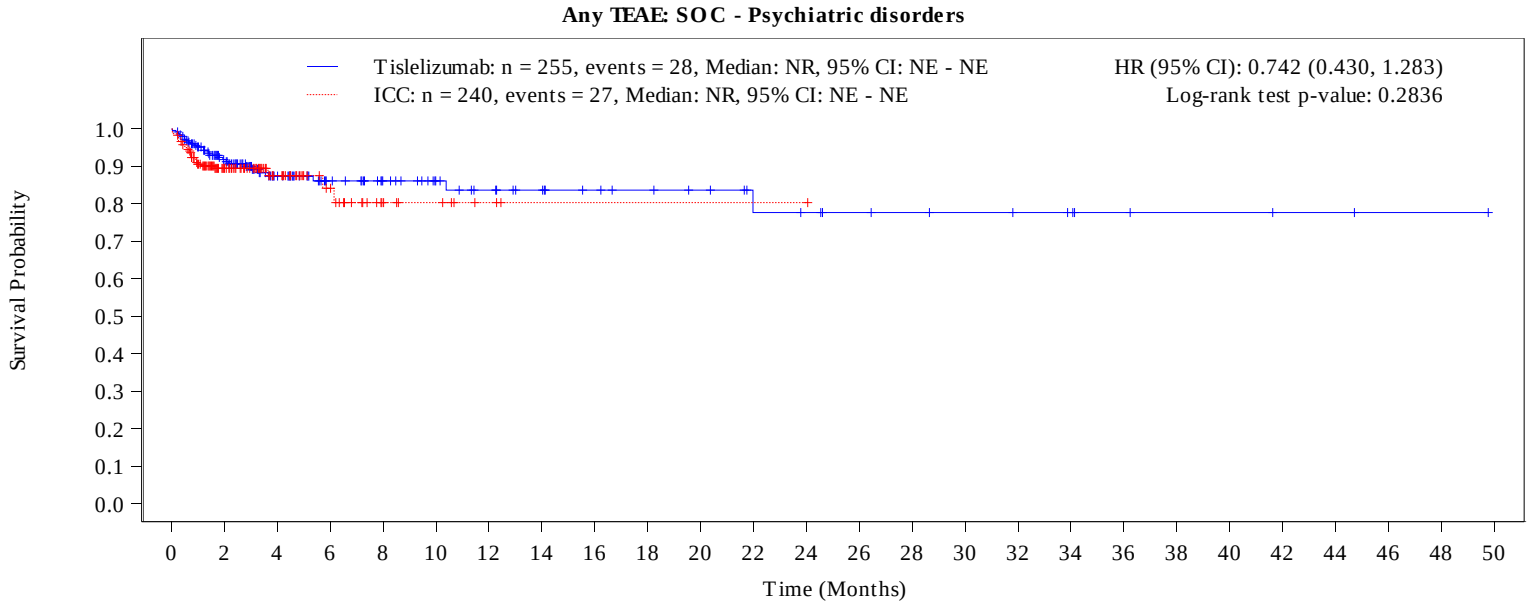

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	161	89	60	47	36	30	26	21	19	17	13	12	10	9	8	7	6	4	3	3	2	2	1	1	0
ICC	240	103	41	23	10	7	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
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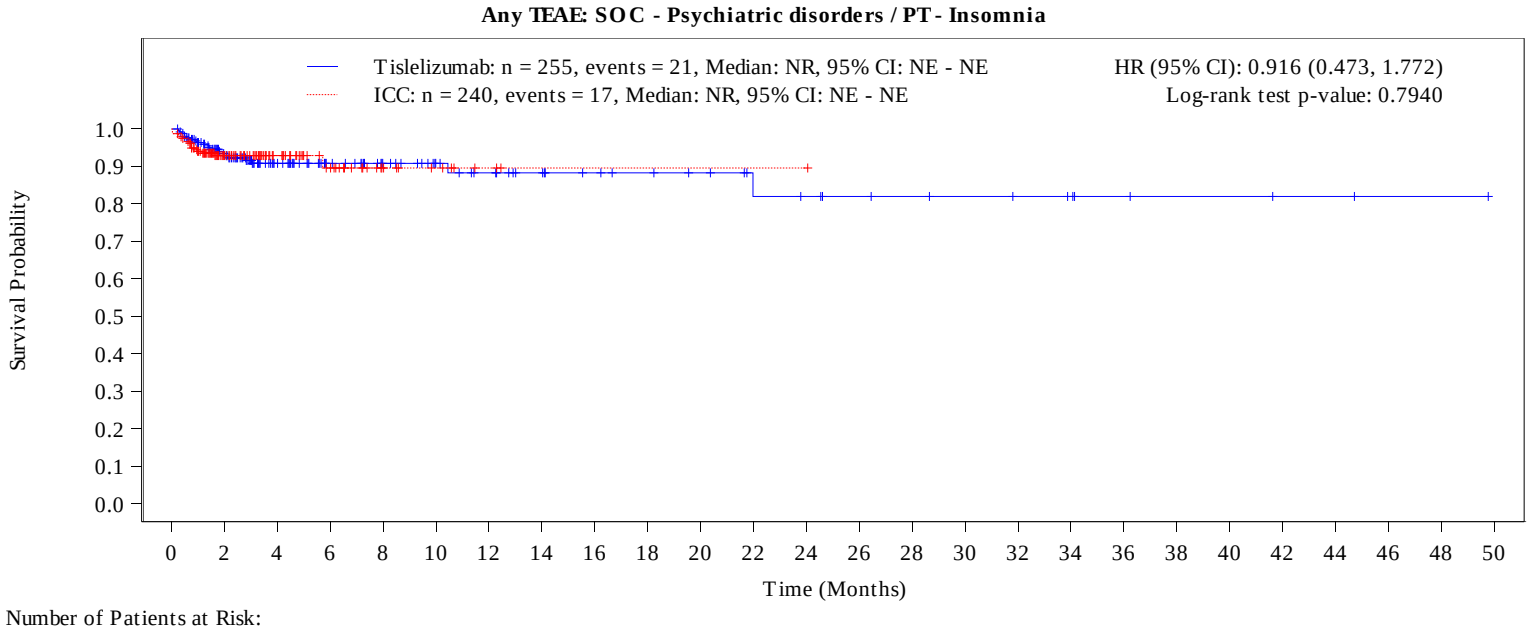
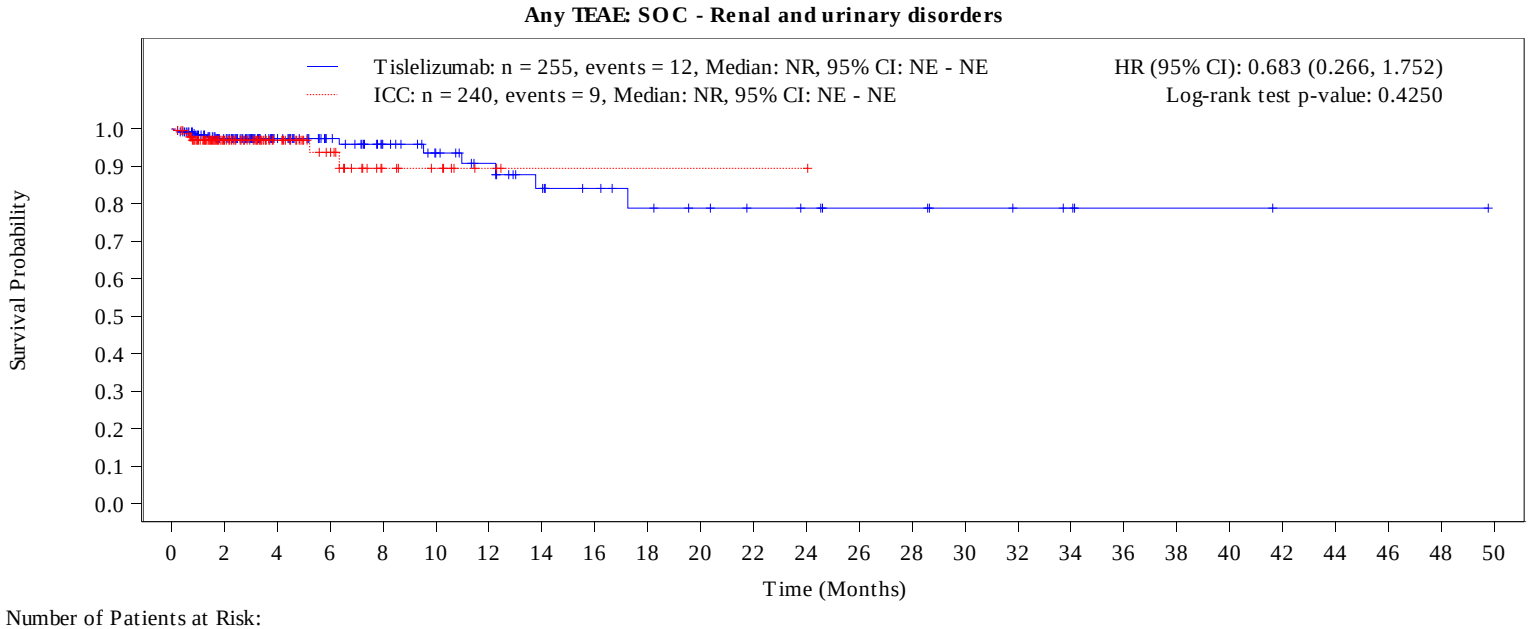


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	162	90	62	48	37	31	26	21	19	17	13	12	10	9	8	7	6	4	3	3	2	2	1	1	0
ICC	240	106	43	24	11	7	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

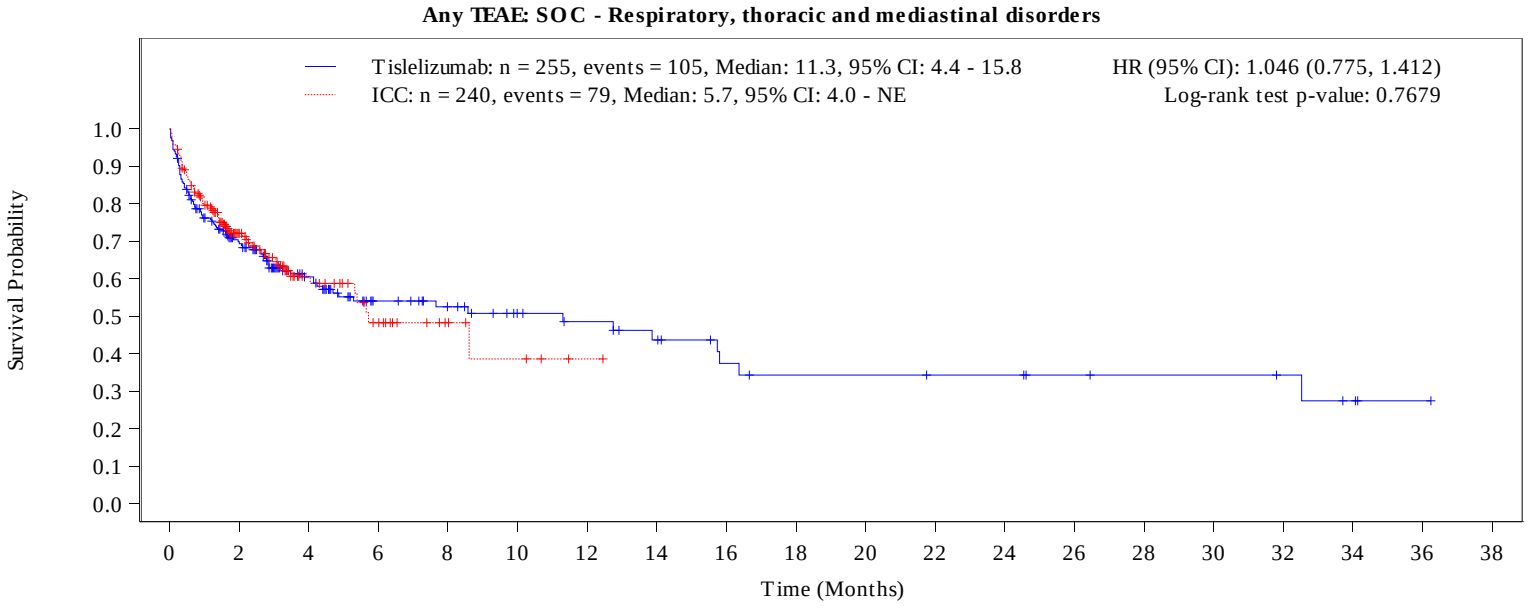


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	170	96	65	48	37	30	23	18	15	13	11	10	8	8	6	5	4	2	2	2	1	1	1	1	0
ICC	240	111	45	25	11	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

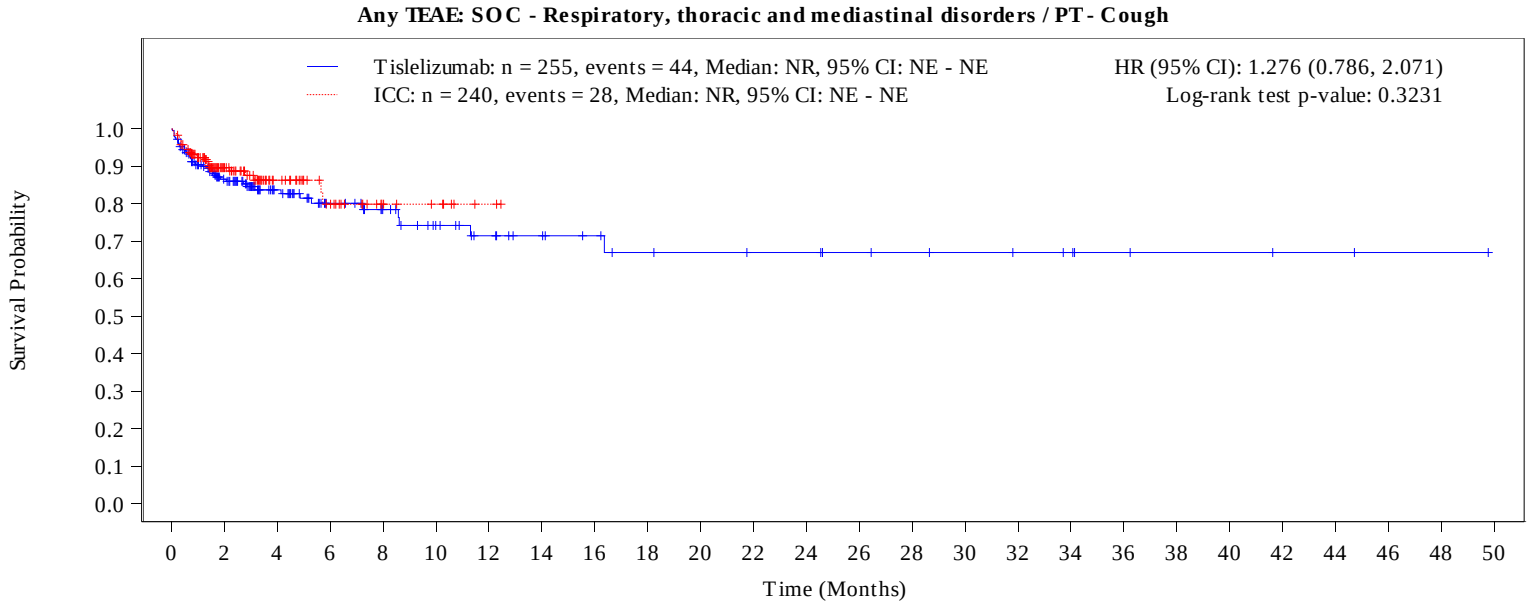


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38
Tislelizumab	255	132	73	42	33	24	21	17	12	10	10	9	9	7	6	6	5	3	1	0
ICC	240	92	32	16	7	4	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

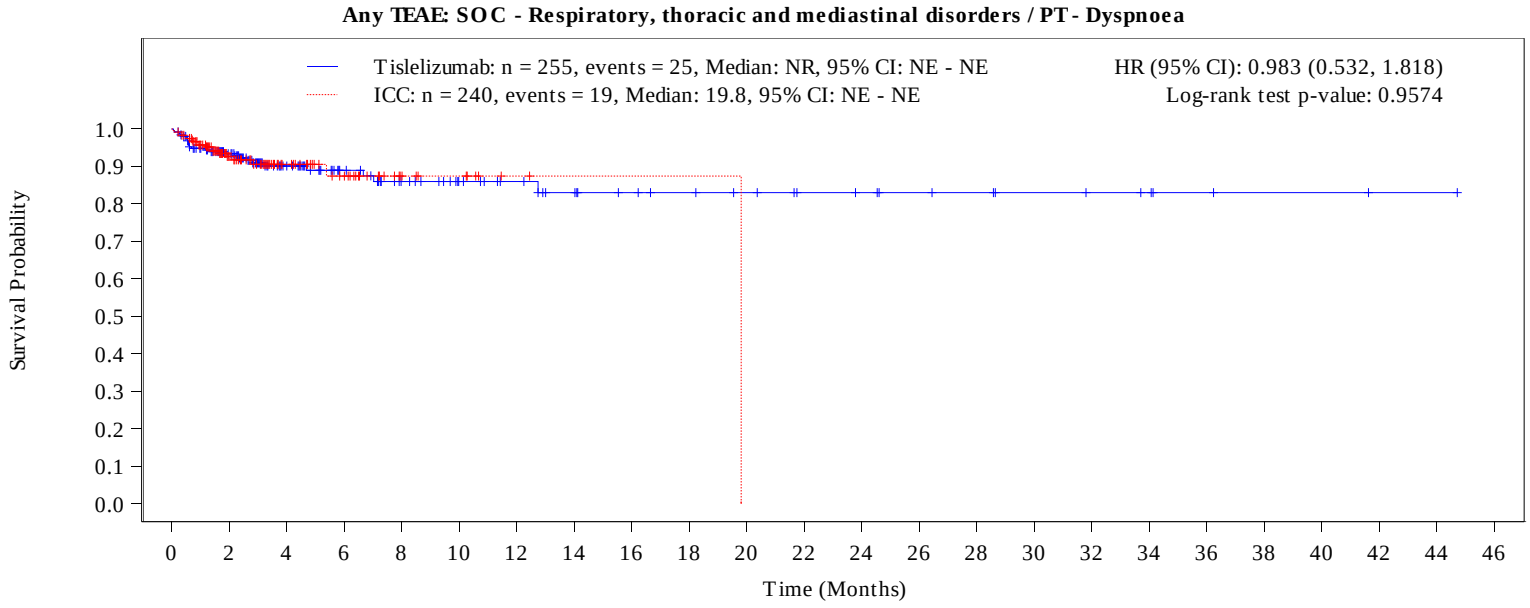


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	150	83	52	40	30	24	20	17	14	13	12	12	10	9	8	7	6	4	3	3	2	2	1	1	0
ICC	240	108	41	22	10	7	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

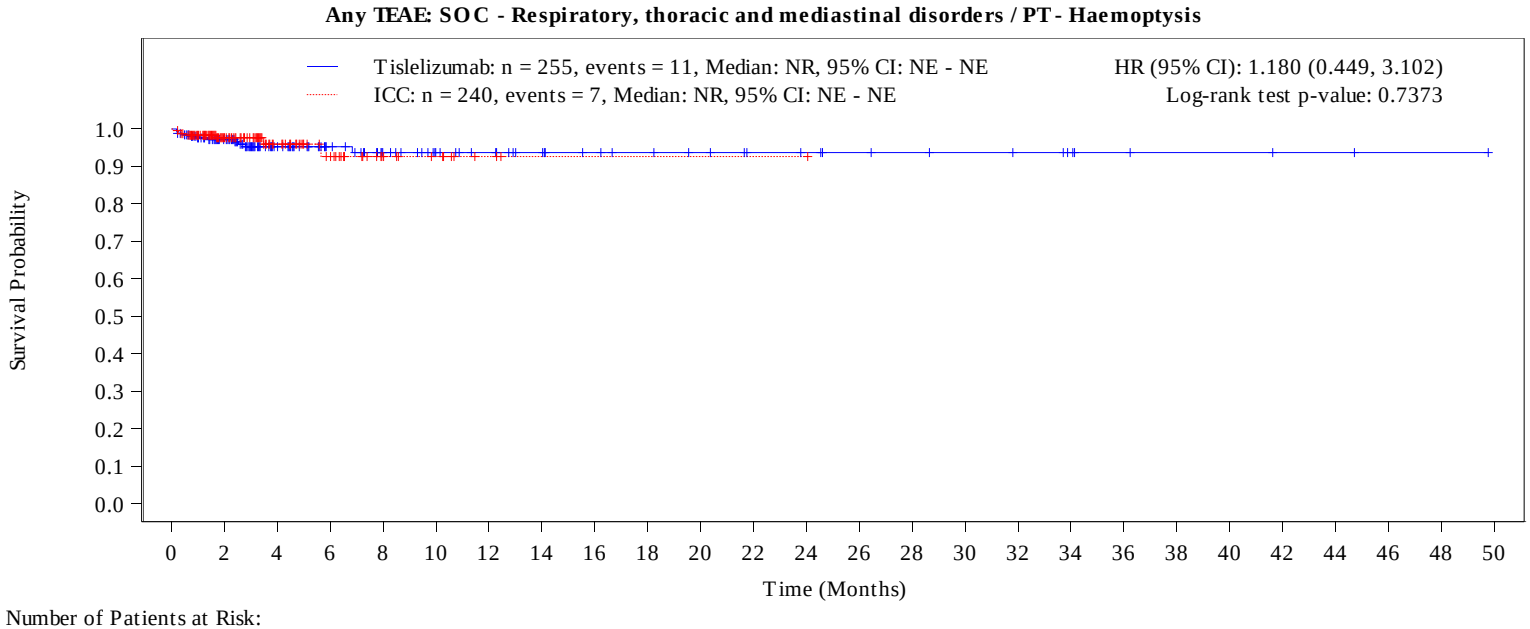


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46
Tislelizumab	255	169	95	62	47	36	30	25	20	18	16	13	12	10	9	7	6	5	3	2	2	1	1	0
ICC	240	106	41	24	10	7	2	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

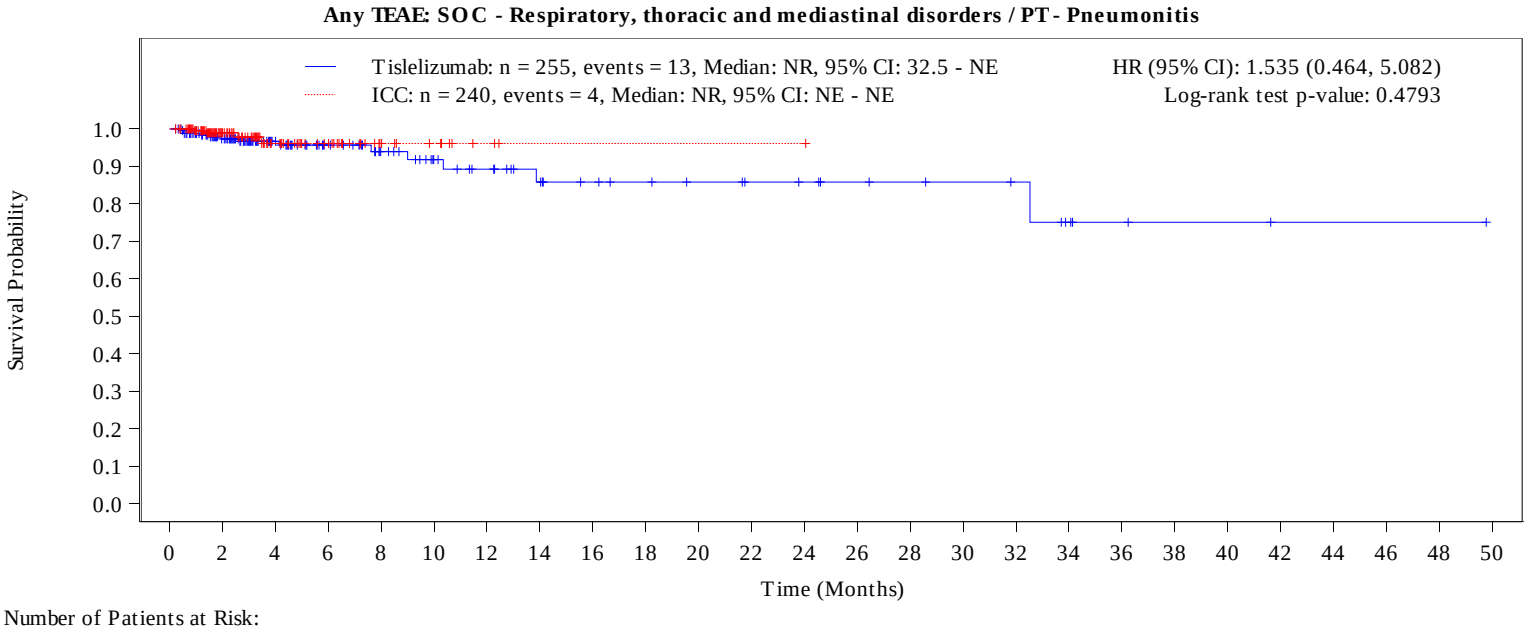


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	173	95	63	47	36	31	26	21	19	17	14	13	11	10	9	8	6	4	3	3	2	2	1	1	0
ICC	240	112	44	25	12	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

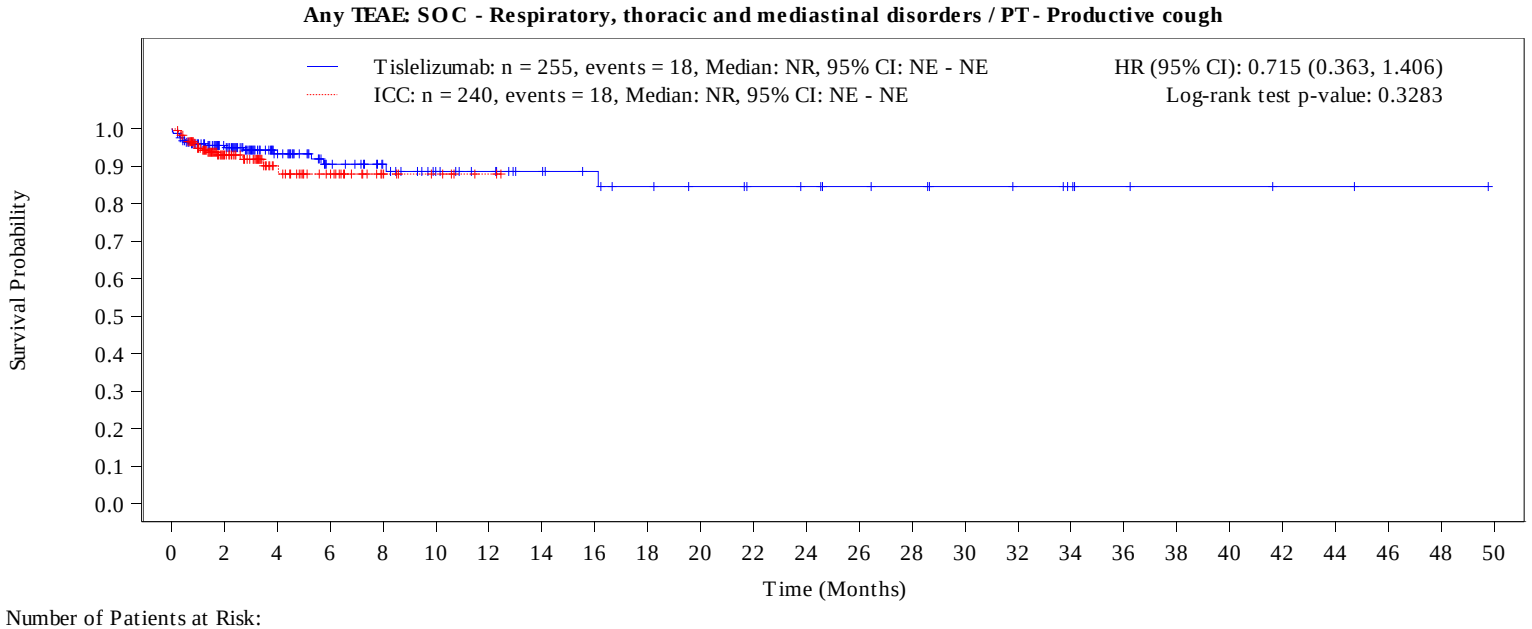


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	174	97	64	48	37	31	25	20	18	16	14	13	11	10	9	8	5	3	2	2	1	1	1	1	0
ICC	240	112	44	26	12	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

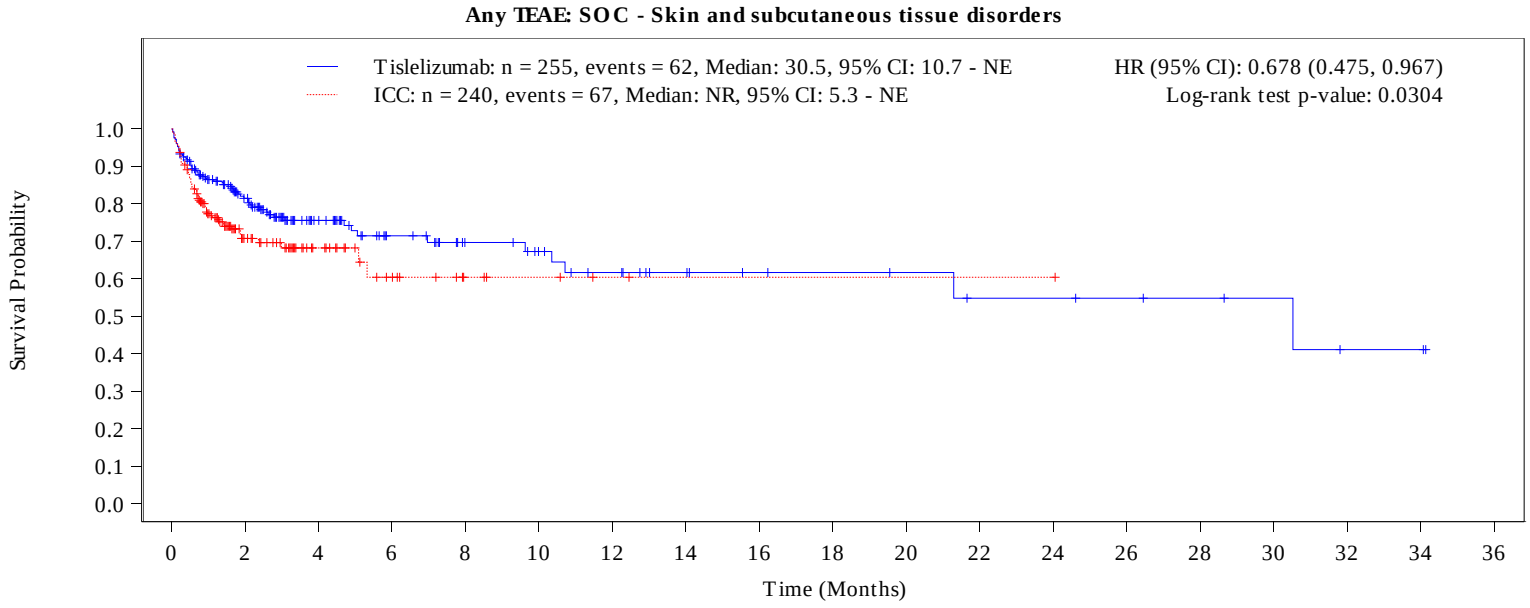


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	168	92	60	47	36	31	26	22	19	17	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	107	41	24	10	6	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

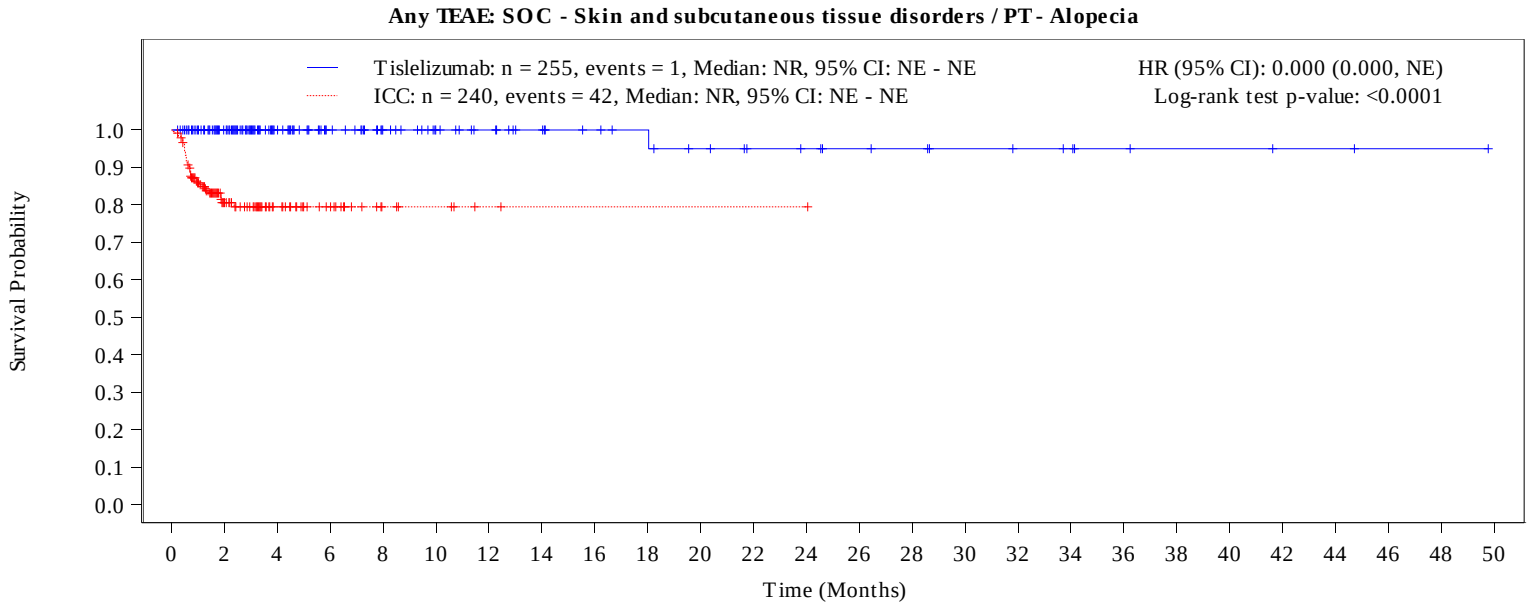


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36
Tislelizumab	255	140	68	42	30	25	19	14	11	10	9	7	7	6	5	4	2	2	0
ICC	240	72	26	13	6	4	2	1	1	1	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

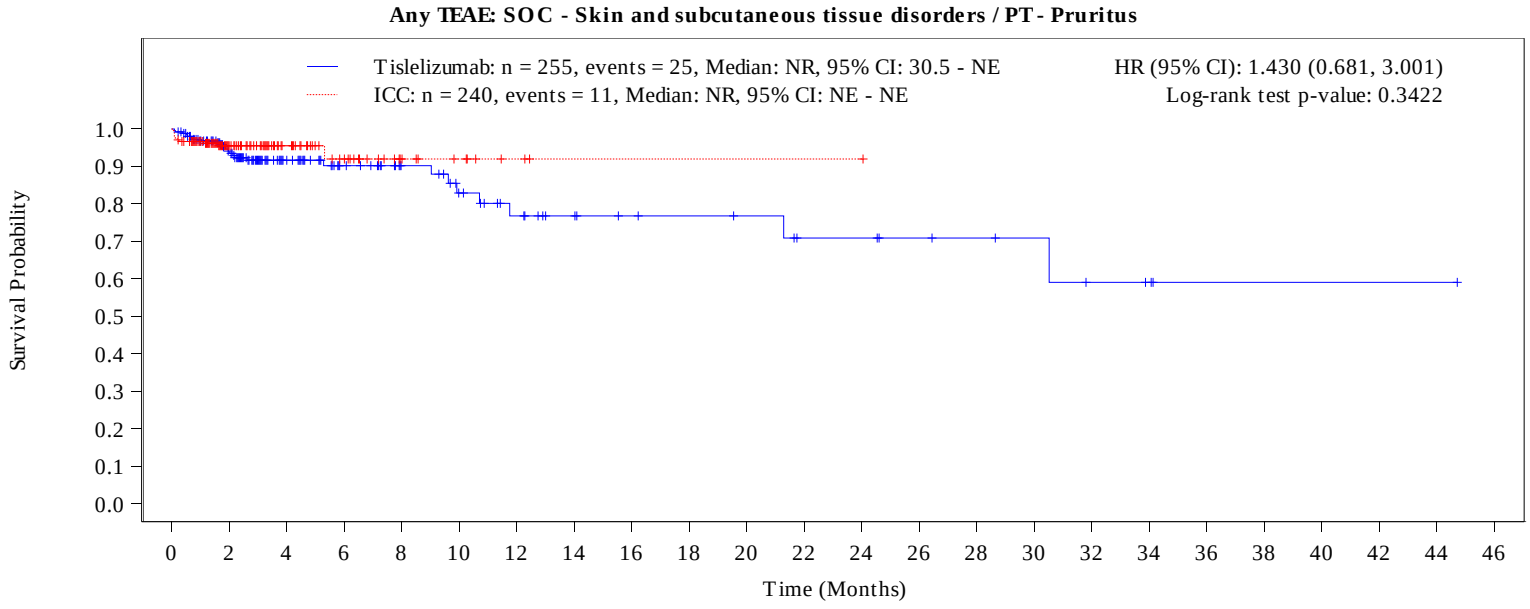


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	175	97	65	49	38	32	27	22	20	17	14	13	11	10	8	7	6	4	3	3	2	2	1	1	0
ICC	240	83	31	18	7	5	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

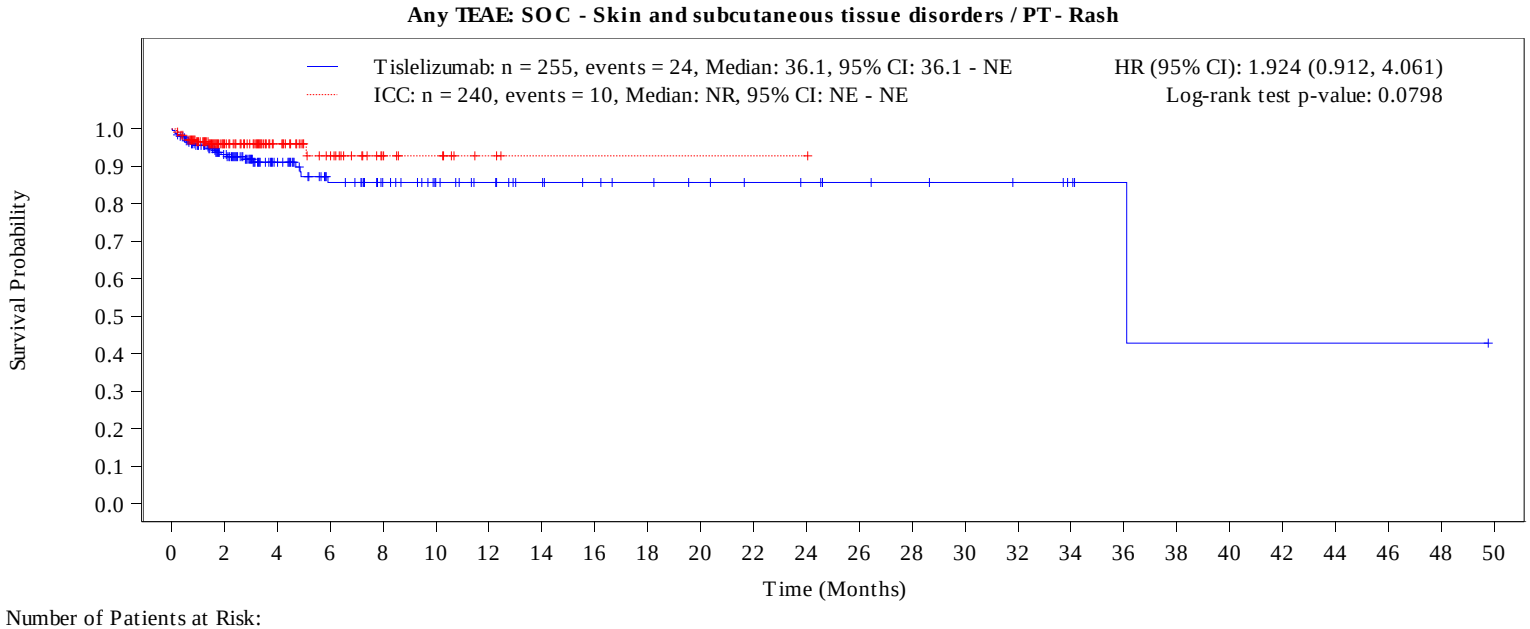


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46
Tislelizumab	255	162	86	55	40	31	23	18	15	14	13	10	10	8	7	6	4	3	1	1	1	1	1	0
ICC	240	105	41	23	11	7	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

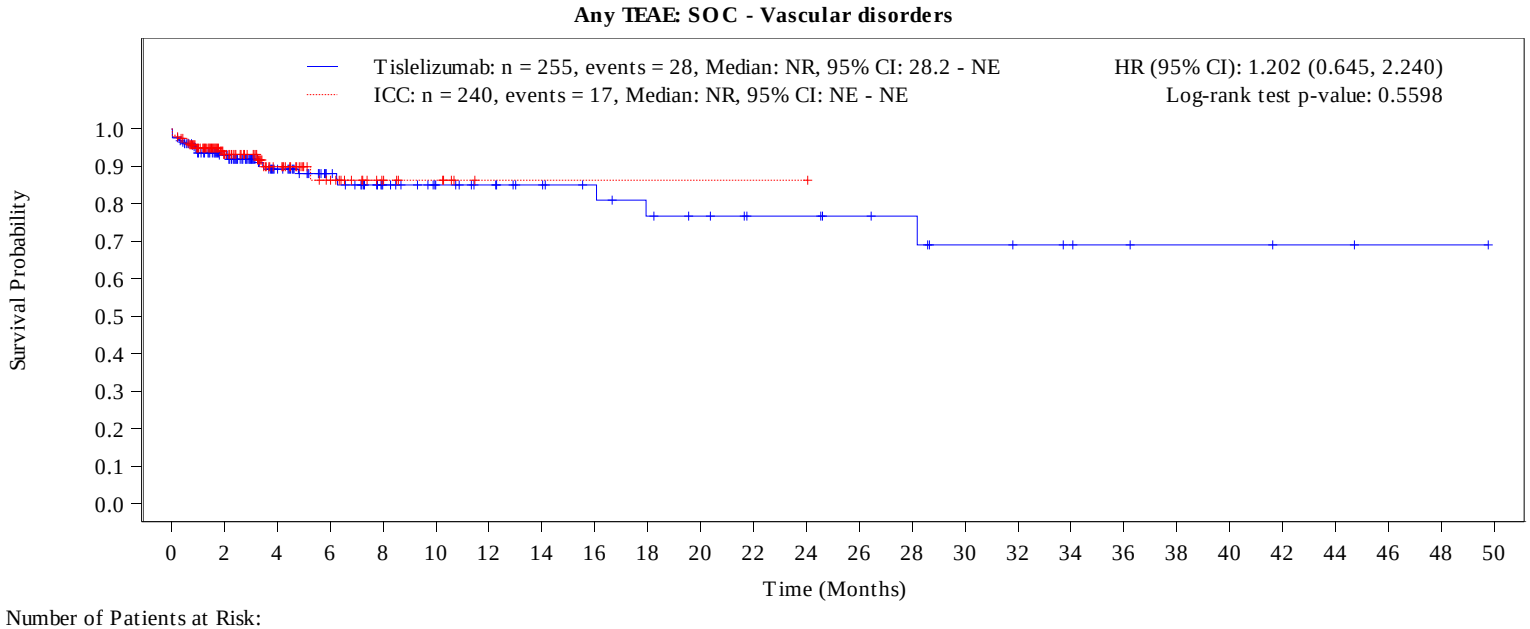


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	163	87	55	43	33	27	22	18	16	14	12	11	9	8	7	6	4	2	1	1	1	1	1	1	0
ICC	240	106	43	24	11	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

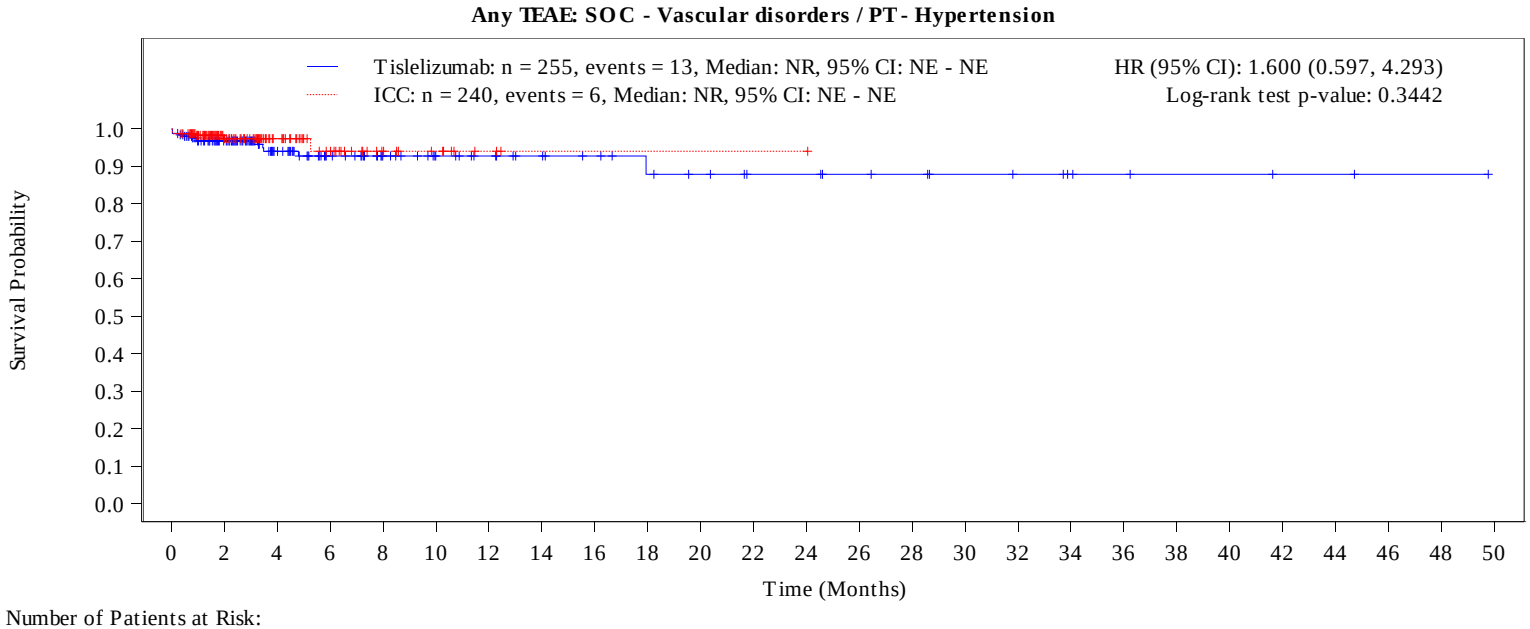


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	166	92	59	42	33	28	24	21	18	16	13	13	11	10	7	6	5	4	3	3	2	2	1	1	0
ICC	240	102	40	20	9	6	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

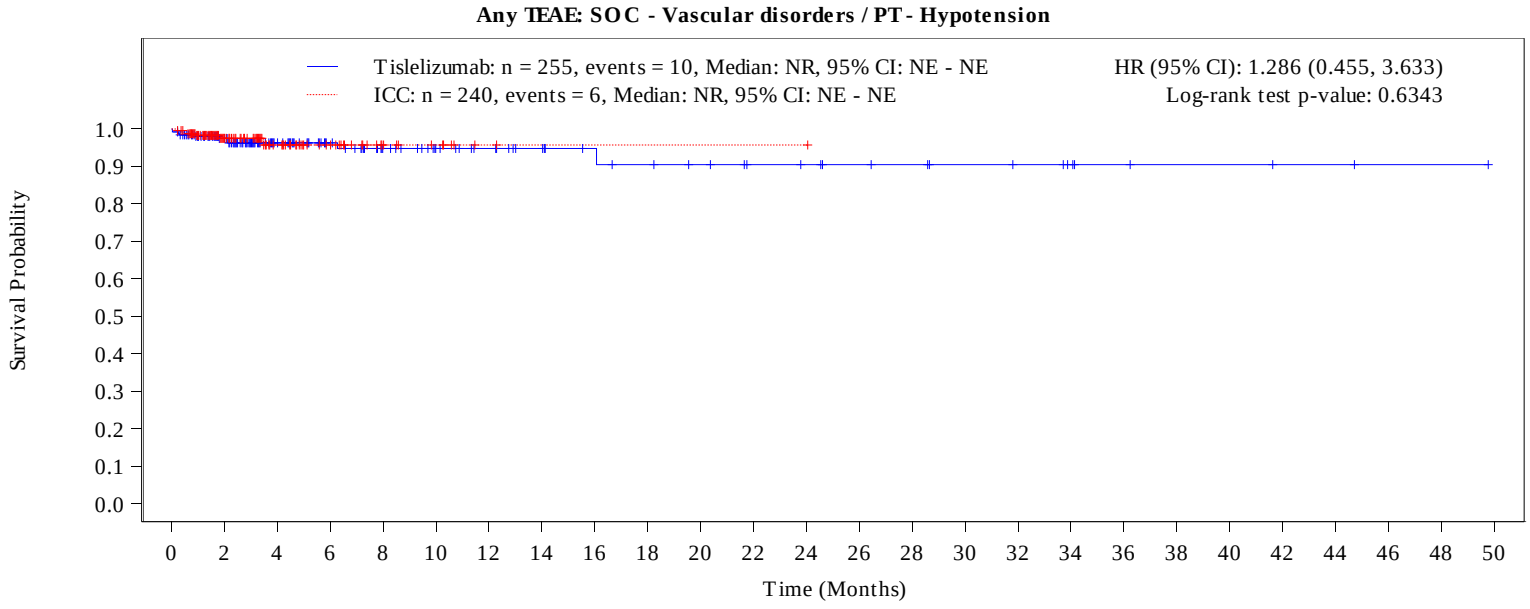


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	170	92	59	43	34	29	25	21	18	16	13	13	11	10	8	7	5	4	3	3	2	2	1	1	0
ICC	240	109	44	24	12	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

Figure 14.3.1.2:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

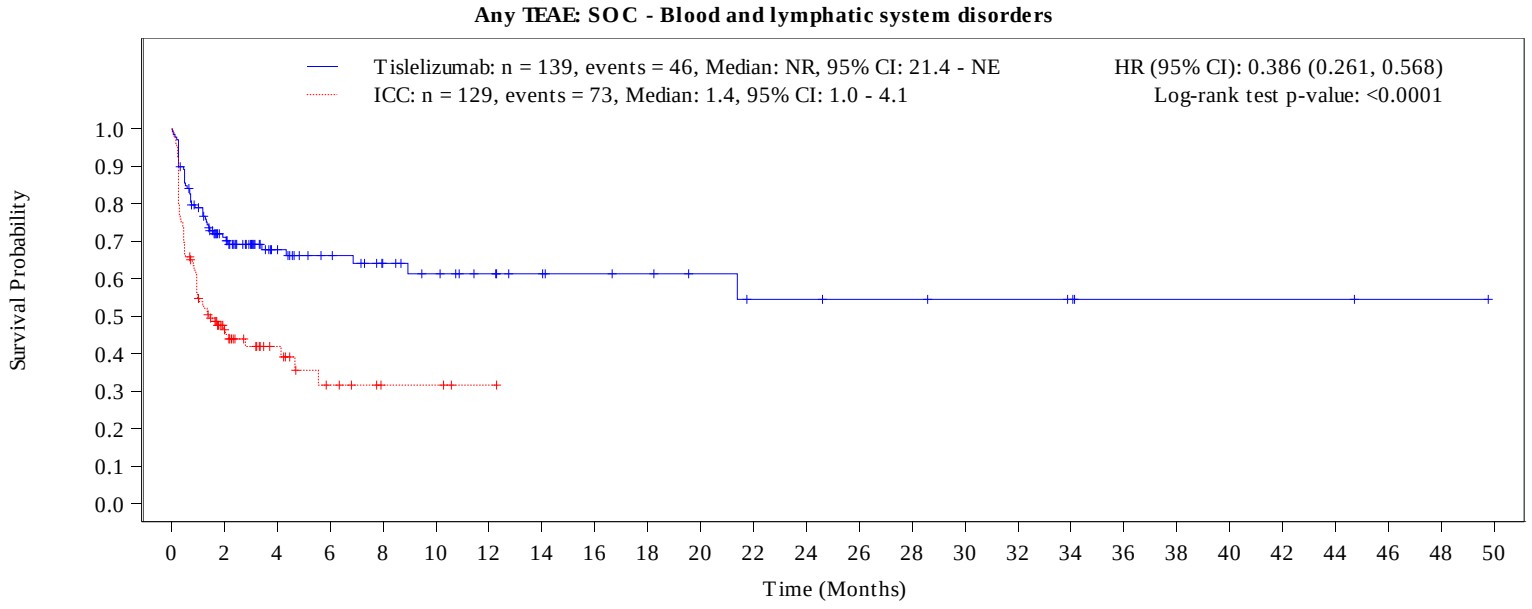


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	171	97	65	48	37	31	26	22	20	18	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	108	43	24	11	7	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-km-aesocpt-safety-cl.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

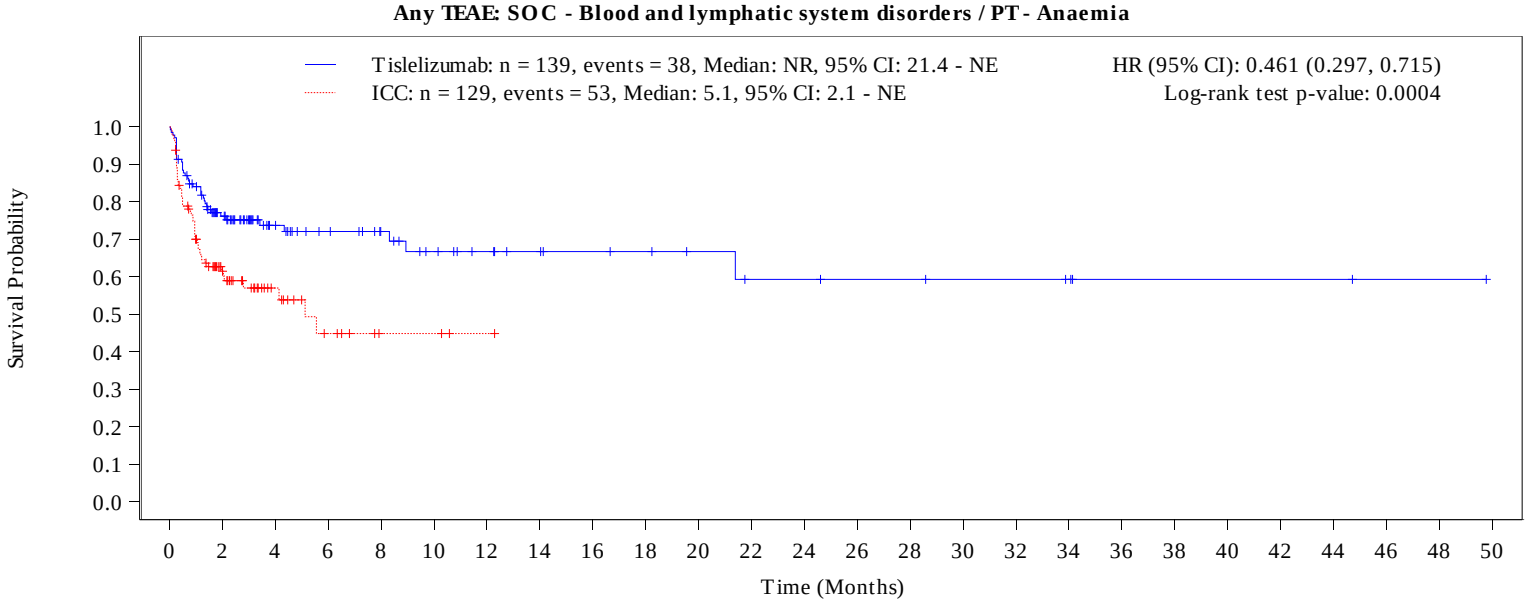


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	76	44	33	25	21	17	14	12	11	9	7	7	6	6	5	5	4	2	2	2	2	2	1	1	0
ICC	129	39	15	7	3	3	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

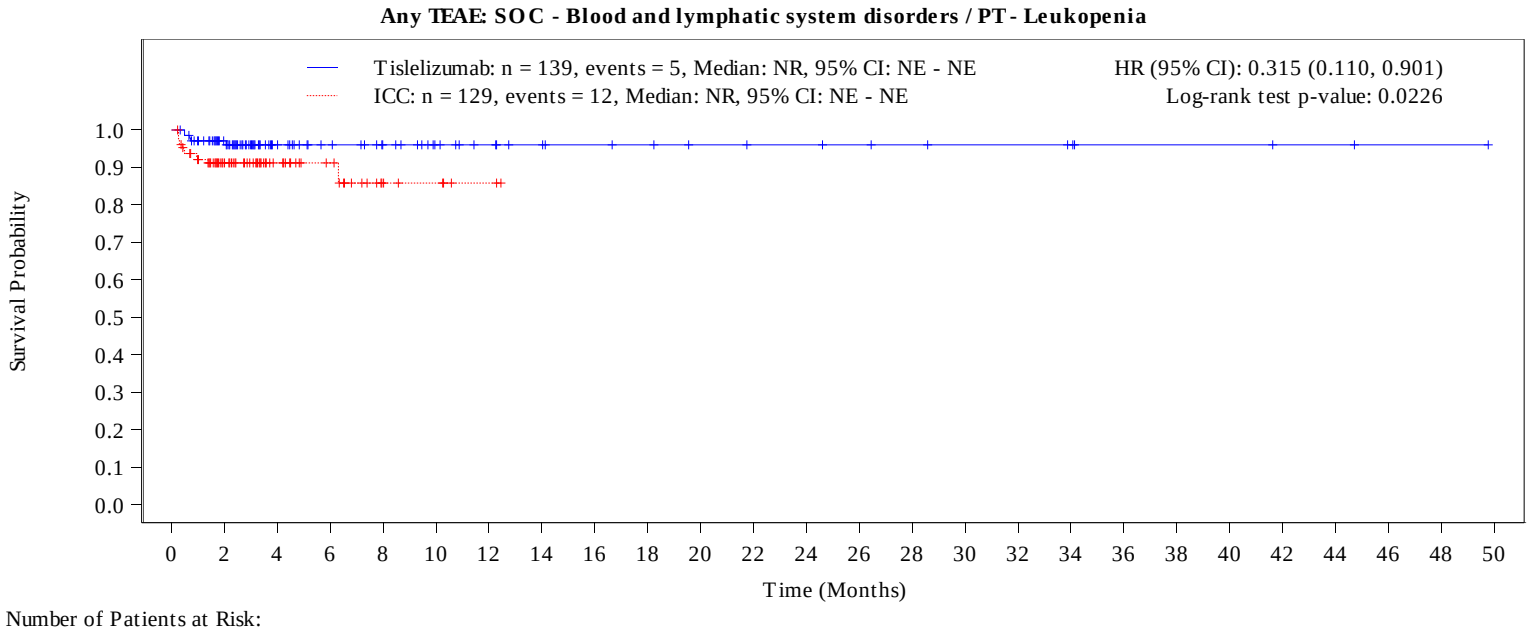


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	80	46	35	28	22	18	15	12	11	9	7	7	6	6	5	5	4	2	2	2	2	2	1	1	0
ICC	129	50	18	8	3	3	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

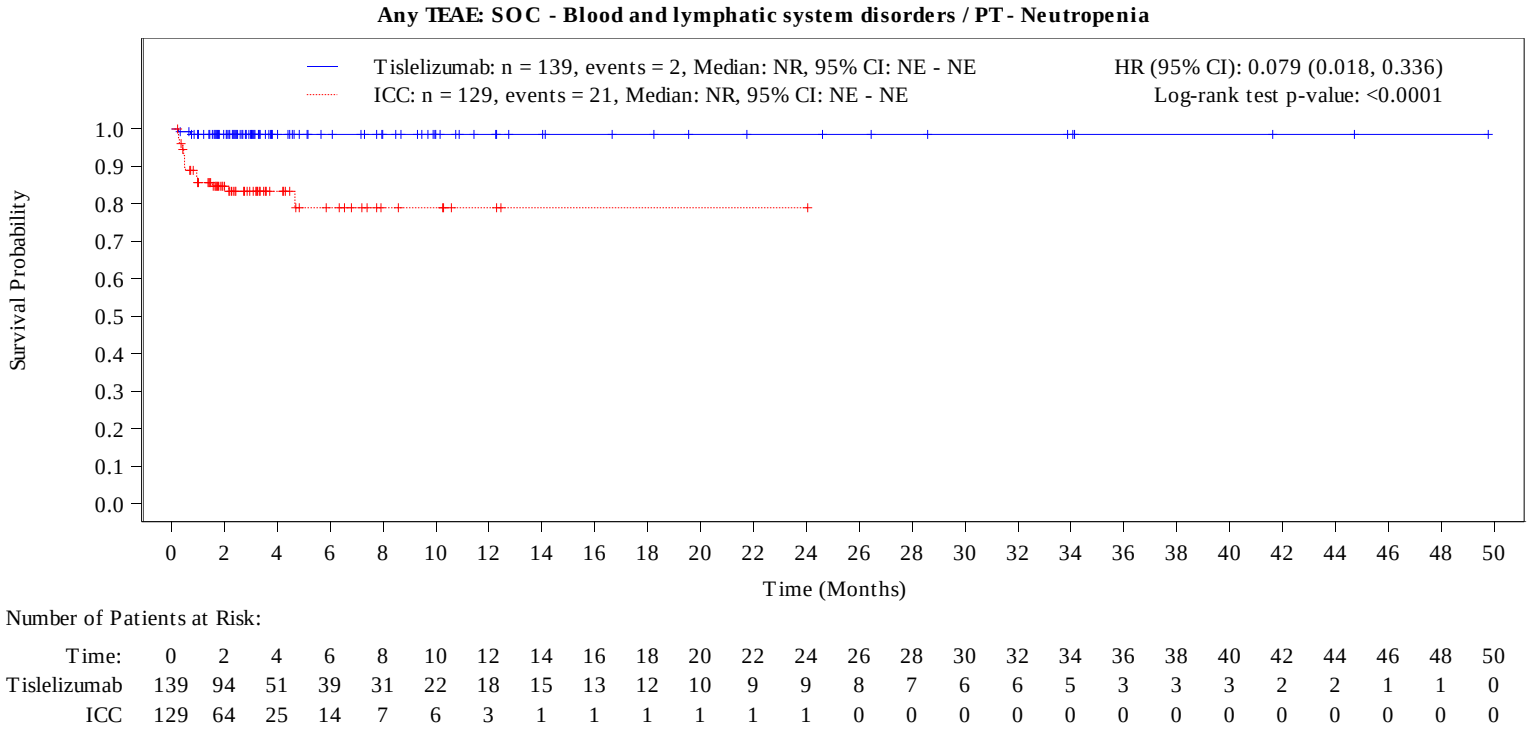


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	92	50	38	30	22	18	15	13	12	10	9	9	8	7	6	6	5	3	3	3	2	2	1	1	0
ICC	129	71	30	18	7	5	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

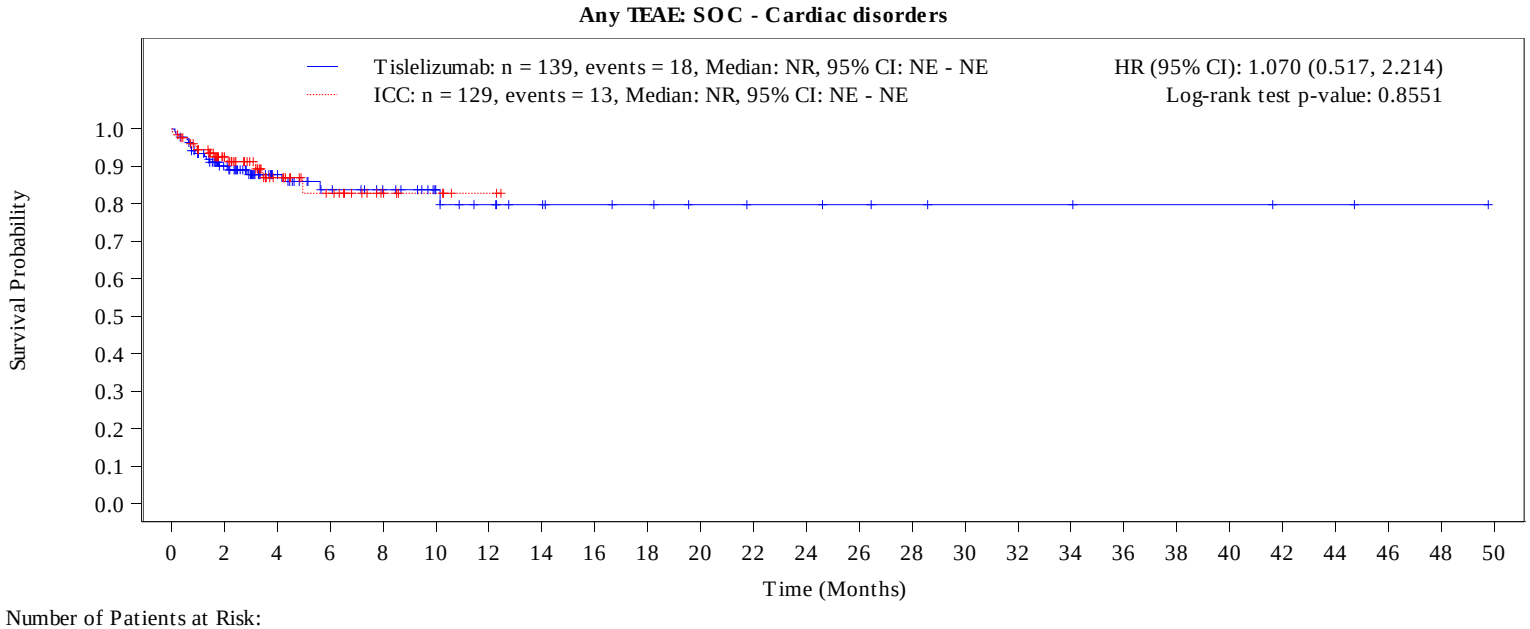


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	94	51	39	31	22	18	15	13	12	10	9	9	8	7	6	6	5	3	3	3	2	2	1	1	0
ICC	129	64	25	14	7	6	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

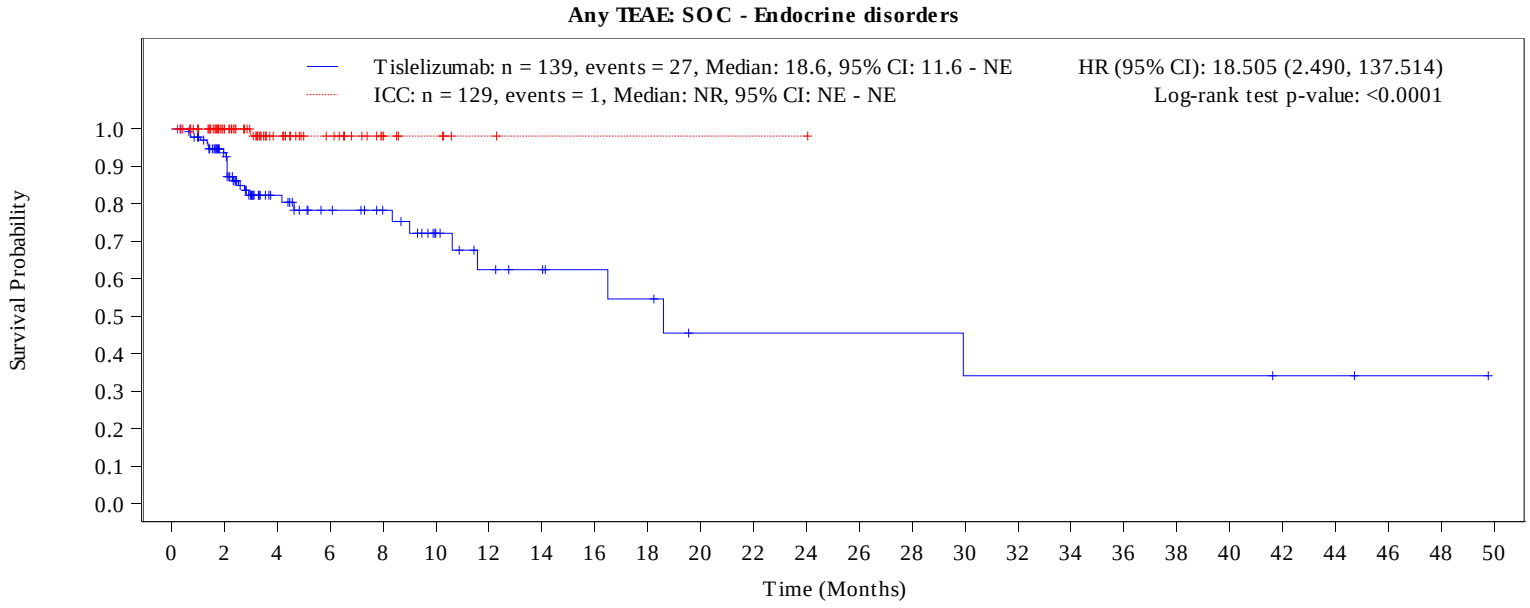


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	88	49	37	30	21	17	14	11	10	8	7	7	6	5	4	4	4	3	3	3	2	2	1	1	0
ICC	129	73	30	17	8	5	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

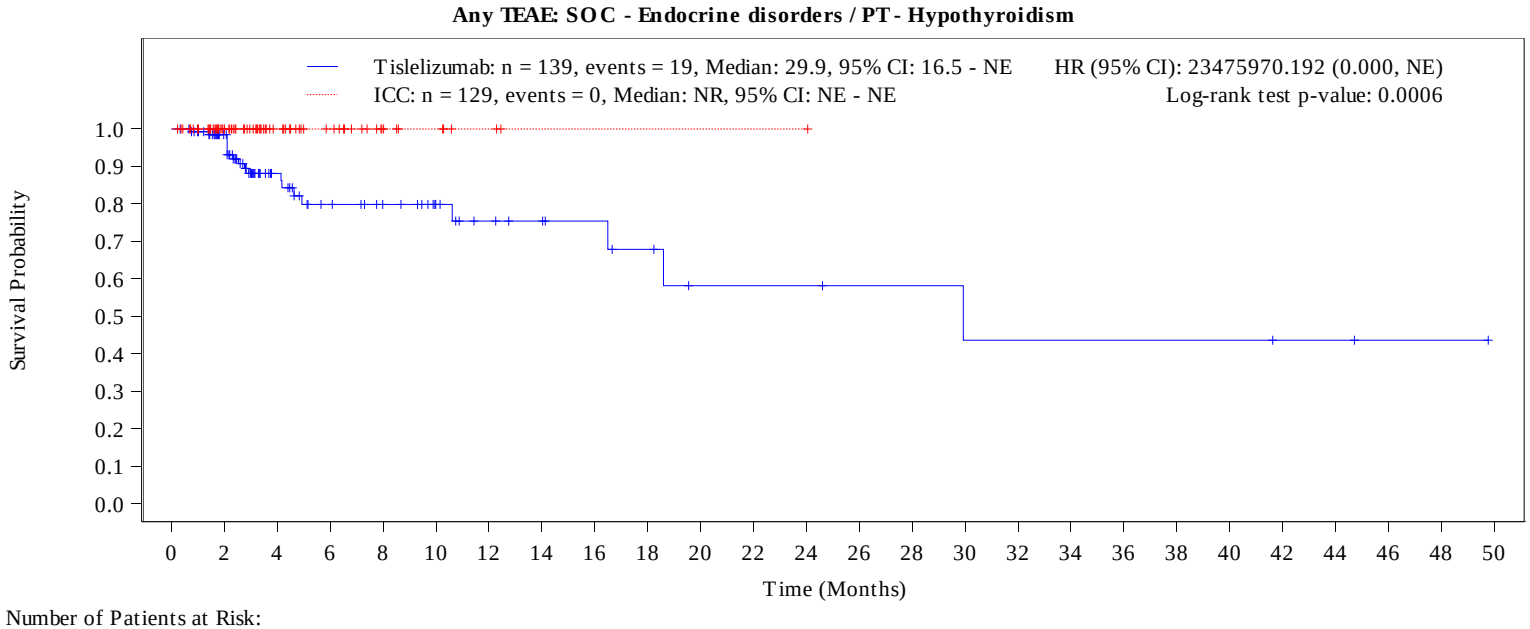


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	89	44	31	26	17	12	10	8	7	4	4	4	4	4	3	3	3	3	3	3	2	2	1	1	0
ICC	129	75	32	18	8	5	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

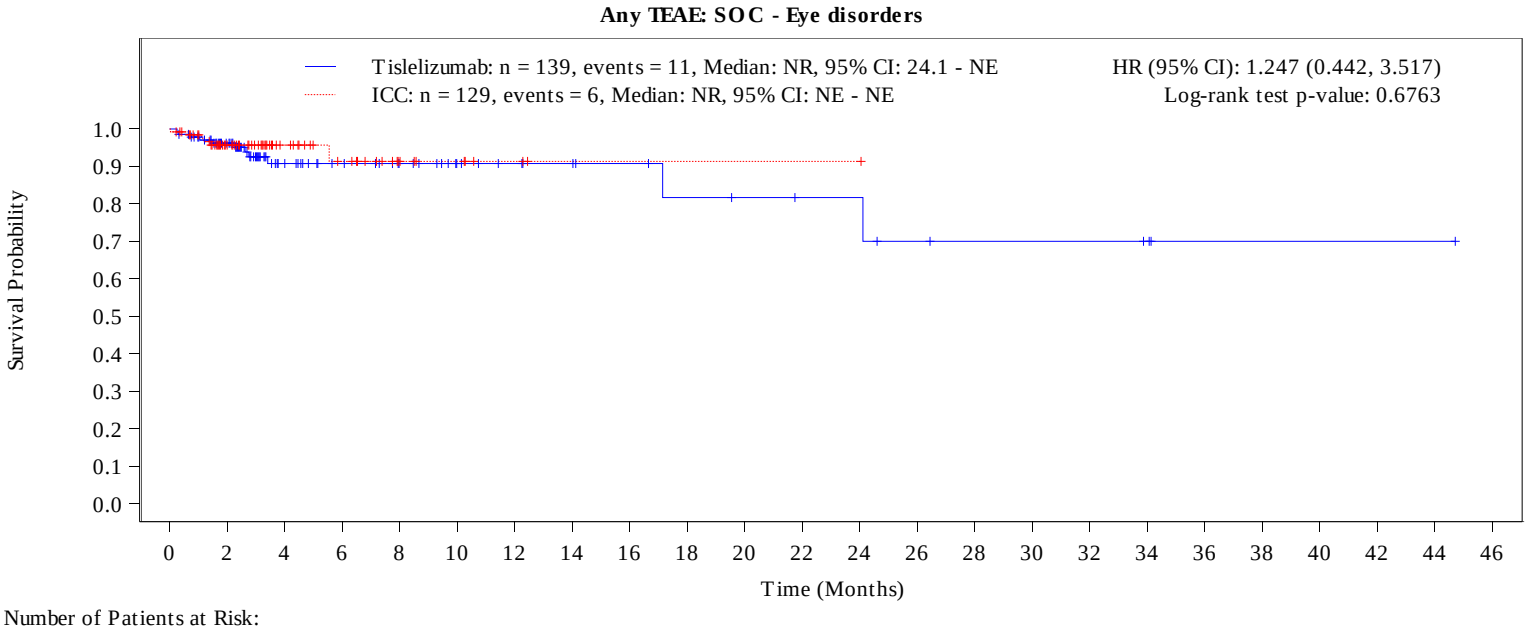


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	93	46	31	26	19	14	12	10	8	5	5	5	4	4	3	3	3	3	3	3	2	2	1	1	0
ICC	129	75	33	19	9	6	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

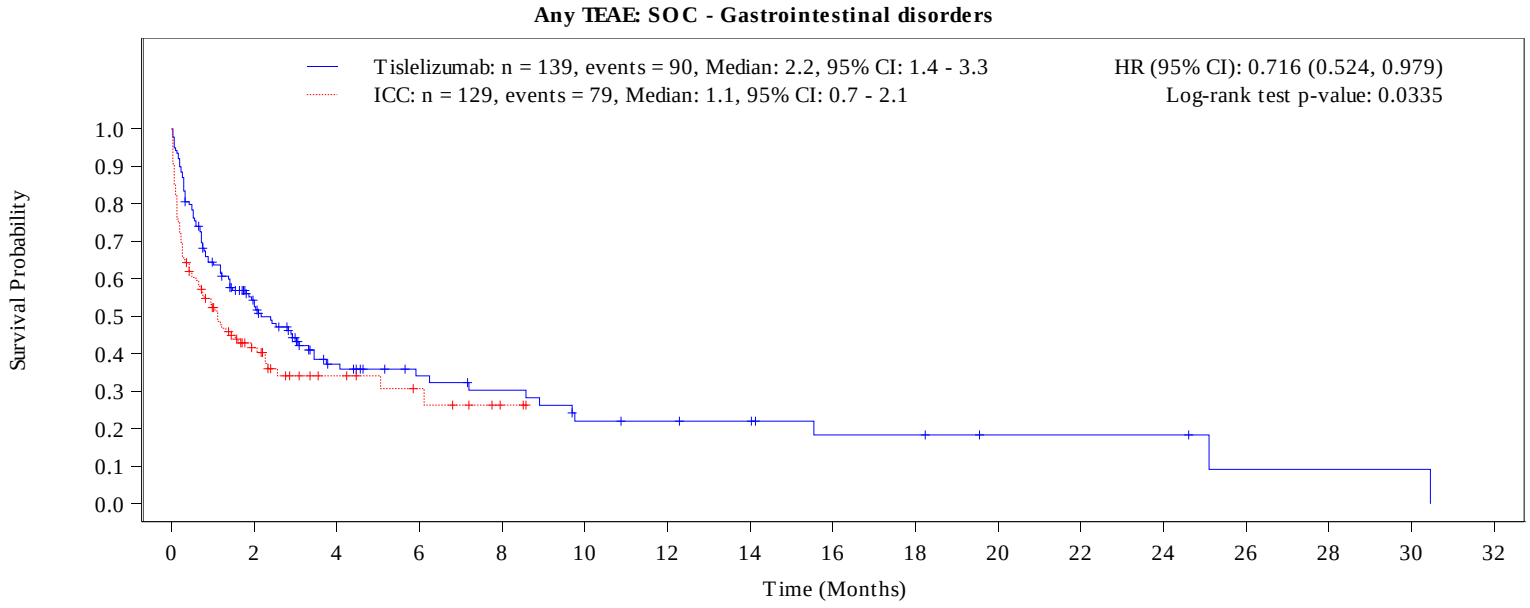


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46
Tislelizumab	139	92	47	35	27	19	16	14	11	9	8	7	7	5	4	4	4	3	1	1	1	1	1	0
ICC	129	73	31	18	9	6	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

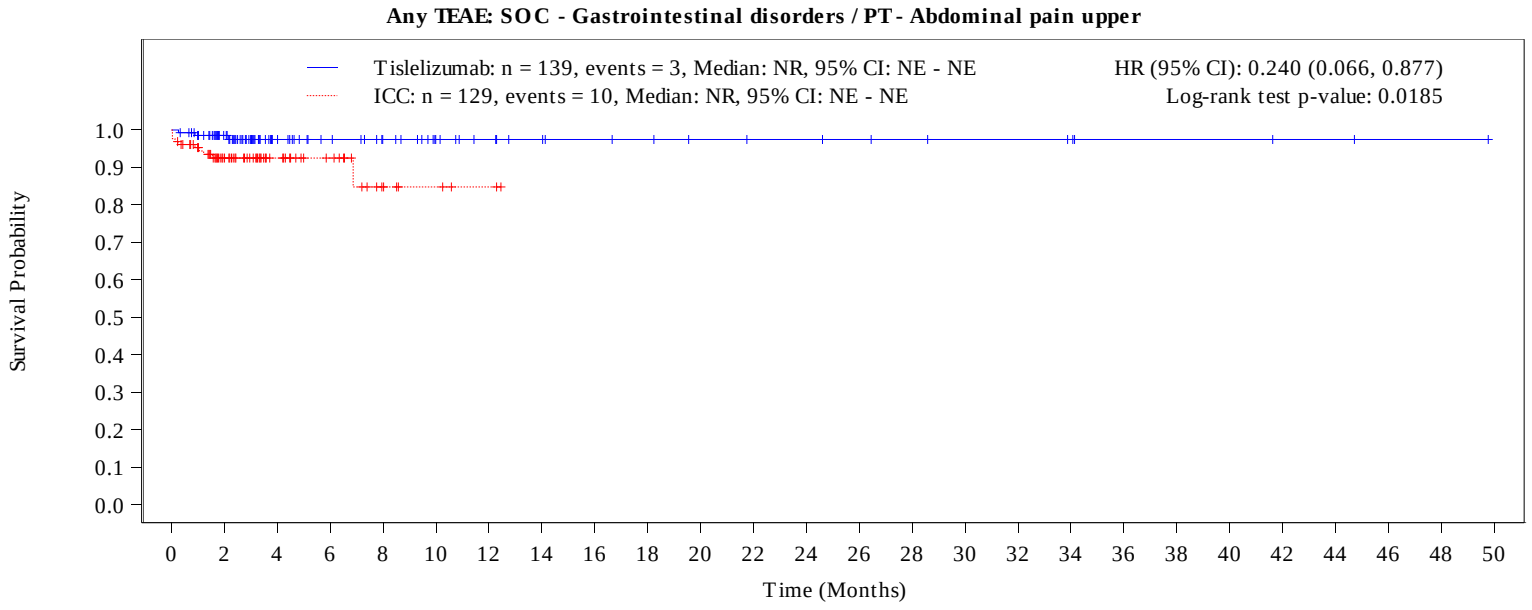


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	139	62	28	19	15	10	9	8	5	5	3	3	3	1	1	1	0
ICC	129	32	13	7	2	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

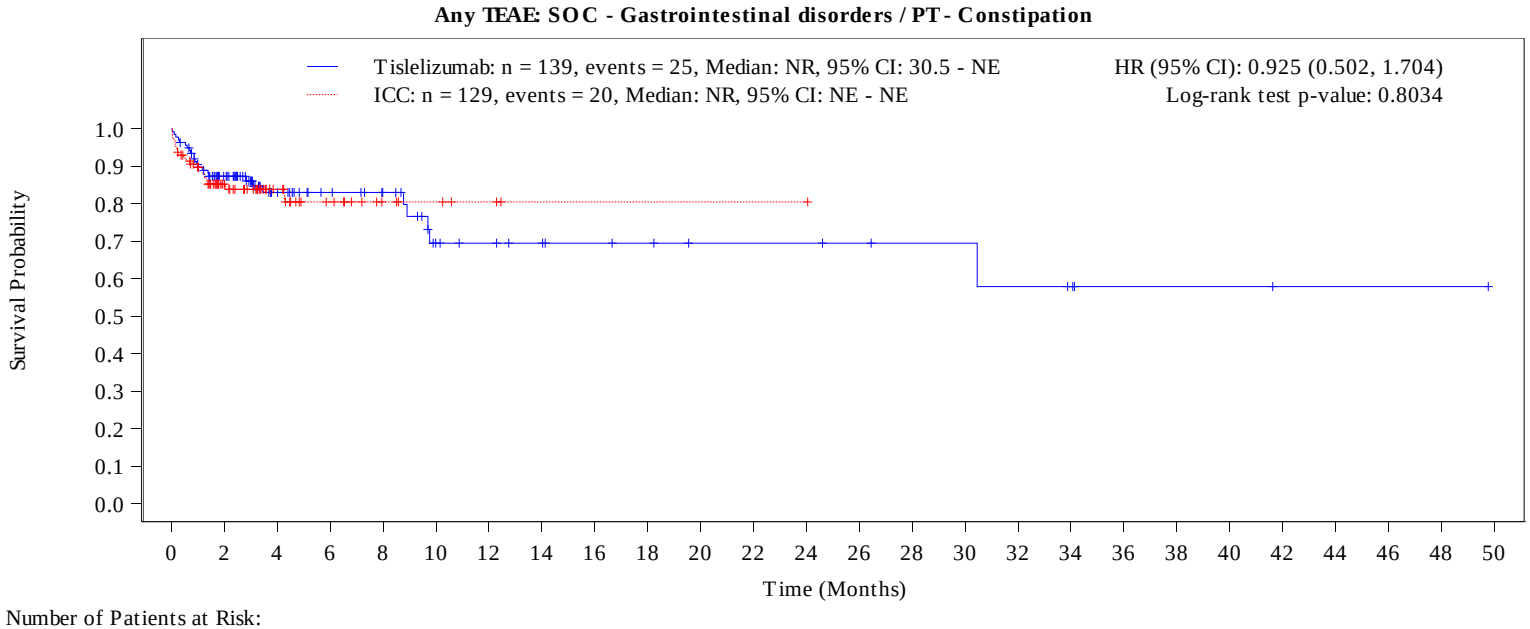


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	94	52	40	32	23	19	16	13	12	10	9	9	8	7	6	6	5	3	3	3	2	2	1	1	0
ICC	129	68	30	17	7	4	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	86	47	35	28	17	15	13	11	10	8	8	8	7	6	6	5	4	2	2	2	1	1	1	1	0
ICC	129	63	27	14	7	5	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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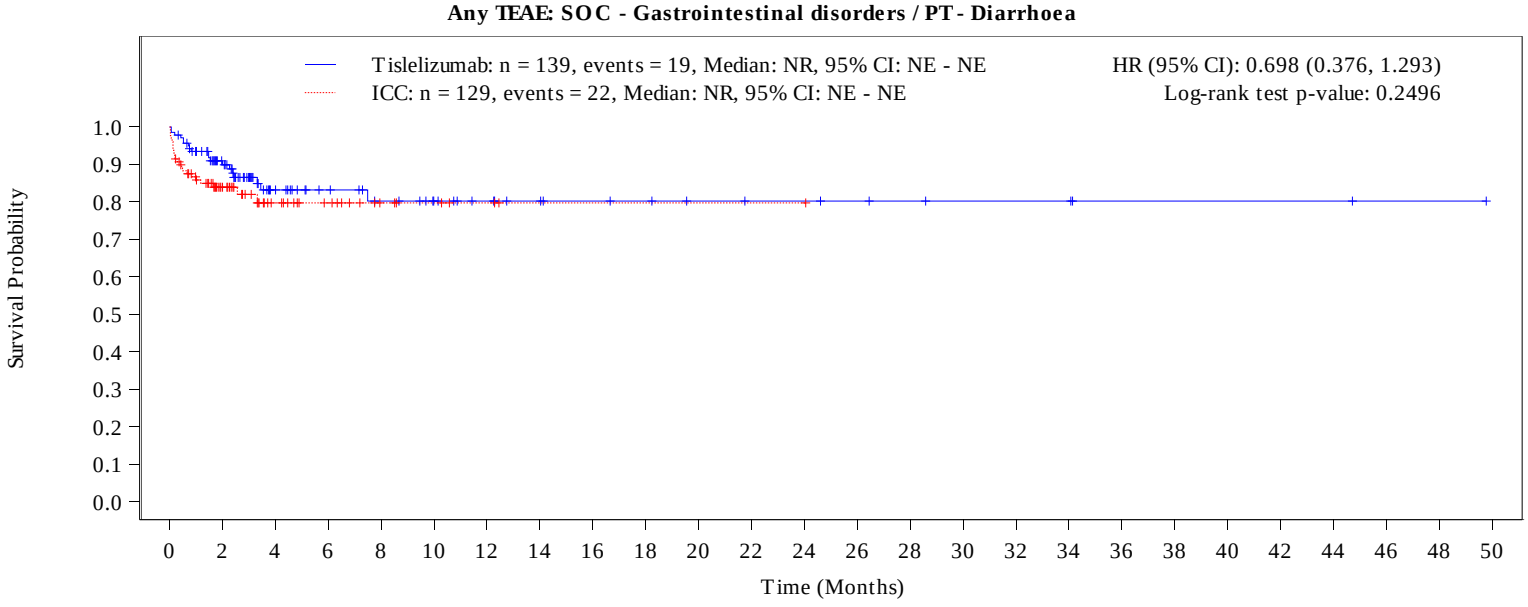
Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

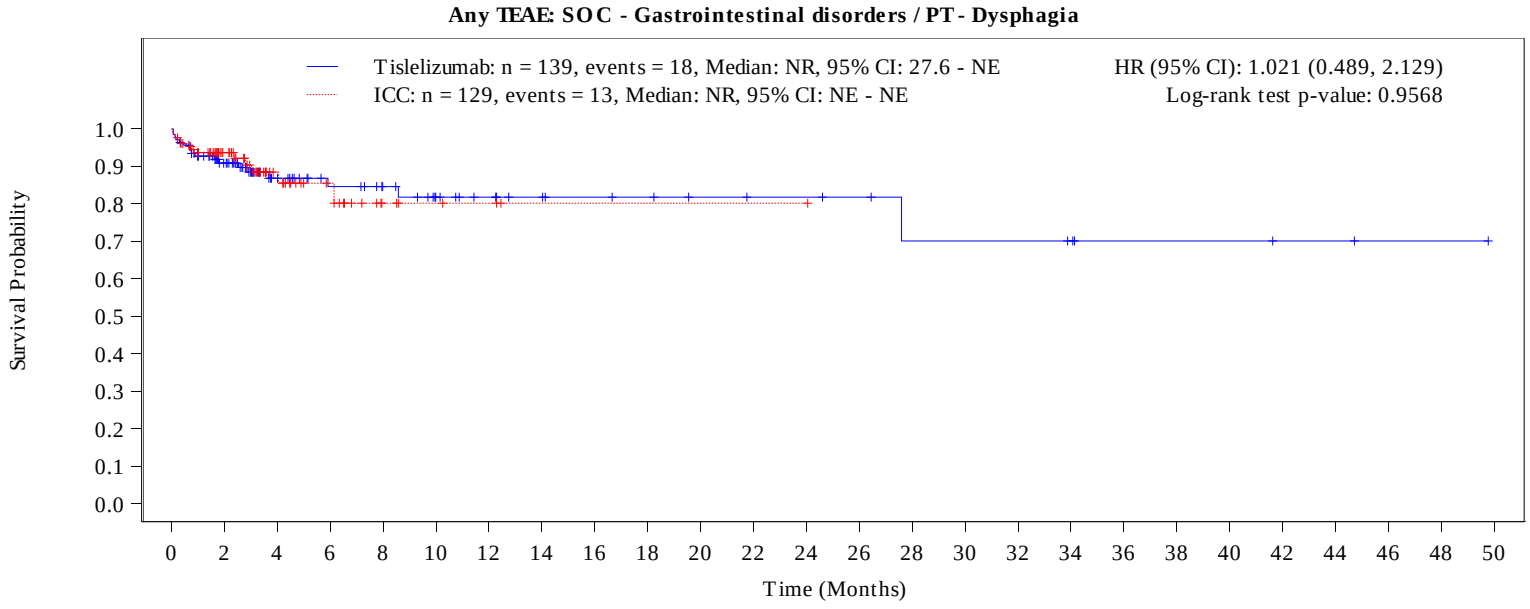


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	86	44	32	26	21	17	14	11	10	8	7	7	6	5	4	4	4	2	2	2	2	2	1	1	0
ICC	129	61	24	14	7	5	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	90	51	38	31	23	19	16	13	12	10	9	9	8	6	6	6	5	3	3	3	2	2	1	1	0
ICC	129	70	30	16	6	4	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

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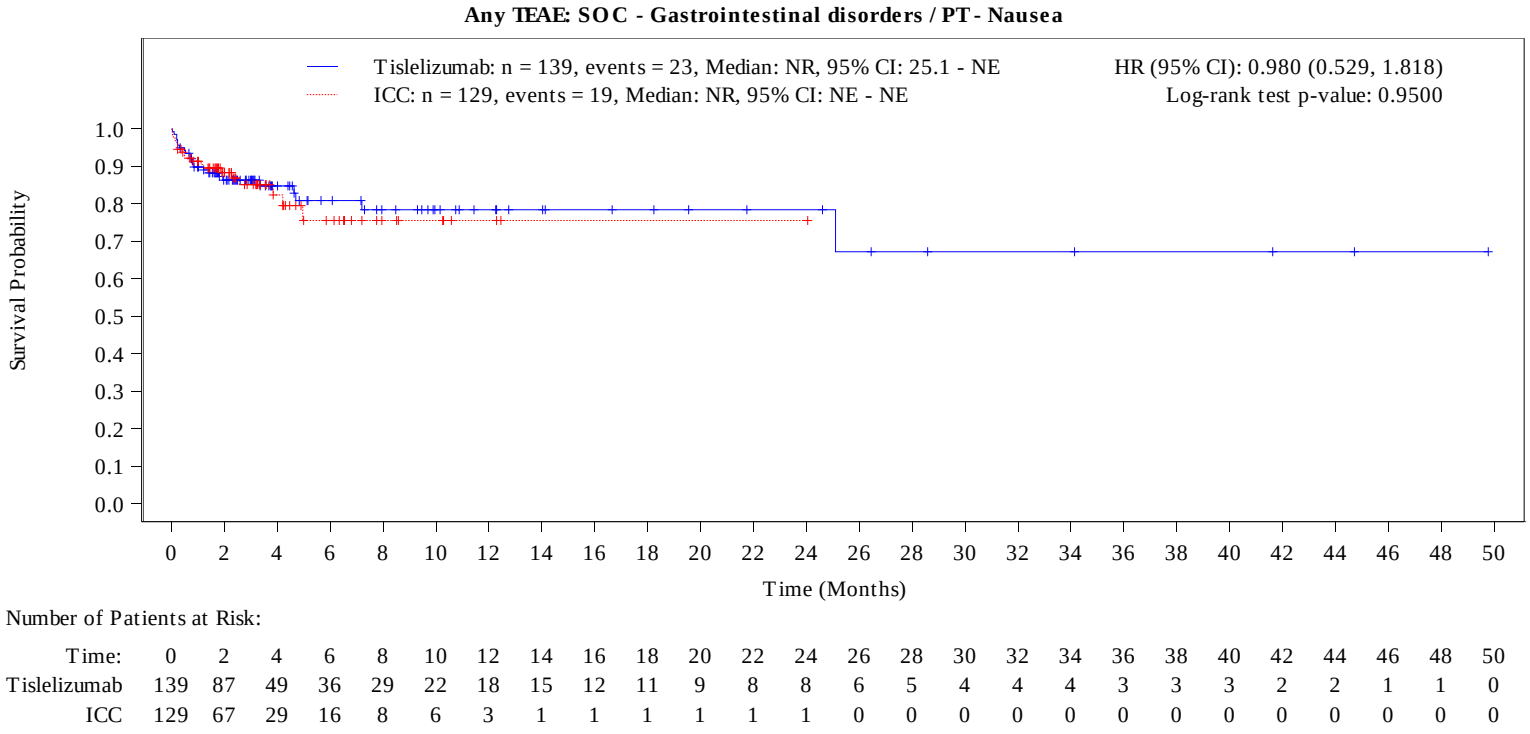
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	87	49	36	29	22	18	15	12	11	9	8	8	6	5	4	4	4	3	3	3	2	2	1	1	0
ICC	129	67	29	16	8	6	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

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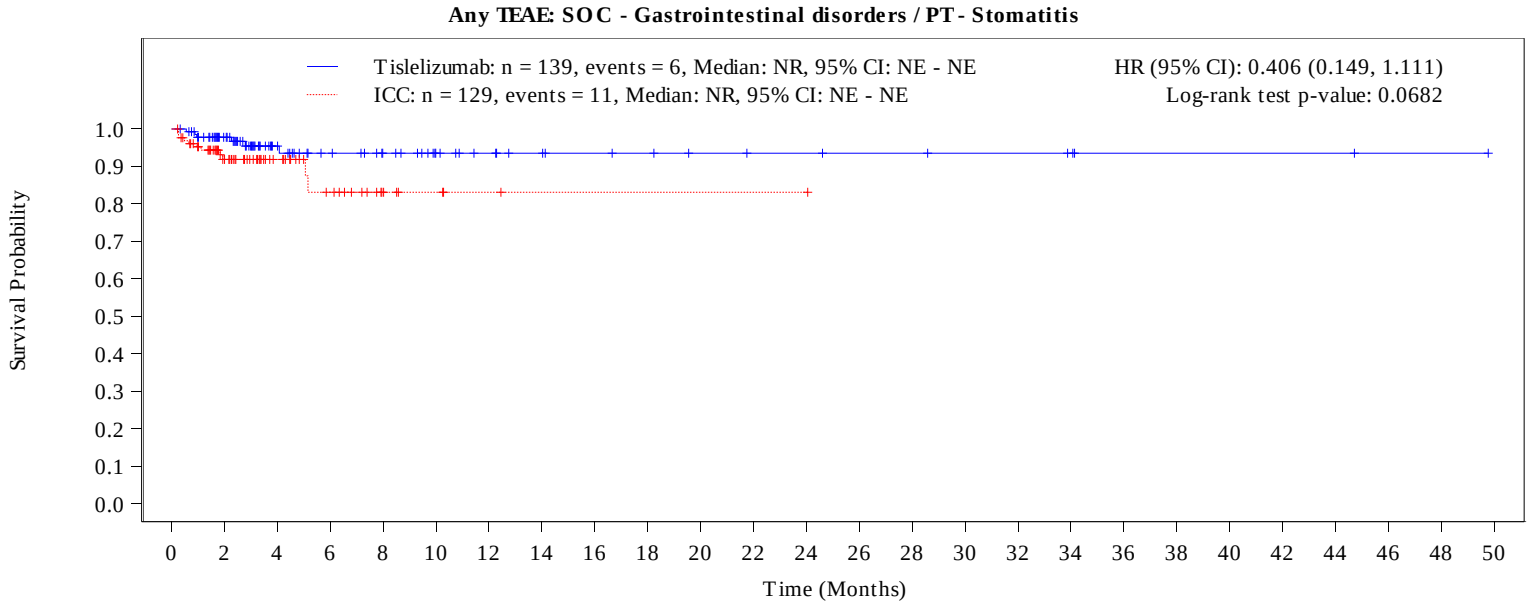
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	93	51	38	30	21	17	14	11	10	8	7	7	6	6	5	5	4	2	2	2	2	2	1	1	0
ICC	129	70	31	16	7	4	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

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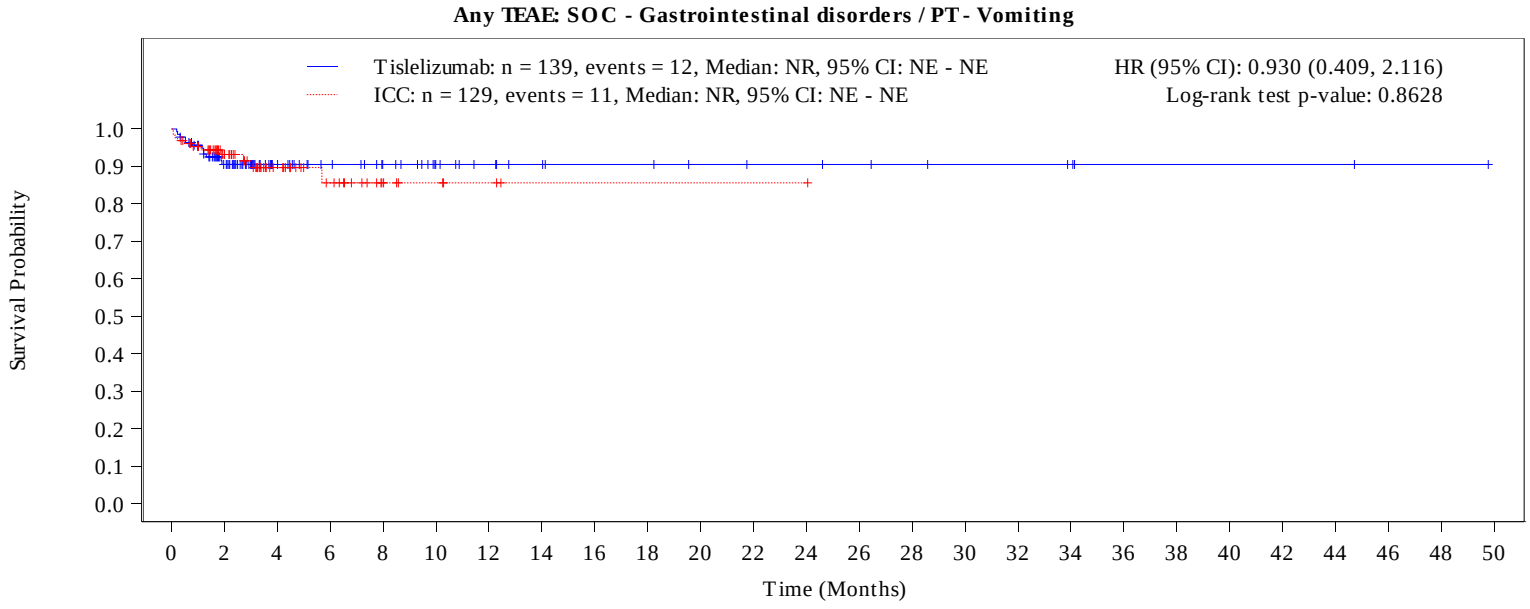
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

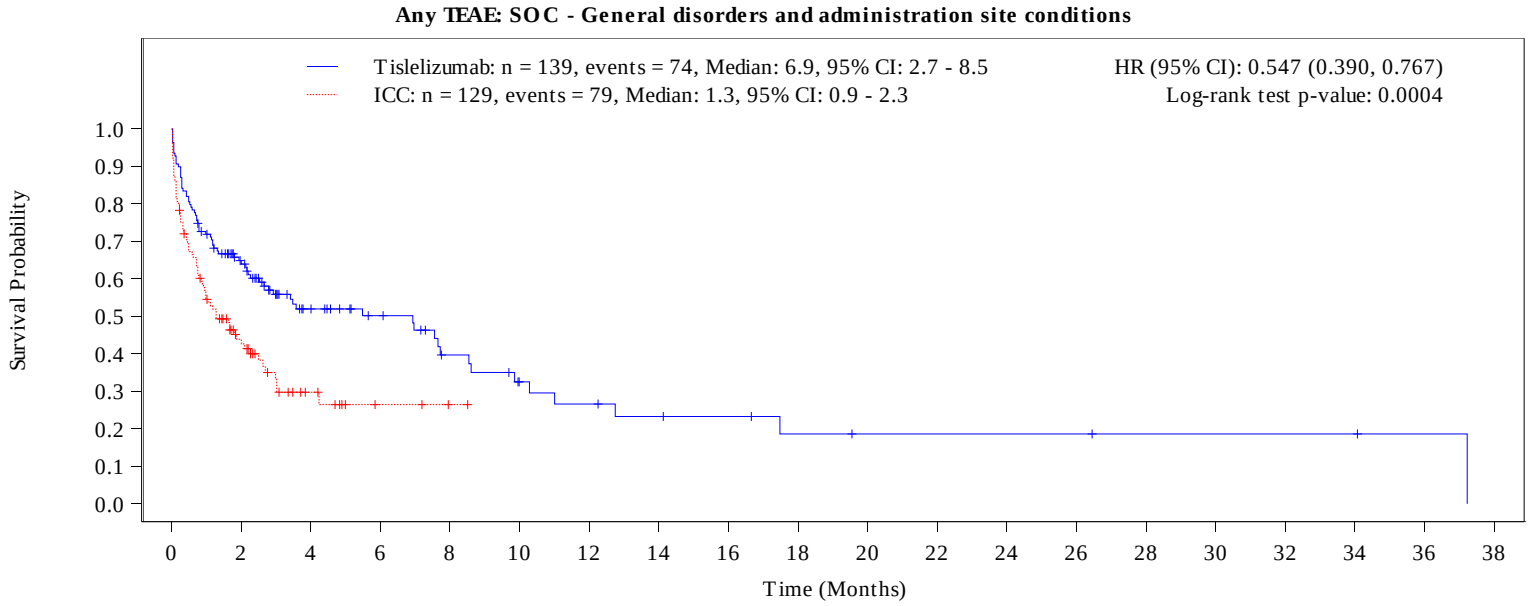


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	89	49	37	30	21	17	14	11	11	9	8	8	7	6	5	5	4	2	2	2	2	2	1	1	0
ICC	129	72	32	18	8	5	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38
Tislelizumab	139	70	37	27	17	11	9	7	6	4	3	3	3	3	2	2	2	2	1	0
ICC	129	35	10	3	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
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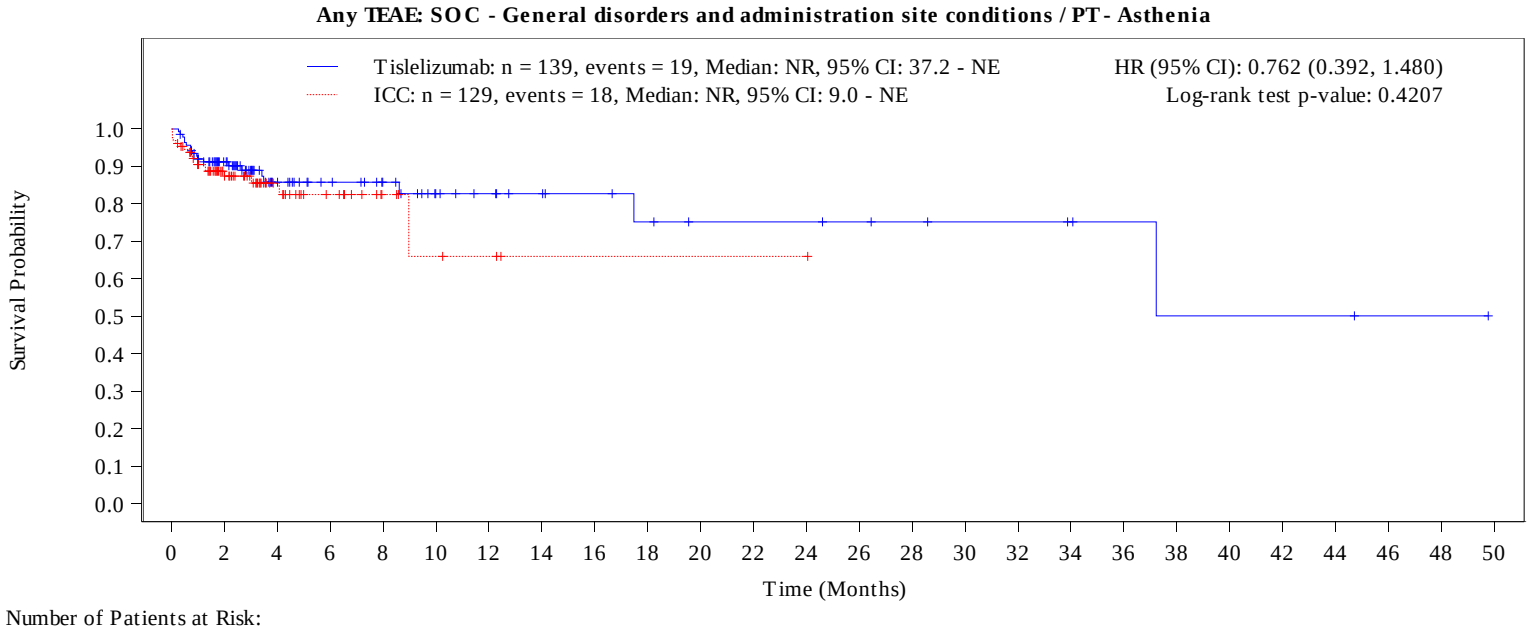
Safety Analysis Set - Subpopulation without Irinotecan

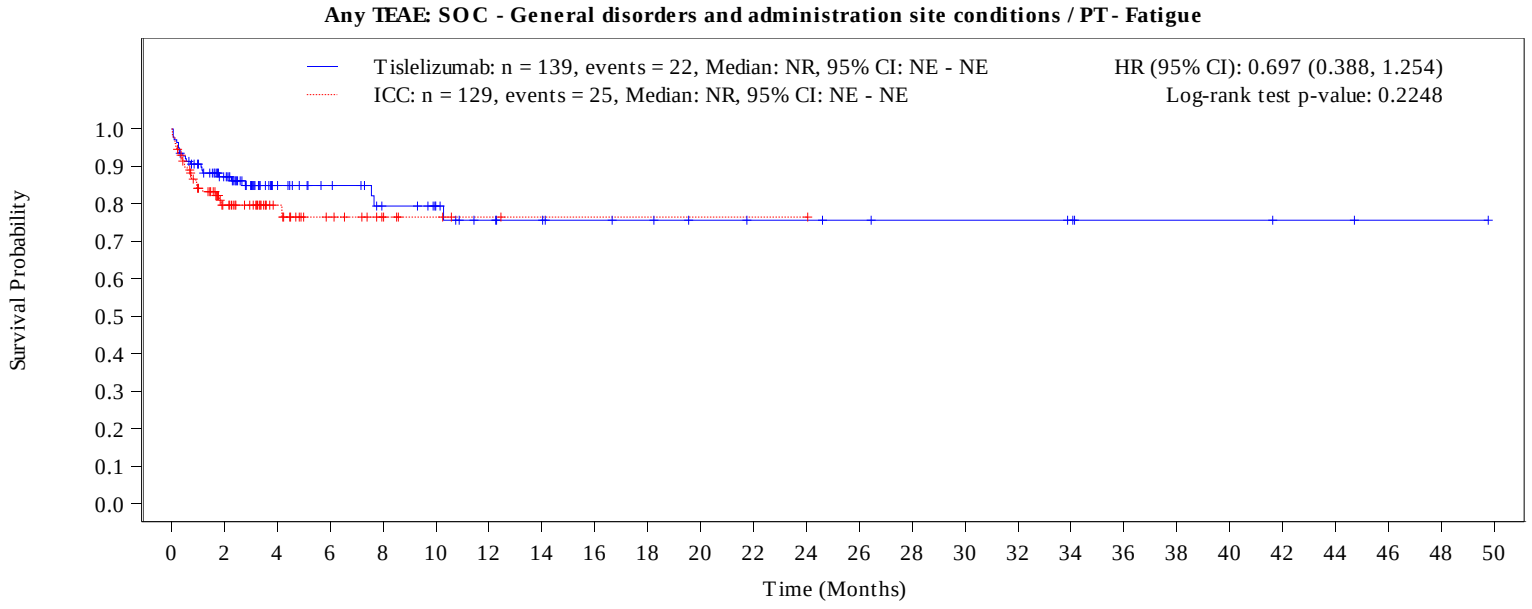


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	90	49	37	29	21	18	15	12	10	8	8	8	7	6	5	5	4	3	2	2	2	2	1	1	0
ICC	129	68	28	15	7	4	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

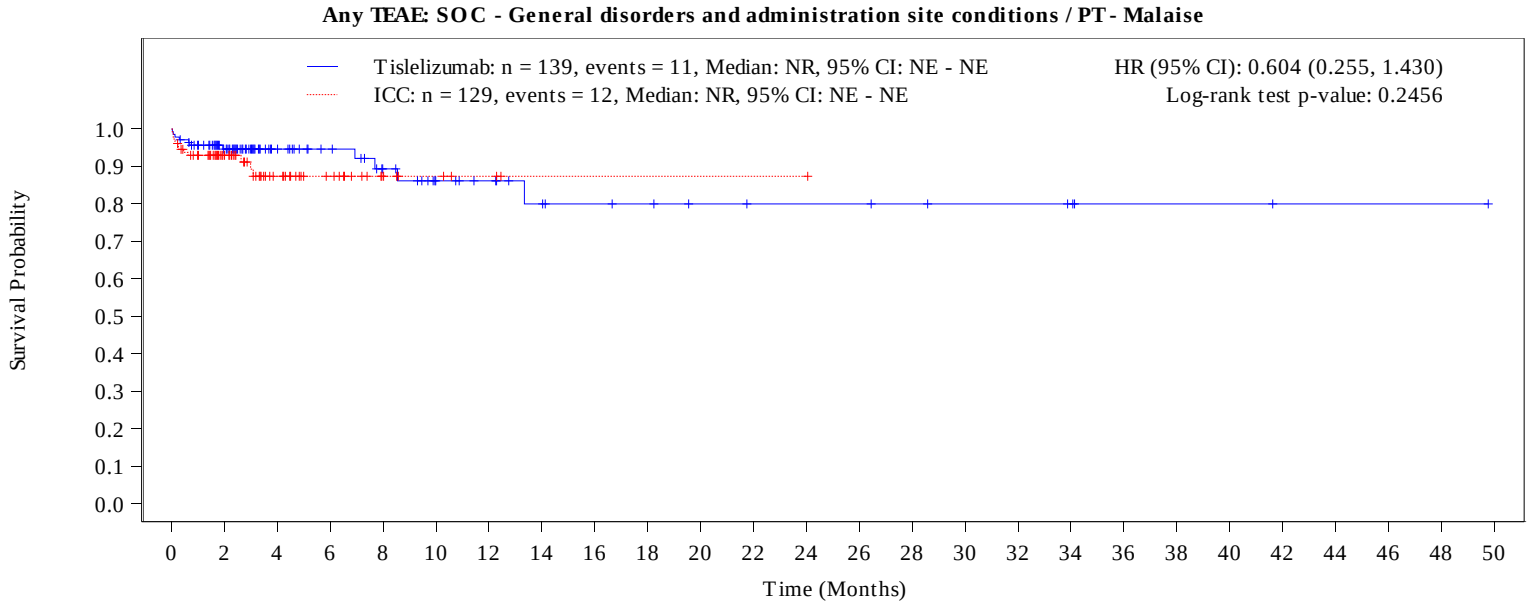


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	85	45	36	27	22	17	15	12	11	9	8	8	7	6	6	6	5	3	3	3	2	2	1	1	0
ICC	129	58	25	13	7	4	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

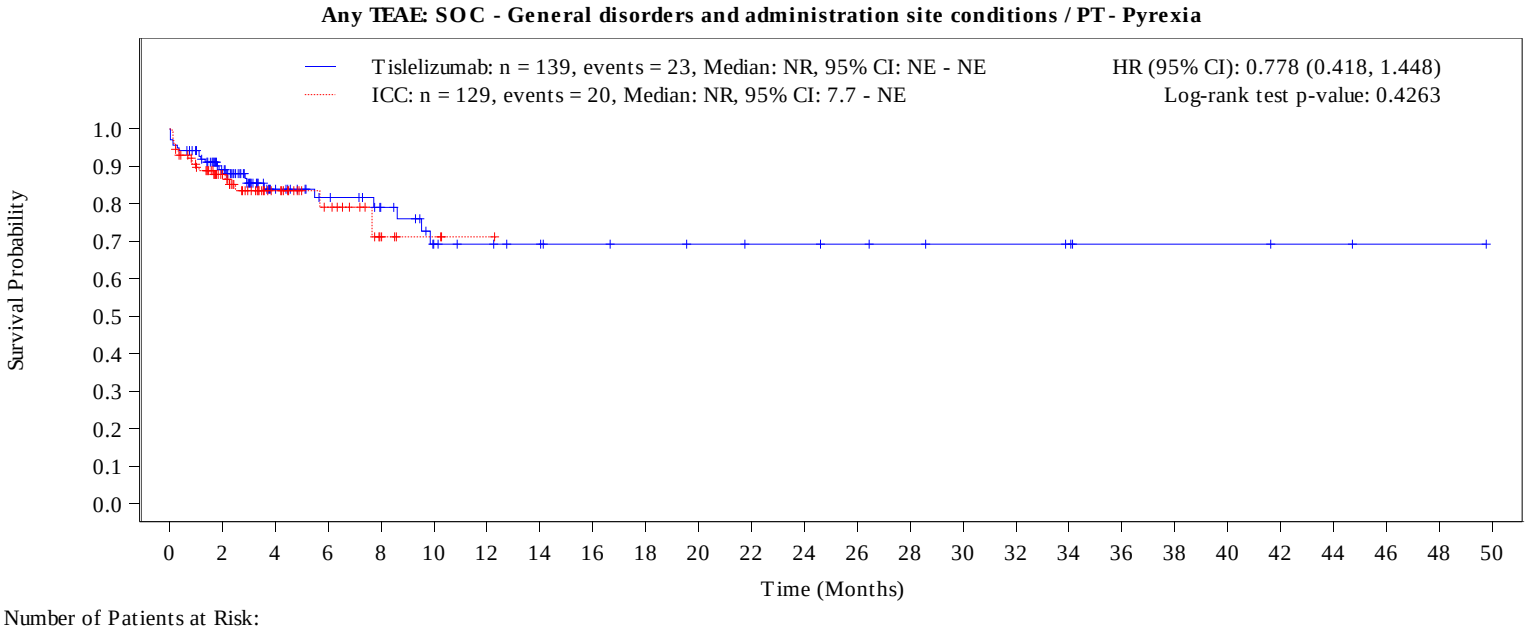


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	91	51	39	29	20	17	13	11	10	8	7	7	7	6	5	5	4	2	2	2	1	1	1	1	0
ICC	129	70	30	17	8	5	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

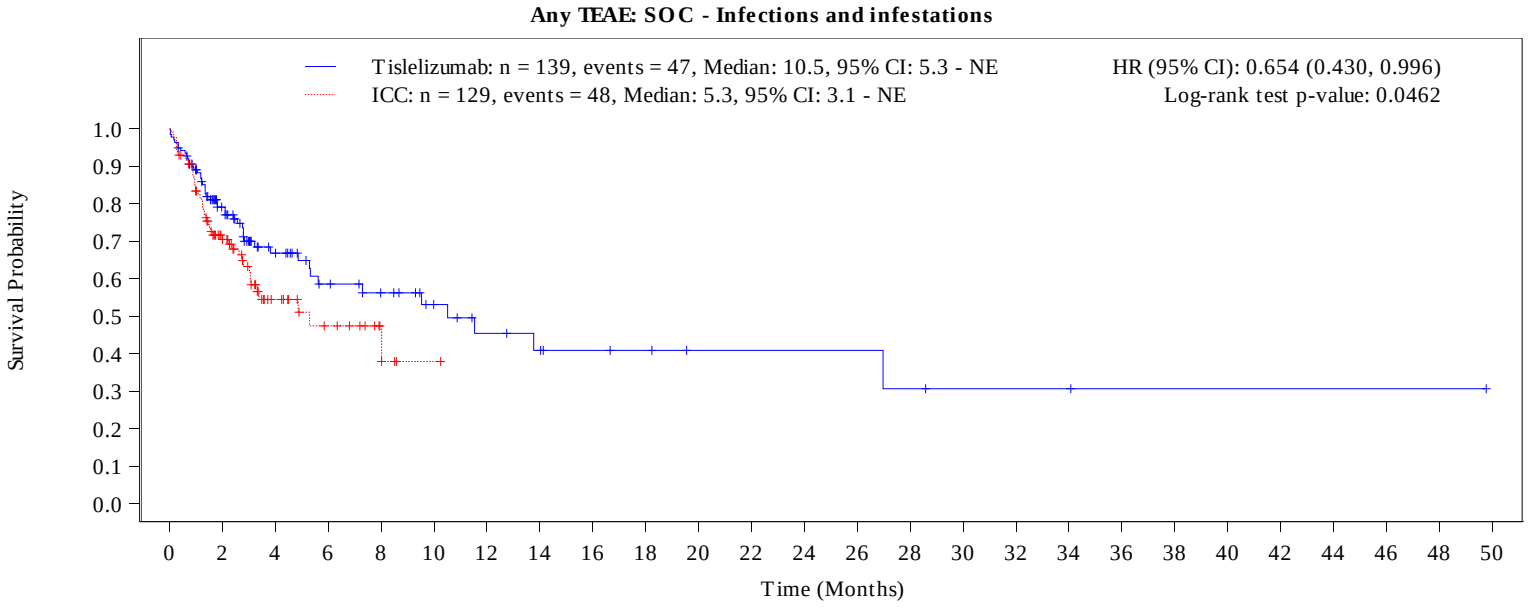


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	87	48	36	27	18	16	14	12	11	10	9	9	8	7	6	6	5	3	3	3	2	2	1	1	0
ICC	129	69	29	16	6	3	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

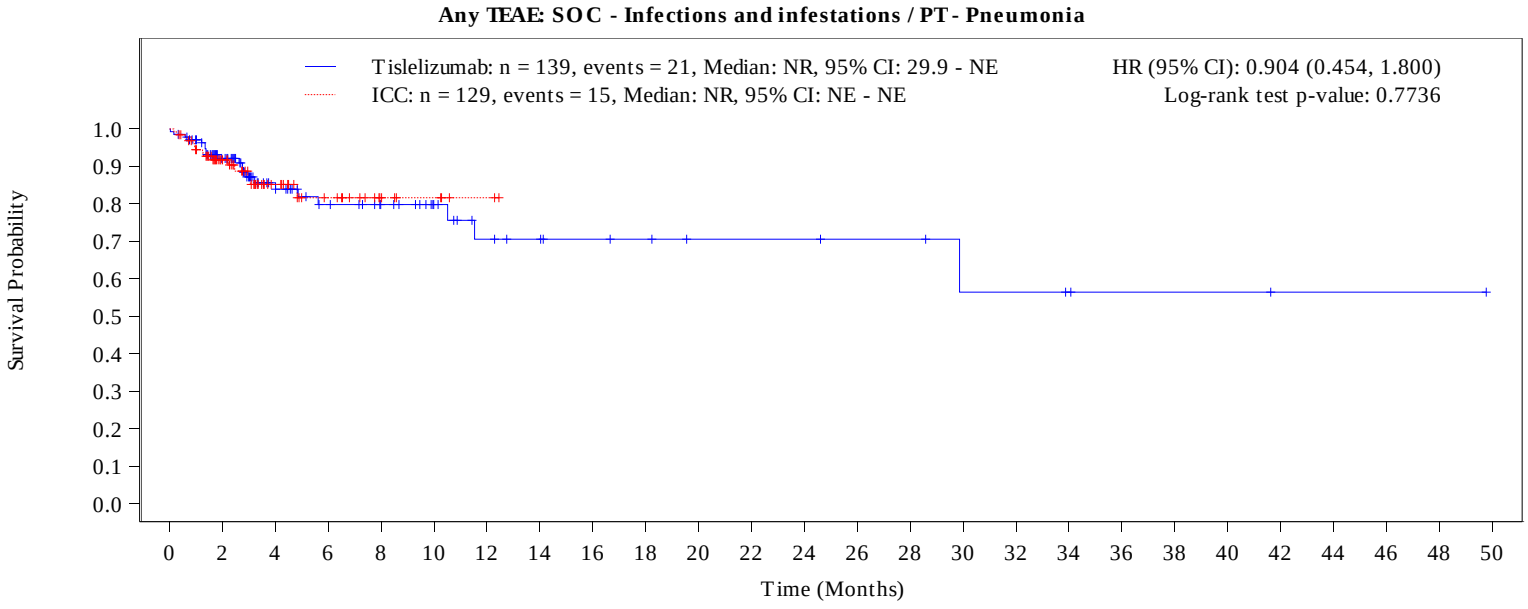


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	77	41	27	22	15	11	9	7	6	4	4	4	4	3	2	2	2	1	1	1	1	1	1	1	0
ICC	129	61	21	12	5	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

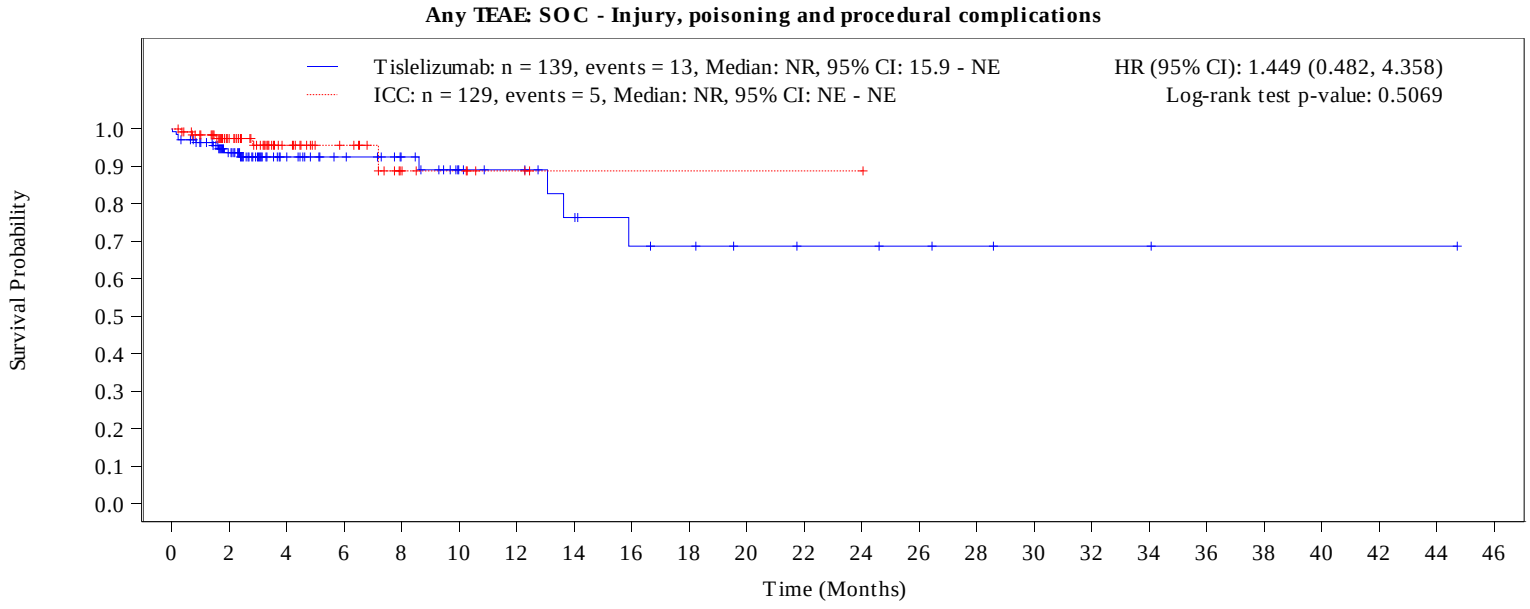


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	89	50	37	29	20	14	12	10	9	7	7	7	6	6	4	4	3	2	2	2	1	1	1	1	0
ICC	129	73	32	17	8	5	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

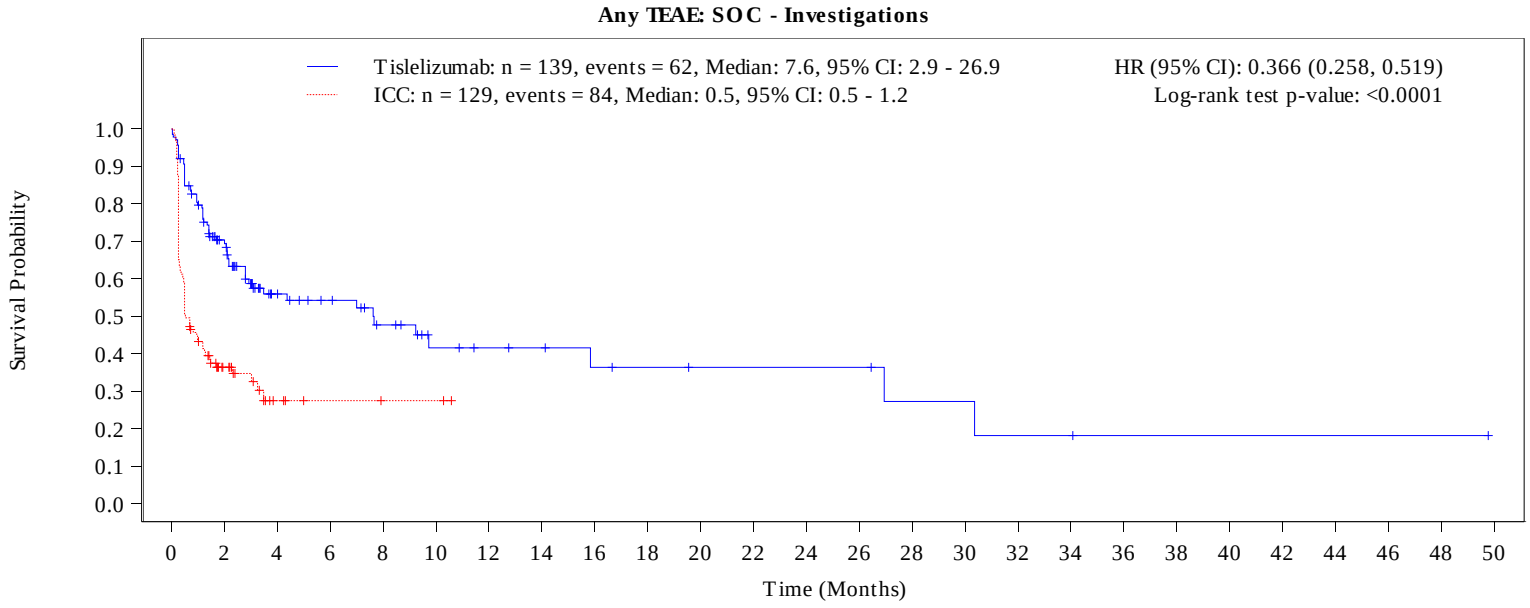


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46
Tislelizumab	139	89	48	36	28	18	16	12	9	8	6	5	5	4	3	2	2	2	1	1	1	1	1	0
ICC	129	73	32	18	8	6	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

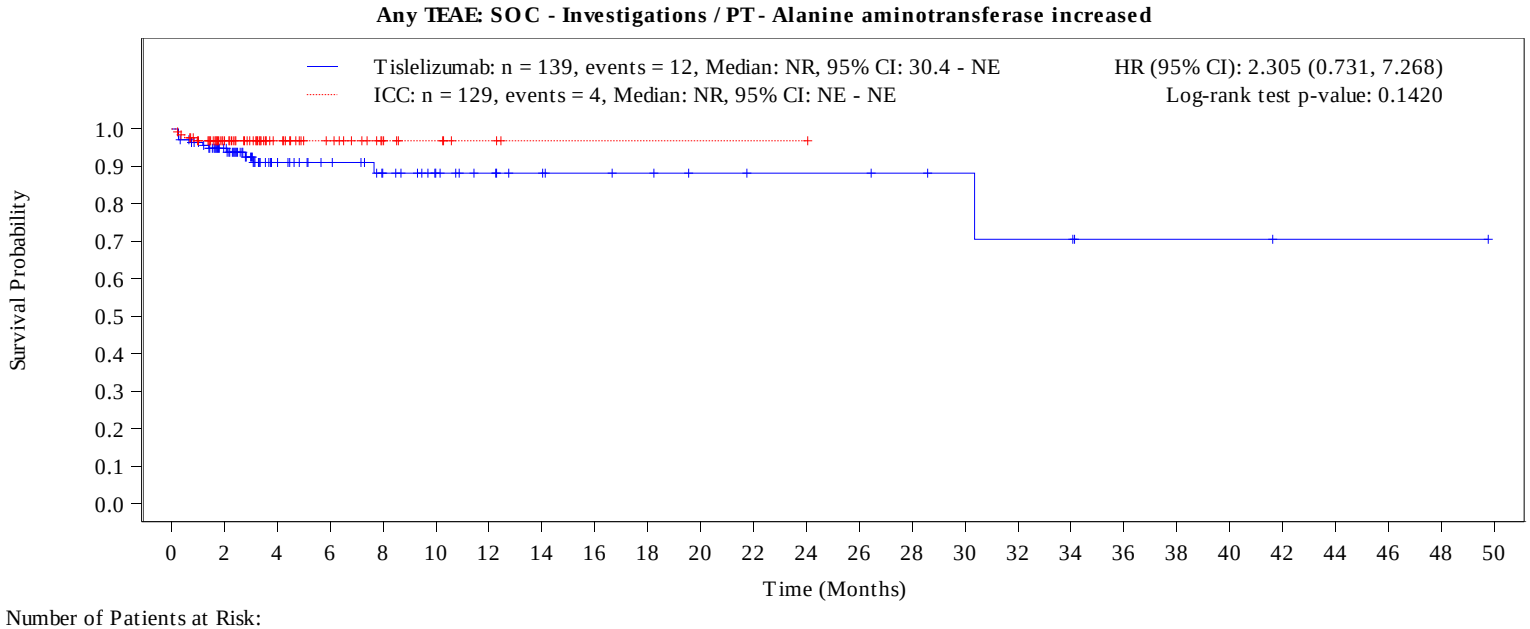


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	71	34	28	20	12	10	9	7	6	5	5	5	5	3	3	2	2	1	1	1	1	1	1	1	0
ICC	129	25	6	3	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	91	48	37	28	20	16	13	11	10	8	7	7	7	6	5	4	4	2	2	2	1	1	1	1	0
ICC	129	74	32	18	9	6	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
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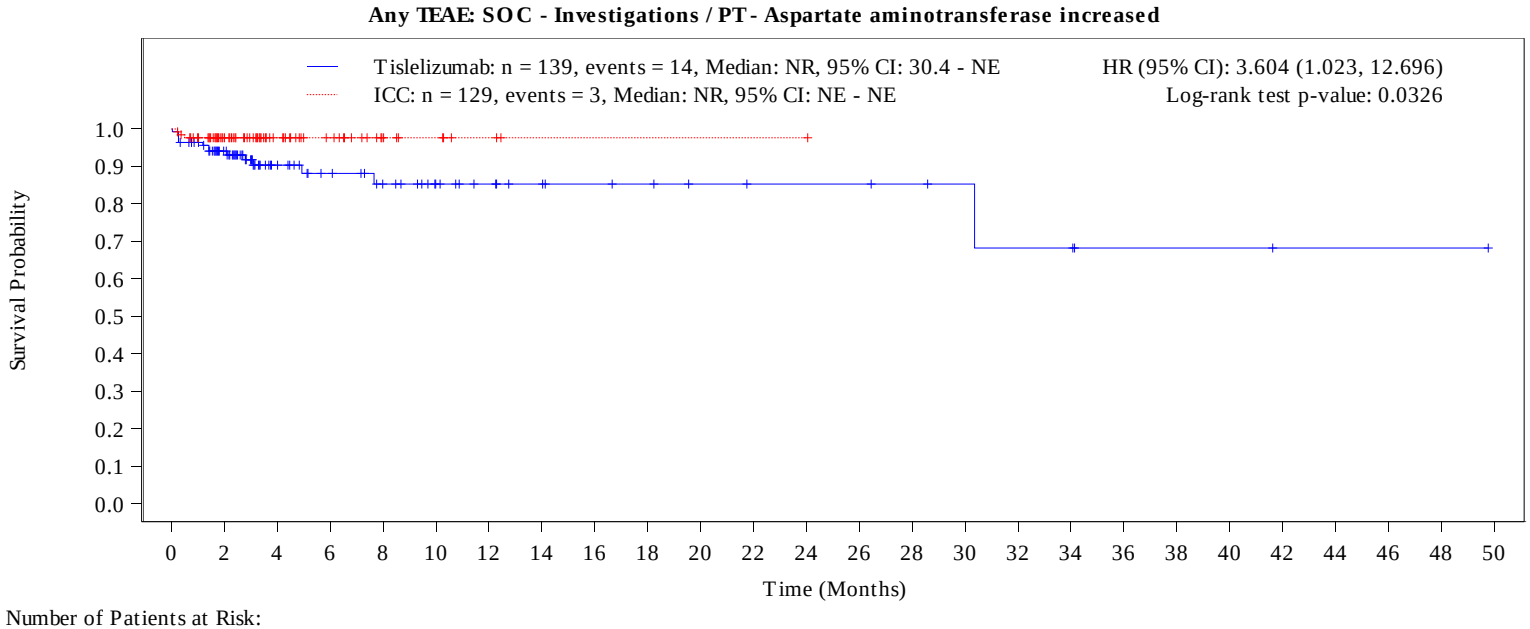
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	92	48	36	28	20	16	13	11	10	8	7	7	7	6	5	4	4	2	2	2	1	1	1	1	0
ICC	129	75	33	19	9	6	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
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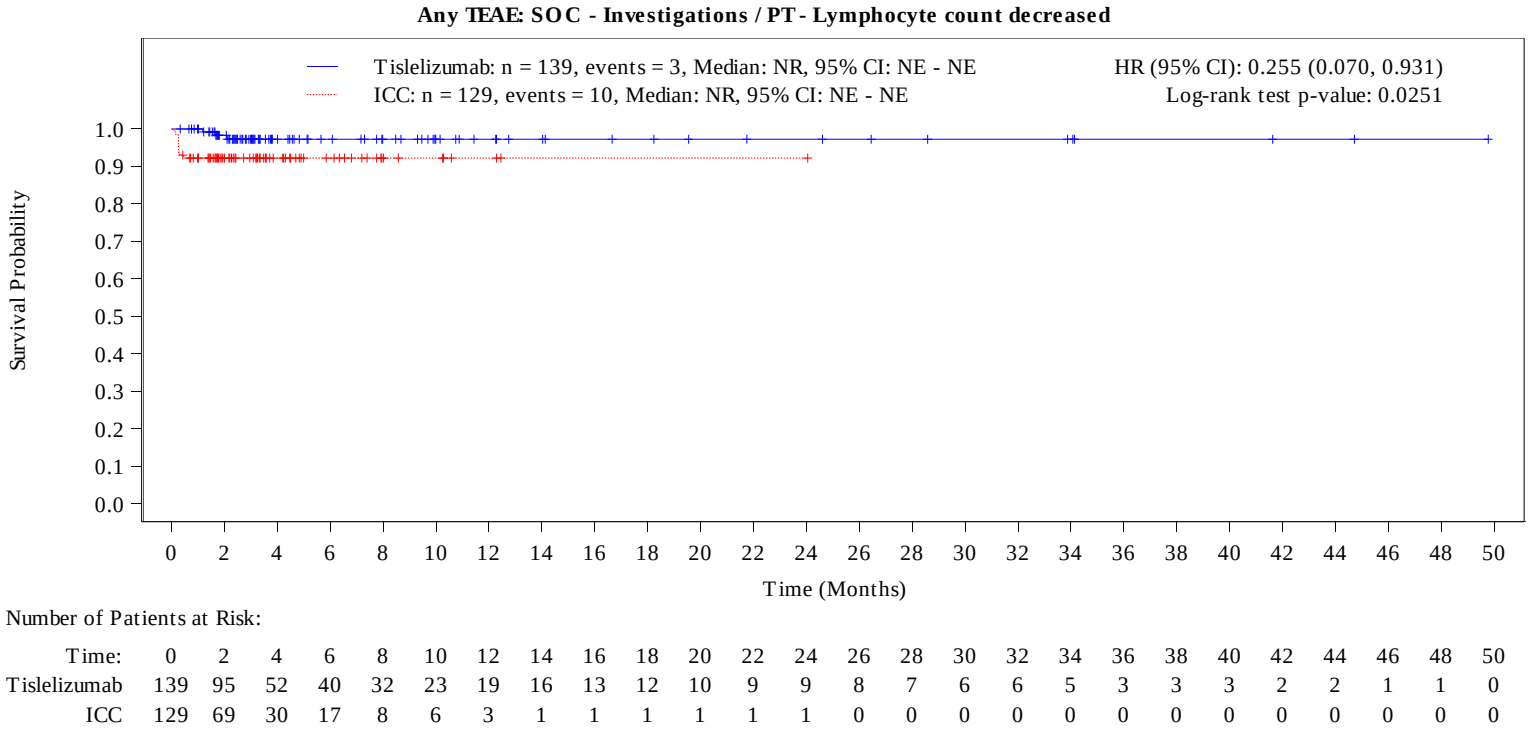
Safety Analysis Set - Subpopulation without Irinotecan

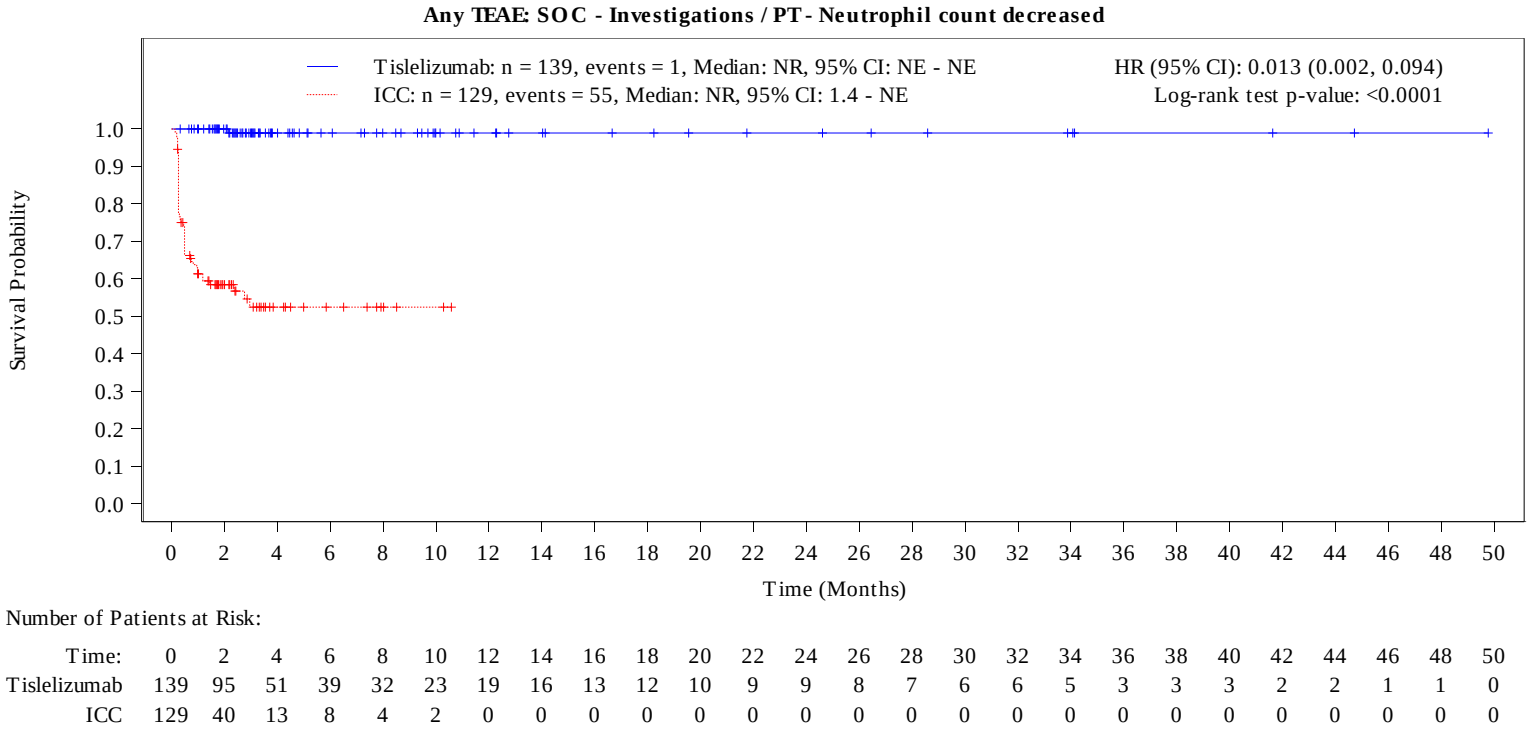


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	95	52	40	32	23	19	16	13	12	10	9	9	8	7	6	6	5	3	3	3	2	2	1	1	0
ICC	129	69	30	17	8	6	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	95	51	39	32	23	19	16	13	12	10	9	9	8	7	6	6	5	3	3	3	2	2	1	1	0
ICC	129	40	13	8	4	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

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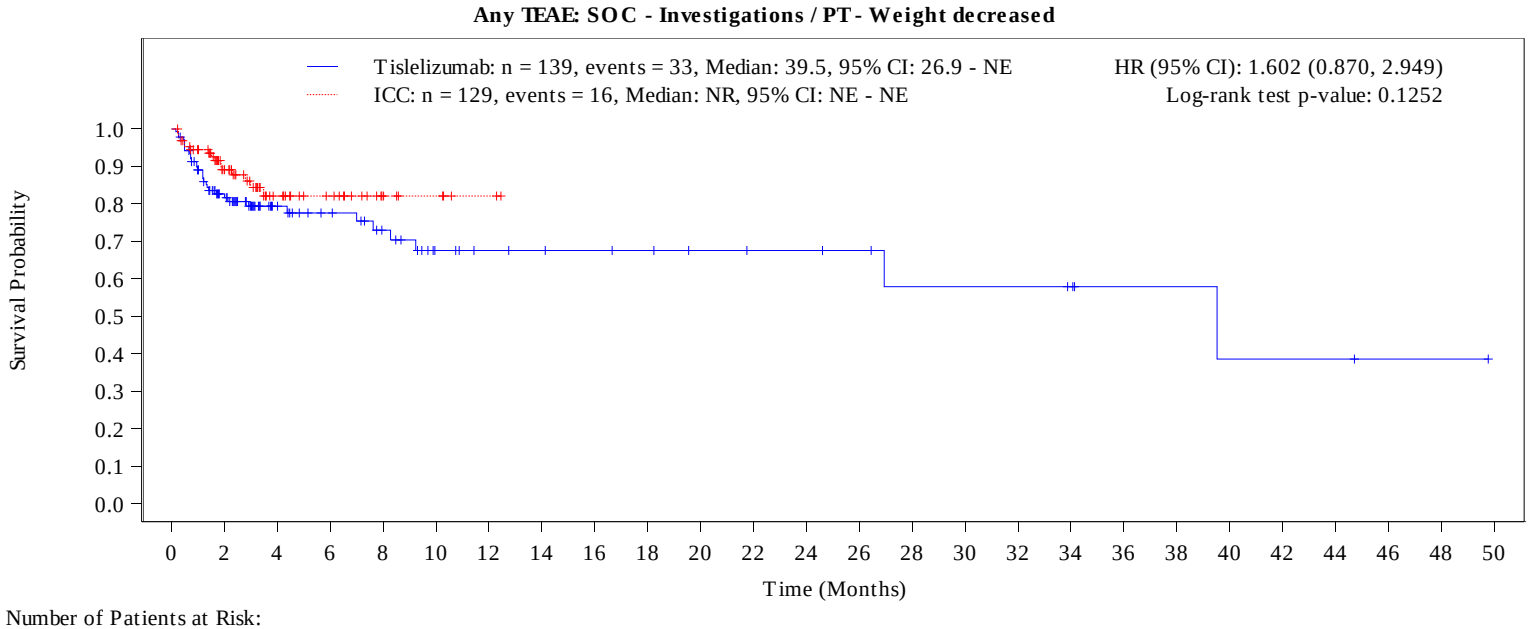
Safety Analysis Set - Subpopulation without Irinotecan

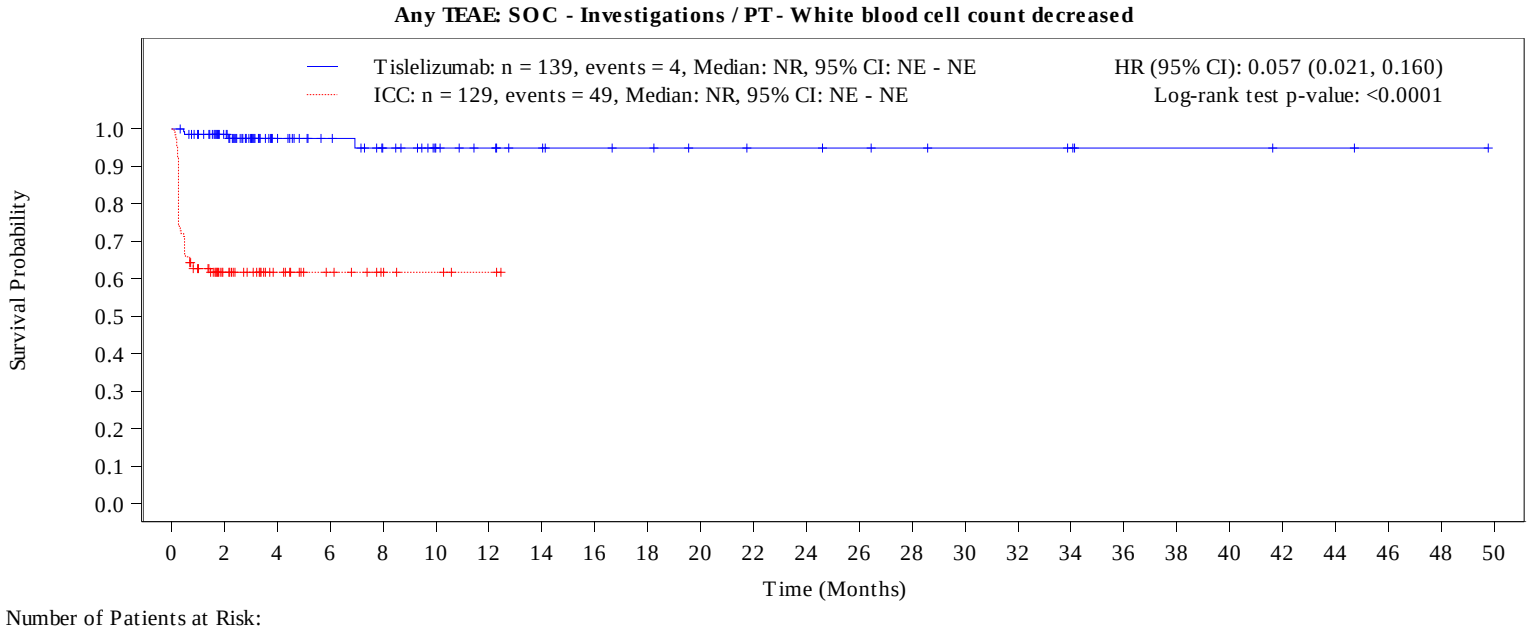


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	82	45	37	28	18	15	14	13	12	10	9	9	8	6	6	6	5	3	3	2	2	2	1	1	0
ICC	129	71	30	18	8	5	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

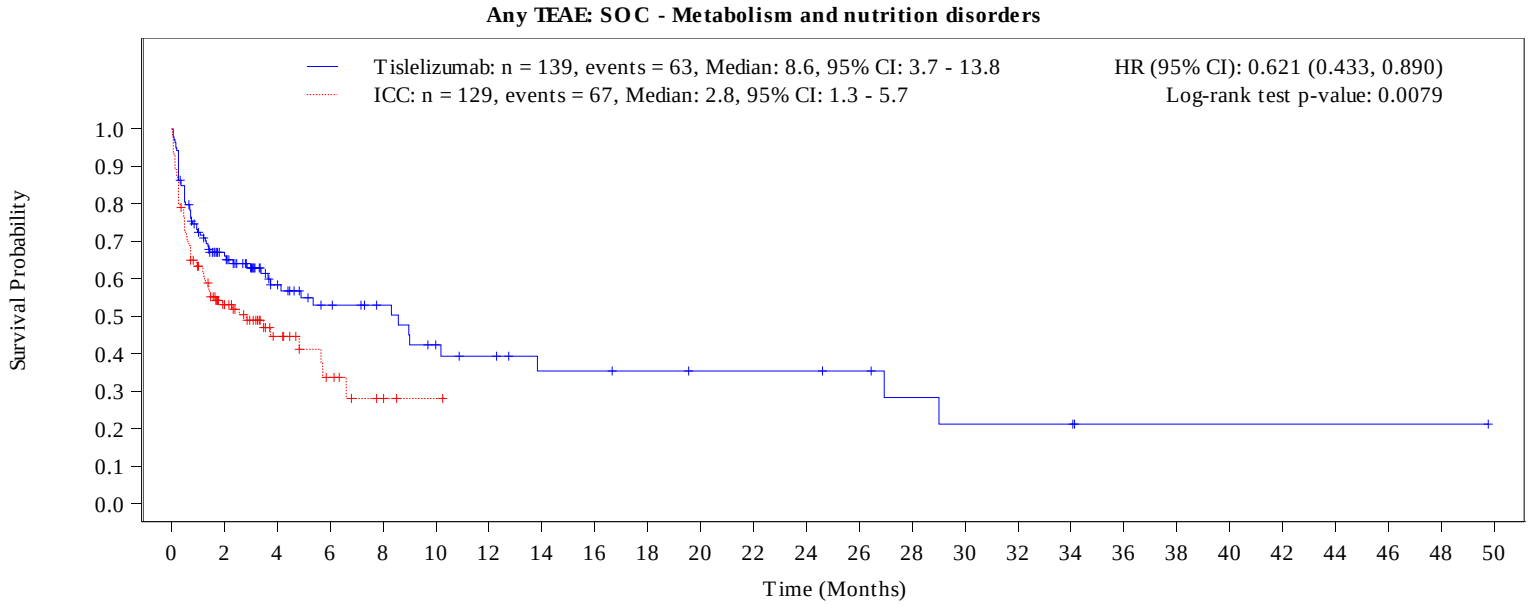


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	94	51	39	30	21	18	15	13	12	10	9	9	8	7	6	6	5	3	3	3	2	2	1	1	0
ICC	129	45	19	11	6	4	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	68	37	26	20	14	12	9	9	8	7	7	7	6	4	3	3	3	1	1	1	1	1	1	1	0
ICC	129	46	18	8	3	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

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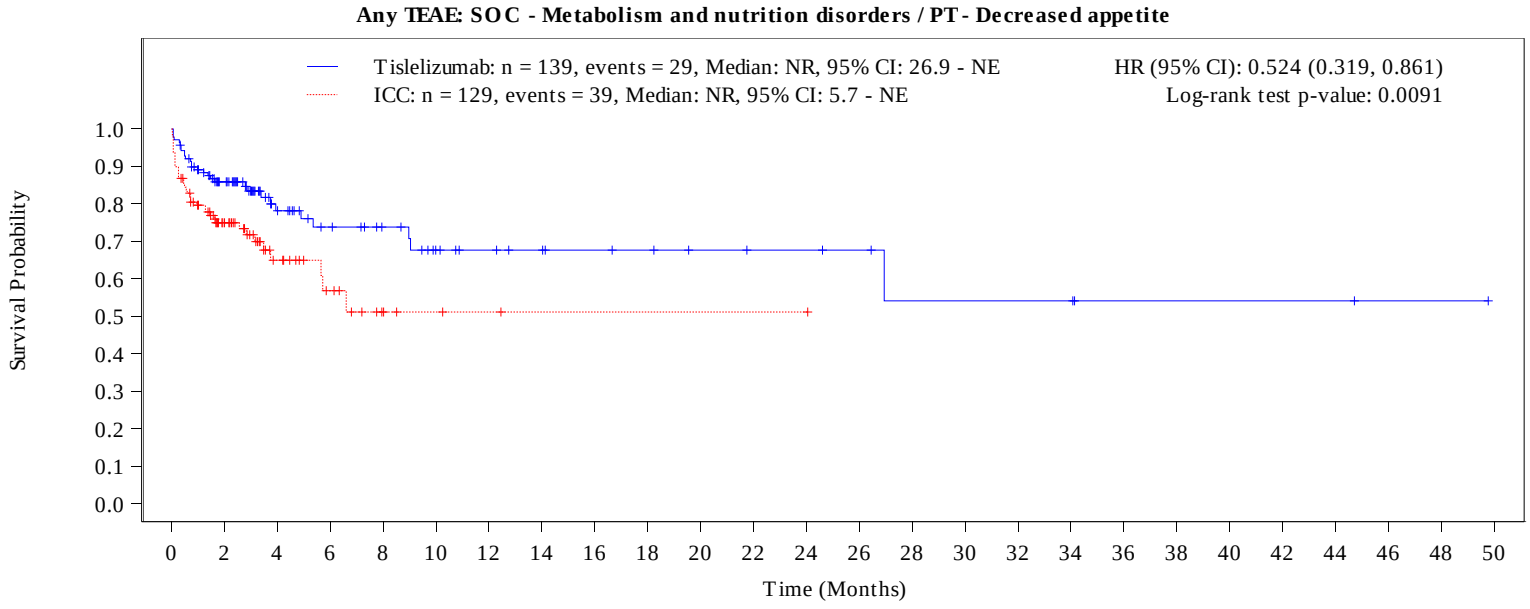
Safety Analysis Set - Subpopulation without Irinotecan

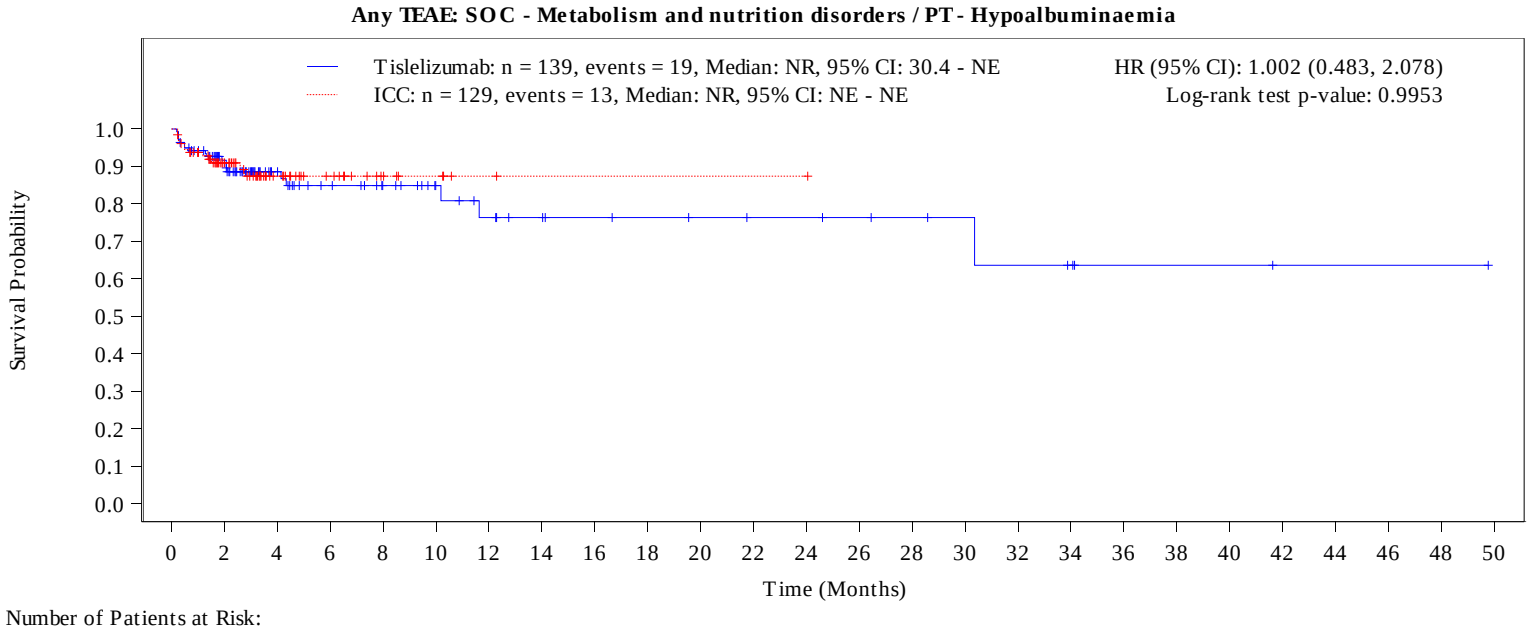


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	84	43	32	25	18	15	13	11	10	8	7	7	6	4	4	4	4	2	2	2	2	2	1	1	0
ICC	129	61	23	12	5	3	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	90	49	37	29	21	17	14	12	11	10	9	9	8	7	6	5	4	2	2	2	1	1	1	1	0
ICC	129	68	30	16	8	5	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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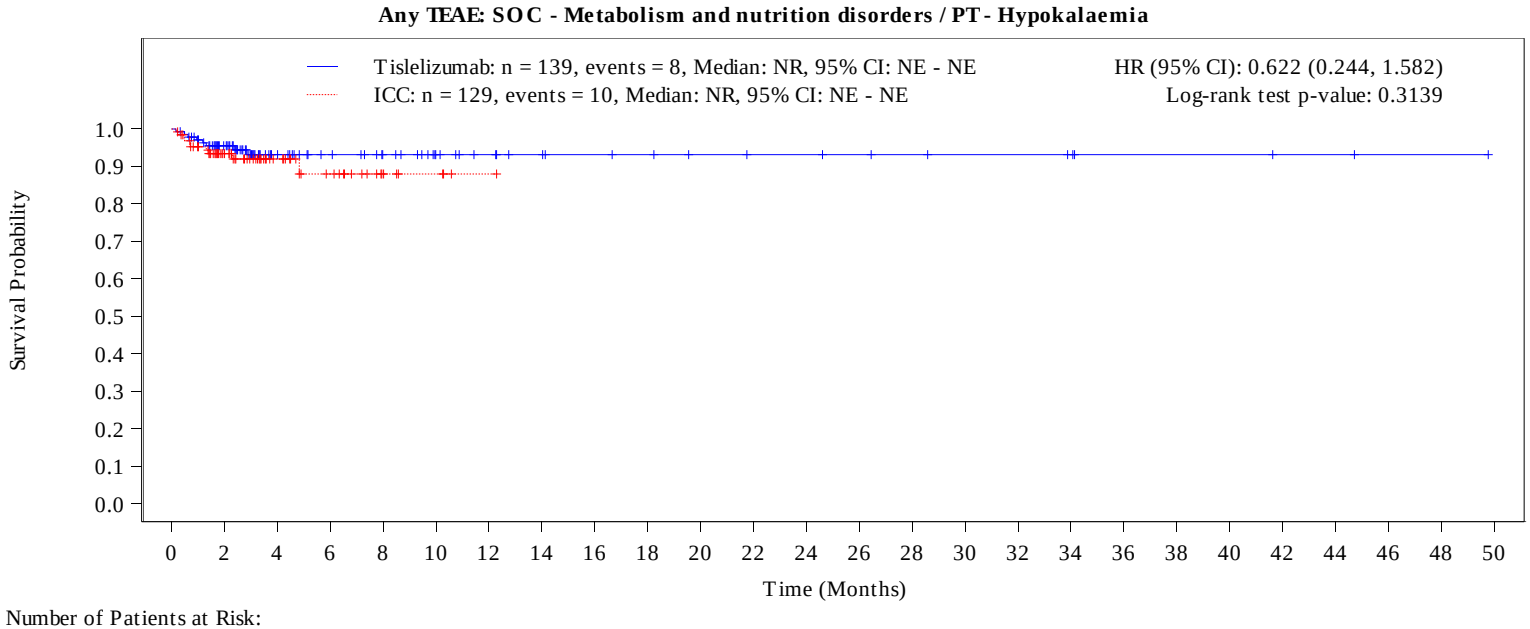
Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	93	52	40	32	23	19	16	13	12	10	9	9	8	7	6	6	5	3	3	3	2	2	1	1	0
ICC	129	72	31	17	7	4	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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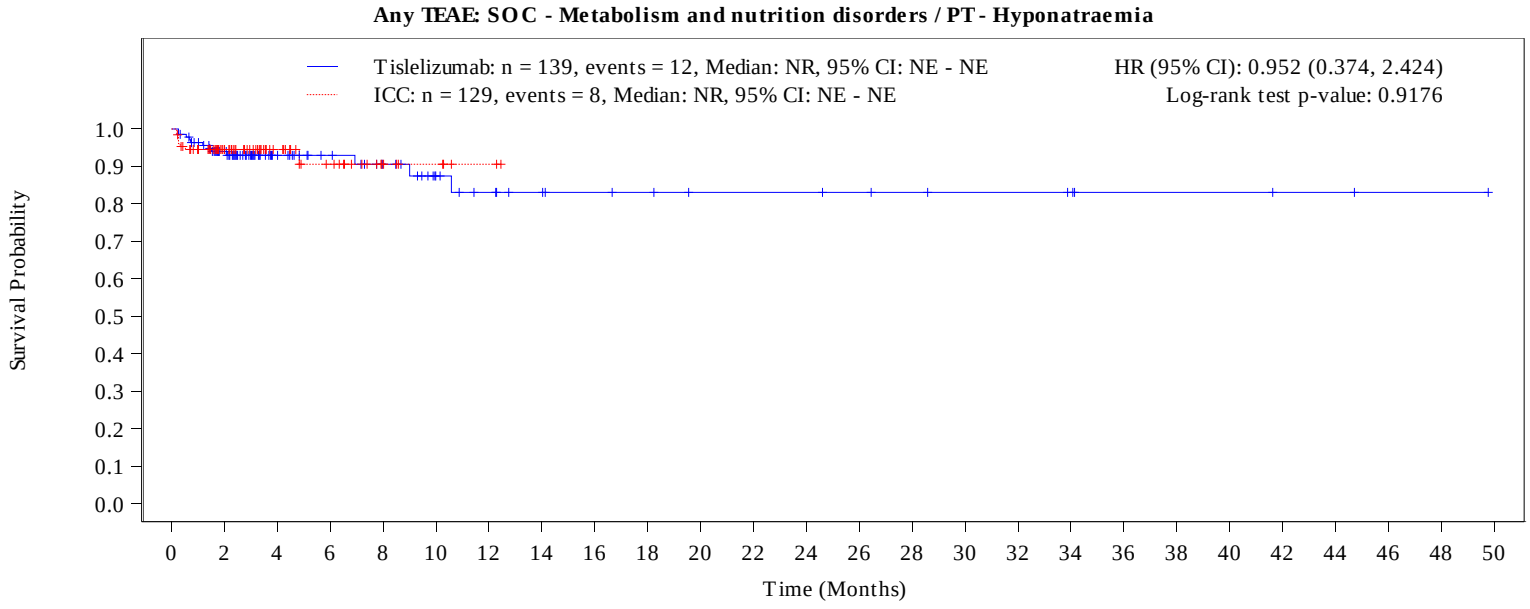
Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	92	52	40	31	21	17	14	12	11	9	9	9	8	7	6	6	5	3	3	3	2	2	1	1	0
ICC	129	70	32	18	8	5	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
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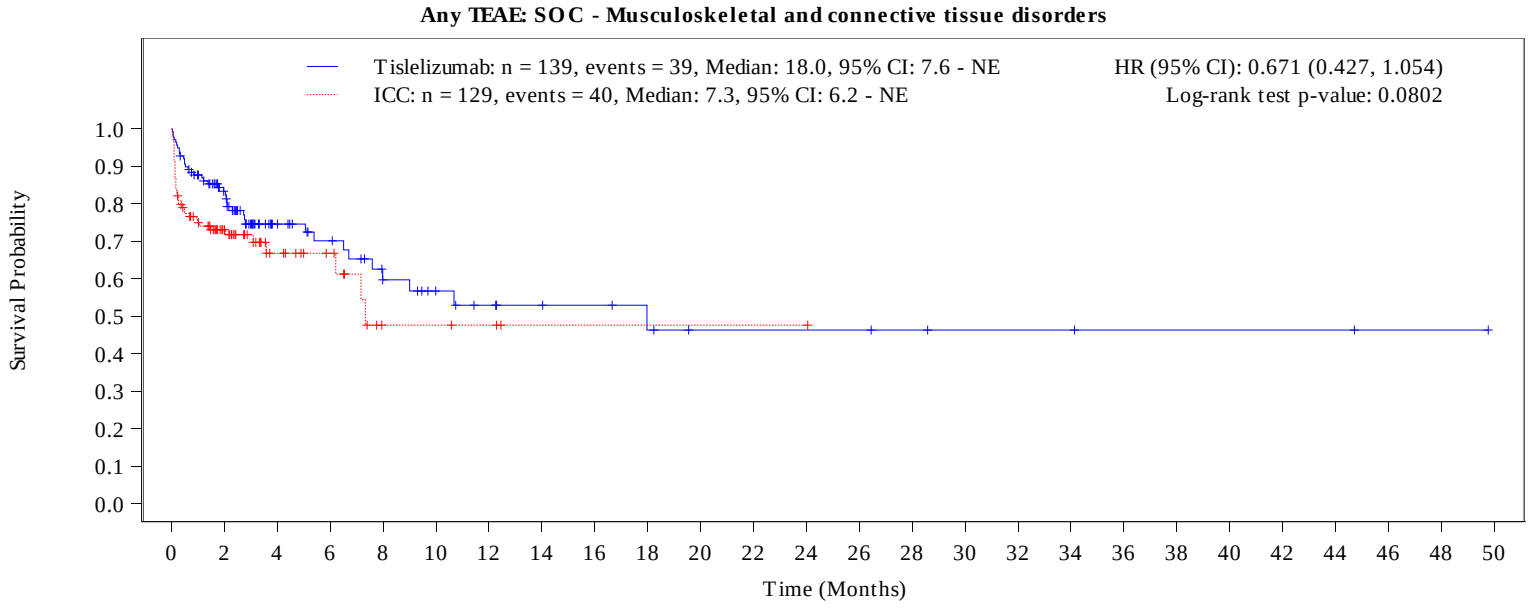
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	82	40	30	20	15	12	10	9	7	5	5	5	5	4	3	3	3	2	2	2	2	2	1	1	0
ICC	129	56	20	13	4	4	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
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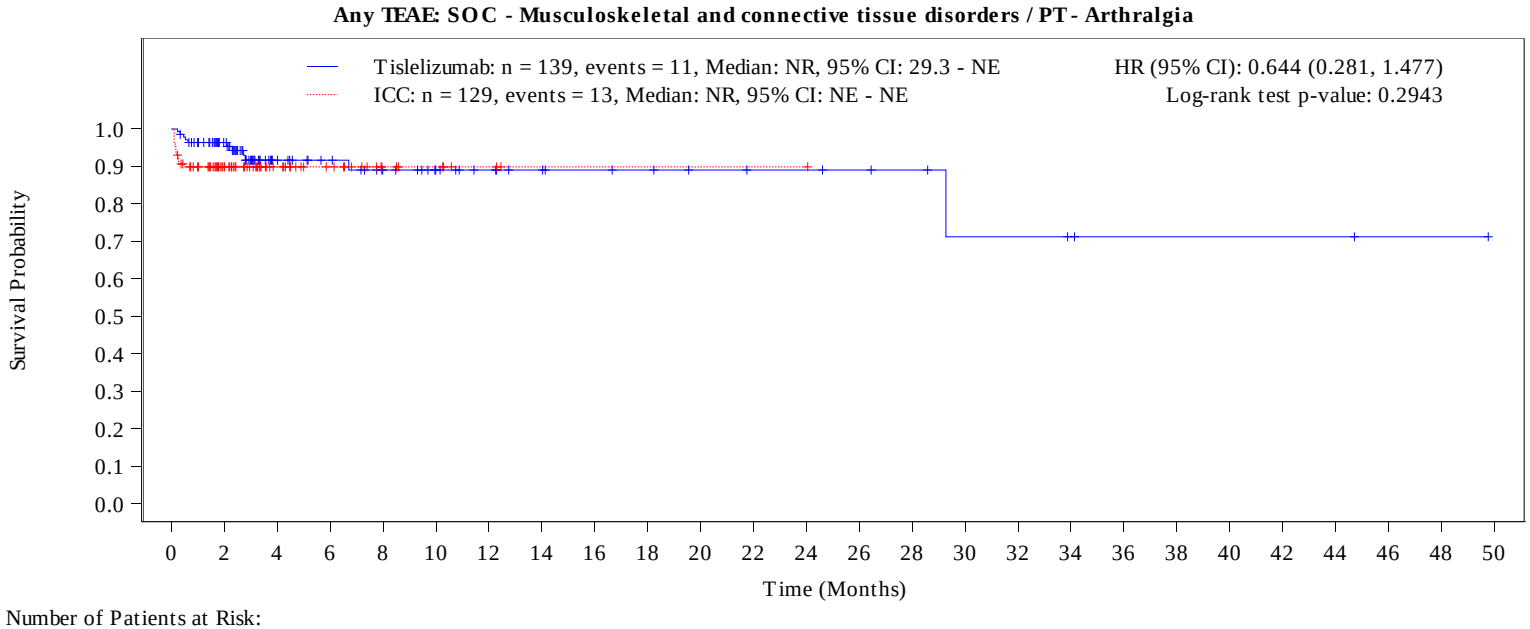
Safety Analysis Set - Subpopulation without Irinotecan

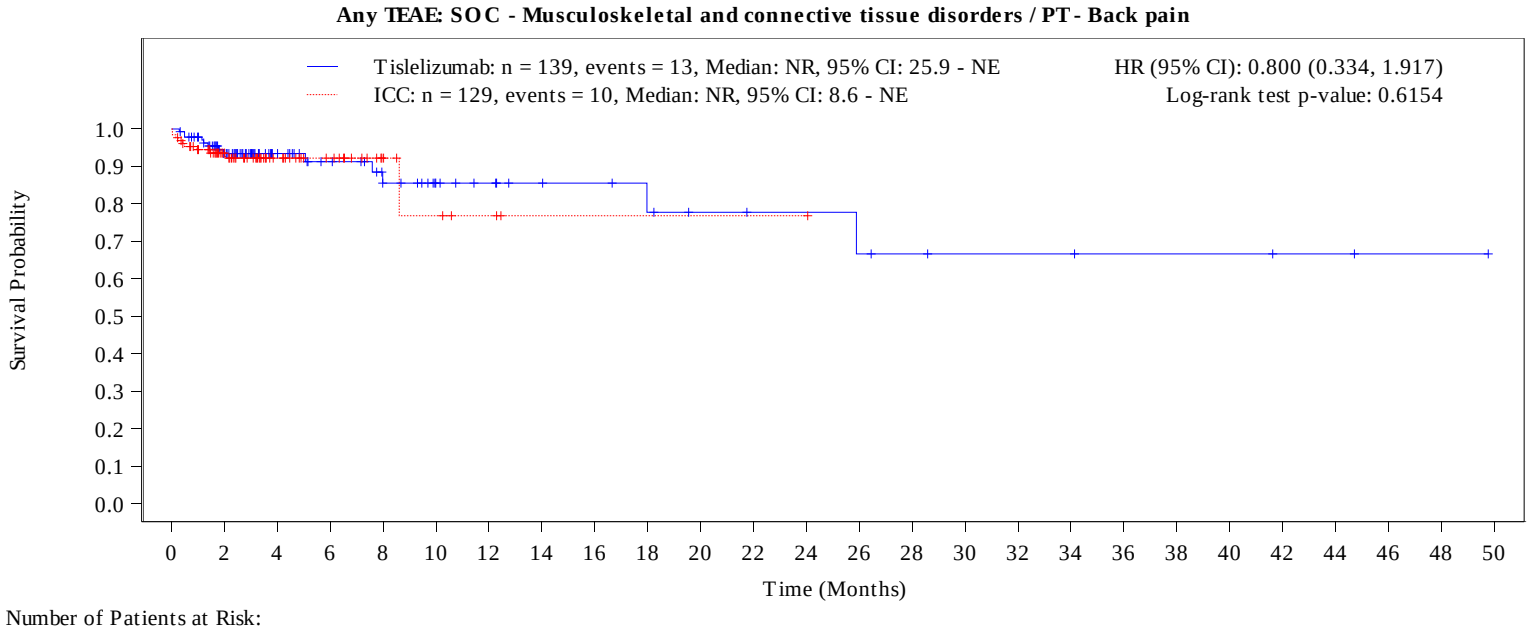


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	93	46	36	27	21	17	14	12	11	9	8	8	7	6	4	4	3	2	2	2	2	2	1	1	0
ICC	129	70	30	17	8	6	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

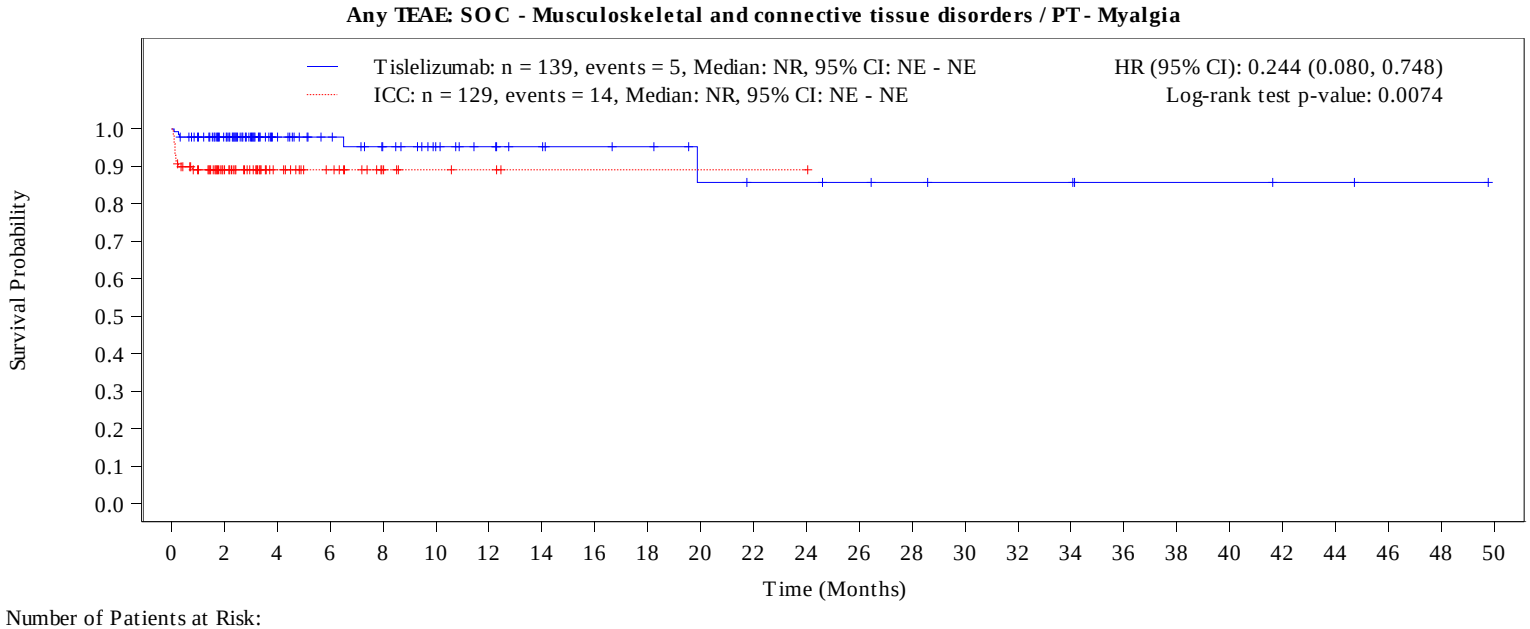


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	90	51	38	28	20	17	14	12	10	8	7	7	6	5	4	4	4	3	3	3	2	2	1	1	0
ICC	129	71	31	18	8	5	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

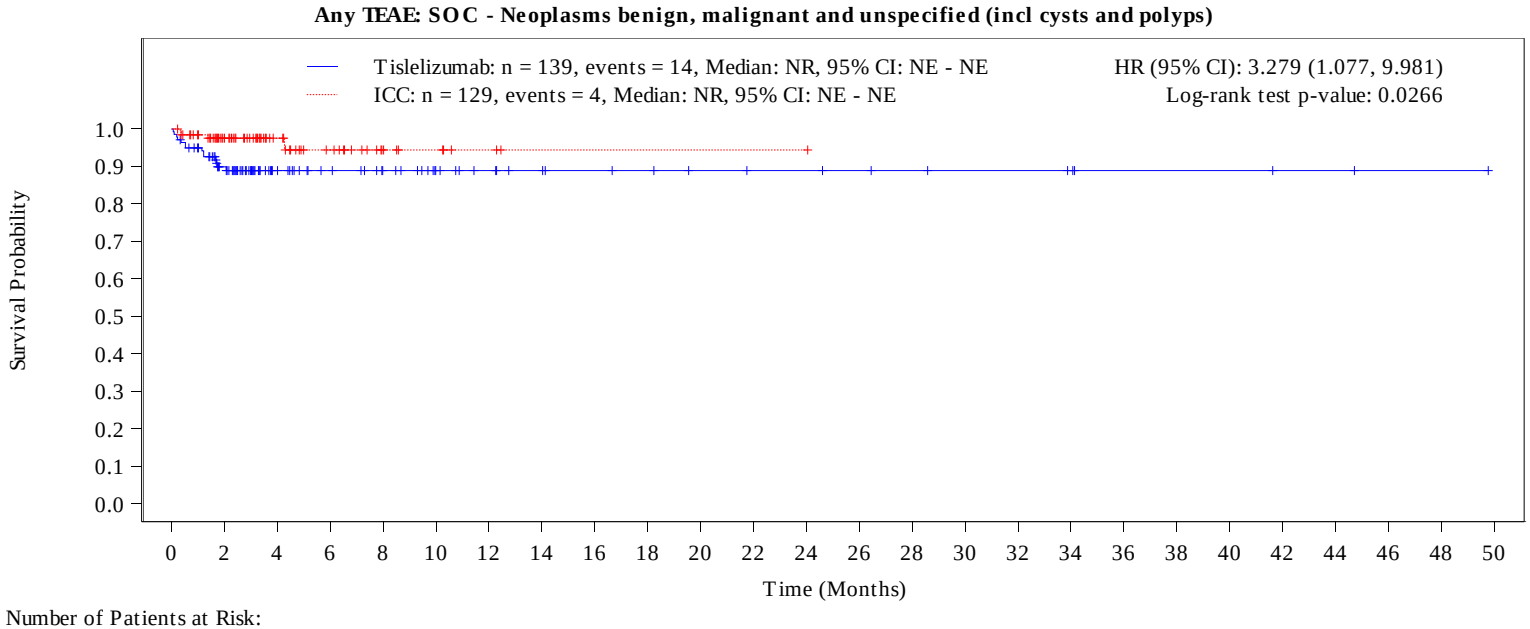


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	94	51	39	31	23	19	16	13	12	9	8	8	7	6	5	5	5	3	3	3	2	2	1	1	0
ICC	129	67	26	16	7	4	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	90	50	38	31	23	19	16	13	12	10	9	9	8	7	6	6	5	3	3	3	2	2	1	1	0
ICC	129	75	33	19	9	6	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
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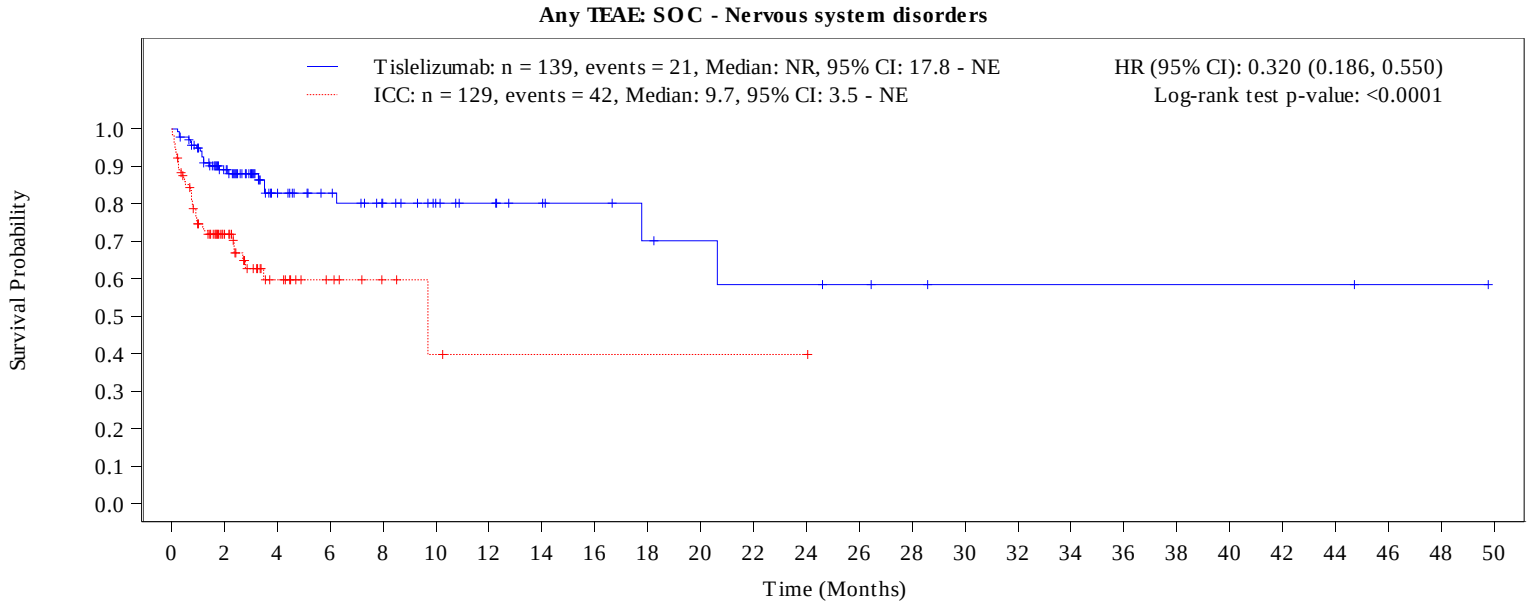
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	85	43	32	24	18	15	12	9	7	6	5	5	4	3	2	2	2	2	2	2	2	2	1	1	0
ICC	129	50	18	8	4	2	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

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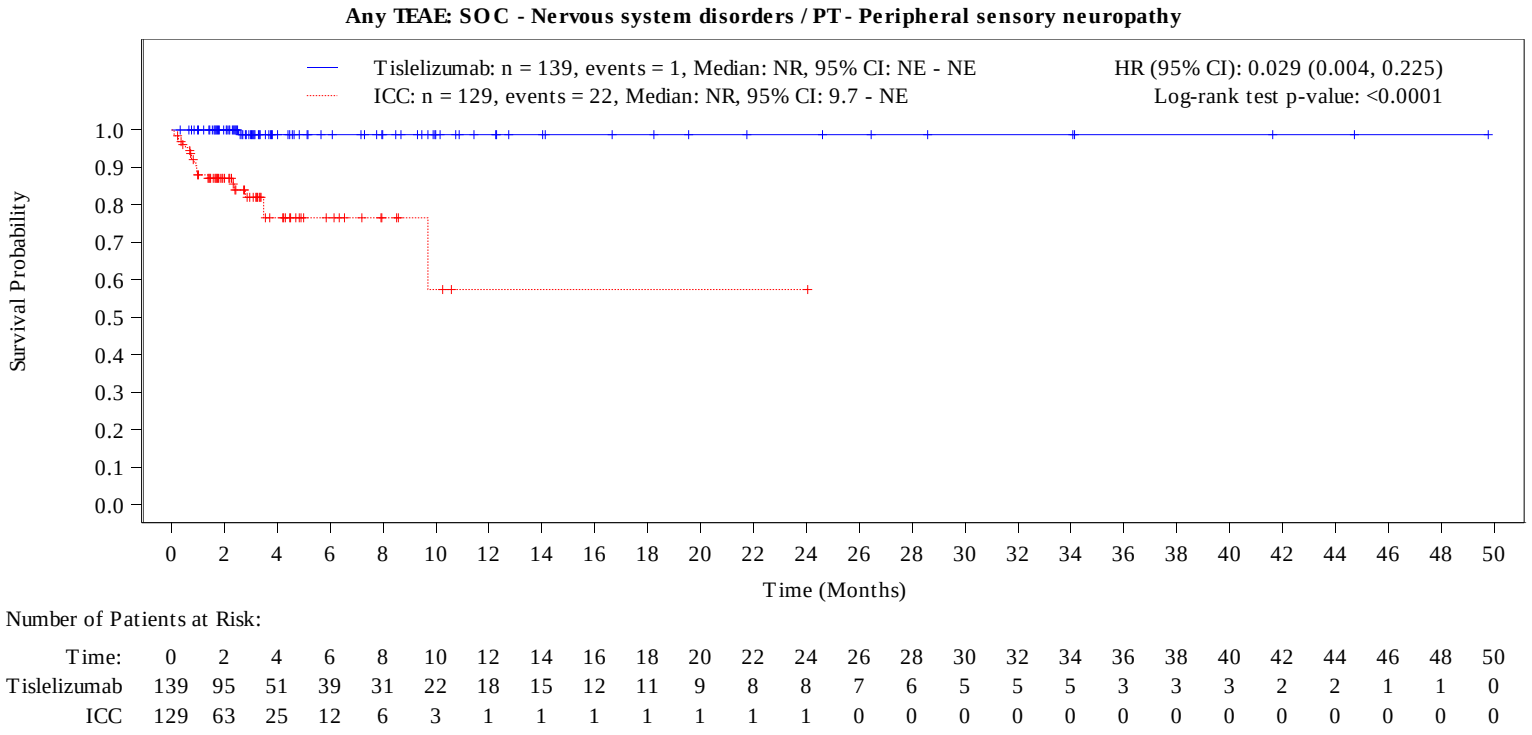
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	95	51	39	31	22	18	15	12	11	9	8	8	7	6	5	5	5	3	3	3	2	2	1	1	0
ICC	129	63	25	12	6	3	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

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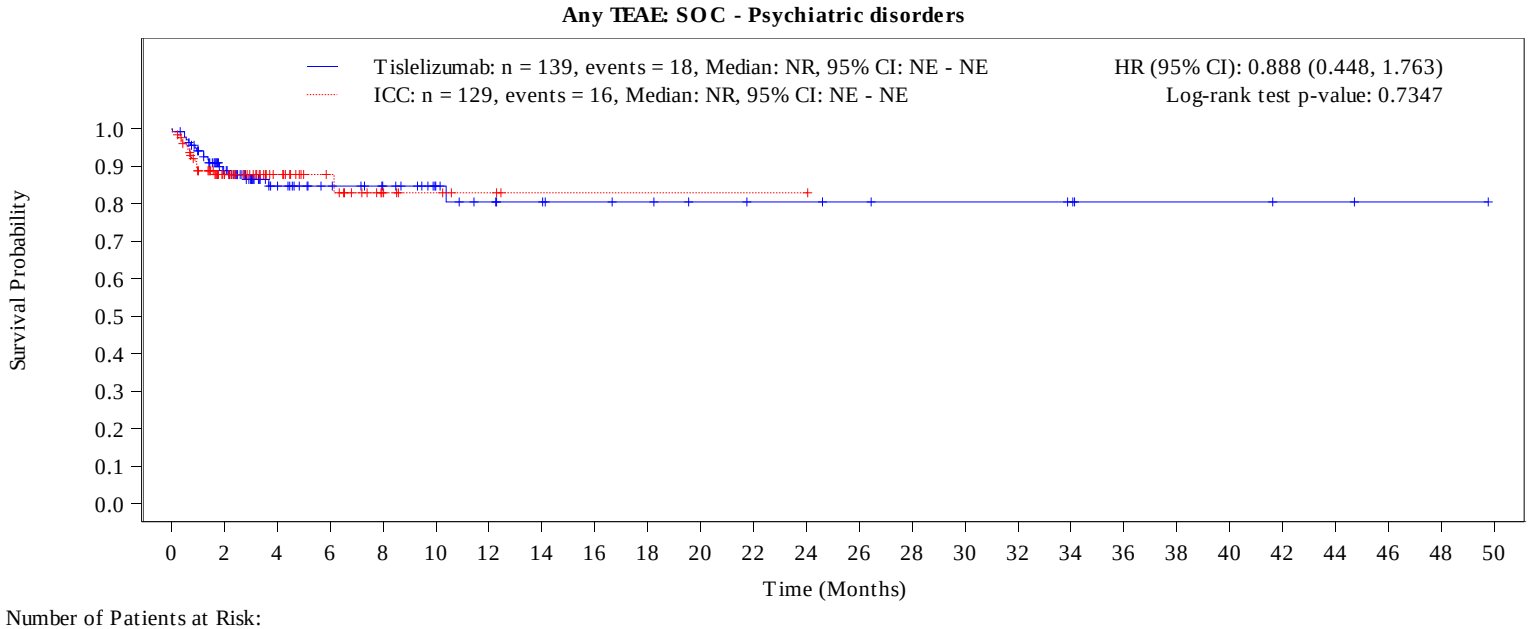
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	84	46	36	30	21	17	15	12	11	9	8	8	7	6	6	6	5	3	3	3	2	2	1	1	0
ICC	129	66	30	18	8	5	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
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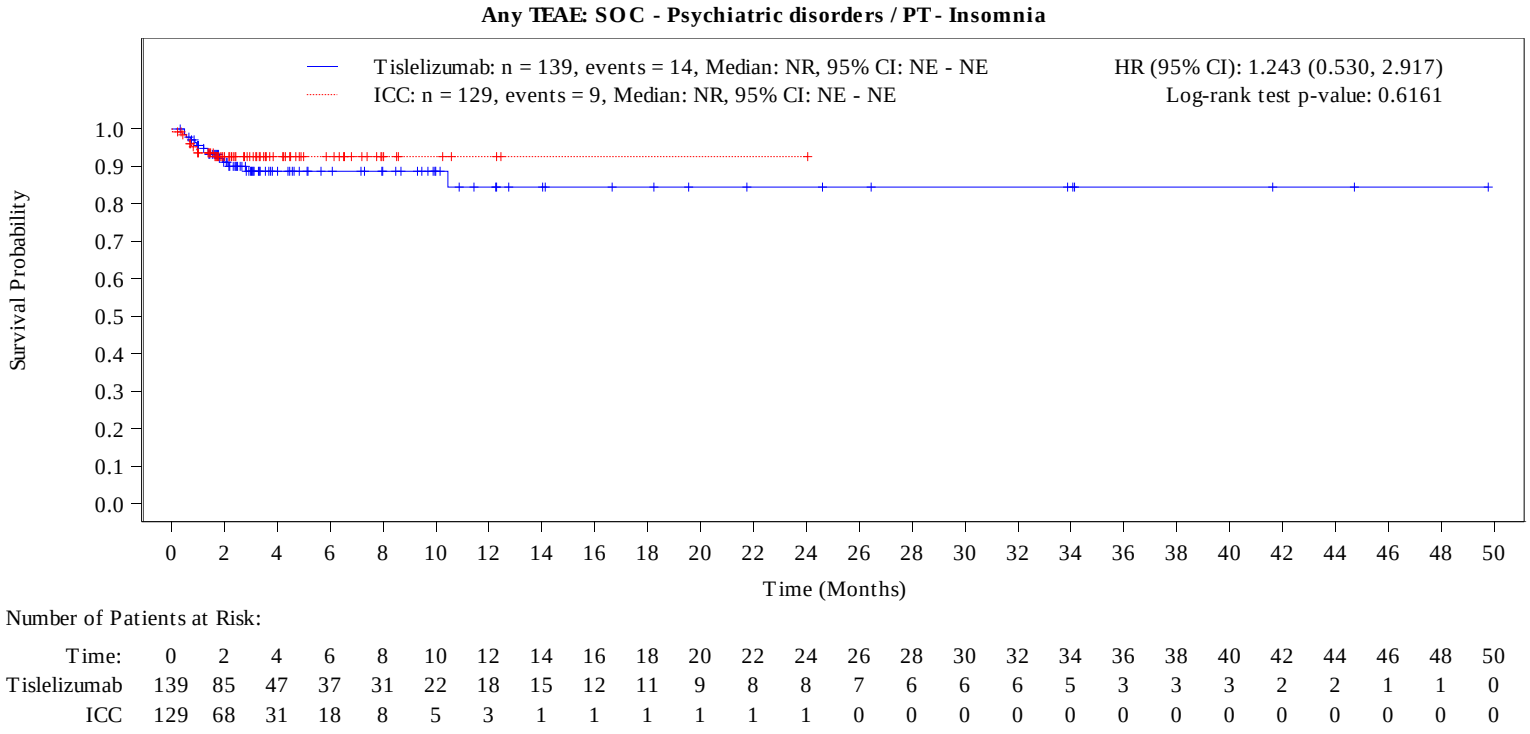
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	85	47	37	31	22	18	15	12	11	9	8	8	7	6	6	6	5	3	3	3	2	2	1	1	0
ICC	129	68	31	18	8	5	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

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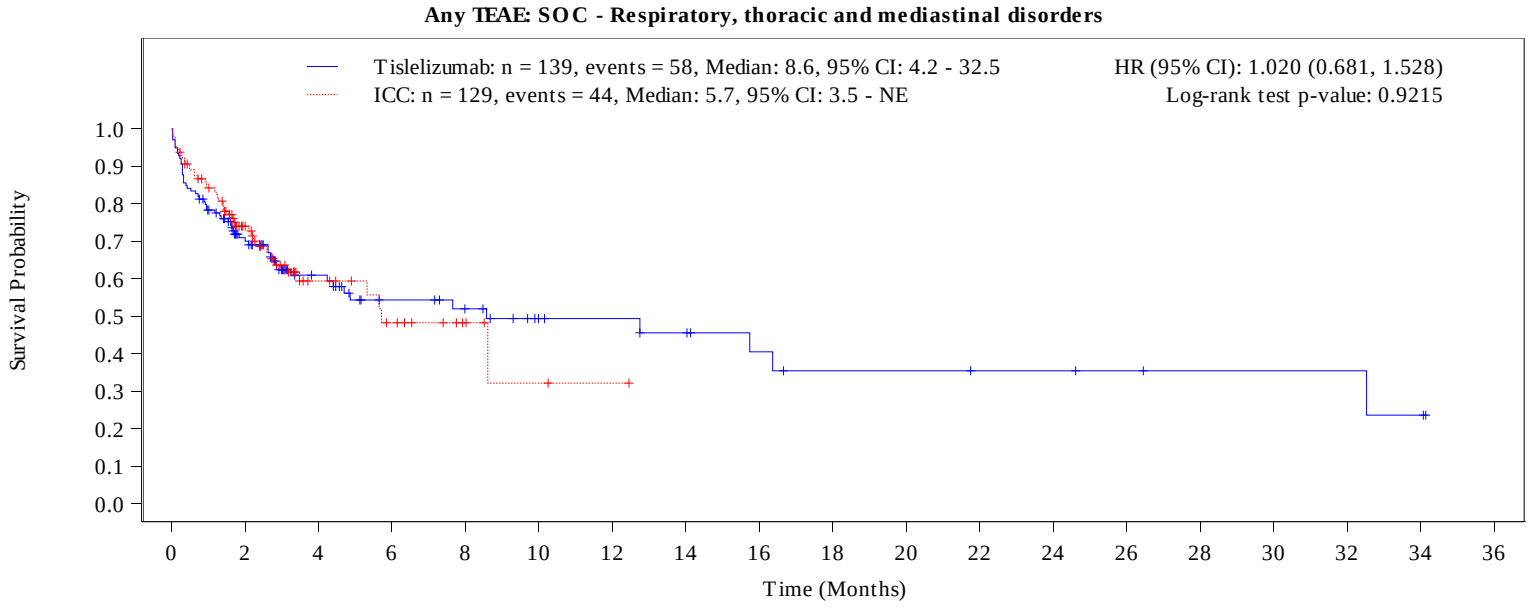
Safety Analysis Set - Subpopulation without Irinotecan

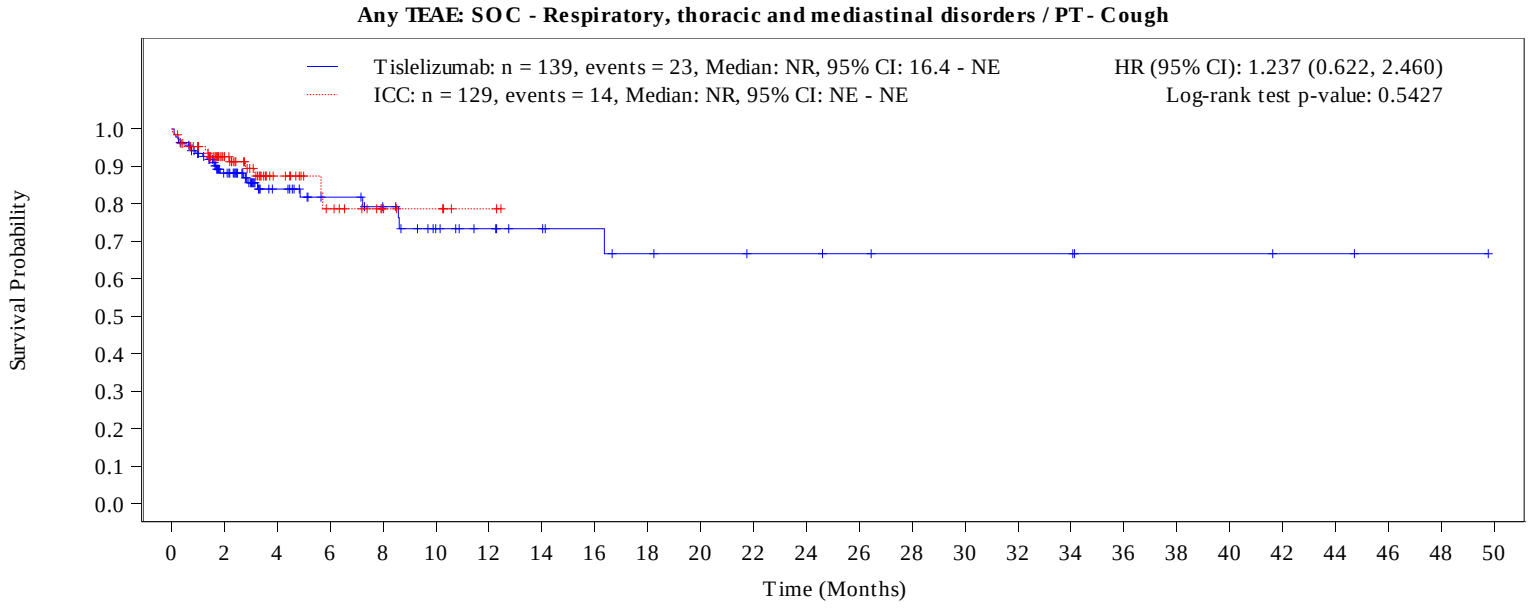


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36
Tislelizumab	139	75	40	27	21	14	13	11	8	6	6	5	5	4	3	3	3	2	0
ICC	129	59	21	11	5	2	1	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

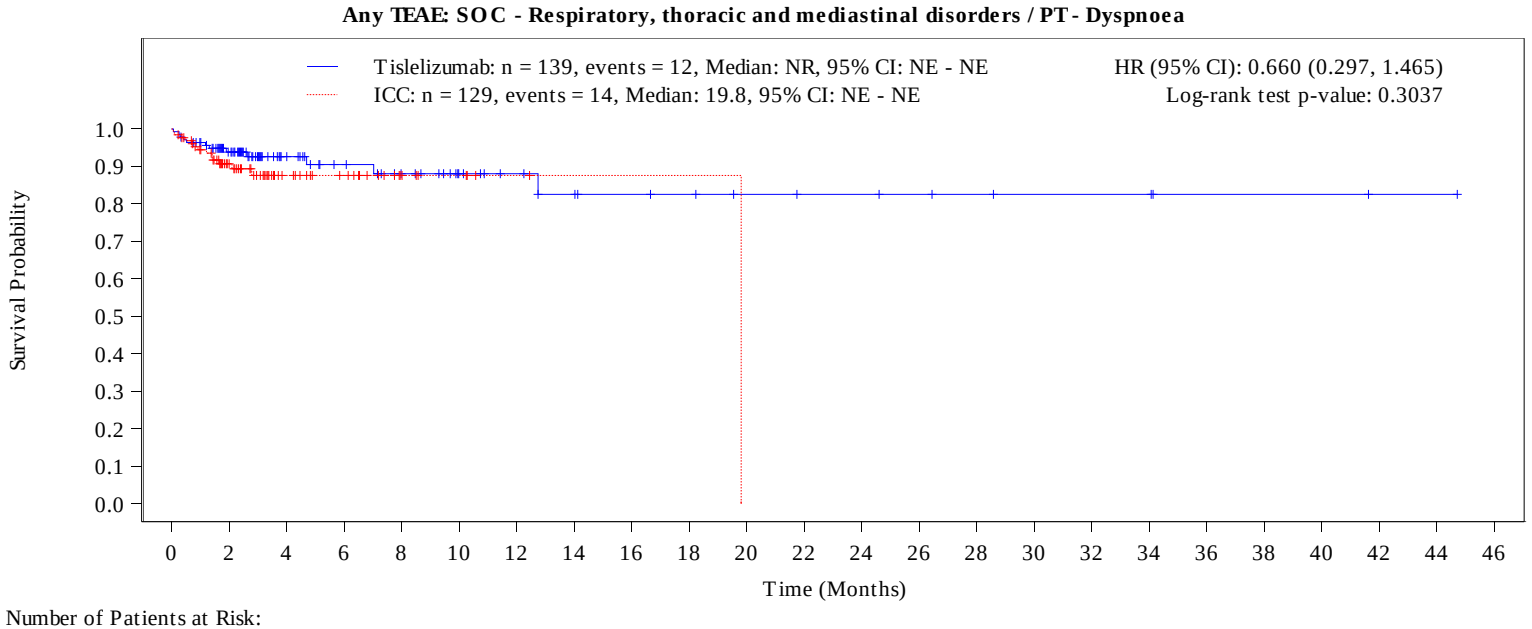


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	84	45	34	28	20	16	13	11	9	8	7	7	6	5	5	5	5	3	3	3	2	2	1	1	0
ICC	129	72	29	15	7	5	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

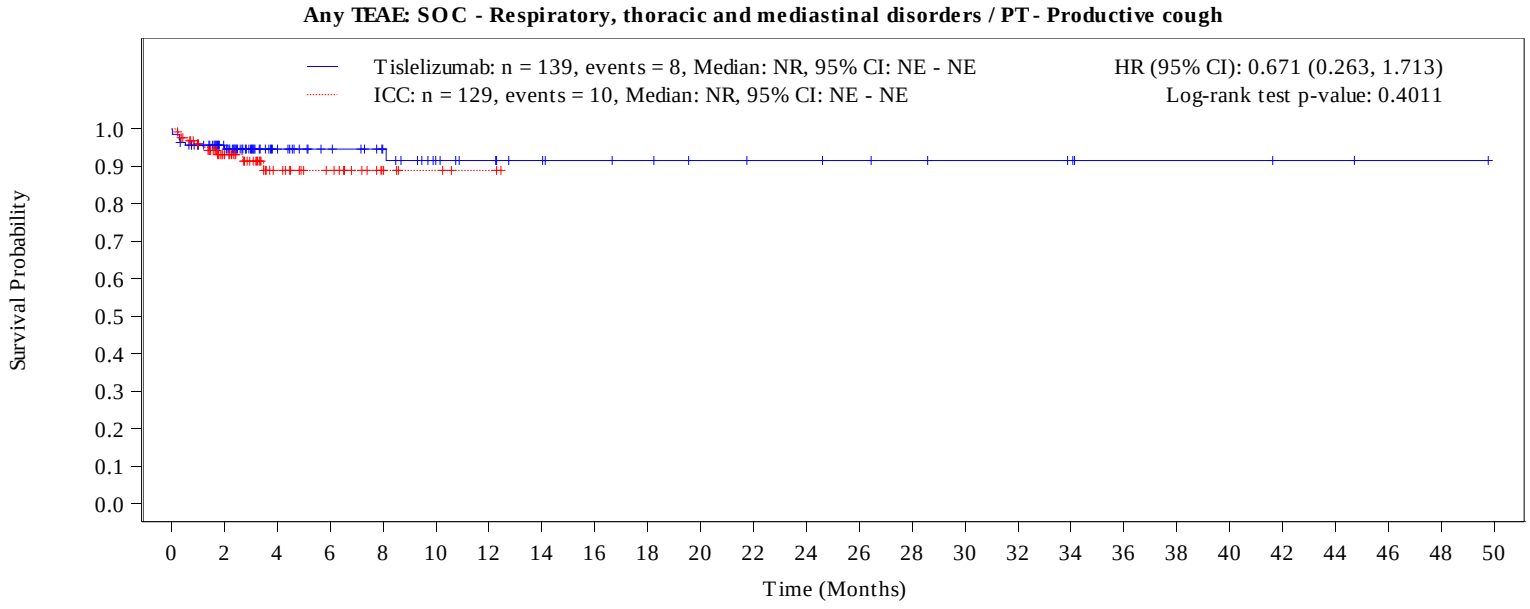


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46
Tislelizumab	139	93	51	38	30	21	17	14	11	10	8	7	7	6	5	4	4	4	2	2	2	1	1	0
ICC	129	69	29	18	8	5	2	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

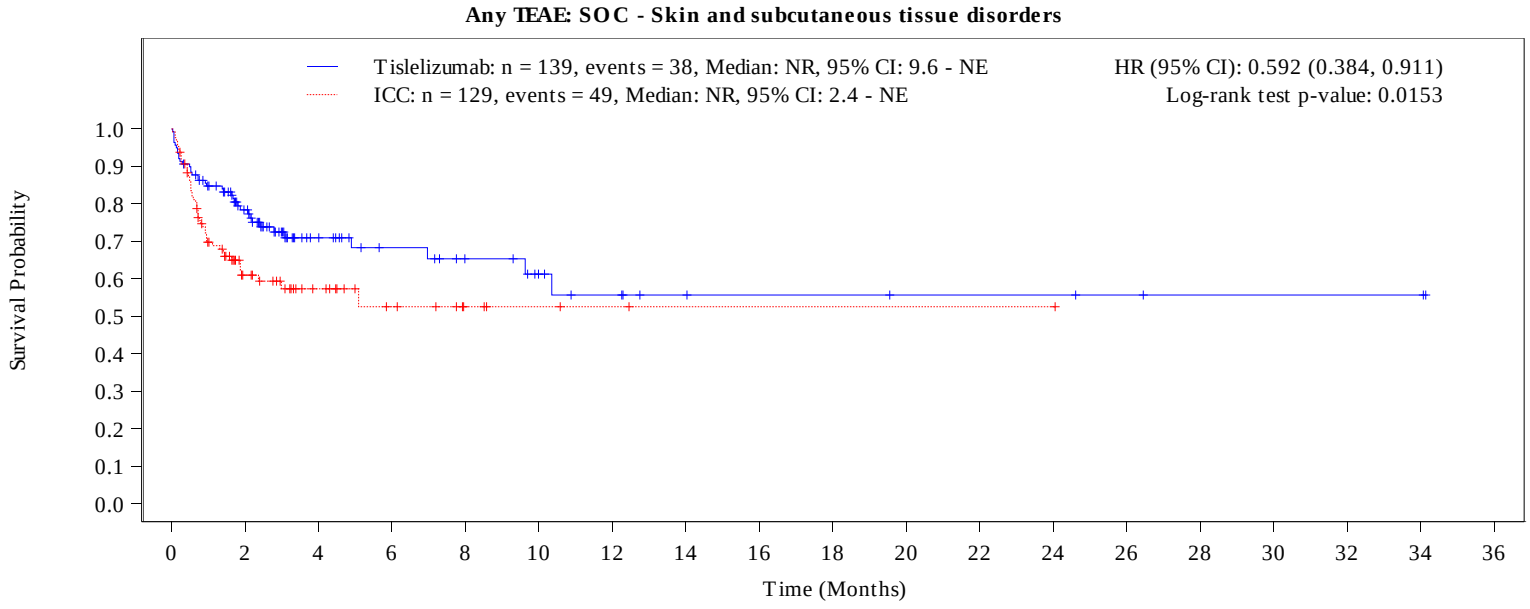


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	92	50	39	31	22	19	16	13	12	10	9	9	8	7	6	6	5	3	3	3	2	2	1	1	0
ICC	129	72	29	17	7	4	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

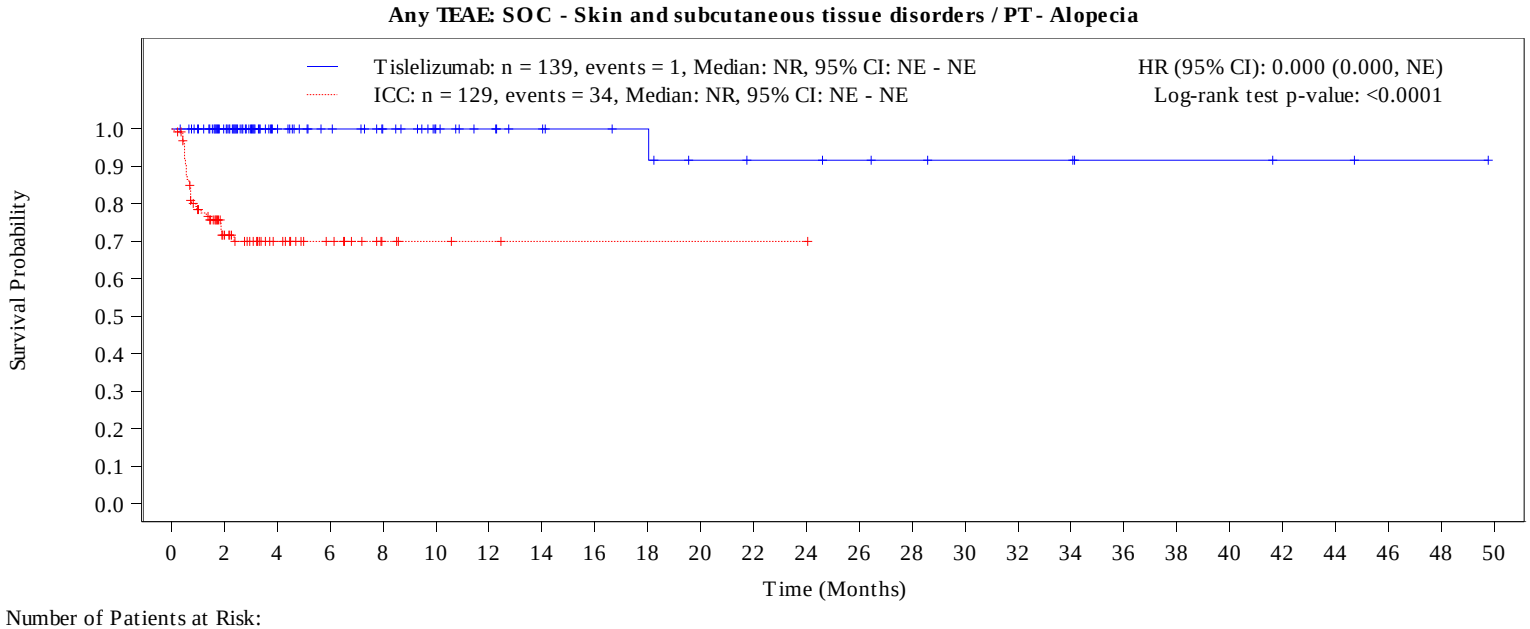


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36
Tislelizumab	139	73	33	23	17	12	9	6	5	5	4	4	4	3	2	2	2	2	0
ICC	129	43	18	10	5	3	2	1	1	1	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

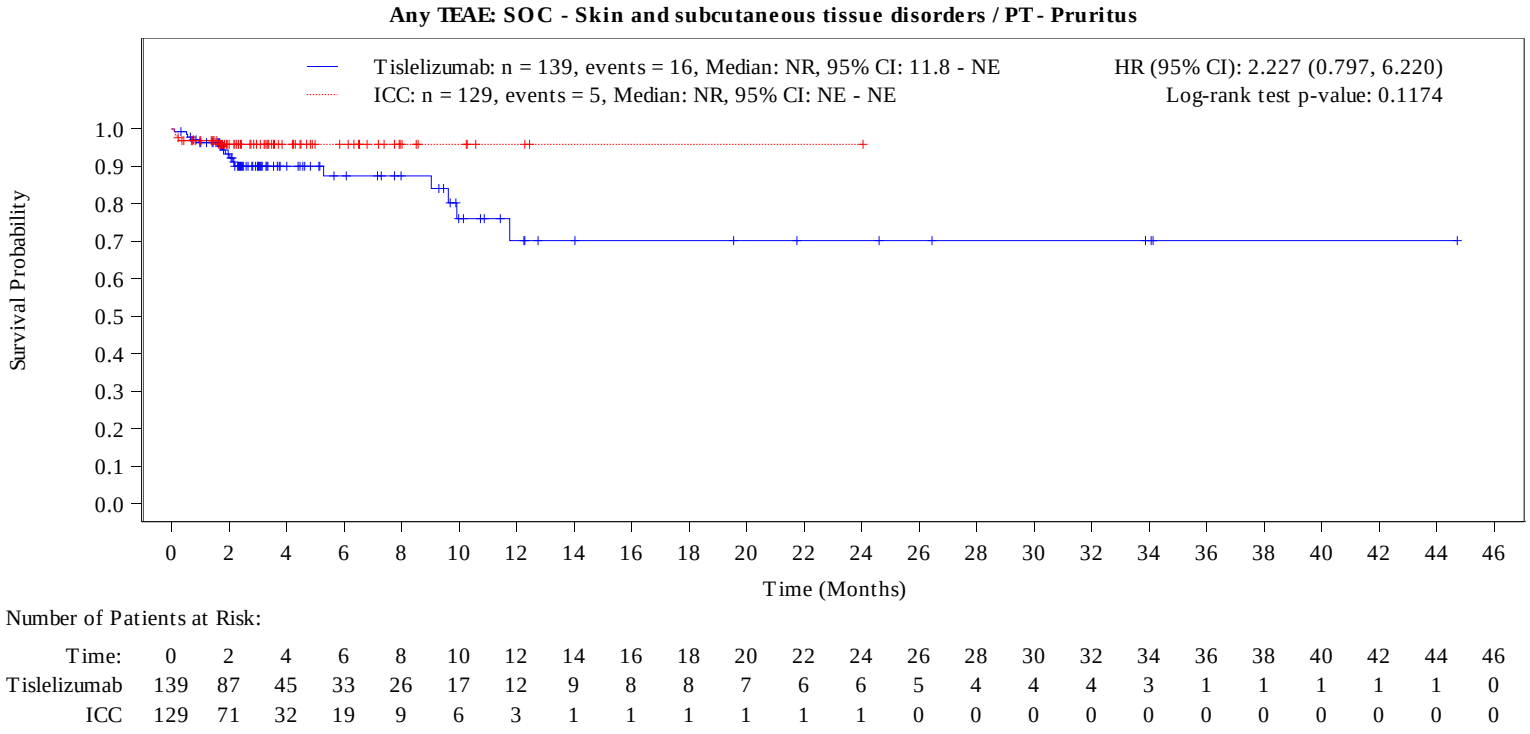


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	95	52	40	32	23	19	16	13	12	9	8	8	7	6	5	5	5	3	3	3	2	2	1	1	0
ICC	129	50	21	13	5	3	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

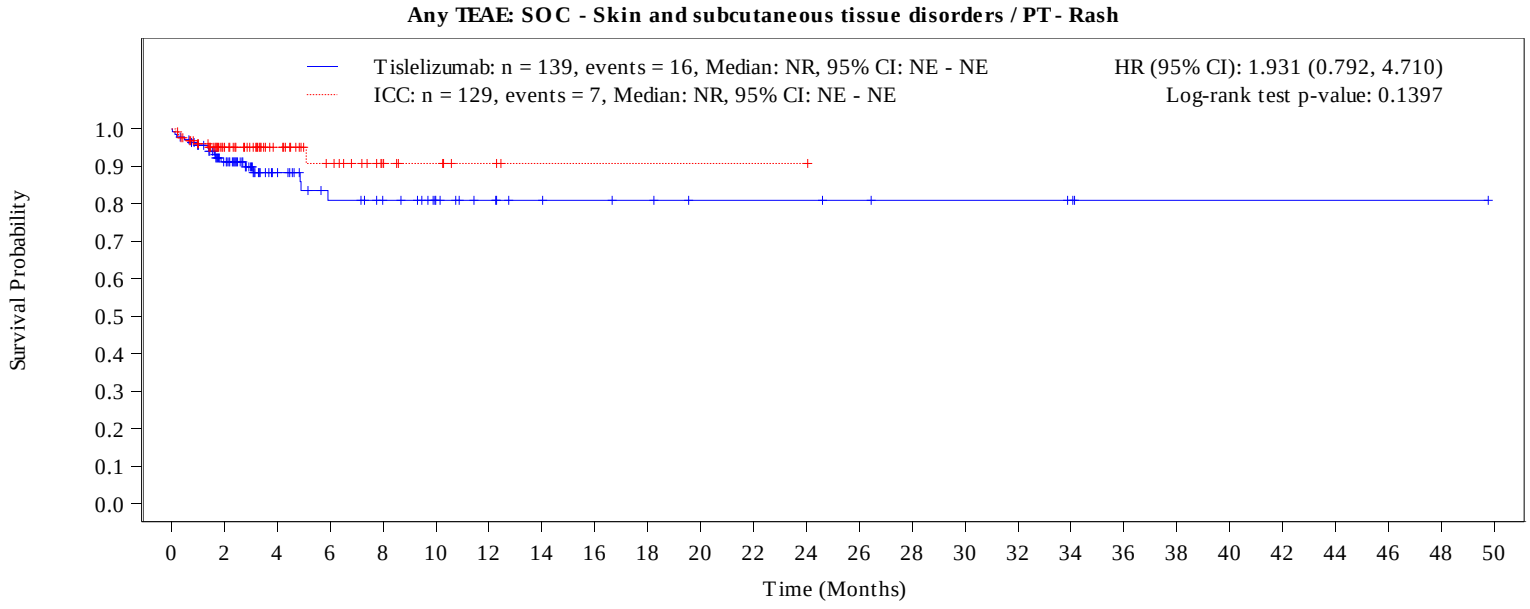


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46
Tislelizumab	139	87	45	33	26	17	12	9	8	8	7	6	6	5	4	4	4	3	1	1	1	1	1	0
ICC	129	71	32	19	9	6	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

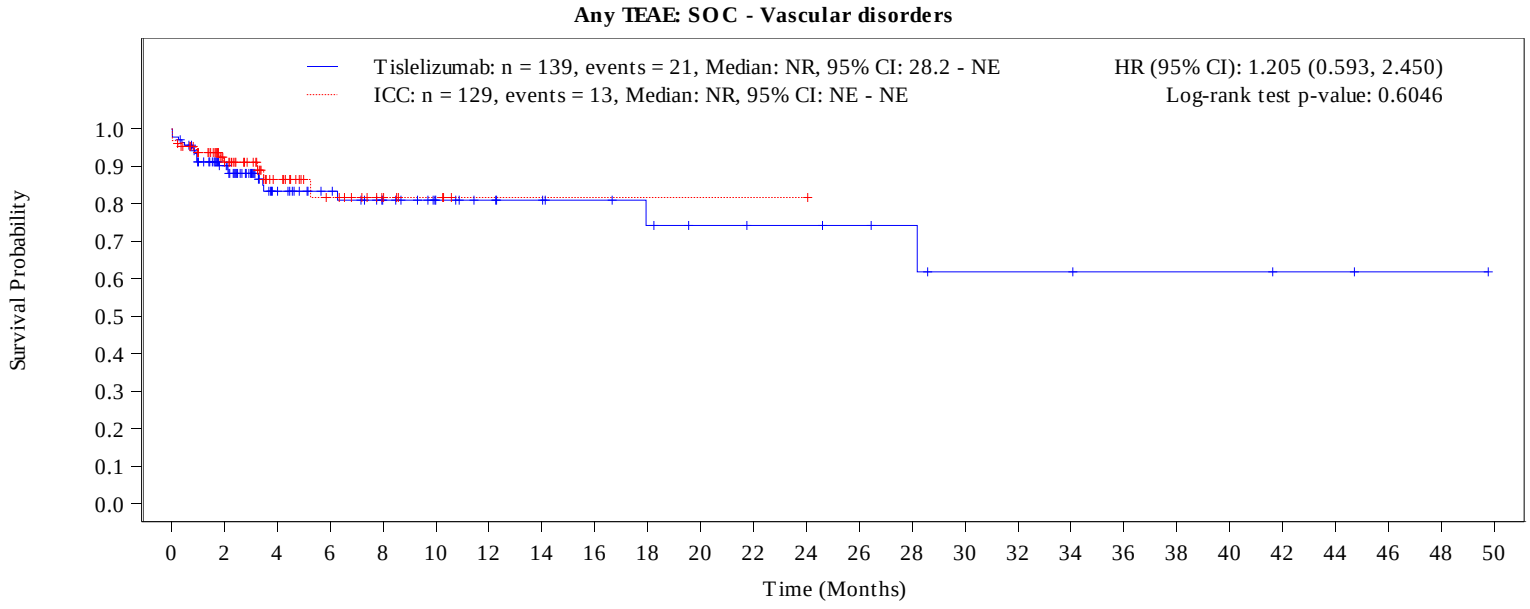


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	86	44	31	26	18	14	11	9	8	6	6	6	5	4	4	4	3	1	1	1	1	1	1	1	0
ICC	129	69	32	18	9	6	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

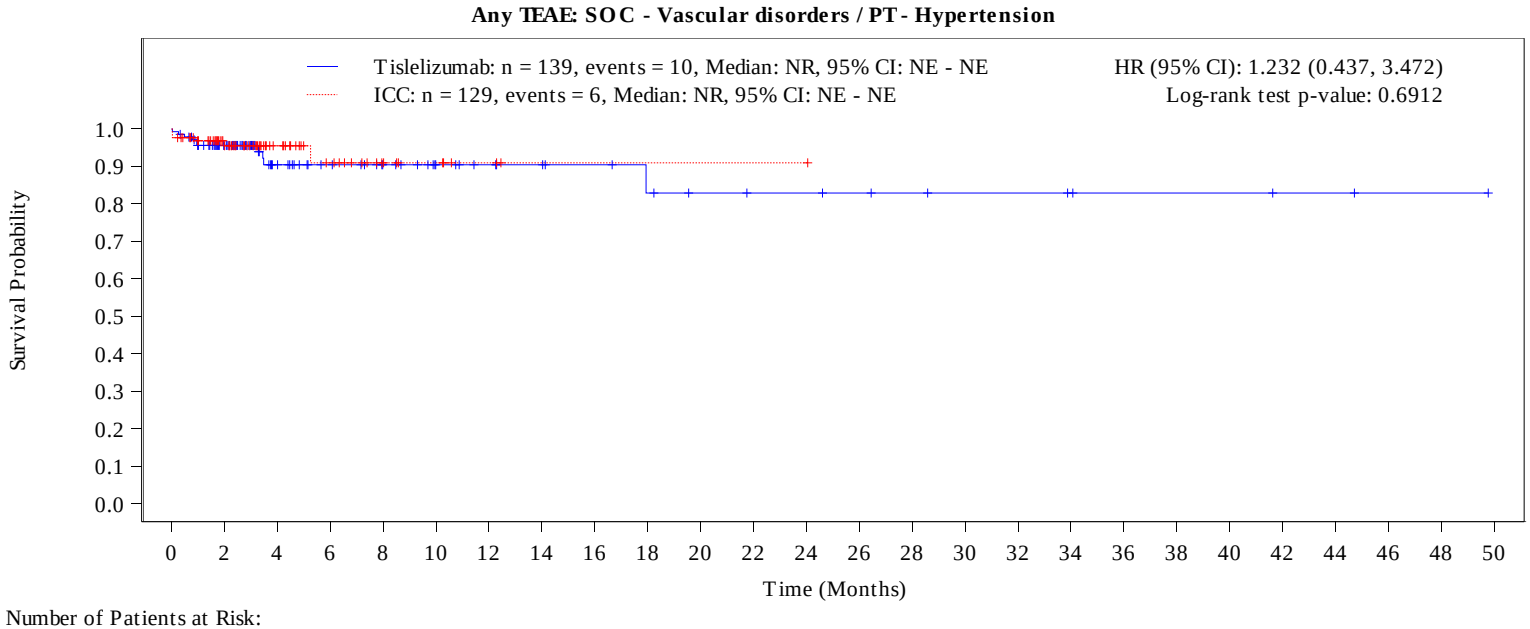


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	89	48	36	27	20	17	15	13	11	9	8	8	7	6	4	4	4	3	3	3	2	2	1	1	0
ICC	129	67	29	14	7	4	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.2.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

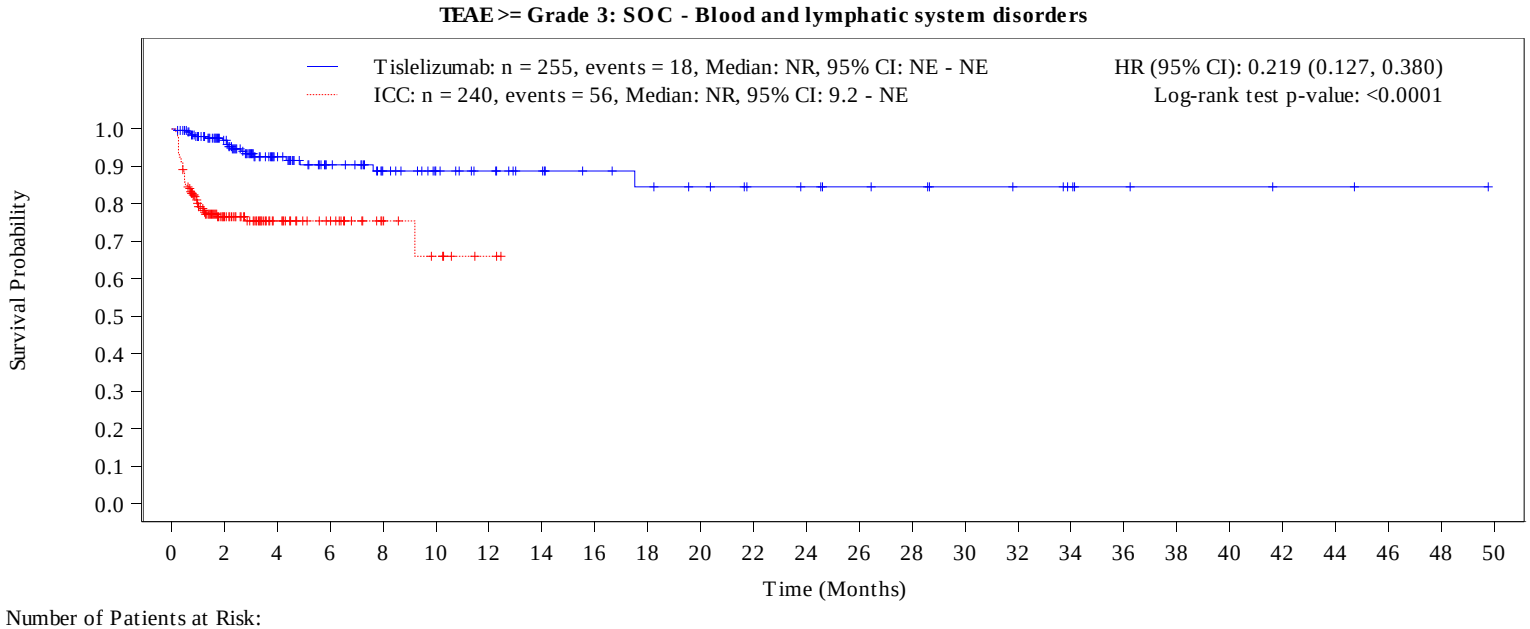


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	91	48	36	28	21	18	16	13	11	9	8	8	7	6	5	5	4	3	3	3	2	2	1	1	0
ICC	129	71	32	17	9	6	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-02-b-km-aesocpt-safetys-cl.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

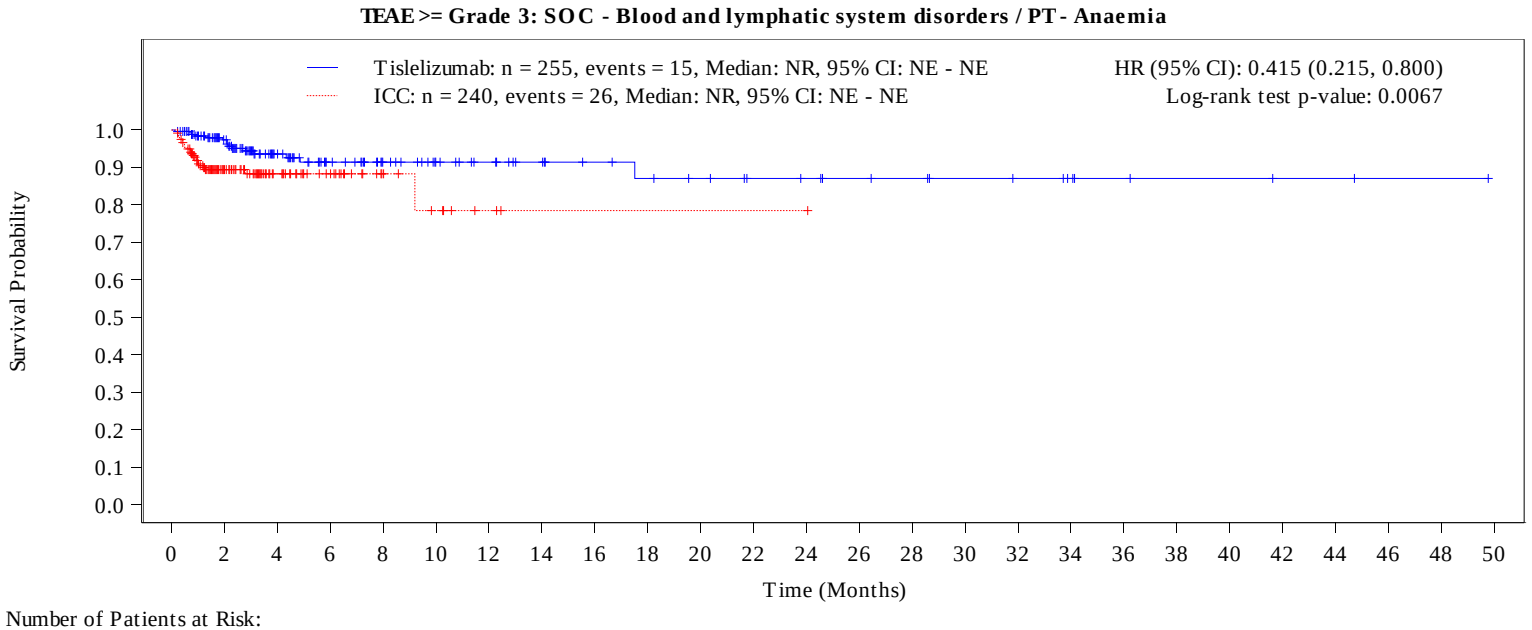


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	172	96	65	48	37	31	26	22	20	18	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	95	37	22	10	6	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-03-km-aesocpt-g3-safety-cl.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

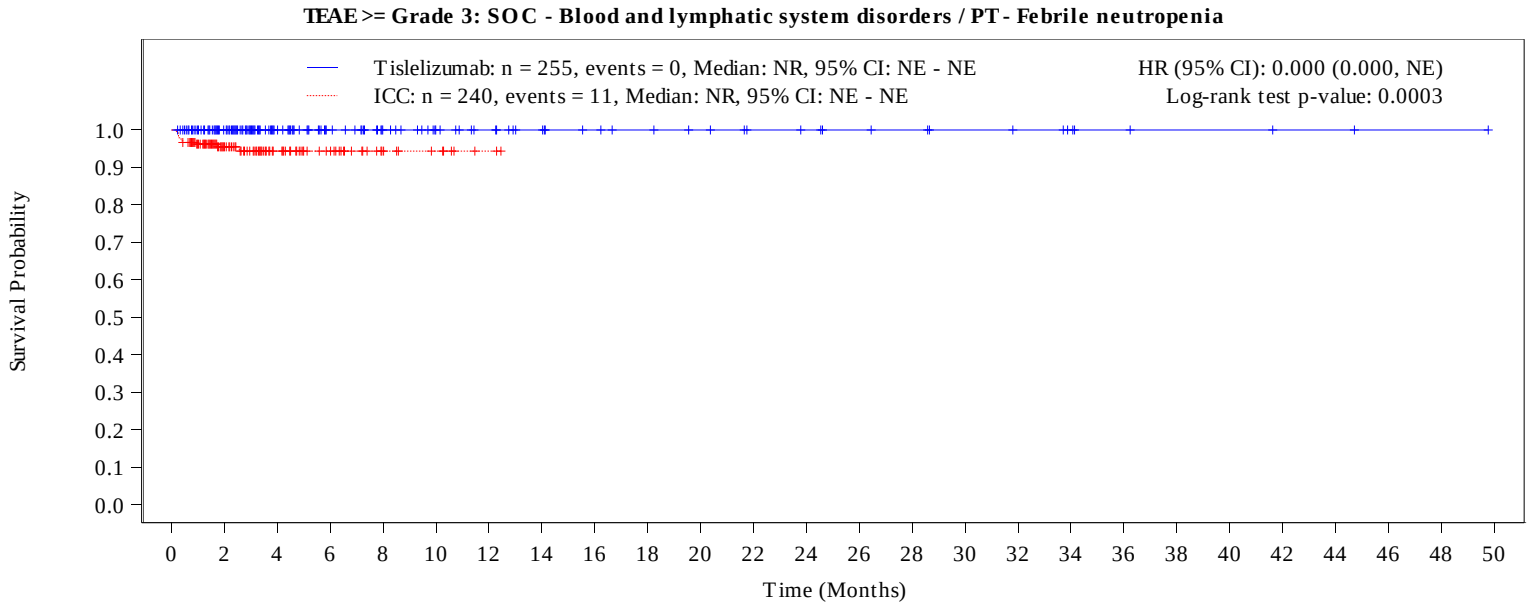


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	172	96	65	49	38	32	27	22	20	18	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	109	42	24	11	7	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-03-km-aesocpt-g3-safety-cl.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

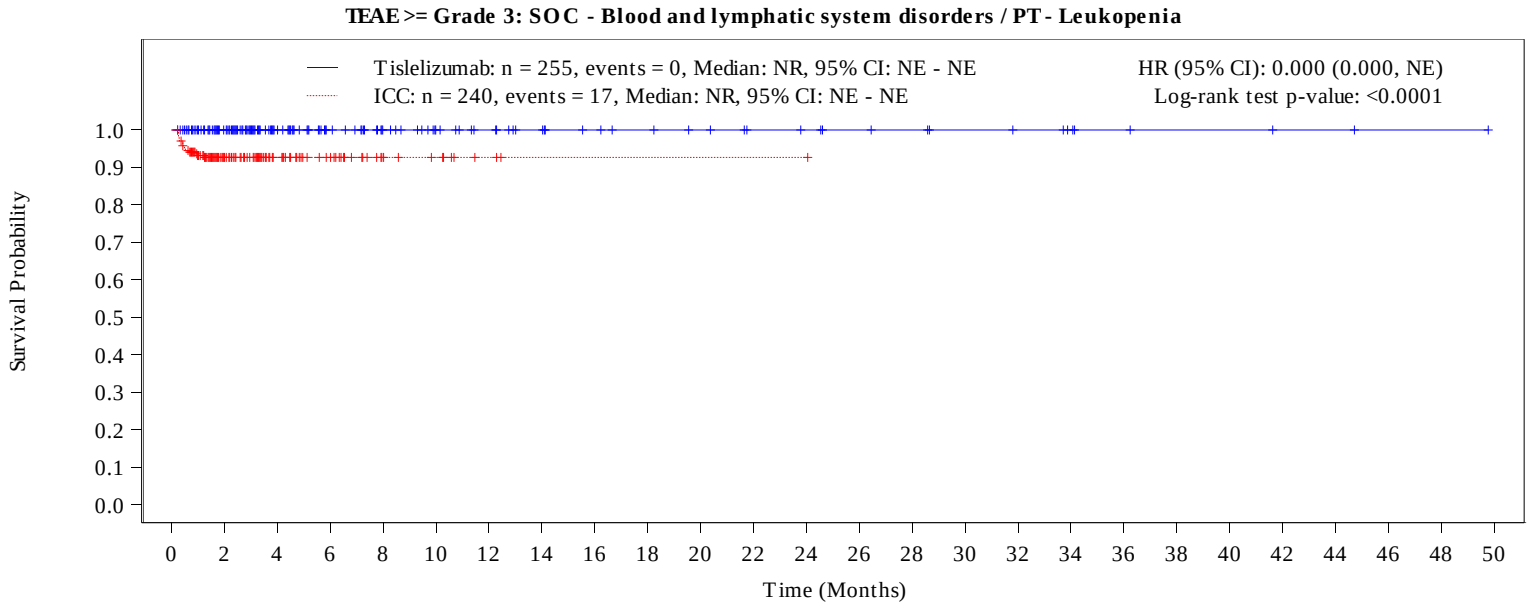


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	175	97	65	49	38	32	27	22	20	18	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	110	44	25	11	7	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-03-km-aesocpt-g3-safety-cl.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

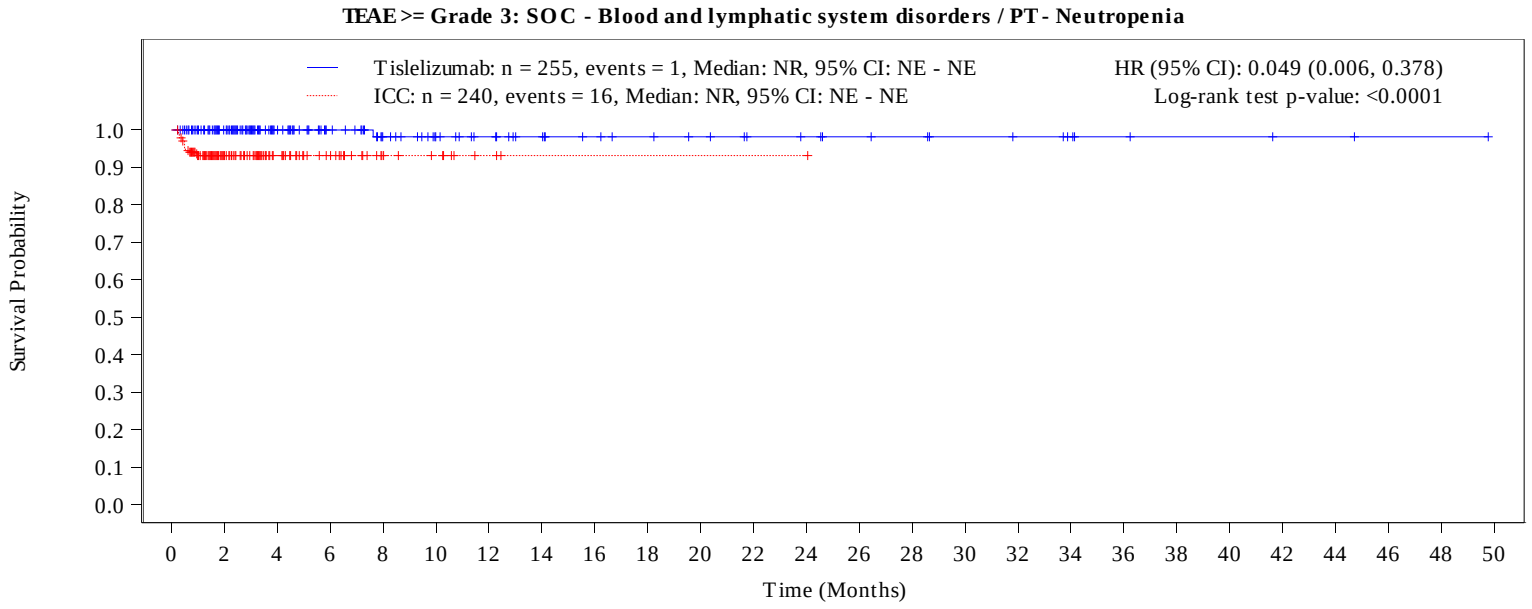


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	175	97	65	49	38	32	27	22	20	18	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	106	42	25	11	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-03-km-aesocpt-g3-safety-cl.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

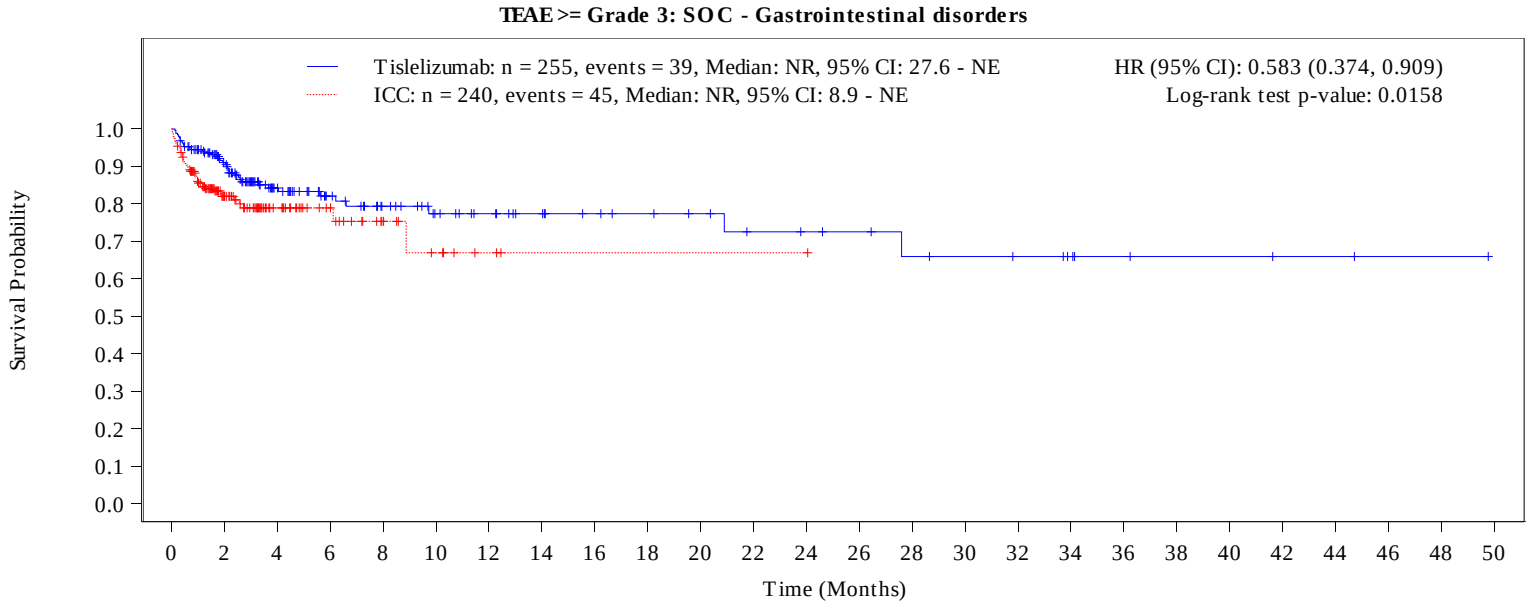


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	175	97	65	48	37	31	26	22	20	18	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	106	41	24	11	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-03-km-aesocpt-g3-safety-cl.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

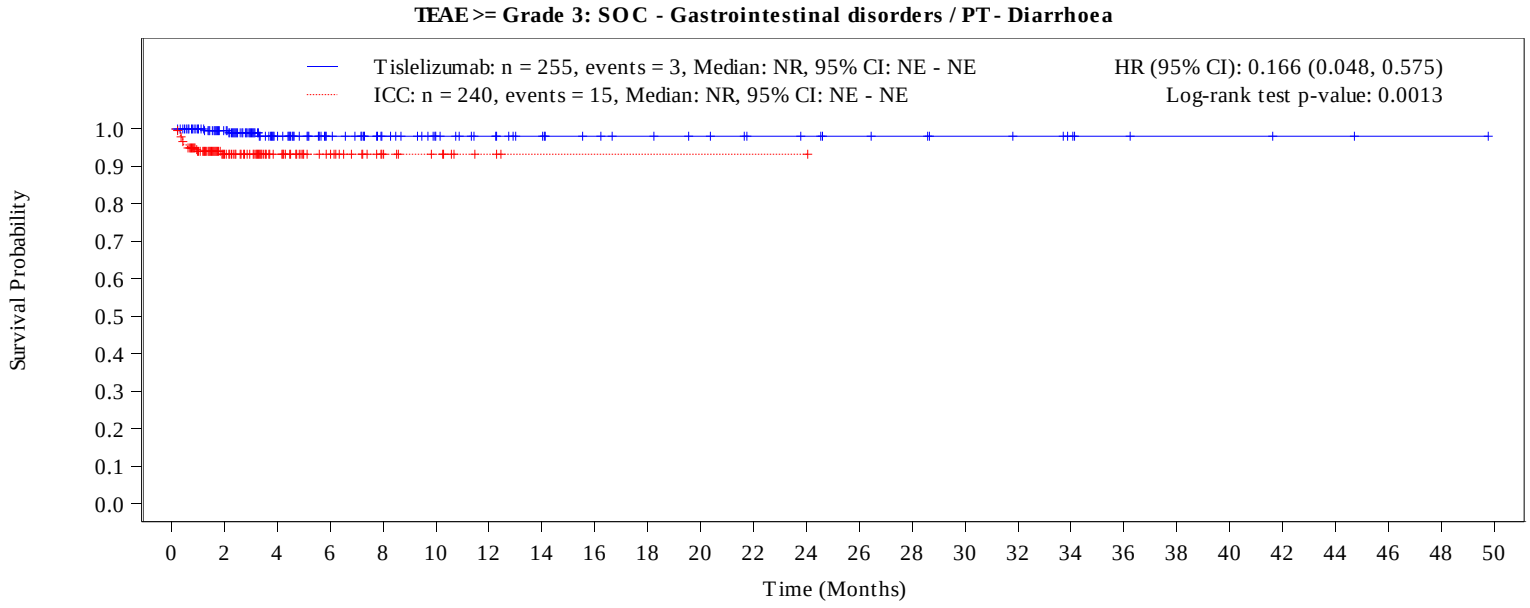


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	167	92	62	48	37	31	26	21	19	17	14	13	12	10	9	8	6	4	3	3	2	2	1	1	0
ICC	240	100	41	23	12	7	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-03-km-aesocpt-g3-safety-cl.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

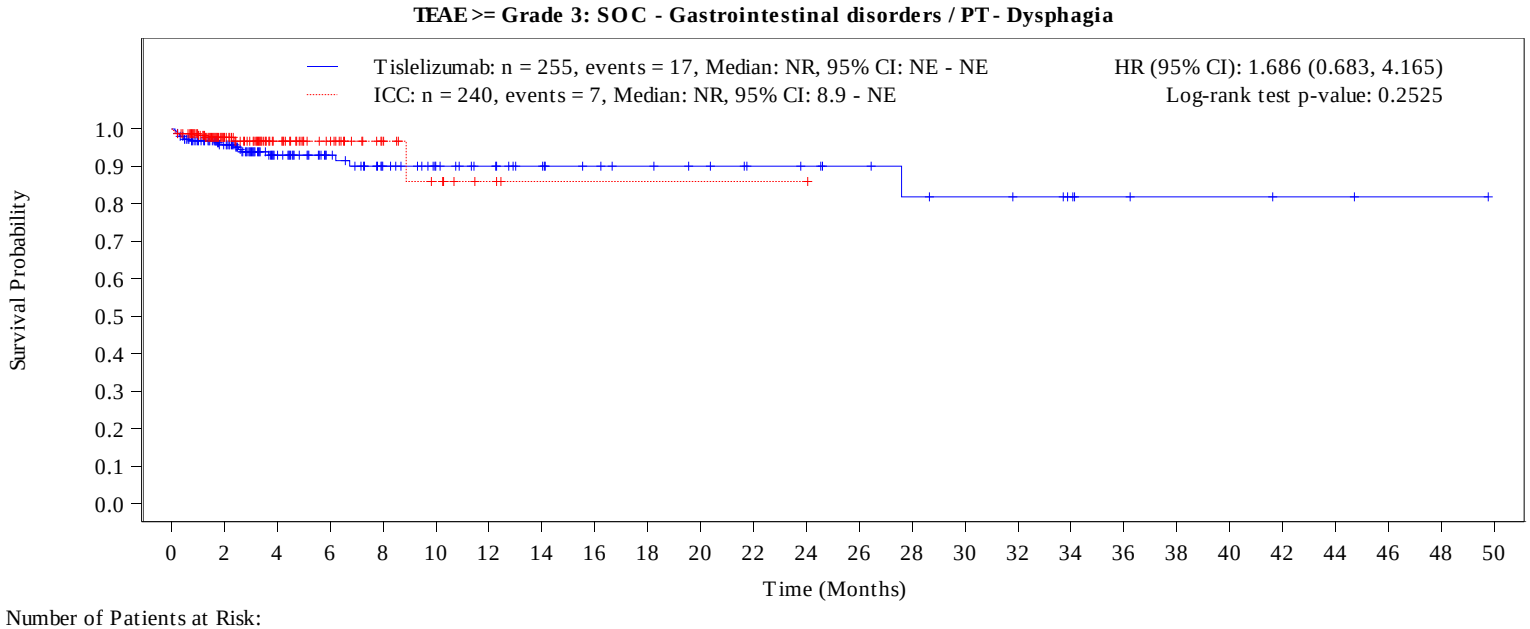


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	174	95	64	49	38	32	27	22	20	18	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	108	43	24	12	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-03-km-aesocpt-g3-safety-cl.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

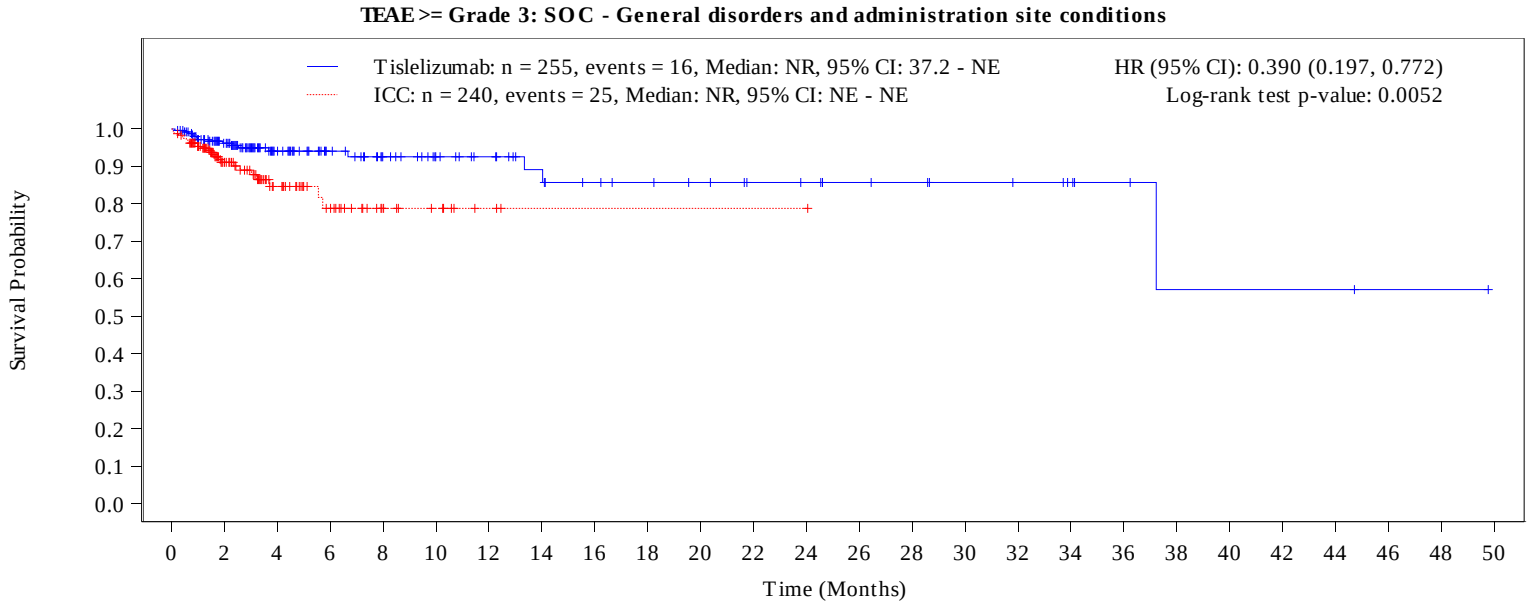


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	171	96	65	49	38	32	27	22	20	18	15	14	12	10	9	8	6	4	3	3	2	2	1	1	0
ICC	240	108	44	25	12	7	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-03-km-aesocpt-g3-safety-cl.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

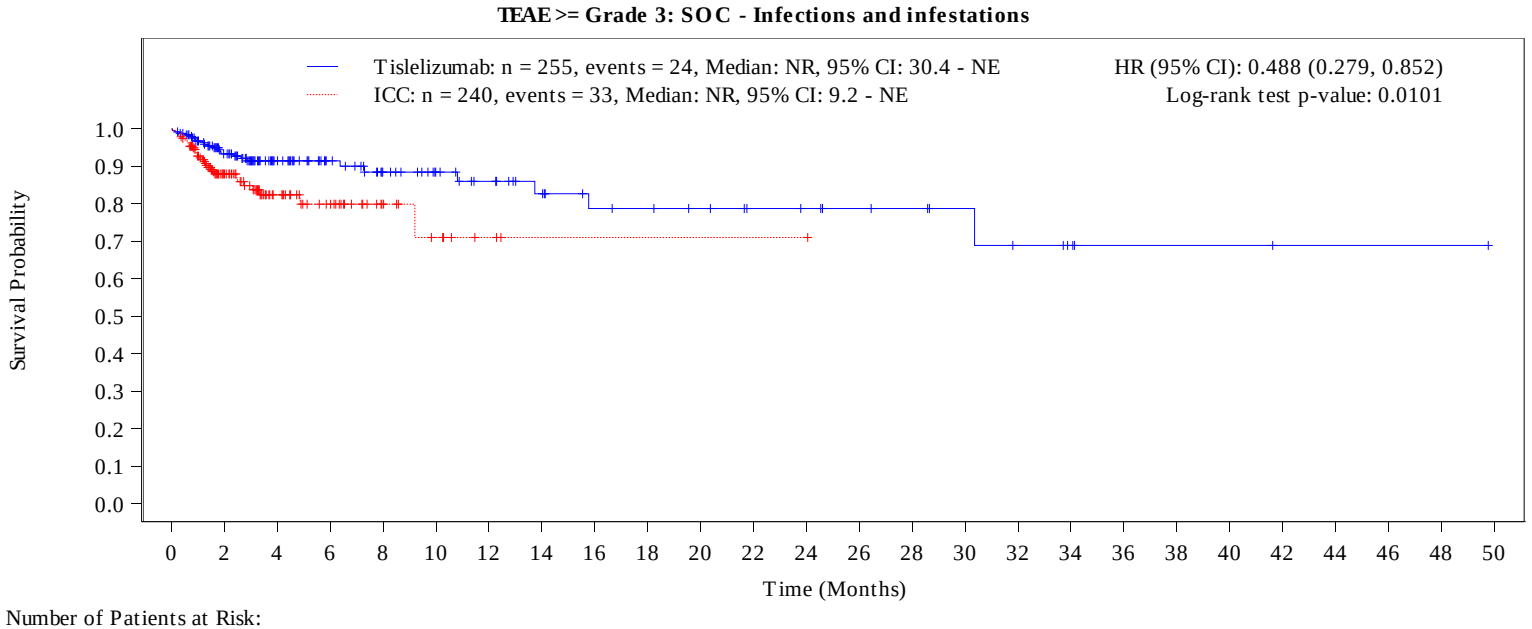


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	173	97	65	49	38	32	26	22	20	18	15	14	12	11	9	8	6	4	2	2	2	2	1	1	0
ICC	240	108	43	25	12	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-03-km-aesocpt-g3-safety-cl.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

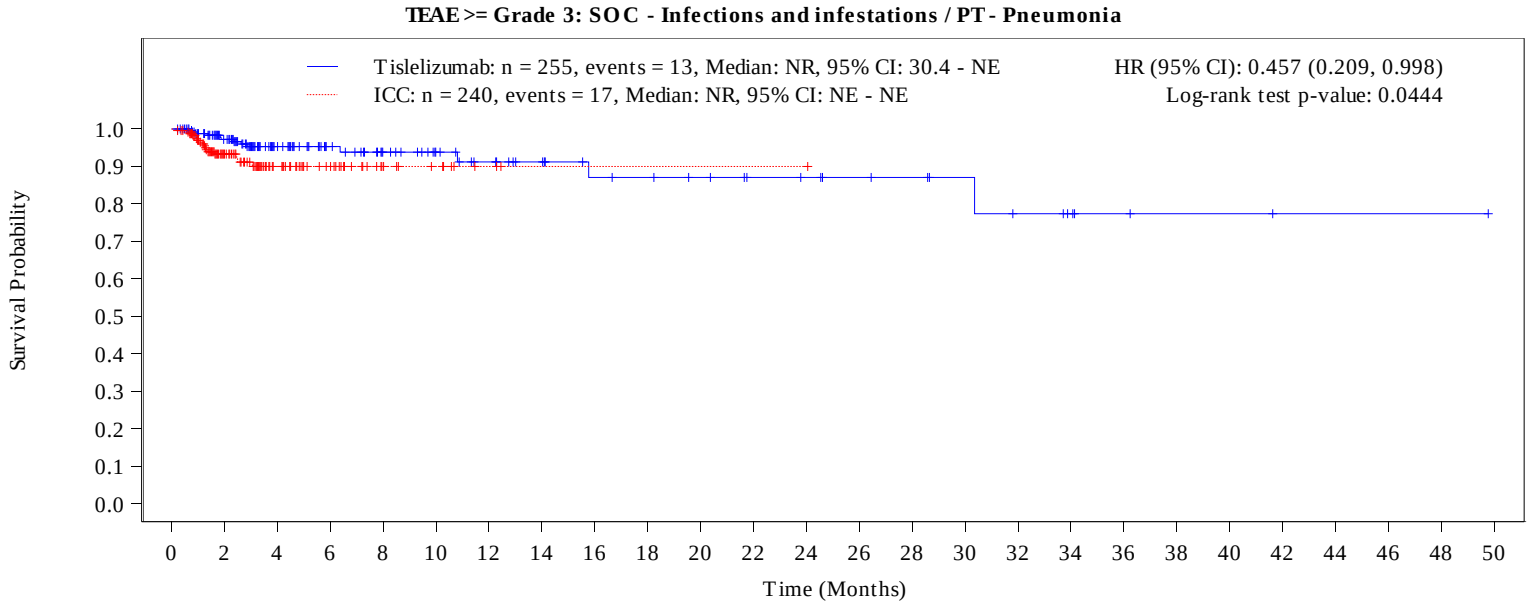


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	168	97	65	49	38	31	25	20	19	17	14	13	11	10	8	6	4	2	2	2	1	1	1	1	0
ICC	240	110	43	26	12	7	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-03-km-aesocpt-g3-safety-cl.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

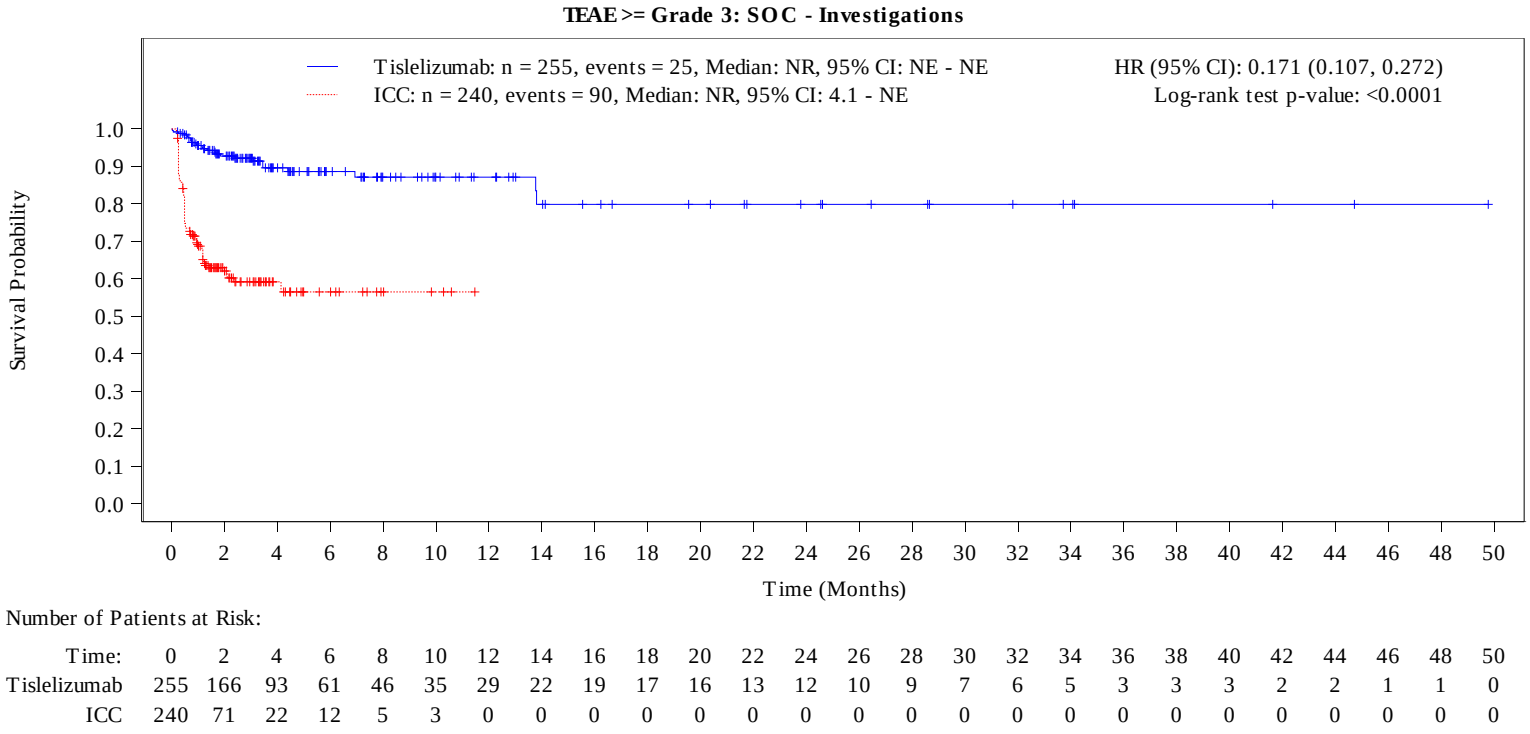


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	173	97	65	49	38	31	26	21	20	18	15	14	12	11	9	7	5	3	2	2	1	1	1	1	0
ICC	240	112	45	26	12	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-03-km-aesocpt-g3-safety-cl.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

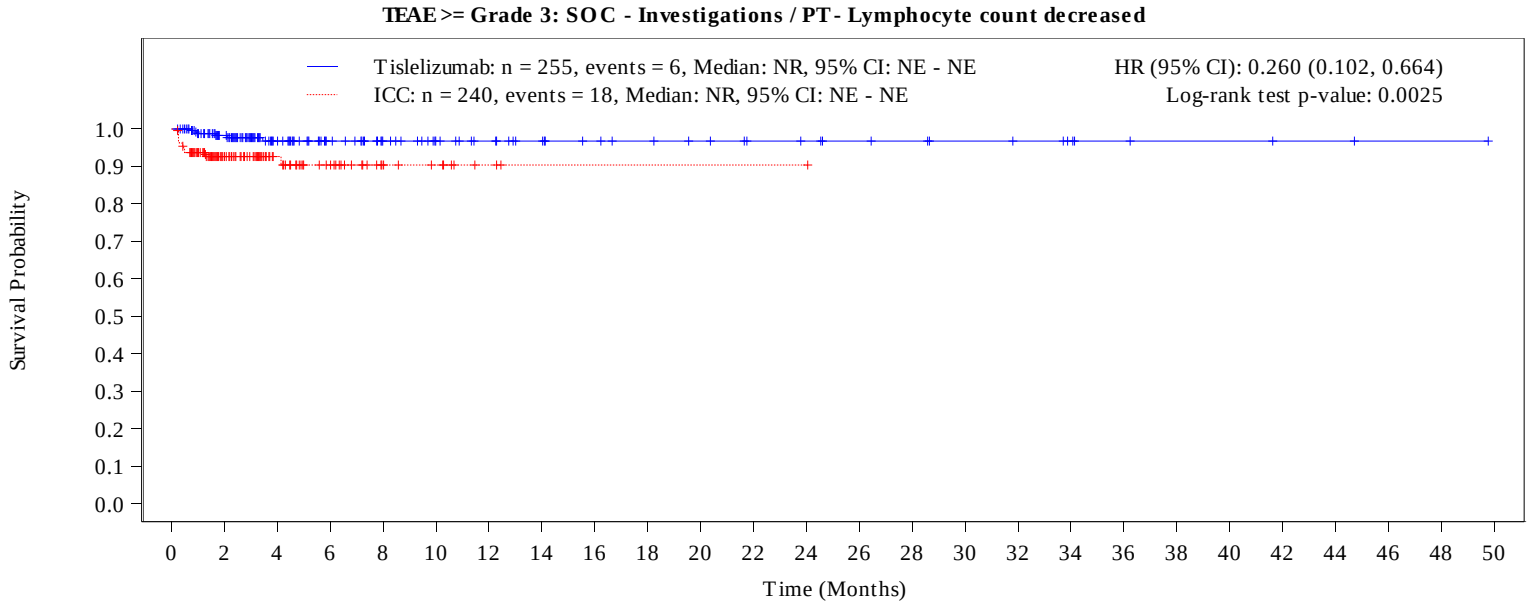


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	166	93	61	46	35	29	22	19	17	16	13	12	10	9	7	6	5	3	3	3	2	2	1	1	0
ICC	240	71	22	12	5	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-03-km-aesocpt-g3-safety-cl.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

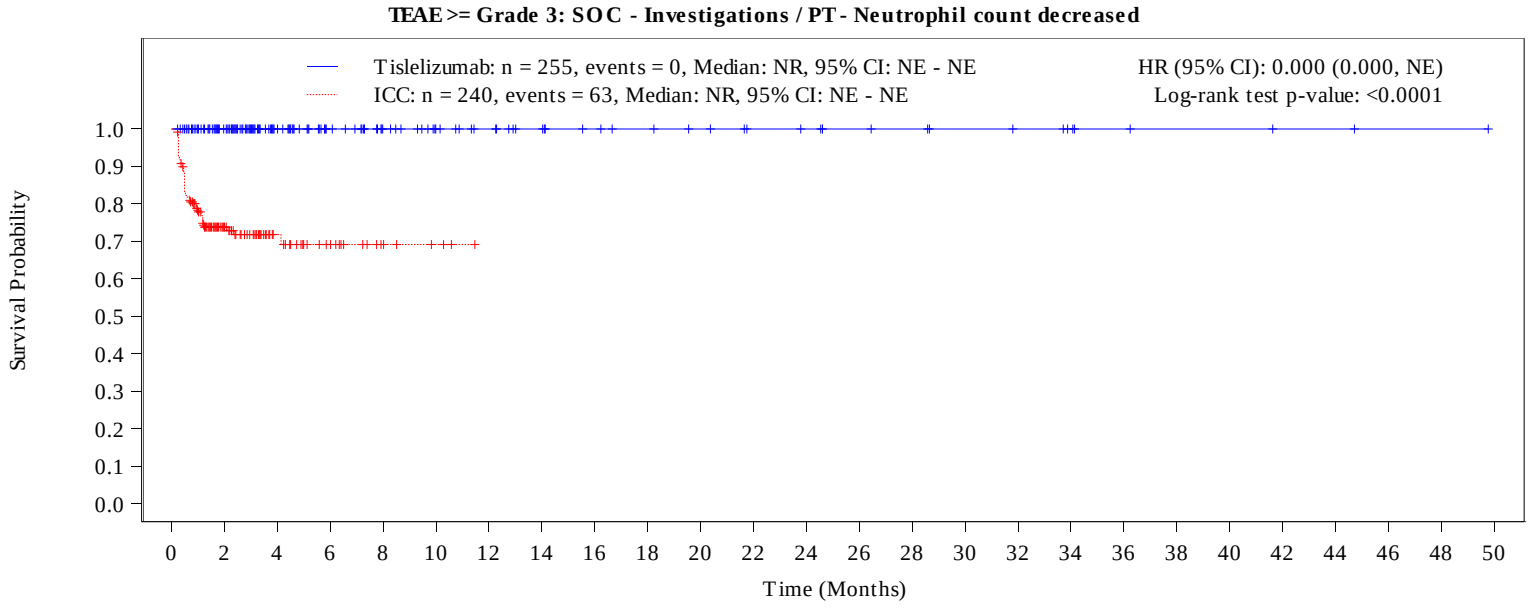


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	172	97	65	49	38	32	27	22	20	18	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	107	41	24	11	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-03-km-aesocpt-g3-safety-cl.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

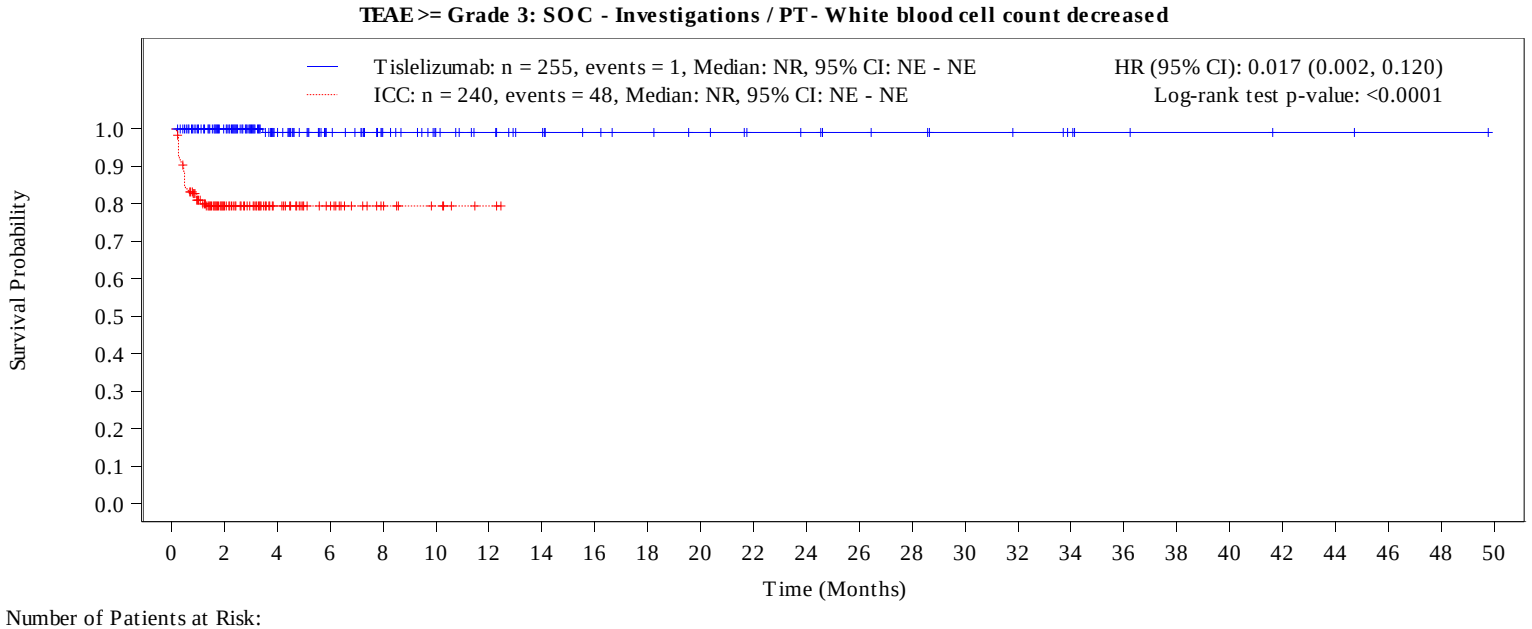


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	175	97	65	49	38	32	27	22	20	18	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	81	27	15	6	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-03-km-aesocpt-g3-safety-cl.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

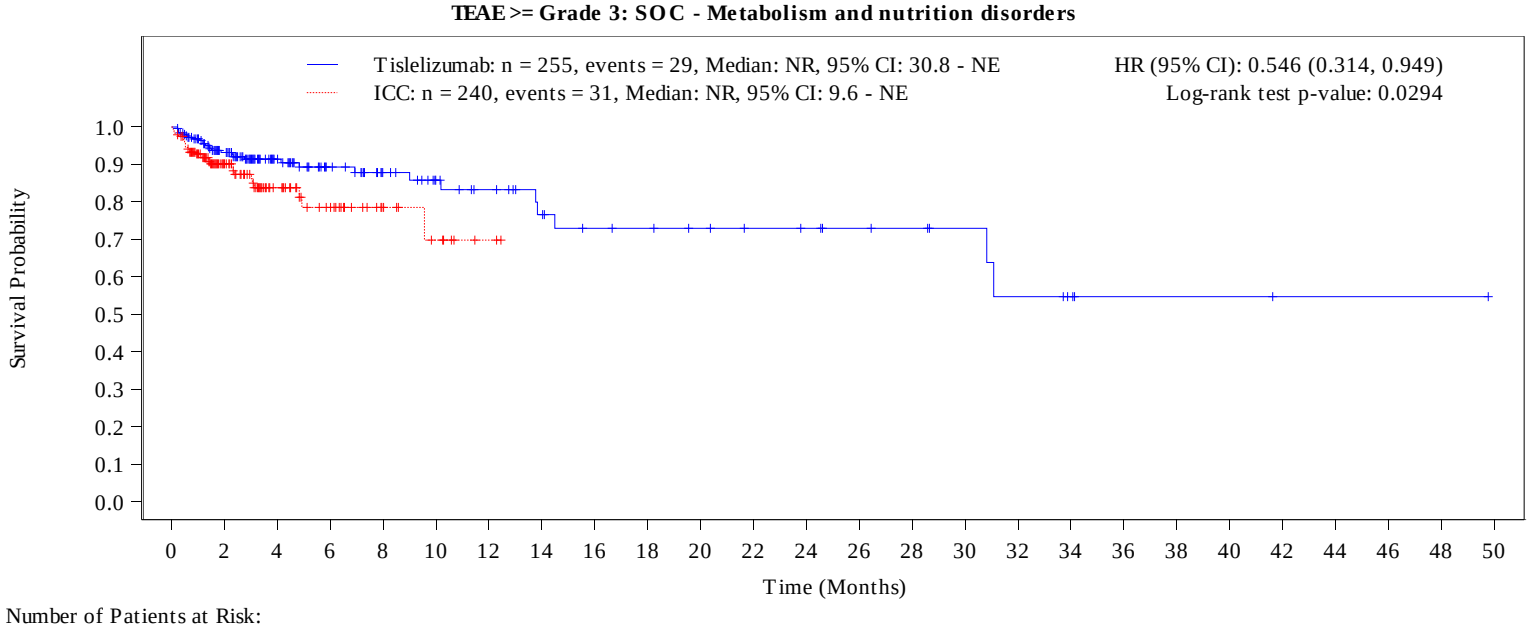


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	175	96	64	49	38	32	27	22	20	18	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	91	36	21	10	6	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-03-km-aesocpt-g3-safety-cl.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

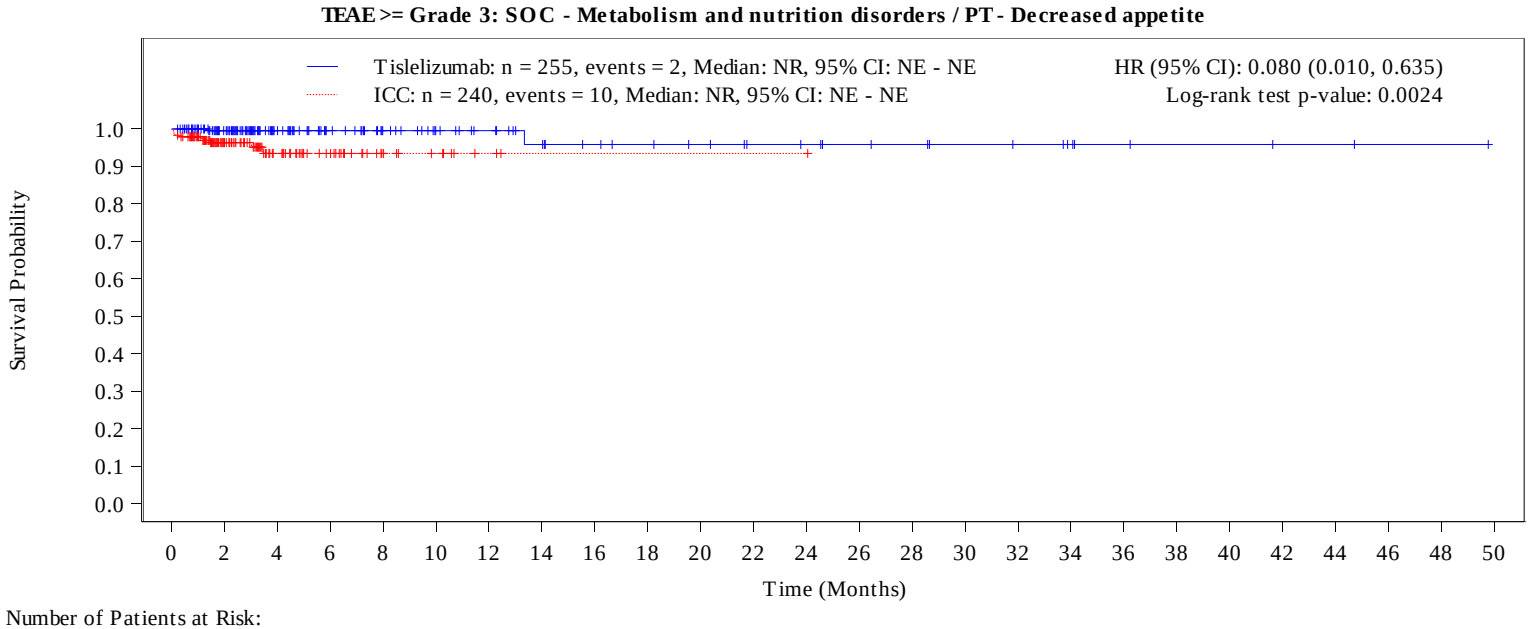


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	169	96	63	46	35	29	23	19	18	16	14	13	11	10	8	6	4	2	2	2	1	1	1	1	0
ICC	240	108	43	25	12	7	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-03-km-aesocpt-g3-safety-cl.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

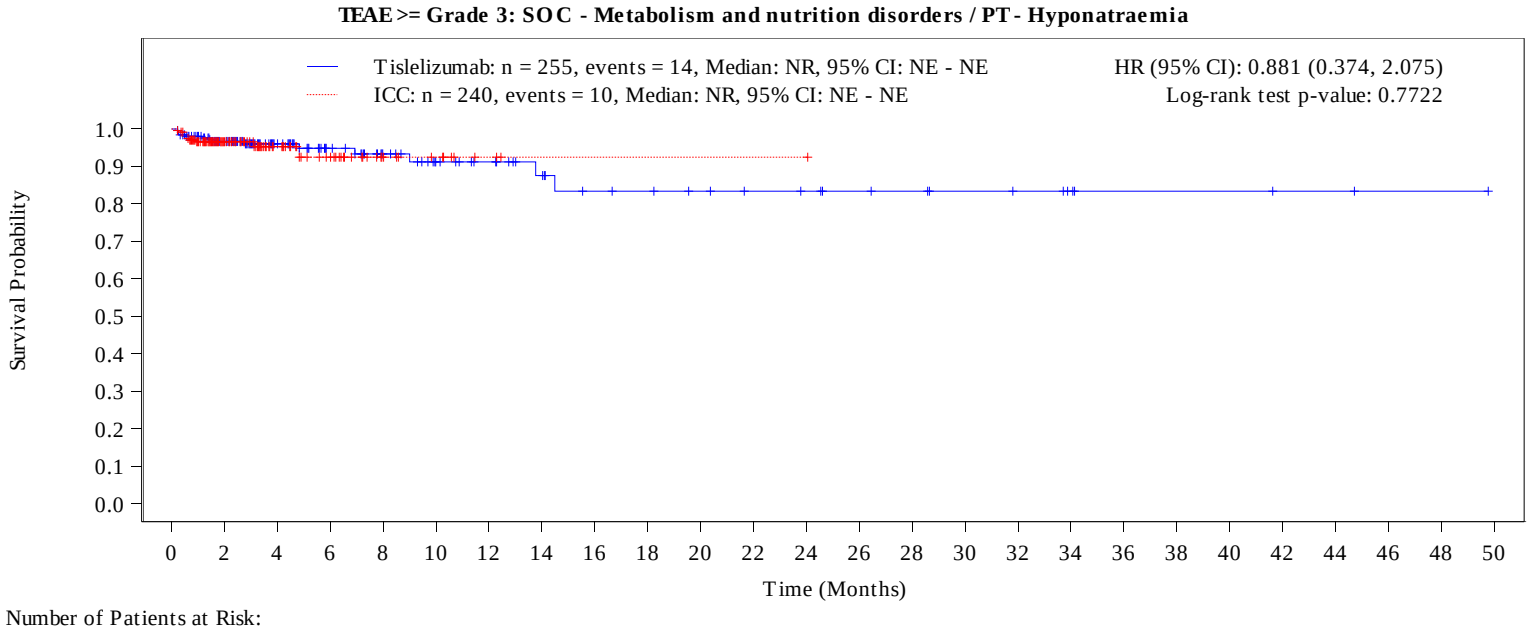


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	174	97	65	49	38	32	26	22	20	18	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	112	45	26	12	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-03-km-aesocpt-g3-safety-cl.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

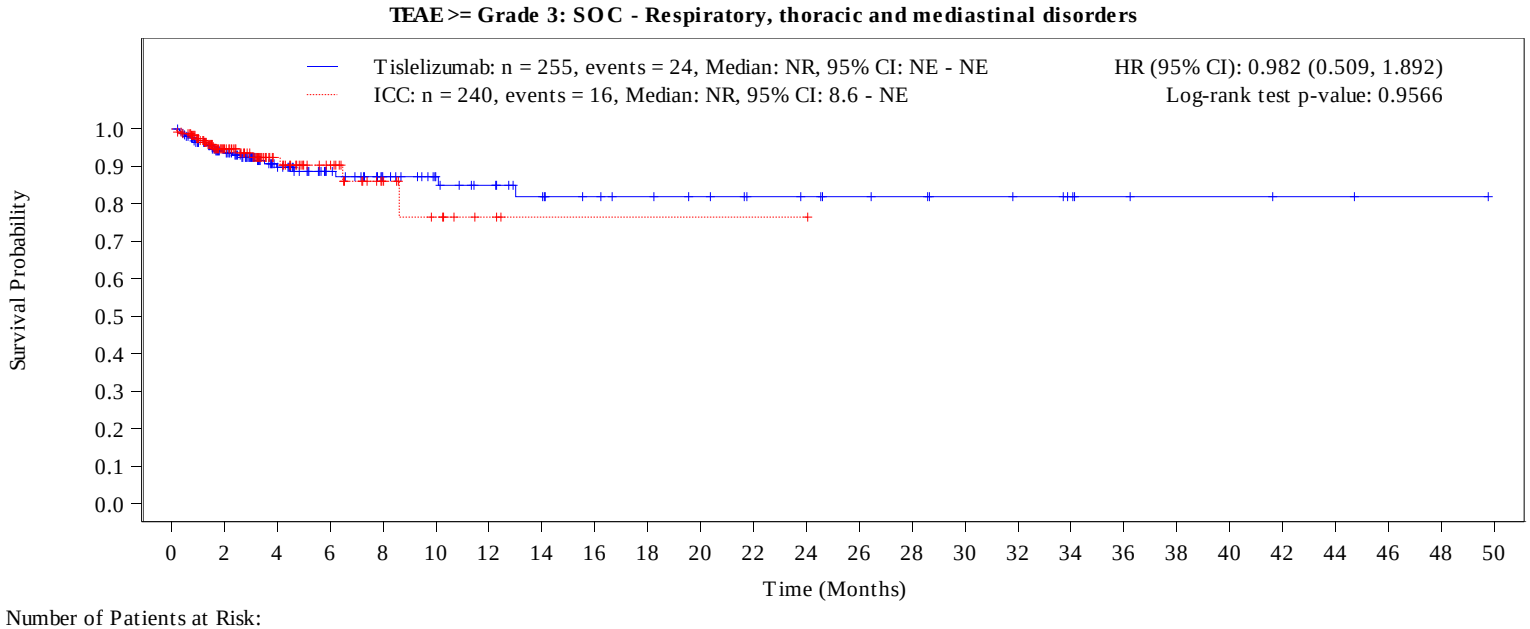


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	173	97	65	48	36	30	24	19	18	16	14	13	11	10	8	7	5	3	3	3	2	2	1	1	0
ICC	240	111	44	26	12	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-03-km-aesocpt-g3-safety-cl.rtf

Figure 14.3.1.3:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set

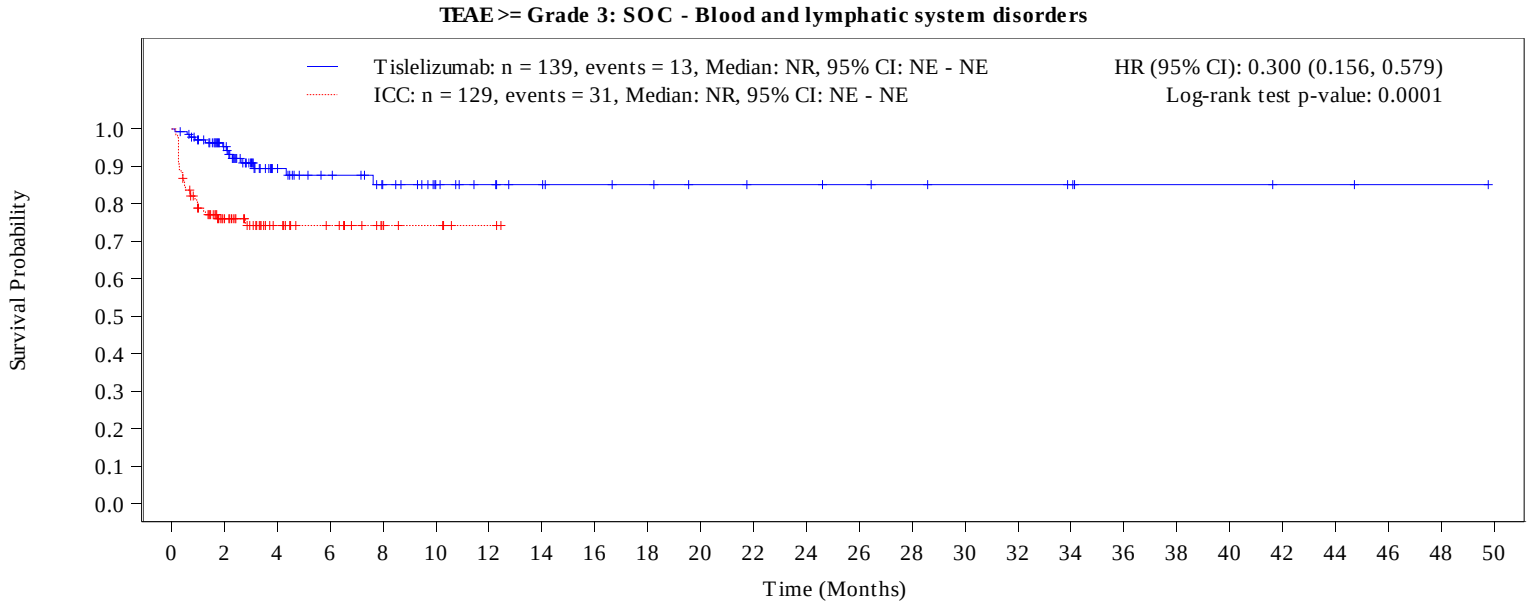


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	171	96	64	49	38	32	27	22	20	18	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	112	45	26	12	7	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-03-km-aesocpt-g3-safety-cl.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

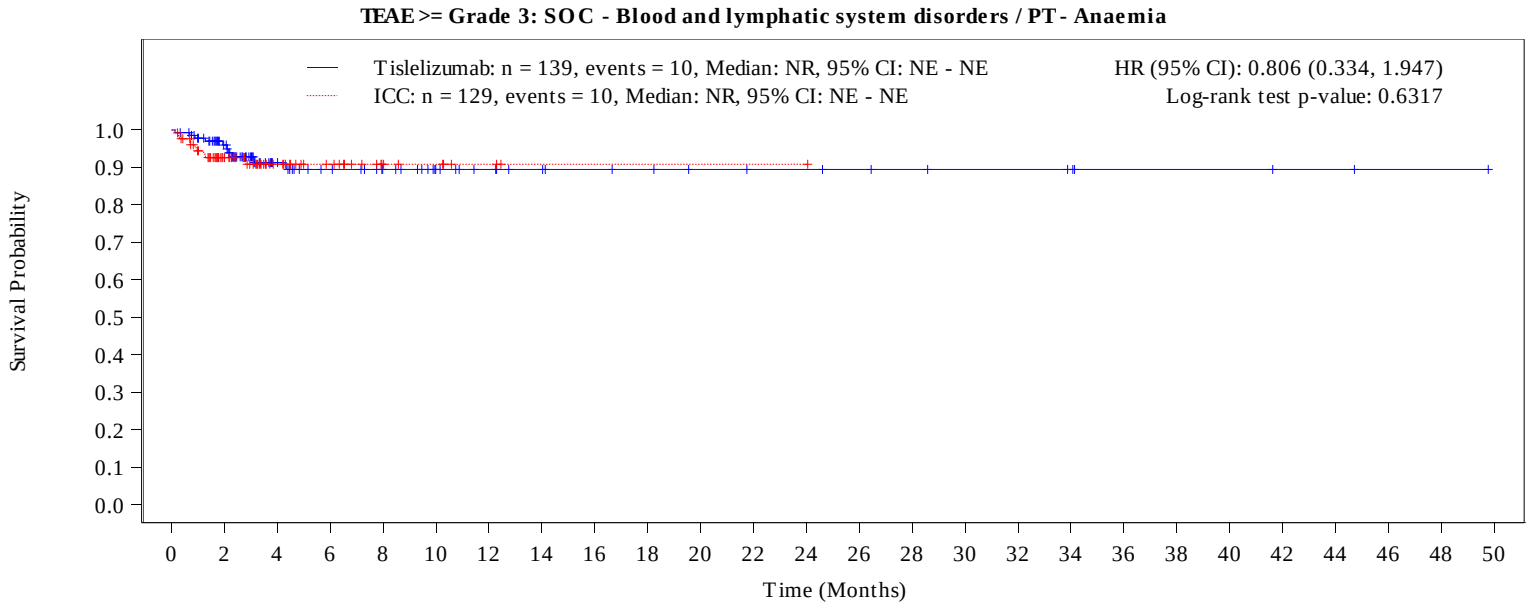


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	93	51	40	31	22	18	15	13	12	10	9	9	8	7	6	6	5	3	3	3	2	2	1	1	0
ICC	129	62	25	15	7	5	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-03-b-km-aesocpt-g3-safetys-cl.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

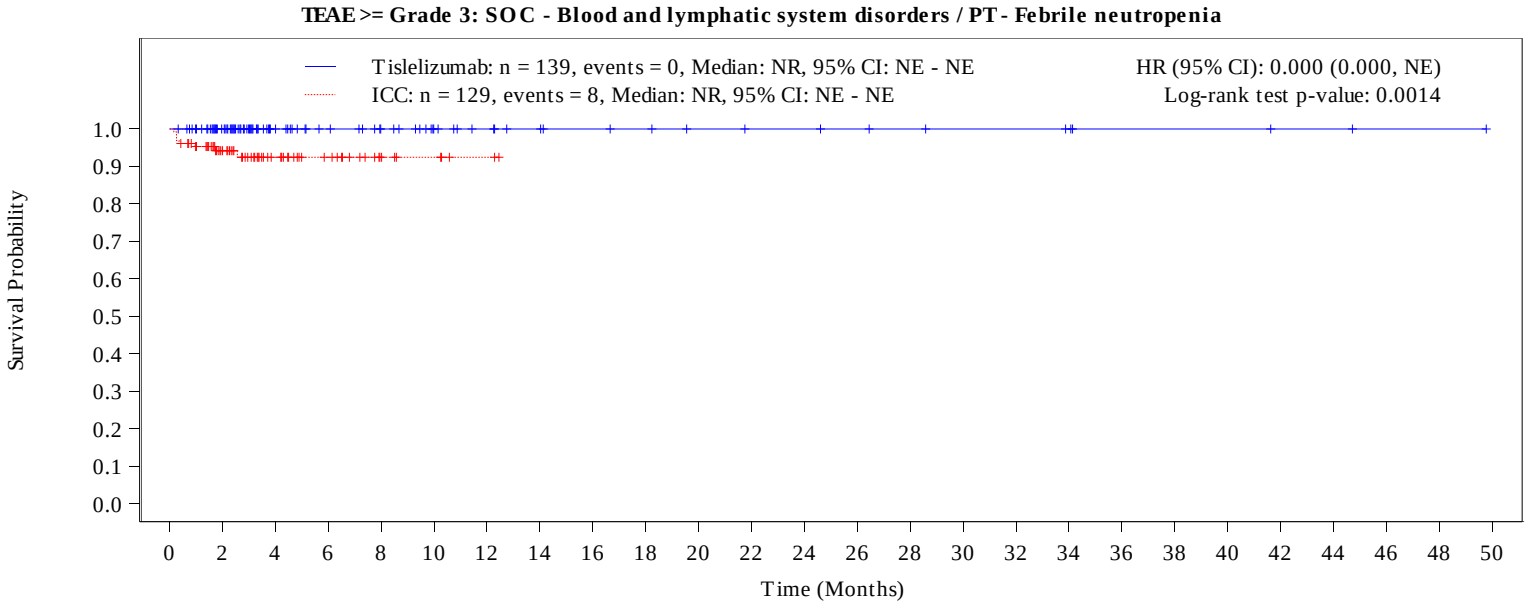


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	93	51	40	32	23	19	16	13	12	10	9	9	8	7	6	6	5	3	3	3	2	2	1	1	0
ICC	129	72	30	17	8	6	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-03-b-km-aesocpt-g3-safetys-cl.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

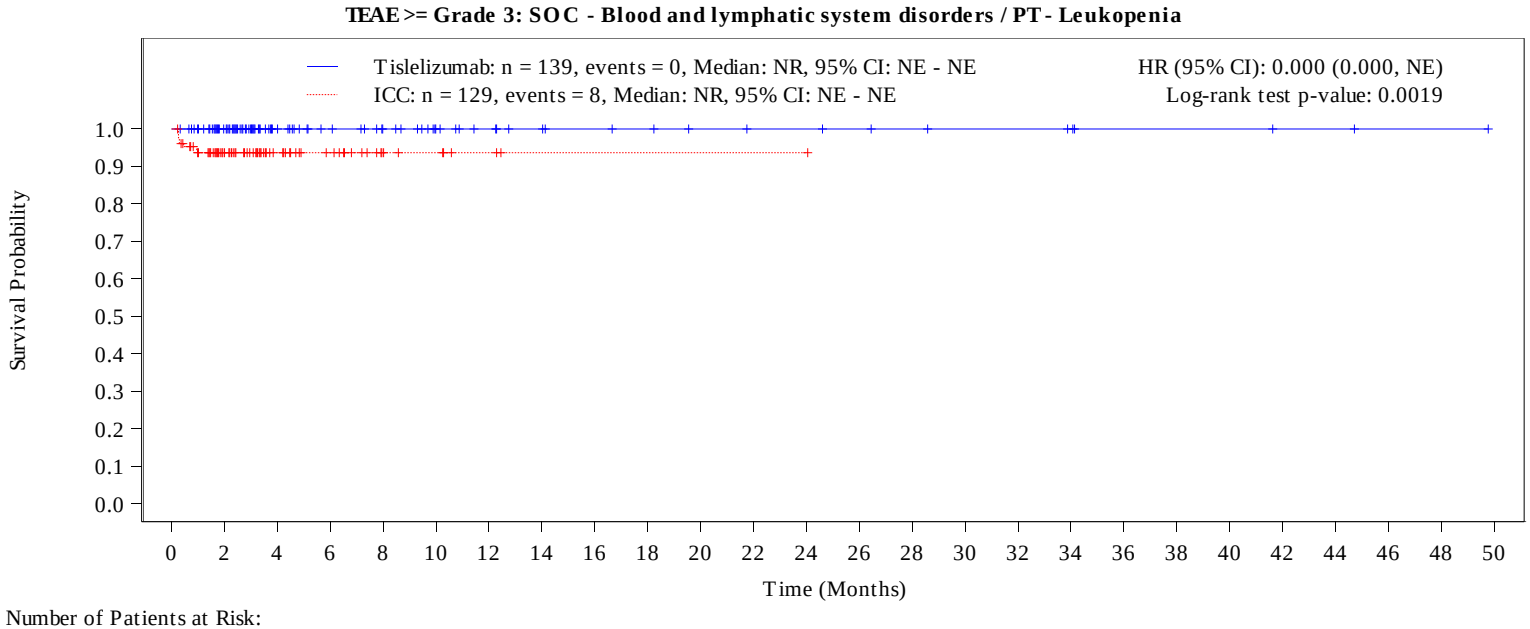


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	95	52	40	32	23	19	16	13	12	10	9	9	8	7	6	6	5	3	3	3	2	2	1	1	0
ICC	129	72	32	18	8	5	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-03-b-km-aesocpt-g3-safetys-cl.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

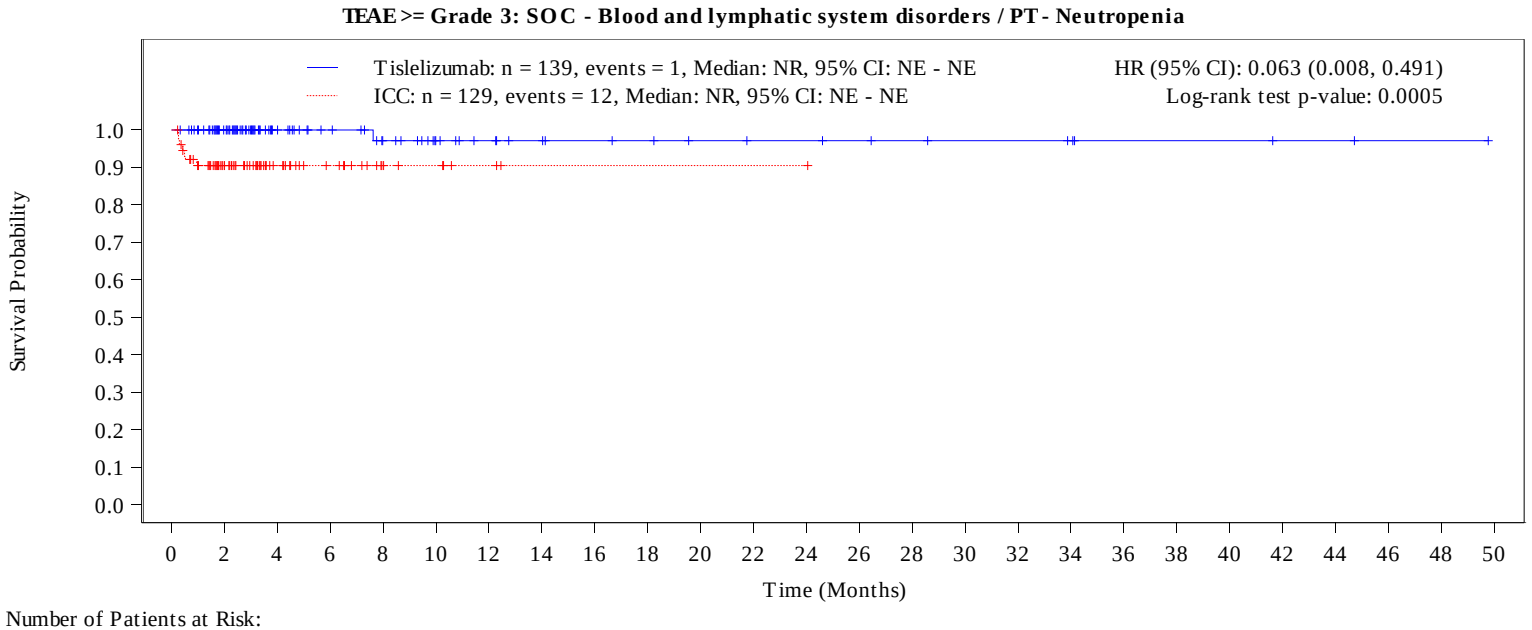


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	95	52	40	32	23	19	16	13	12	10	9	9	8	7	6	6	5	3	3	3	2	2	1	1	0
ICC	129	72	30	18	8	6	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-03-b-km-aesocpt-g3-safetys-cl.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

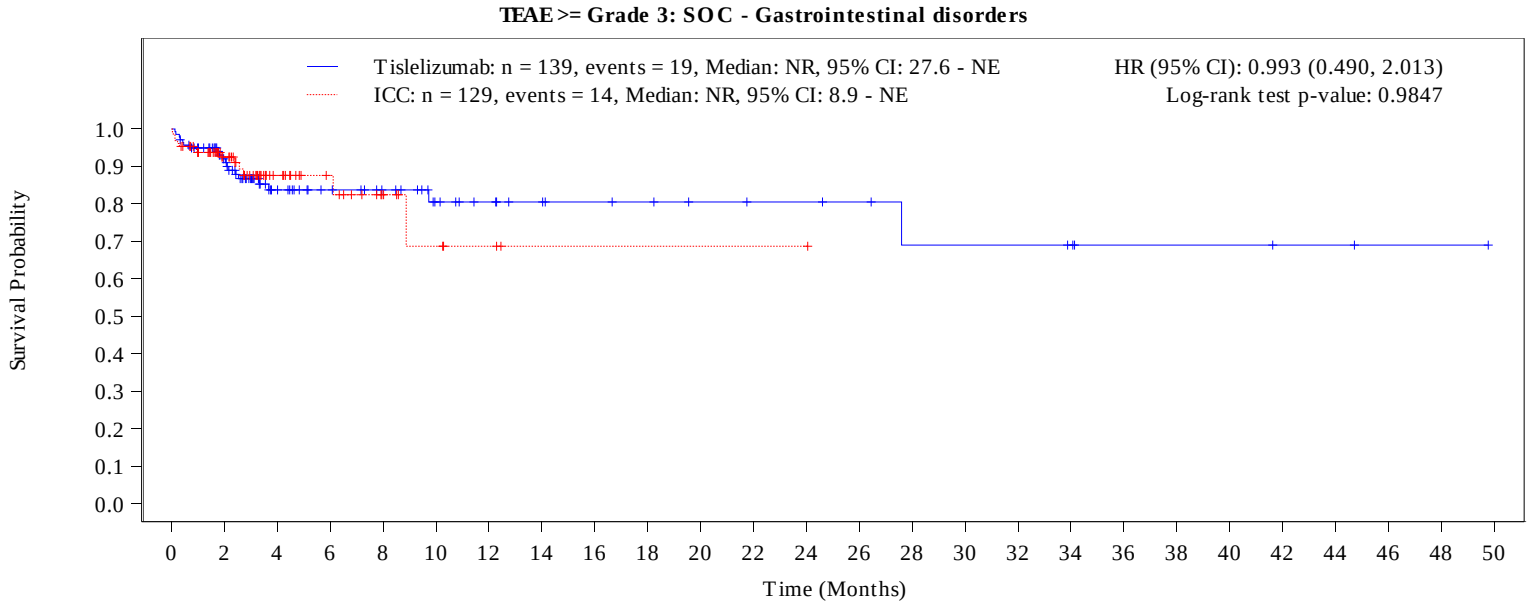


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	95	52	40	31	22	18	15	13	12	10	9	9	8	7	6	6	5	3	3	3	2	2	1	1	0
ICC	129	70	29	17	8	6	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-03-b-km-aesocpt-g3-safetys-cl.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

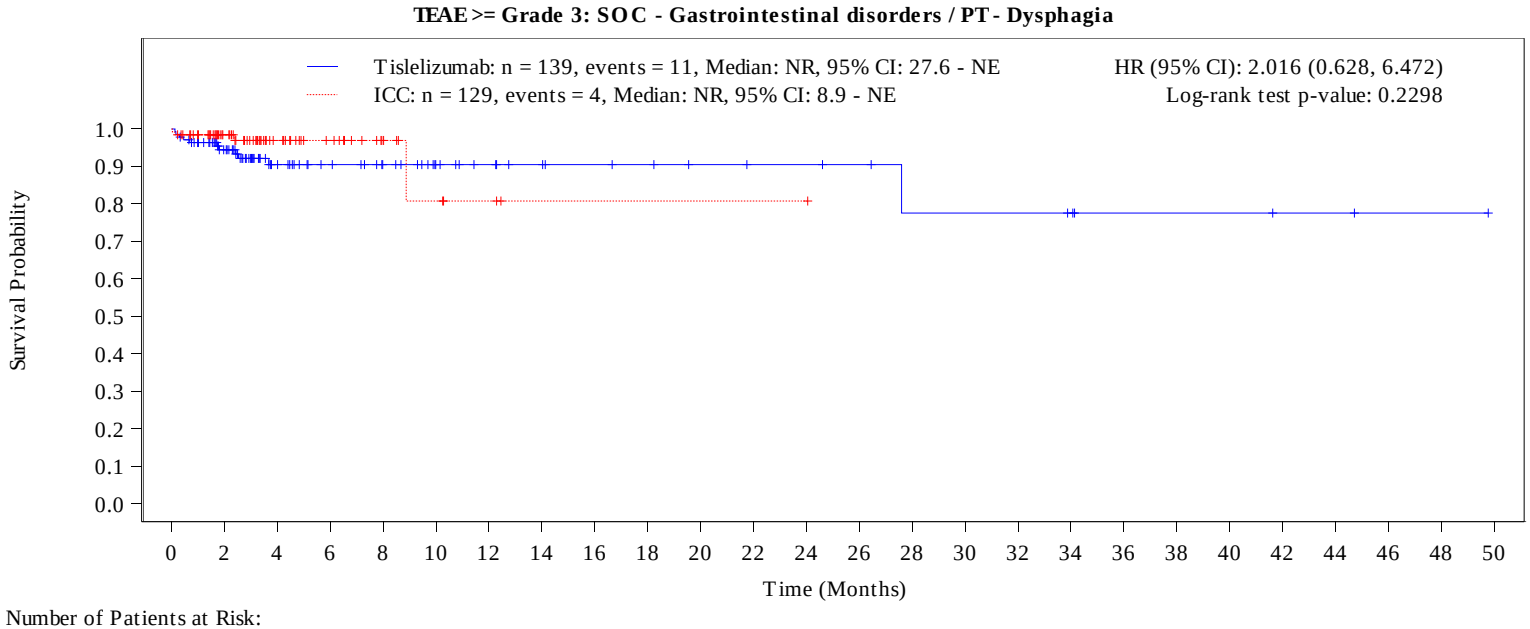


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	91	51	39	32	23	19	16	13	12	10	9	9	8	6	6	6	5	3	3	3	2	2	1	1	0
ICC	129	71	30	17	9	5	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-03-b-km-aesocpt-g3-safetys-cl.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

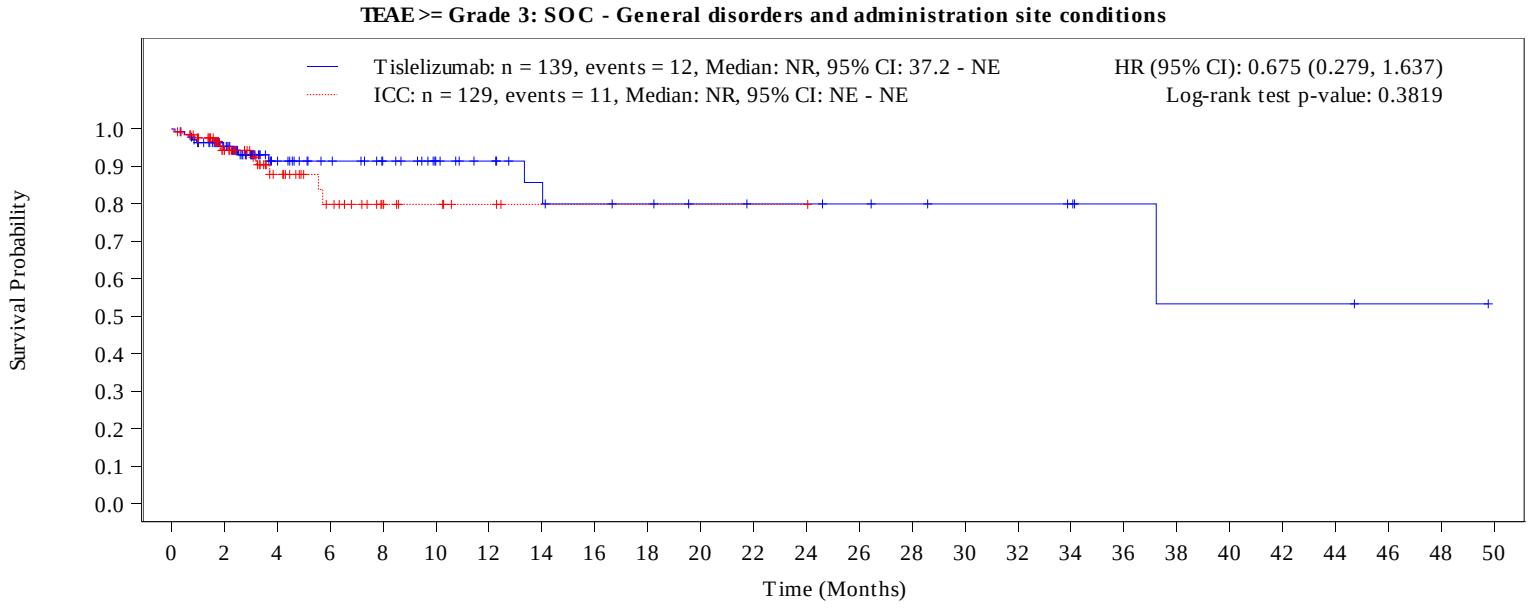


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	92	52	40	32	23	19	16	13	12	10	9	9	8	6	6	6	5	3	3	3	2	2	1	1	0
ICC	129	73	32	18	9	5	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-03-b-km-aesocpt-g3-safetys-cl.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

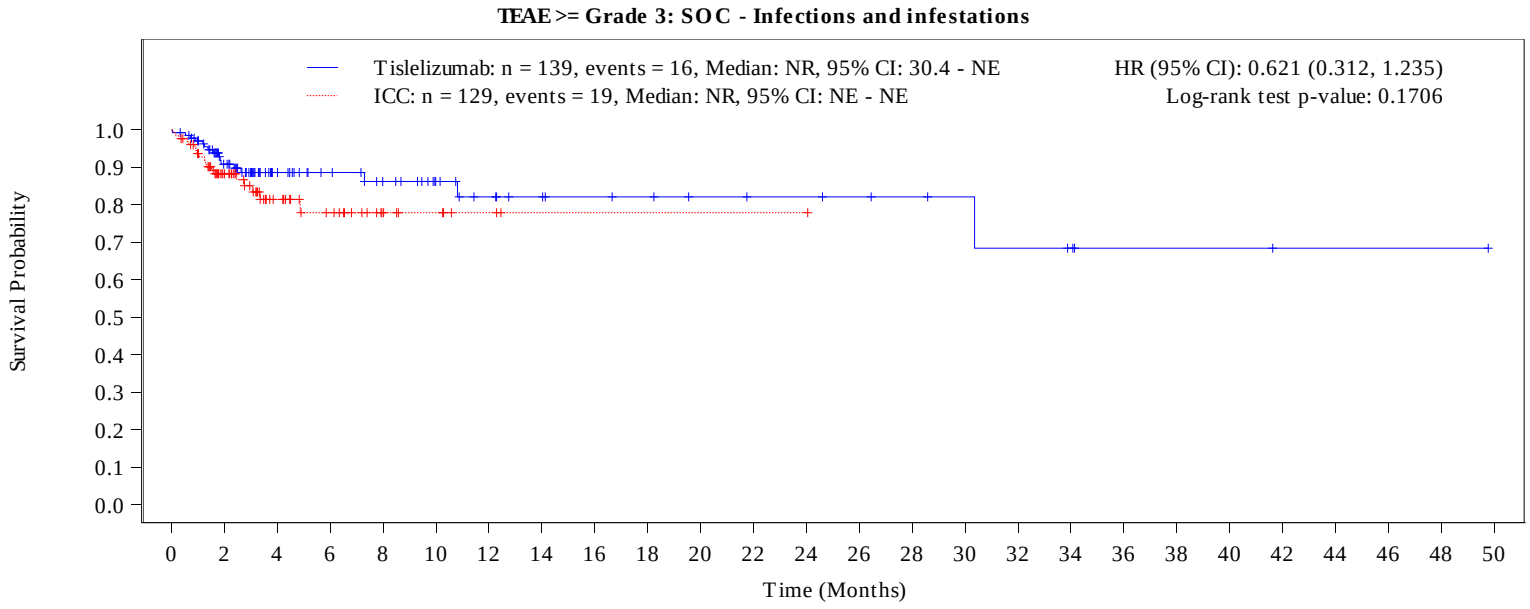


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	94	52	40	32	23	19	15	13	12	10	9	9	8	7	6	6	5	3	2	2	2	2	1	1	0
ICC	129	73	32	18	9	6	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-03-b-km-aesocpt-g3-safetys-cl.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

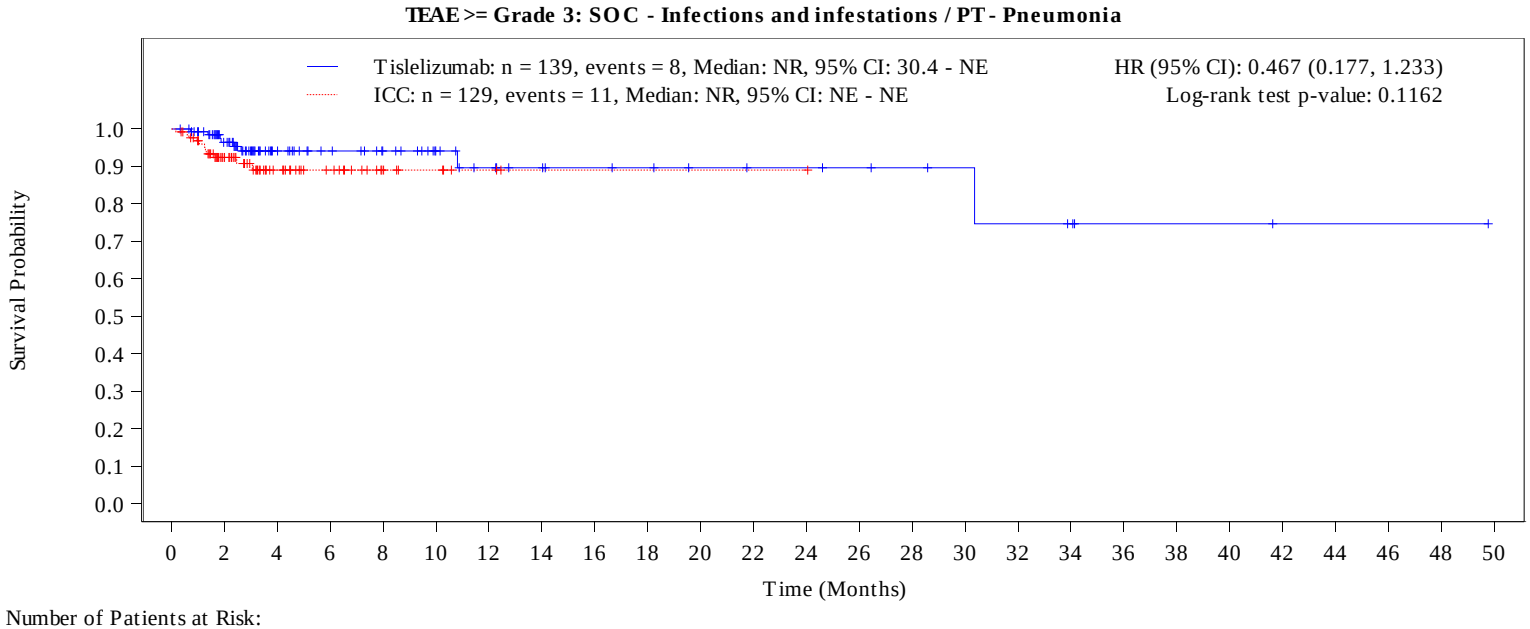


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	89	52	40	32	23	18	15	13	12	10	9	9	8	7	6	5	4	2	2	2	1	1	1	1	0
ICC	129	73	31	19	9	6	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-03-b-km-aesocpt-g3-safetys-cl.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

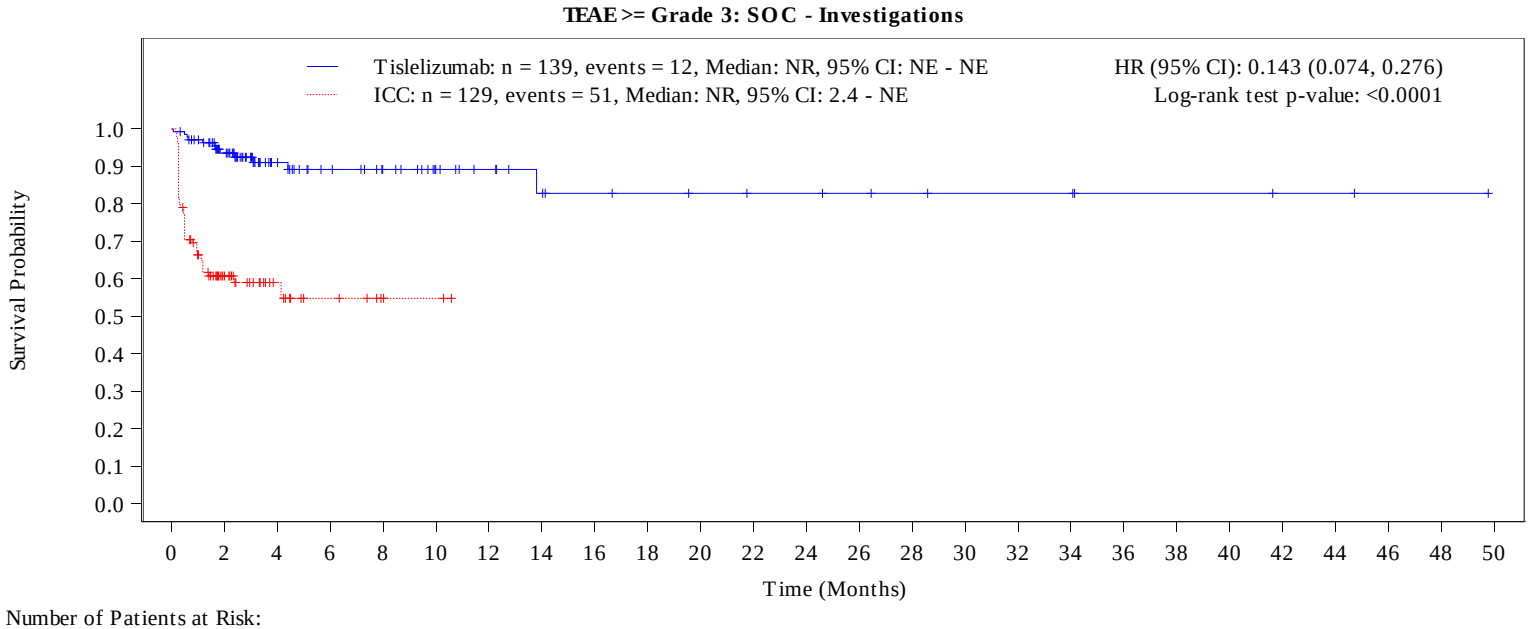


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	93	52	40	32	23	18	15	13	12	10	9	9	8	7	6	5	4	2	2	2	1	1	1	1	0
ICC	129	74	33	19	9	6	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-03-b-km-aesocpt-g3-safetys-cl.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

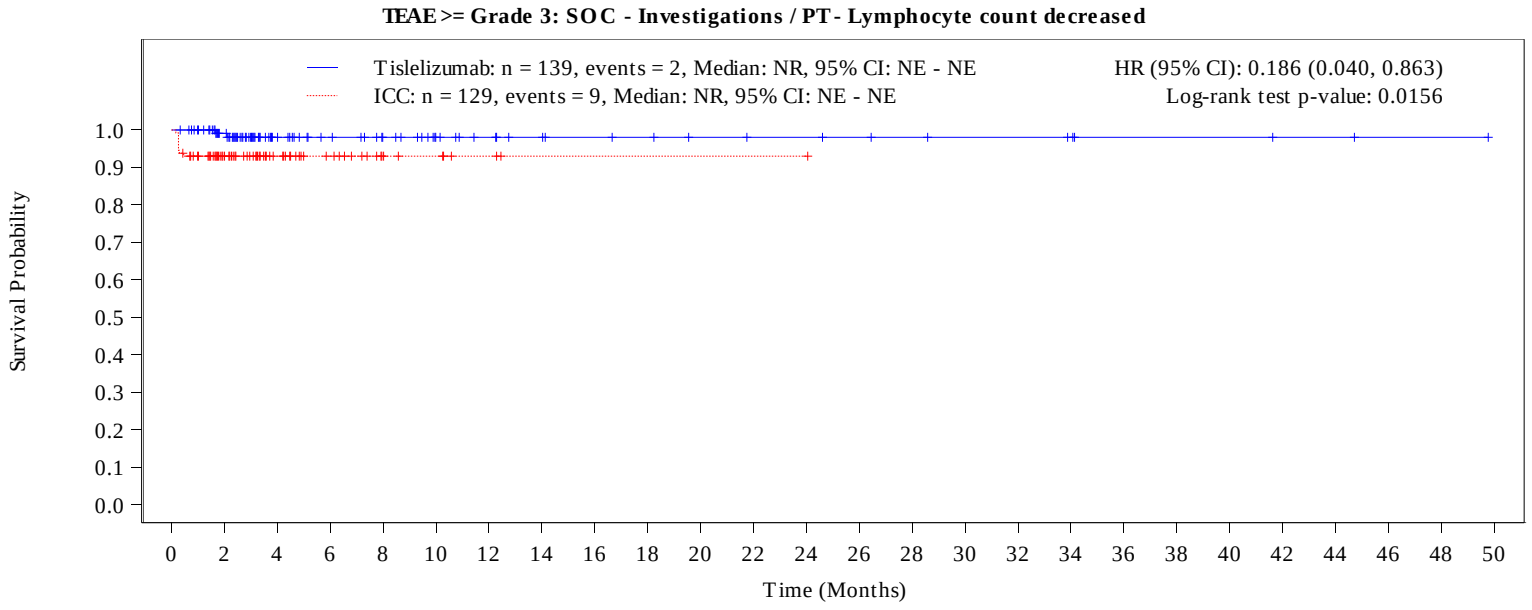


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	91	50	38	30	21	17	13	11	10	9	8	8	7	6	5	5	5	3	3	3	2	2	1	1	0
ICC	129	43	14	7	3	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-03-b-km-aesocpt-g3-safetys-cl.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

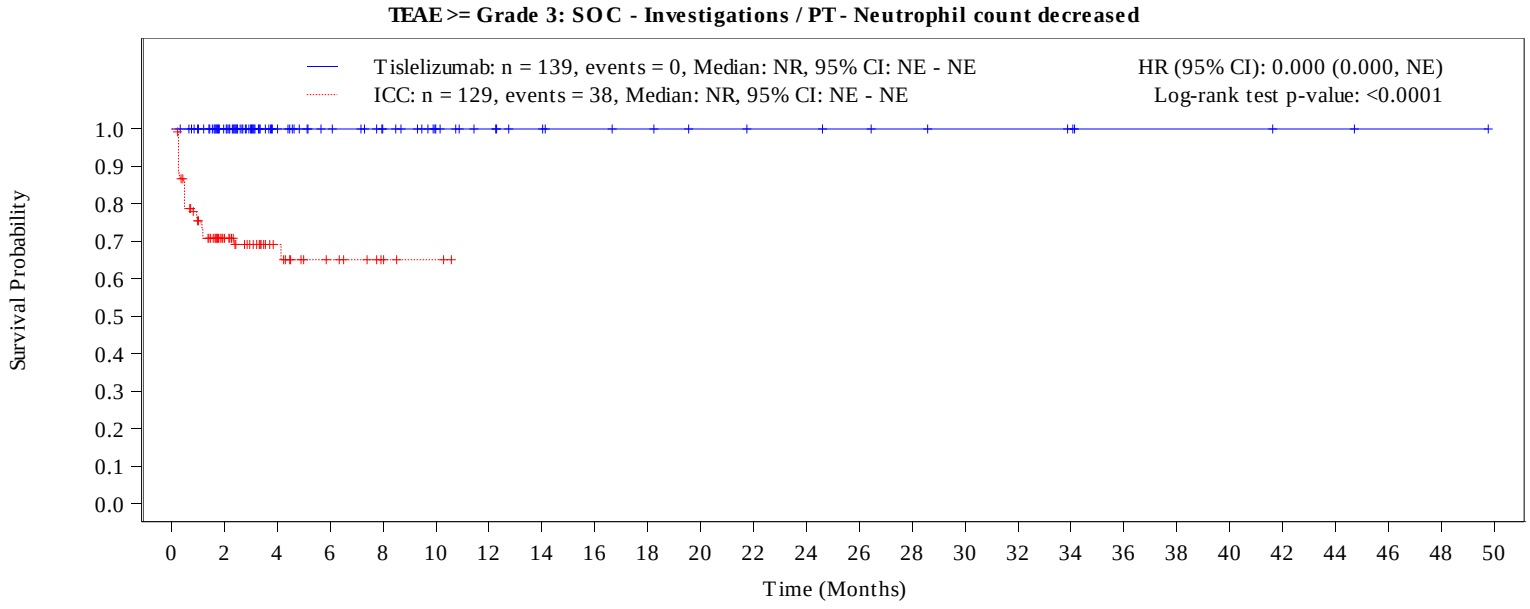


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	95	52	40	32	23	19	16	13	12	10	9	9	8	7	6	6	5	3	3	3	2	2	1	1	0
ICC	129	70	30	17	8	6	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-03-b-km-aesocpt-g3-safetys-cl.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

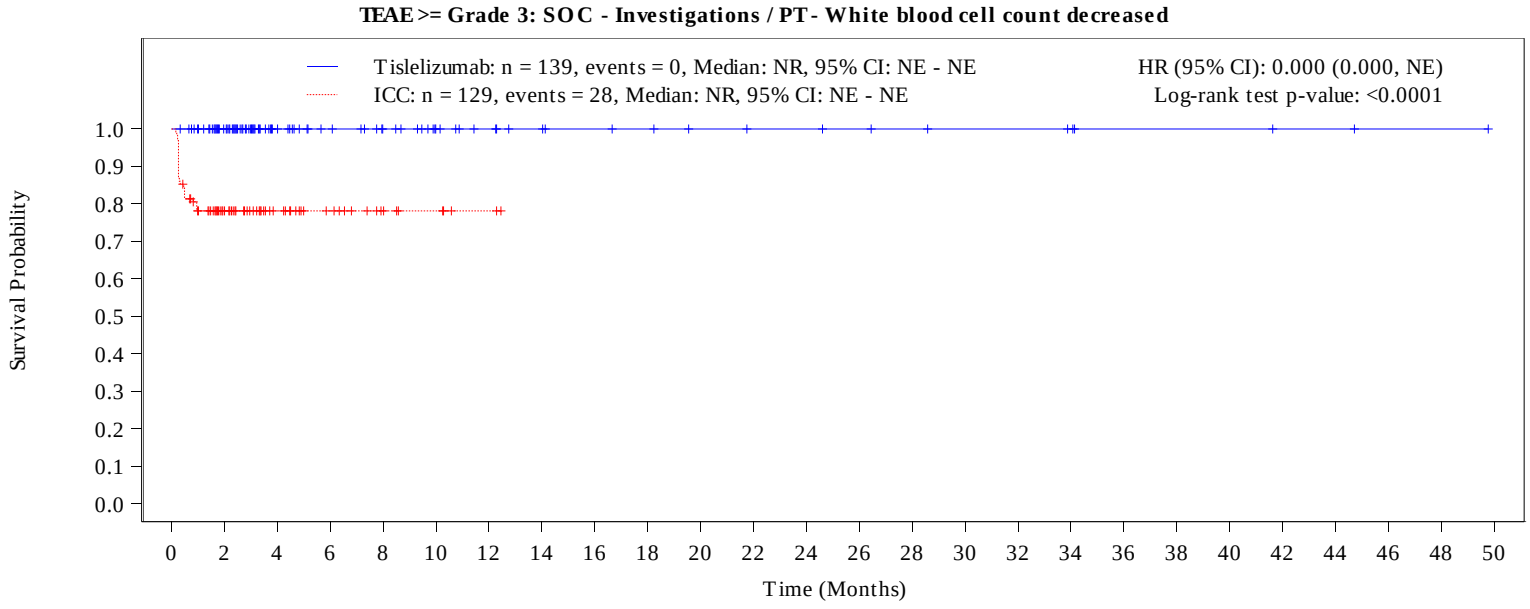


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	95	52	40	32	23	19	16	13	12	10	9	9	8	7	6	6	5	3	3	3	2	2	1	1	0
ICC	129	51	17	9	4	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-03-b-km-aesocpt-g3-safetys-cl.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

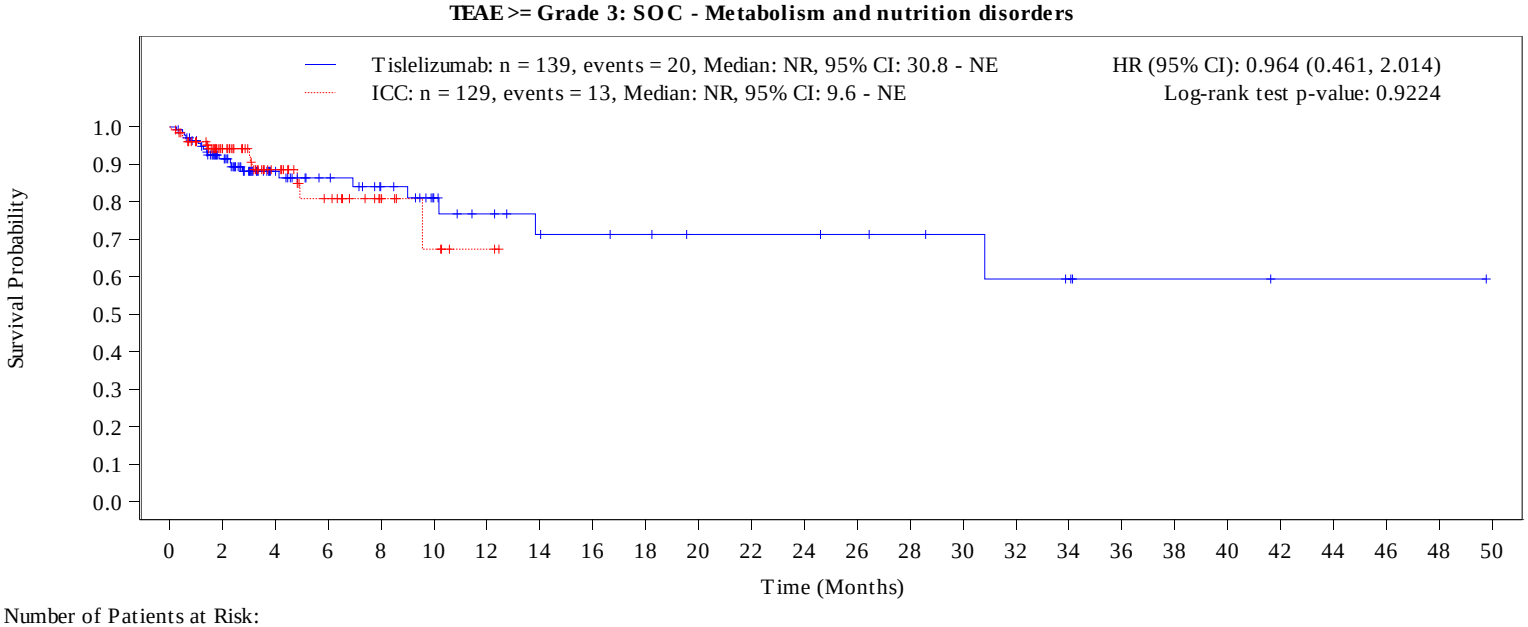


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	95	52	40	32	23	19	16	13	12	10	9	9	8	7	6	6	5	3	3	3	2	2	1	1	0
ICC	129	58	25	15	8	5	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-03-b-km-aesocpt-g3-safetys-cl.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

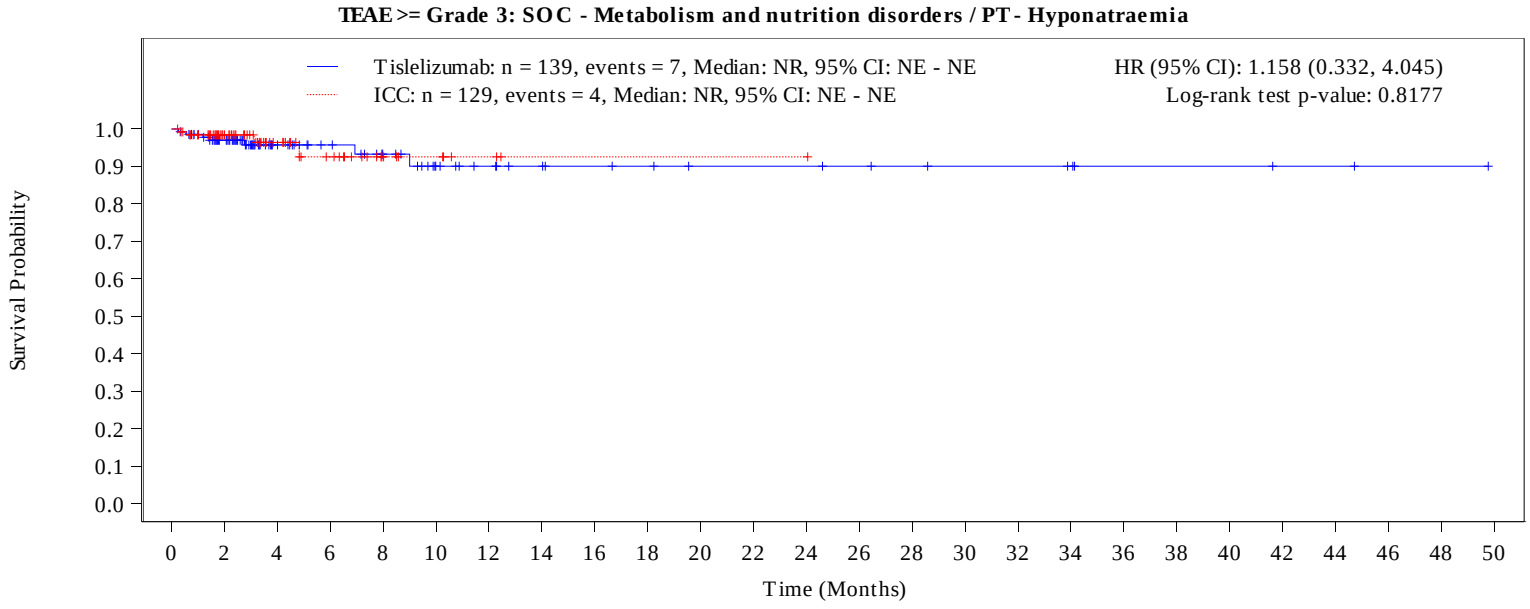


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	90	51	38	29	20	16	13	12	11	9	9	9	8	7	6	5	4	2	2	2	1	1	1	1	0
ICC	129	72	32	18	9	5	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-03-b-km-aesocpt-g3-safetys-cl.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

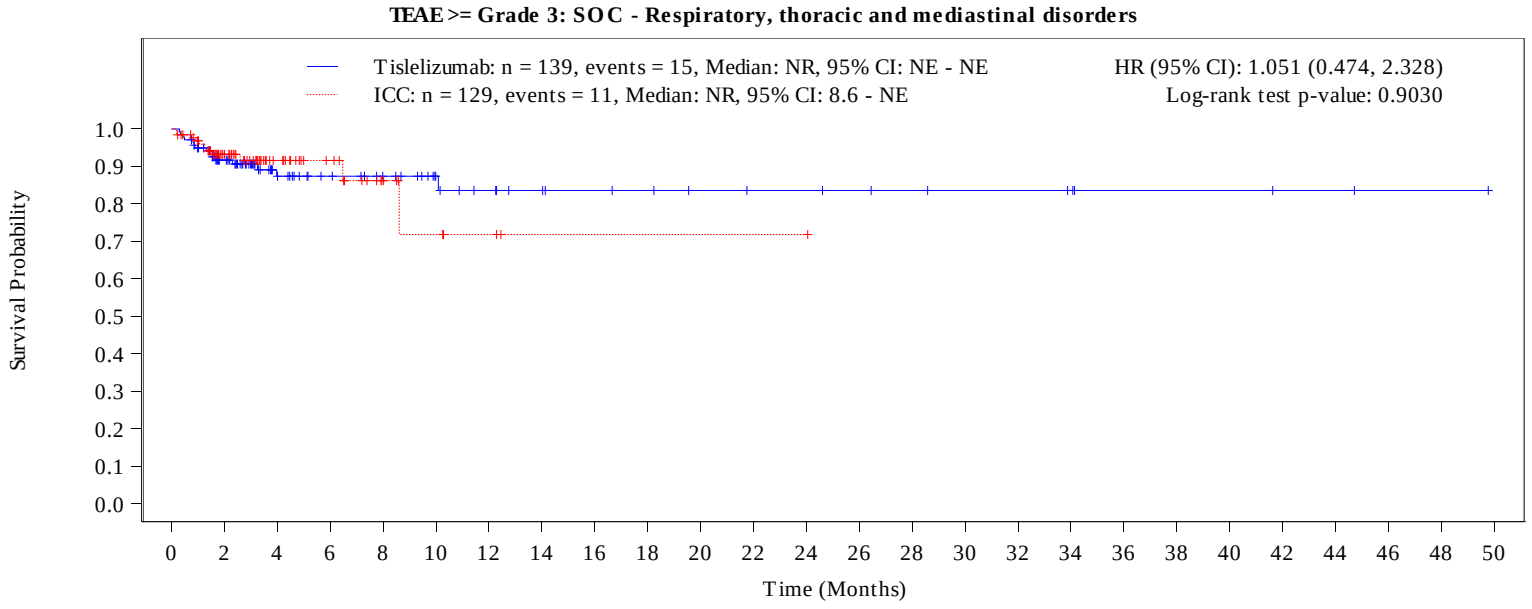


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	94	52	40	31	21	17	14	12	11	9	9	9	8	7	6	6	5	3	3	3	2	2	1	1	0
ICC	129	74	33	19	9	6	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-03-b-km-aesocpt-g3-safetys-cl.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

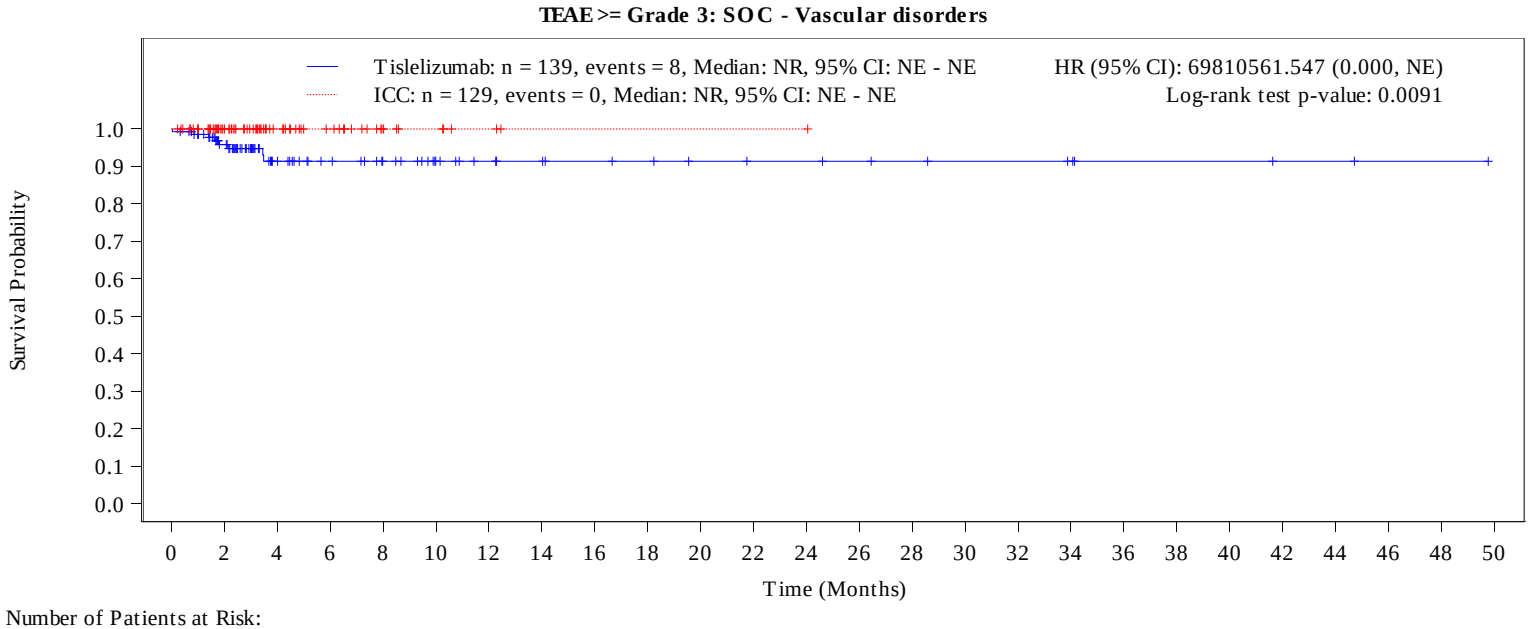


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	92	51	39	32	23	19	16	13	12	10	9	9	8	7	6	6	5	3	3	3	2	2	1	1	0
ICC	129	75	33	19	9	5	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-03-b-km-aesocpt-g3-safetys-cl.rtf

Figure 14.3.1.3.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

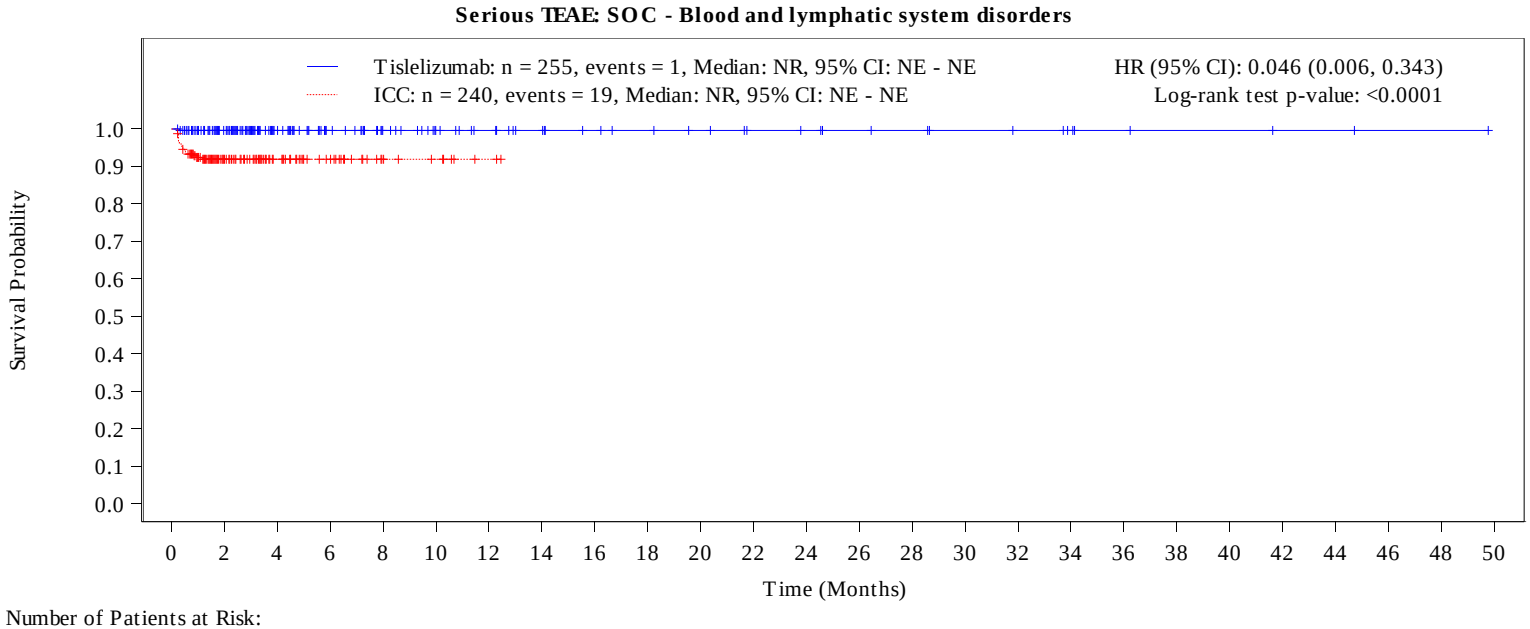


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	92	50	38	30	22	18	16	13	12	10	9	9	8	7	6	6	5	3	3	3	2	2	1	1	0
ICC	129	75	33	19	9	6	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-03-b-km-aesocpt-g3-safetys-cl.rtf

Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

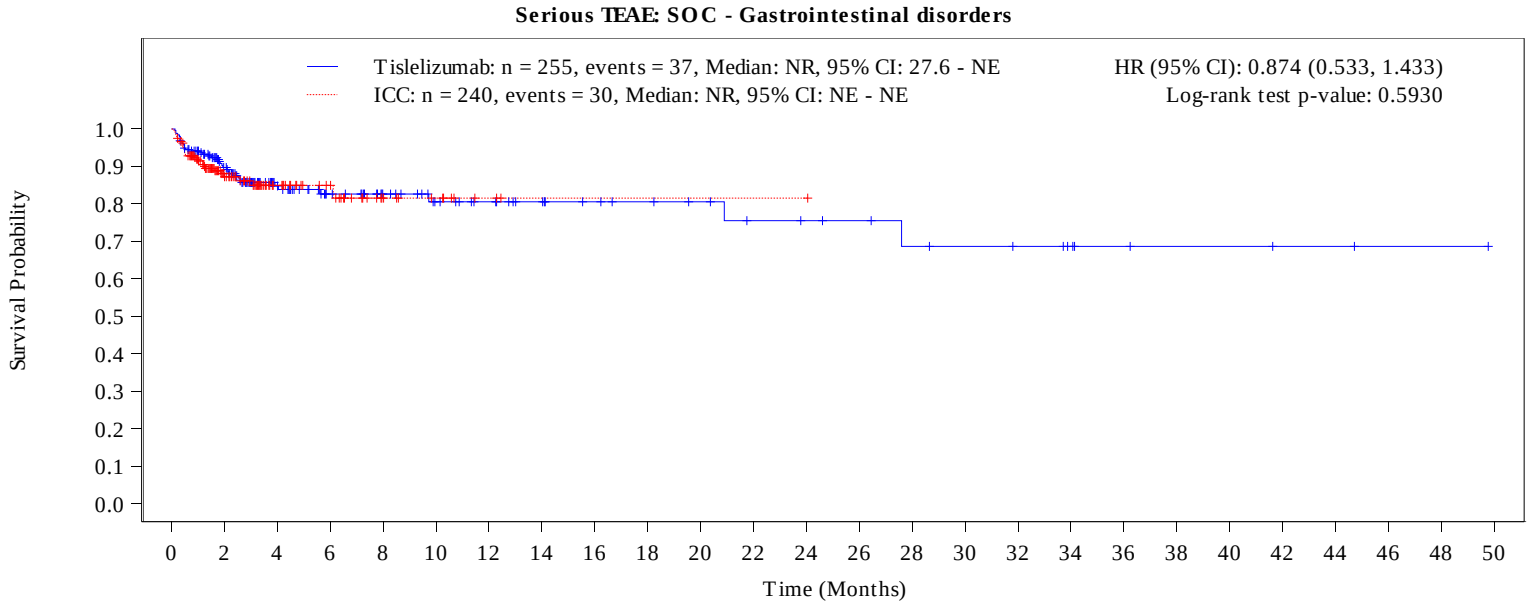


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	175	97	65	49	38	32	27	22	20	18	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	107	43	24	10	7	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-04-km-aesocpt-sae-safety-cl.rtf

Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

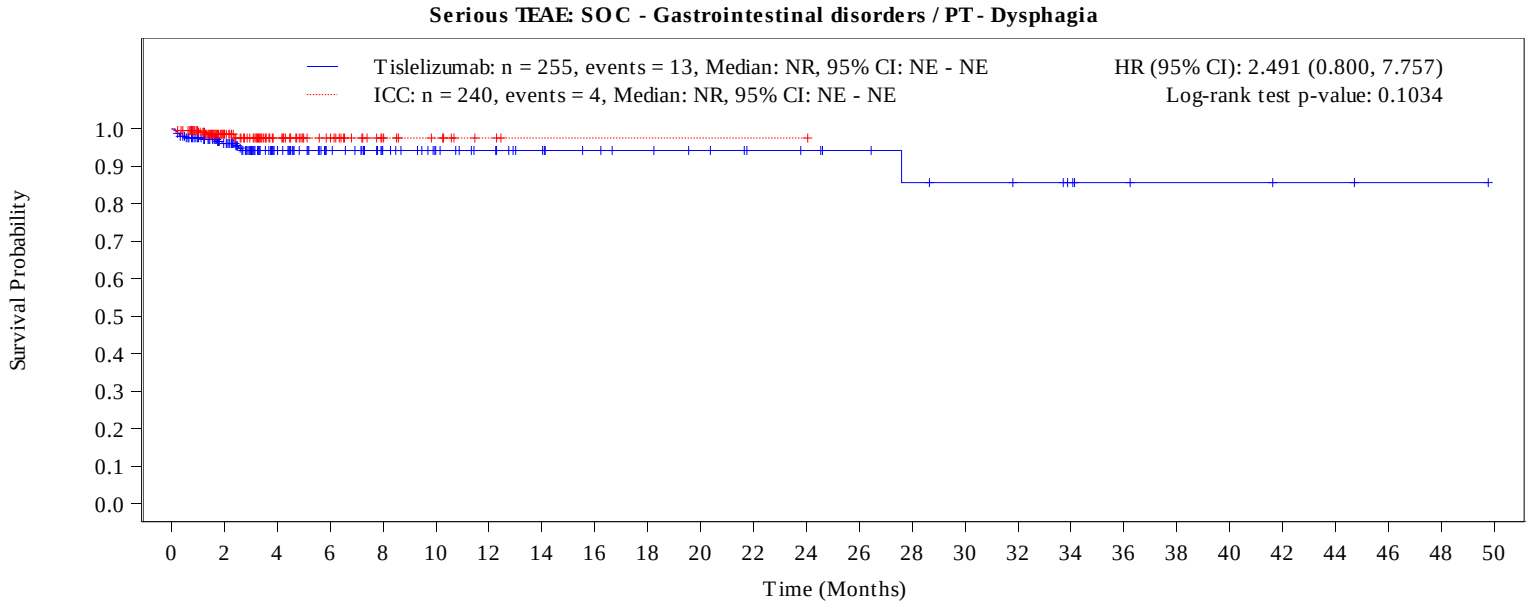


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	167	91	63	48	37	31	26	21	19	17	14	13	12	10	9	8	6	4	3	3	2	2	1	1	0
ICC	240	103	42	26	12	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-04-km-aesocpt-sae-safety-cl.rtf

Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

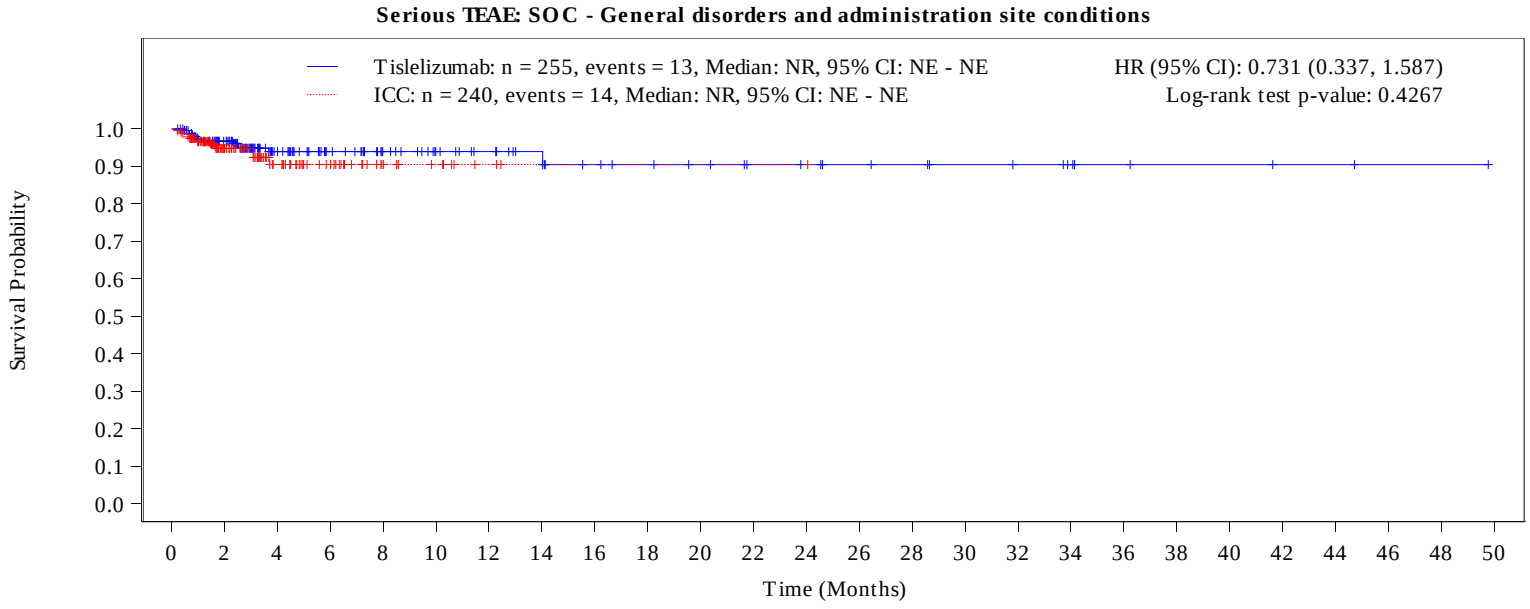


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	172	96	65	49	38	32	27	22	20	18	15	14	12	10	9	8	6	4	3	3	2	2	1	1	0
ICC	240	110	45	26	12	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-04-km-aesocpt-sae-safety-cl.rtf

Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

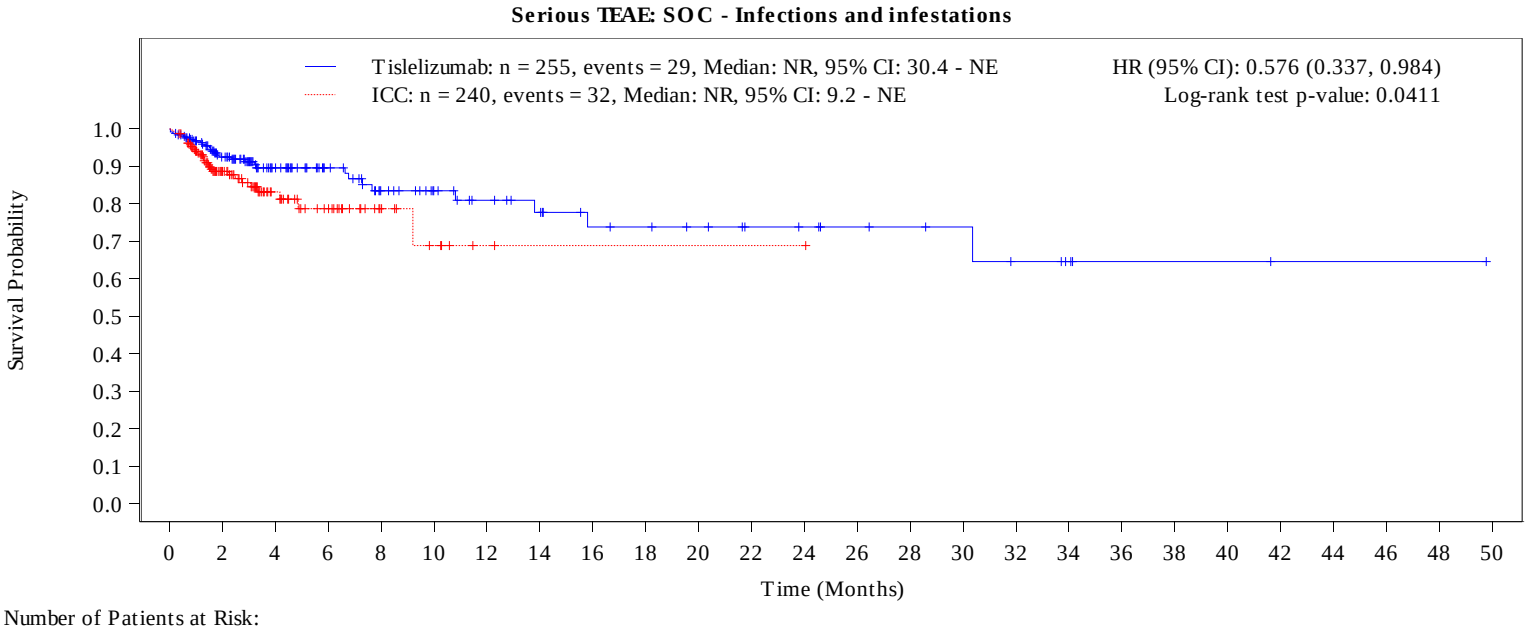


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	174	96	65	49	38	32	27	22	20	18	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	112	45	26	12	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-04-km-aesocpt-sae-safety-cl.rtf

Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

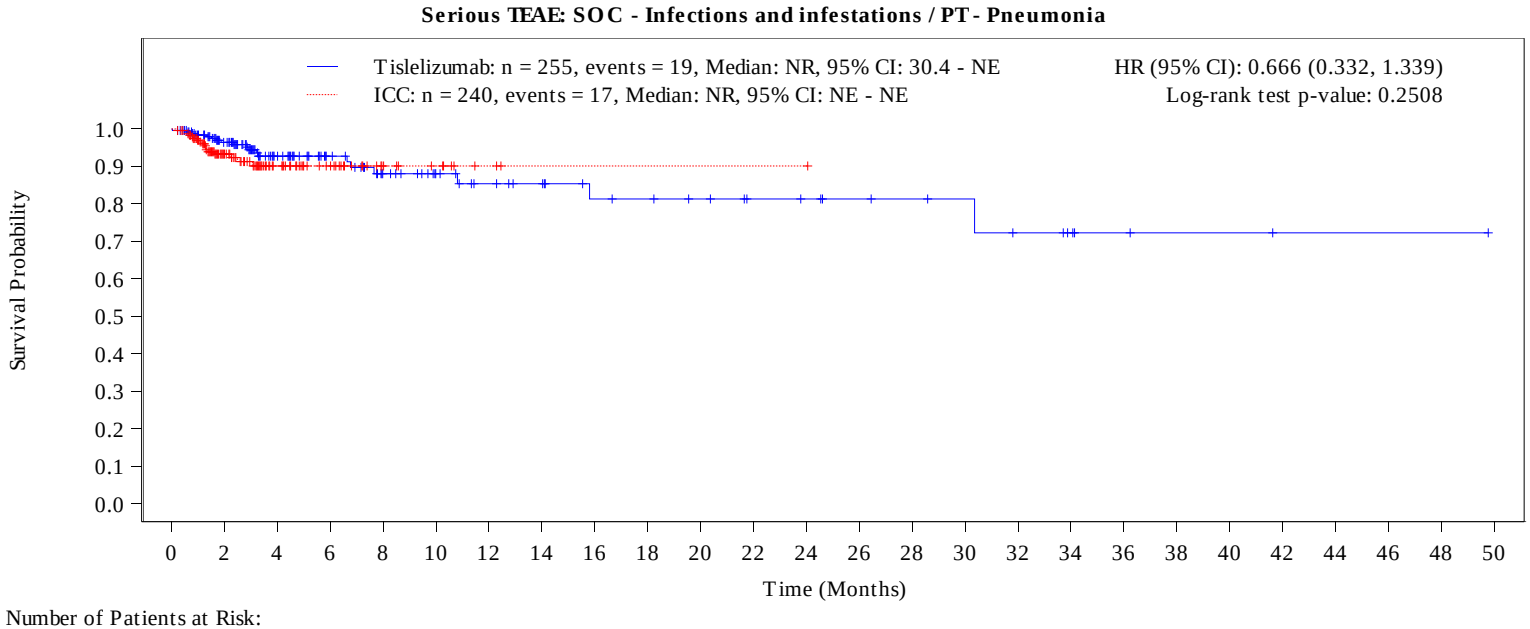


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	167	96	64	46	35	28	24	19	18	16	13	12	10	9	8	6	4	2	2	2	1	1	1	1	0
ICC	240	109	43	25	11	6	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-04-km-aesocpt-sae-safety-cl.rtf

Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

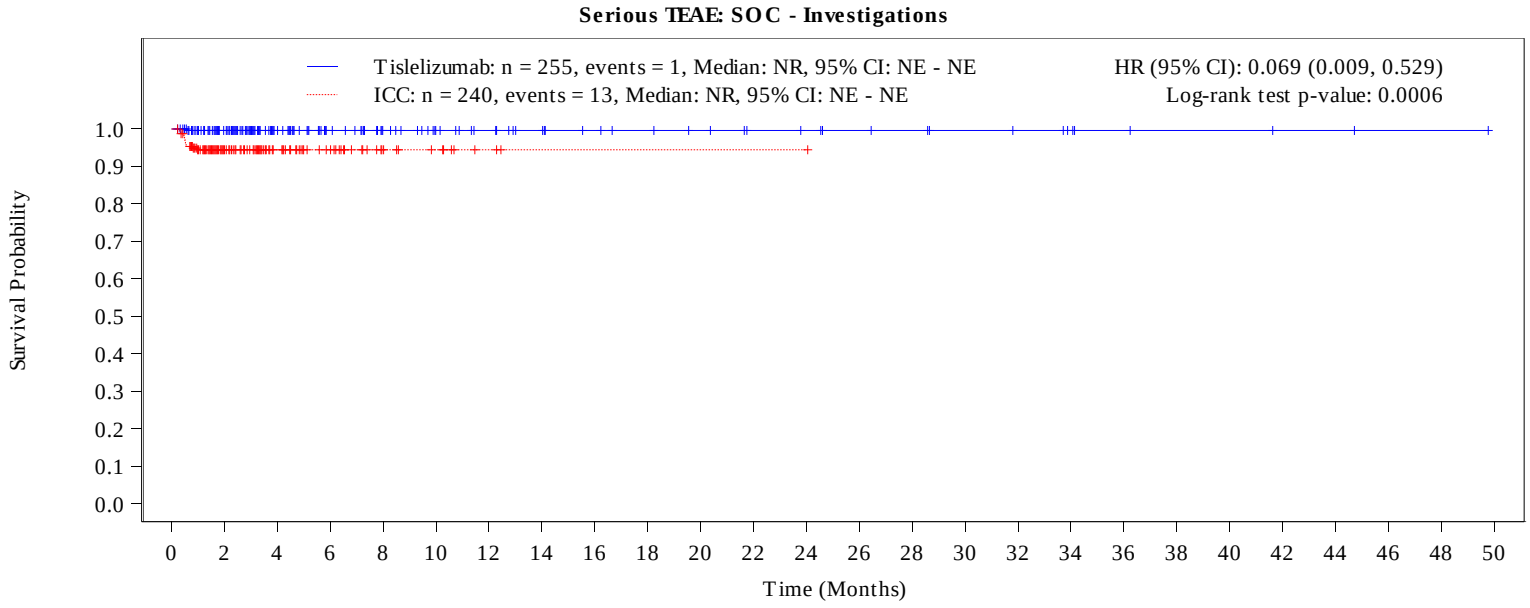


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	172	96	64	46	35	28	25	20	19	17	14	13	11	10	9	7	5	3	2	2	1	1	1	1	0
ICC	240	112	45	26	12	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-04-km-aesocpt-sae-safety-cl.rtf

Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

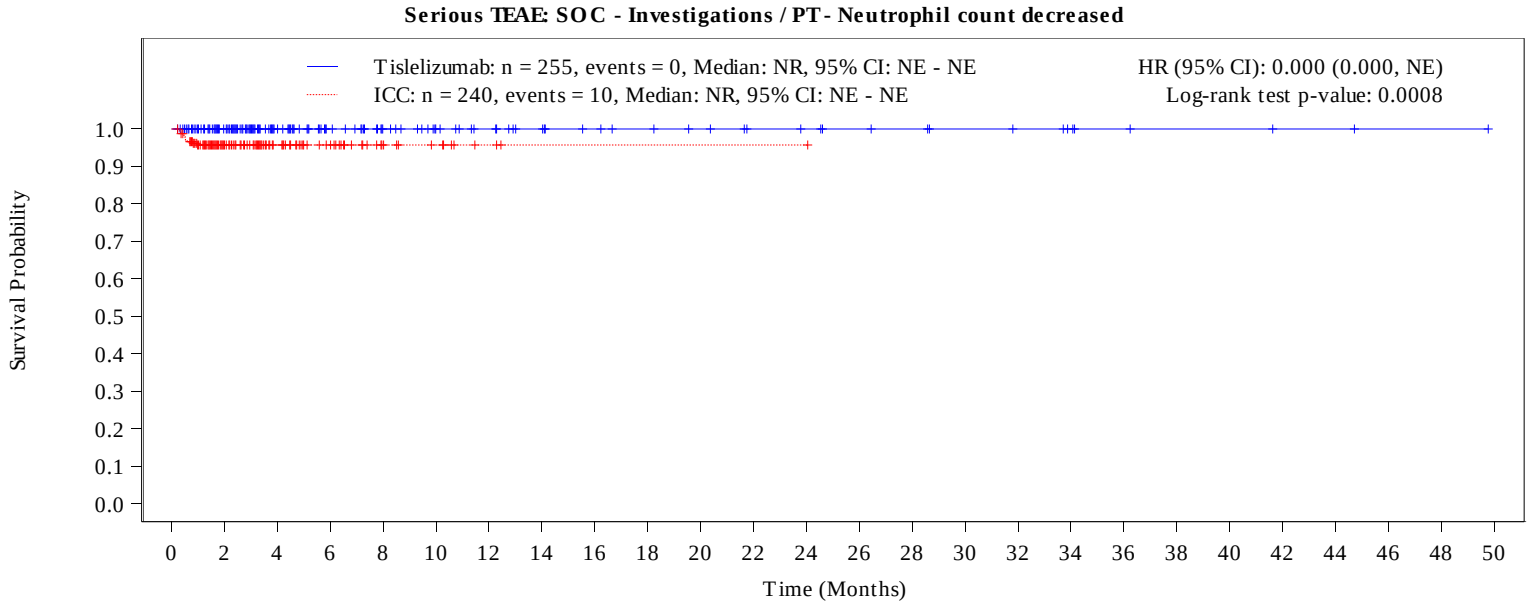


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	175	97	65	49	38	32	27	22	20	18	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	111	45	26	12	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-04-km-aesocpt-sae-safety-cl.rtf

Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

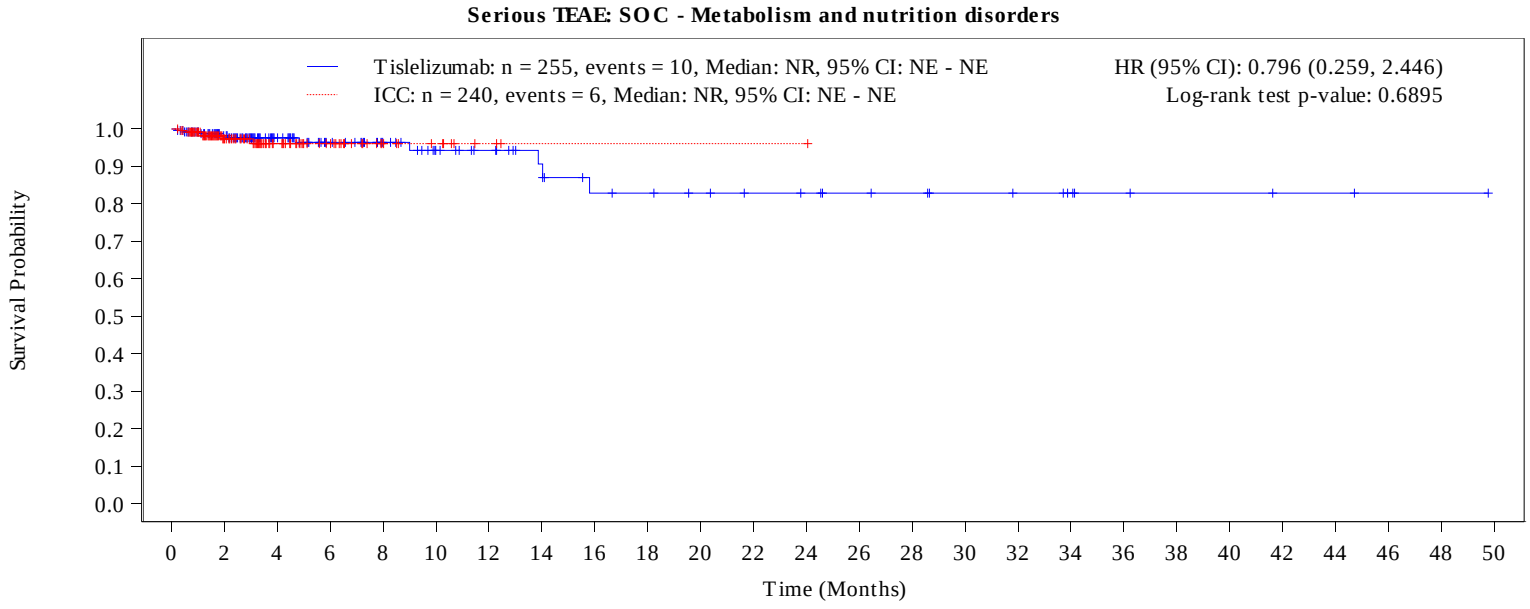


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	175	97	65	49	38	32	27	22	20	18	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	112	45	26	12	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-04-km-aesocpt-sae-safety-cl.rtf

Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

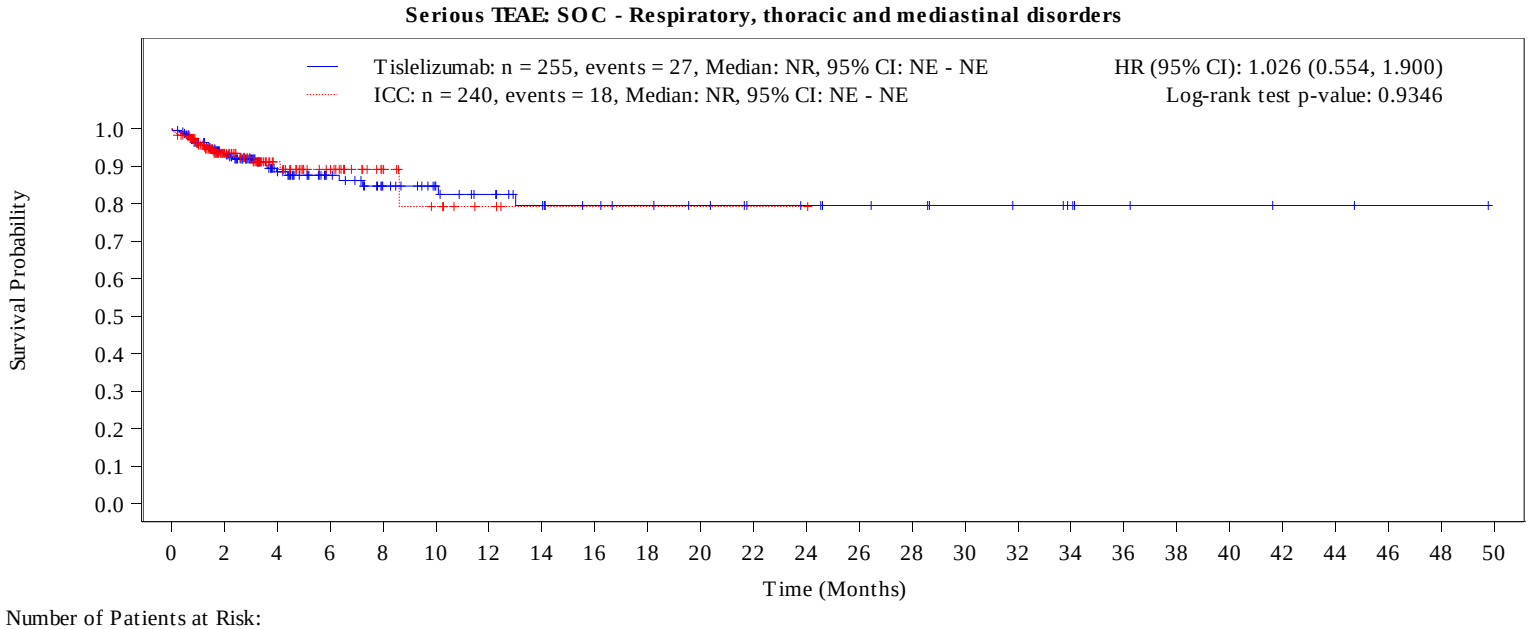


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	173	97	65	49	37	31	25	20	19	17	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	111	45	26	12	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-04-km-aesocpt-sae-safety-cl.rtf

Figure 14.3.1.4:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

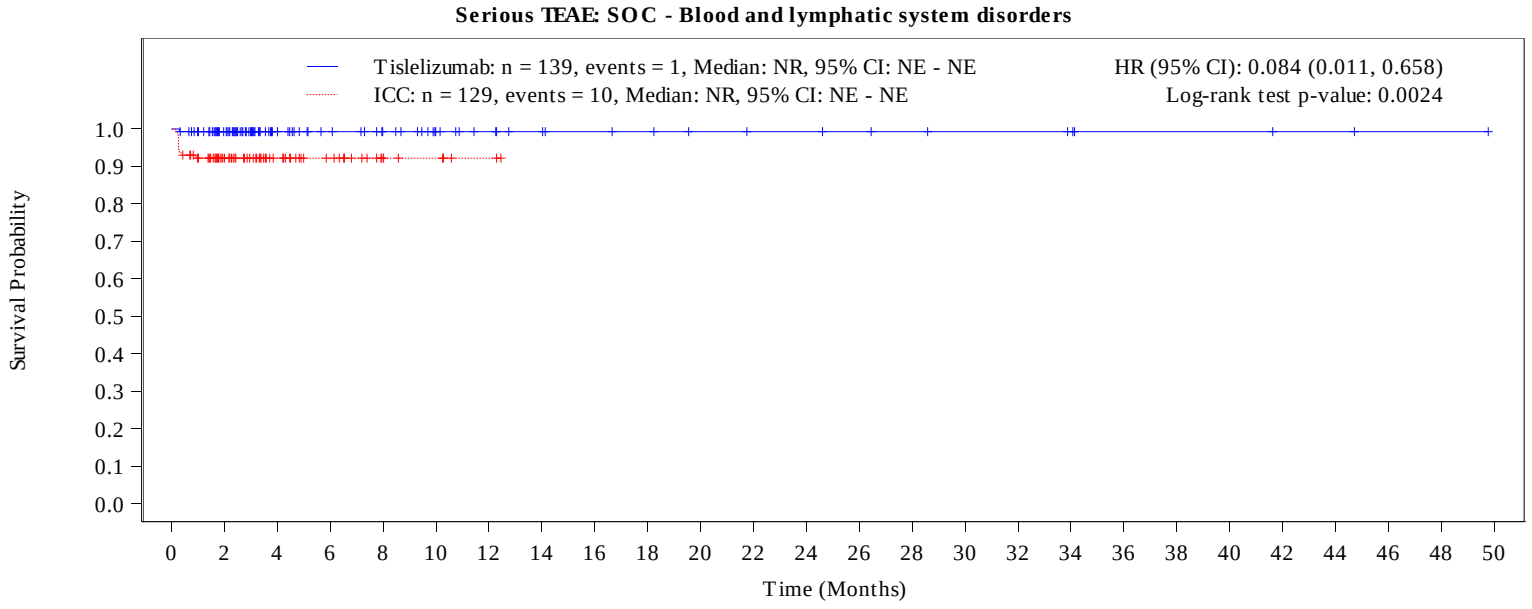


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	173	97	64	48	38	32	27	22	20	18	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	112	45	26	12	7	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-04-km-aesocpt-sae-safety-cl.rtf

Figure 14.3.1.4.b:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

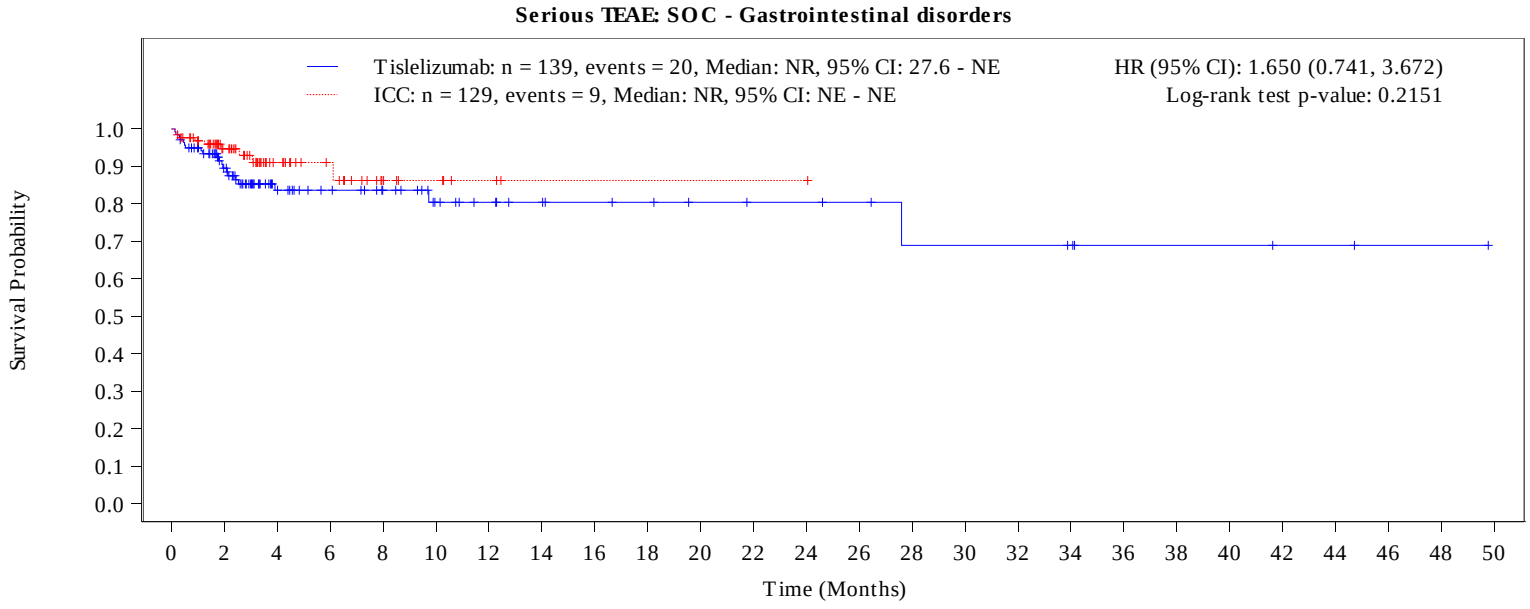


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	95	52	40	32	23	19	16	13	12	10	9	9	8	7	6	6	5	3	3	3	2	2	1	1	0
ICC	129	70	31	17	7	5	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-04-b-km-aesocpt-sae-safetys-cl.rtf

Figure 14.3.1.4.b:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

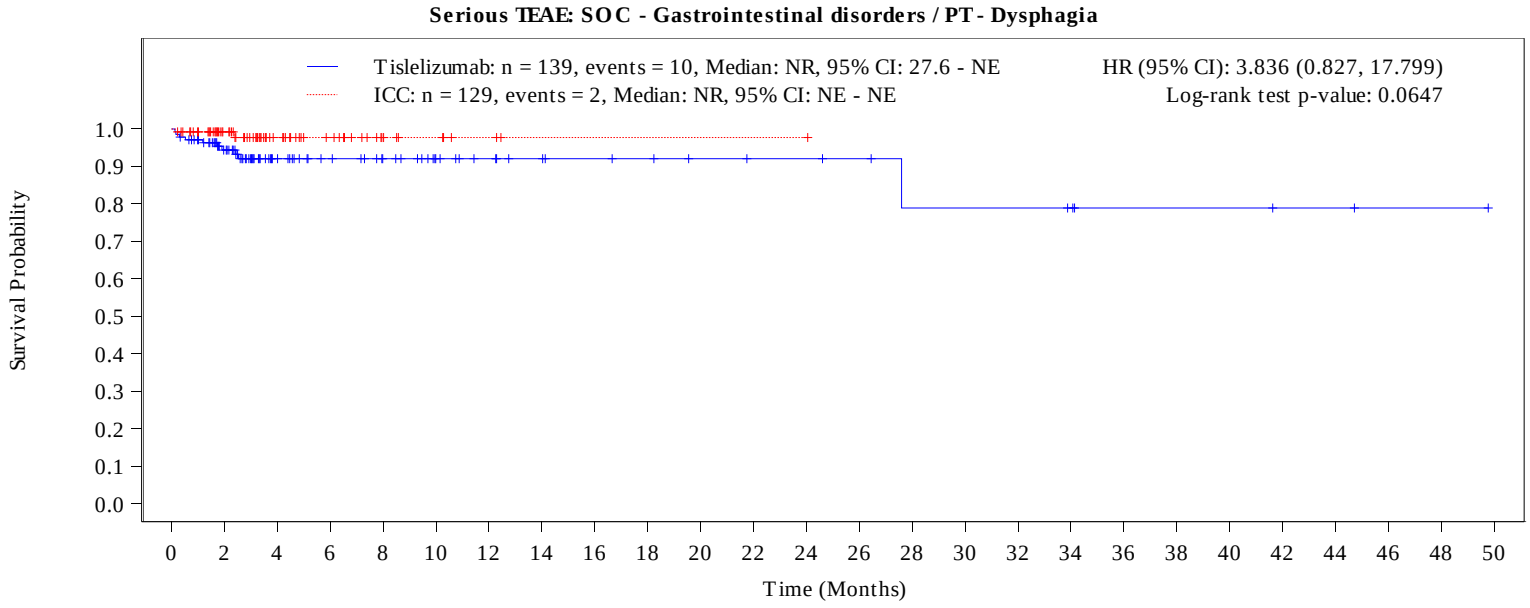


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	90	50	40	32	23	19	16	13	12	10	9	9	8	6	6	6	5	3	3	3	2	2	1	1	0
ICC	129	71	31	19	9	6	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-04-b-km-aesocpt-sae-safetys-cl.rtf

Figure 14.3.1.4.b:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	92	52	40	32	23	19	16	13	12	10	9	9	8	6	6	6	5	3	3	3	2	2	1	1	0
ICC	129	74	33	19	9	6	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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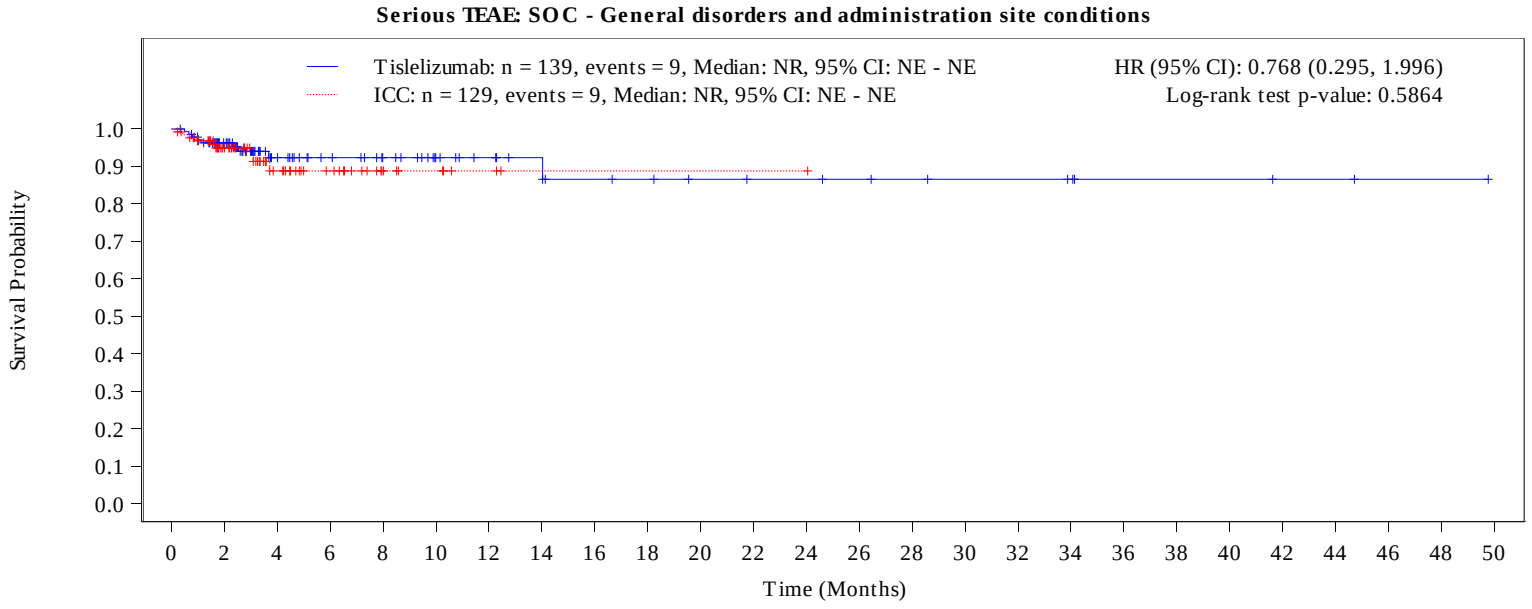
Figure 14.3.1.4.b:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan

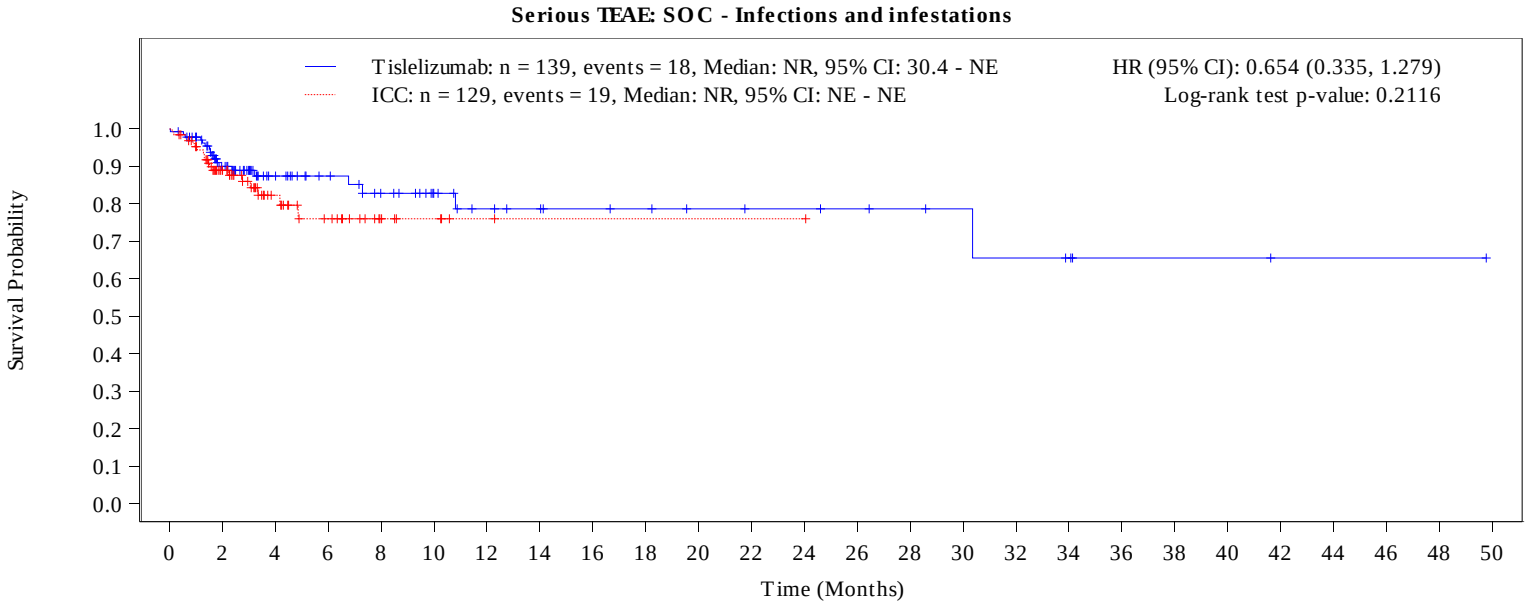


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	95	52	40	32	23	19	16	13	12	10	9	9	8	7	6	6	5	3	3	3	2	2	1	1	0
ICC	129	74	33	19	9	6	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-04-b-km-aesocpt-sae-safetys-cl.rtf

Figure 14.3.1.4.b:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	88	52	40	31	22	17	15	13	12	10	9	9	8	7	6	5	4	2	2	2	1	1	1	1	0
ICC	129	72	31	18	8	5	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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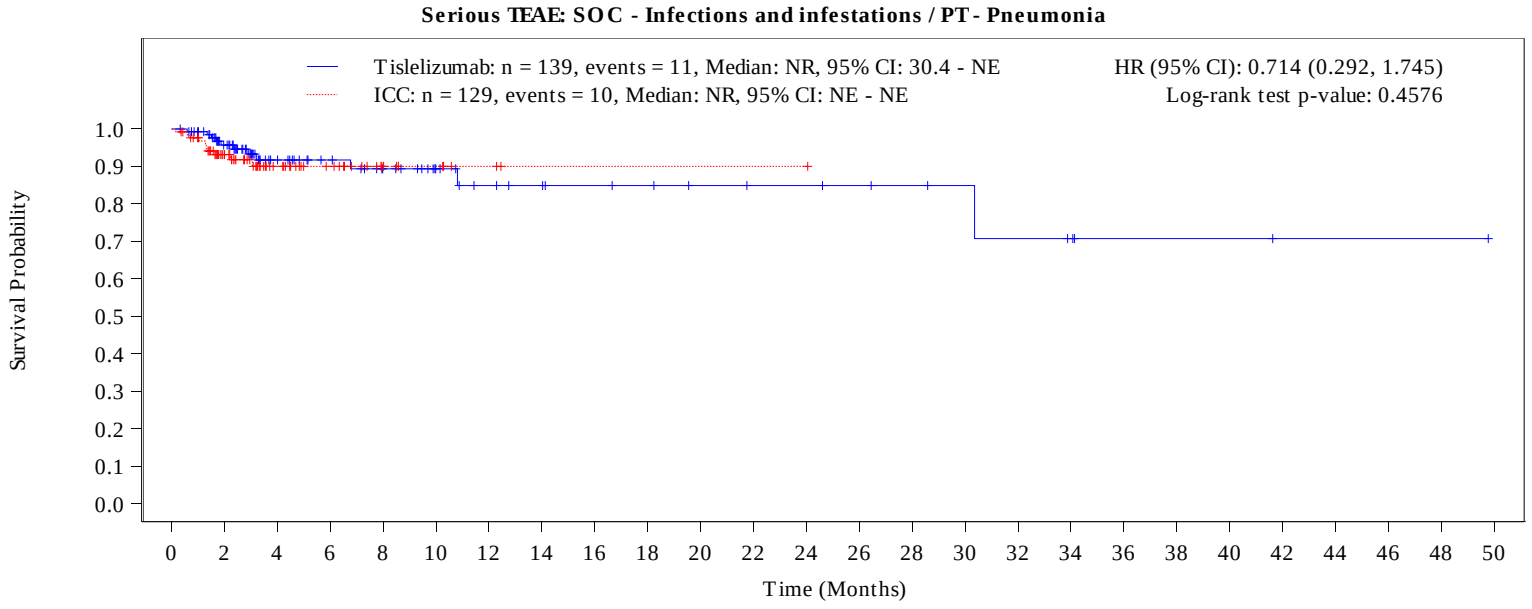
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	92	52	40	31	22	17	15	13	12	10	9	9	8	7	6	5	4	2	2	2	1	1	1	1	0
ICC	129	74	33	19	9	6	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
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Figure 14.3.1.4.b:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
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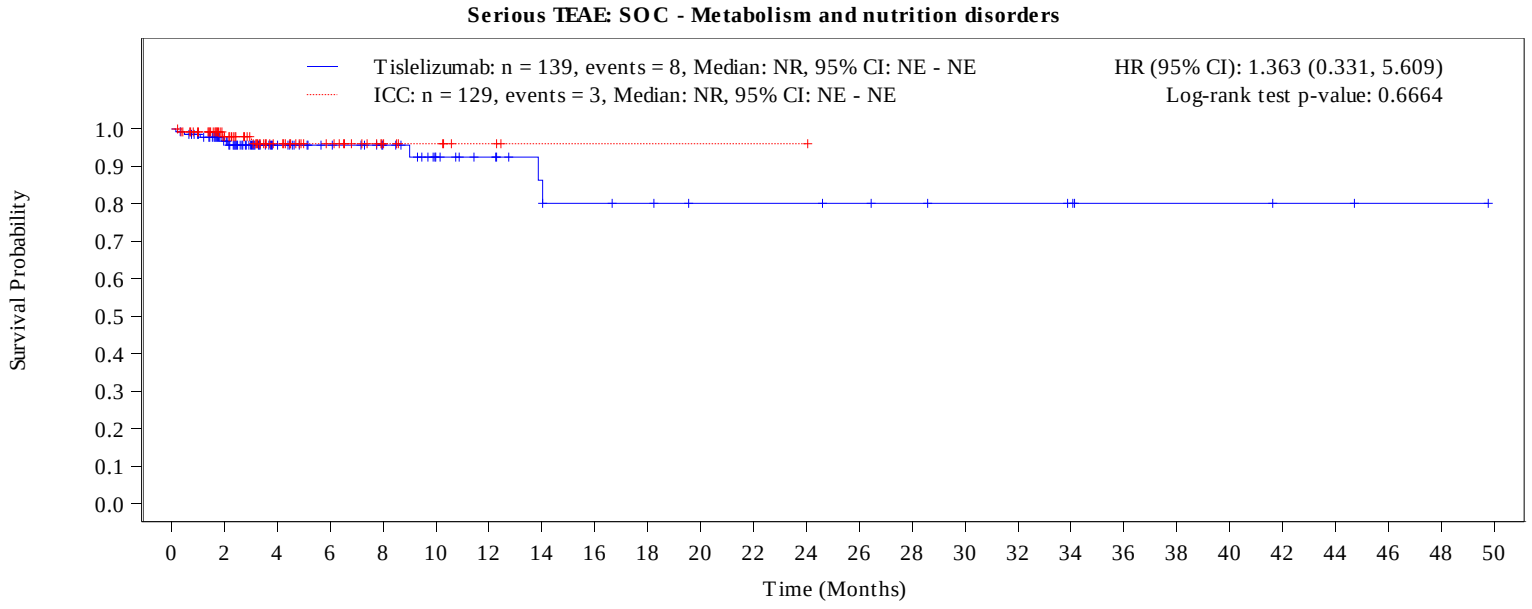

Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	93	52	40	32	22	18	14	12	11	9	9	9	8	7	6	6	5	3	3	3	2	2	1	1	0
ICC	129	74	33	19	9	6	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-04-b-km-aesocpt-sae-safetys-cl.rtf

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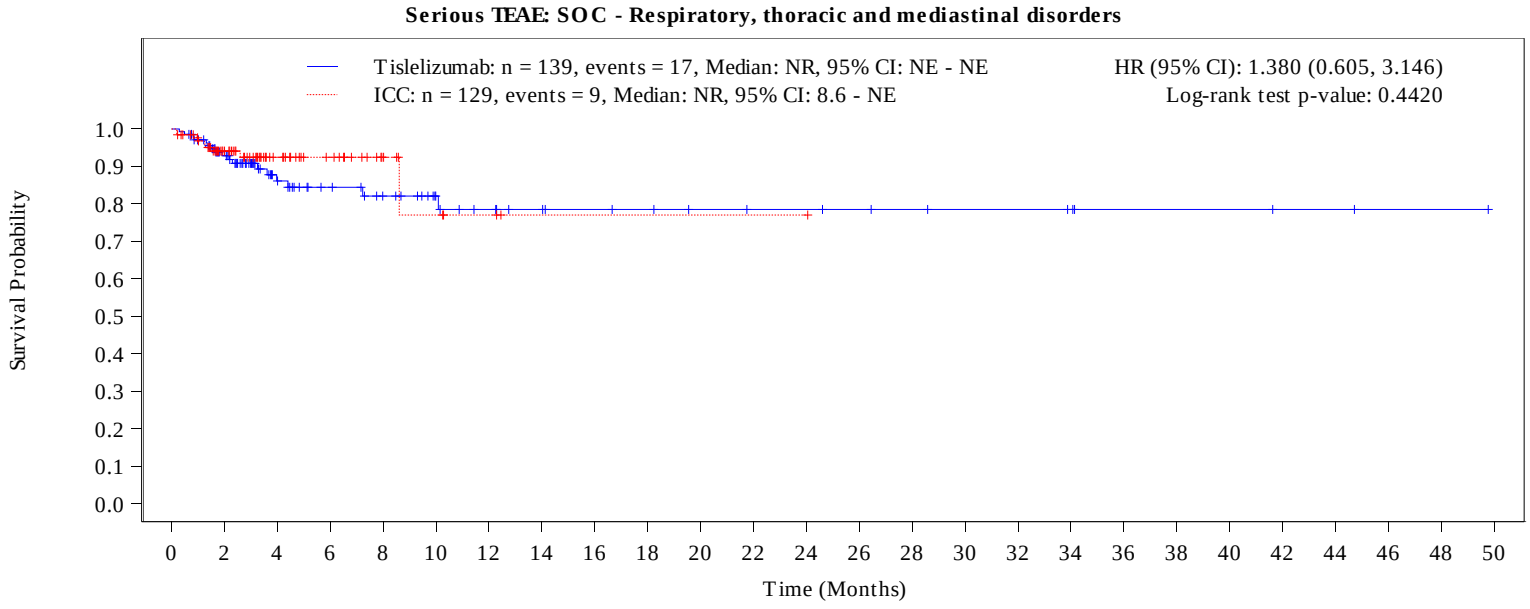
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	94	52	39	31	23	19	16	13	12	10	9	9	8	7	6	6	5	3	3	3	2	2	1	1	0
ICC	129	75	33	19	9	5	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesocpt.sas 06AUG2024 02:06 f-14-03-01-04-b-km-aesocpt-sae-safetys-cl.rtf

Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	60 (39.5)	9.0 (6.9, 12.5)	146	86 (58.9)	1.0 (0.8, 2.0)	0.447 (0.318, 0.628)	<0.0001
>= 65 Years	103	35 (34.0)	19.4 (8.9, NE)	94	54 (57.4)	1.2 (0.5, 4.1)	0.367 (0.234, 0.576)	<0.0001
Interaction								0.3748
Gender								
Male	216	83 (38.4)	11.0 (7.6, 21.4)	204	123 (60.3)	1.0 (0.8, 1.7)	0.397 (0.297, 0.531)	<0.0001
Female	39	12 (30.8)	NR (4.9, NE)	36	17 (47.2)	NR (0.5, NE)	0.511 (0.242, 1.079)	0.0688
Interaction								0.9489

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	67 (35.8)	14.7 (12.4, NE)	183	106 (57.9)	1.2 (0.9, 2.3)	0.397 (0.289, 0.546)	<0.0001
Non-Smoker	68	28 (41.2)	8.9 (4.9, NE)	57	34 (59.6)	1.0 (0.5, NE)	0.447 (0.266, 0.753)	0.0016
Interaction								0.6865

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	24 (28.9)	NR (21.4, NE)	79	36 (45.6)	4.1 (1.2, NE)	0.515 (0.303, 0.872)	0.0112
Docetaxel	56	22 (39.3)	NR (3.4, NE)	50	37 (74.0)	0.9 (0.3, 1.3)	0.313 (0.181, 0.542)	<0.0001
Irinotecan	116	49 (42.2)	8.9 (4.9, 12.4)	111	67 (60.4)	0.8 (0.5, 2.3)	0.392 (0.265, 0.579)	<0.0001
Interaction								0.4834

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	18 (28.6)	21.4 (7.6, NE)	57	27 (47.4)	2.6 (1.7, NE)	0.389 (0.208, 0.729)	0.0021
1	192	77 (40.1)	9.0 (6.2, 19.4)	183	113 (61.7)	0.9 (0.6, 1.1)	0.408 (0.302, 0.552)	<0.0001
Interaction								0.8894
Region #1								
Asia	201	78 (38.8)	12.4 (7.6, 21.4)	191	117 (61.3)	1.0 (0.7, 1.2)	0.389 (0.288, 0.526)	<0.0001
Europe/North America	54	17 (31.5)	NR (4.9, NE)	49	23 (46.9)	4.7 (1.0, NE)	0.527 (0.280, 0.992)	0.0421
Interaction								0.4682

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	76 (43.2)	8.9 (4.9, 14.7)	168	111 (66.1)	0.8 (0.5, 1.0)	0.390 (0.287, 0.530)	<0.0001
Japan	25	2 (8.0)	NR (21.4, NE)	23	6 (26.1)	NR (2.8, NE)	0.122 (0.015, 1.026)	0.0203
Europe/North America	54	17 (31.5)	NR (4.9, NE)	49	23 (46.9)	4.7 (1.0, NE)	0.527 (0.280, 0.992)	0.0421
Interaction								0.5601

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	79 (38.9)	12.4 (7.6, 21.4)	198	119 (60.1)	1.0 (0.8, 1.4)	0.406 (0.301, 0.546)	<0.0001
White	52	16 (30.8)	NR (4.9, NE)	42	21 (50.0)	4.7 (0.6, NE)	0.473 (0.245, 0.910)	0.0209
Interaction								0.7709

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	32 (40.0)	12.4 (3.4, NE)	60	35 (58.3)	1.0 (0.5, 4.1)	0.421 (0.256, 0.695)	0.0004
vCPS < 10%	100	38 (38.0)	9.0 (4.3, NE)	119	78 (65.5)	1.0 (0.7, 1.2)	0.377 (0.254, 0.561)	<0.0001
Missing	75	25 (33.3)	14.7 (6.9, 23.6)	61	27 (44.3)	4.7 (1.0, NE)	0.499 (0.280, 0.889)	0.0146
Interaction								0.5495

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	49 (32.2)	13.8 (8.3, NE)	146	69 (47.3)	2.8 (1.2, NE)	0.491 (0.337, 0.715)	0.0001
>= 65 Years	103	31 (30.1)	21.4 (14.7, NE)	94	40 (42.6)	5.1 (1.2, NE)	0.455 (0.277, 0.747)	0.0013
Interaction								0.7865
Gender								
Male	216	70 (32.4)	19.4 (9.0, NE)	204	96 (47.1)	2.8 (1.3, 5.6)	0.459 (0.333, 0.634)	<0.0001
Female	39	10 (25.6)	NR (4.9, NE)	36	13 (36.1)	NR (0.6, NE)	0.560 (0.243, 1.291)	0.1628
Interaction								0.9585

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	57 (30.5)	21.4 (14.7, NE)	183	86 (47.0)	2.8 (1.3, 5.6)	0.433 (0.305, 0.614)	<0.0001
Non-Smoker	68	23 (33.8)	9.0 (4.9, NE)	57	23 (40.4)	NR (1.0, NE)	0.618 (0.341, 1.119)	0.1066
Interaction								0.3153

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

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Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	21 (25.3)	NR (21.4, NE)	79	27 (34.2)	NR (4.1, NE)	0.639 (0.357, 1.141)	0.1239
Docetaxel	56	17 (30.4)	NR (8.3, NE)	50	26 (52.0)	2.0 (1.0, NE)	0.353 (0.185, 0.673)	0.0009
Irinotecan	116	42 (36.2)	11.0 (6.2, 19.4)	111	56 (50.5)	2.3 (0.8, NE)	0.427 (0.279, 0.653)	<0.0001
Interaction								0.6635

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Safety Analysis Set

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	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	13 (20.6)	NR (13.8, NE)	57	18 (31.6)	NR (2.8, NE)	0.420 (0.196, 0.897)	0.0208
1	192	67 (34.9)	14.7 (8.3, NE)	183	91 (49.7)	2.1 (1.0, 5.1)	0.476 (0.343, 0.661)	<0.0001
Interaction								0.9935
Region #1								
Asia	201	64 (31.8)	19.4 (11.0, NE)	191	93 (48.7)	2.6 (1.1, NE)	0.429 (0.307, 0.599)	<0.0001
Europe/North America	54	16 (29.6)	NR (4.9, NE)	49	16 (32.7)	5.6 (5.1, NE)	0.749 (0.373, 1.506)	0.4134
Interaction								0.1866

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	62 (35.2)	13.8 (8.3, NE)	168	89 (53.0)	1.3 (1.0, 3.7)	0.427 (0.304, 0.601)	<0.0001
Japan	25	2 (8.0)	NR (21.4, NE)	23	4 (17.4)	NR (2.8, NE)	0.194 (0.021, 1.743)	0.1014
Europe/North America	54	16 (29.6)	NR (4.9, NE)	49	16 (32.7)	5.6 (5.1, NE)	0.749 (0.373, 1.506)	0.4134
Interaction								0.3812

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

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Any TEAE: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	65 (32.0)	19.4 (11.0, NE)	198	94 (47.5)	2.8 (1.2, NE)	0.452 (0.324, 0.630)	<0.0001
White	52	15 (28.8)	NR (4.9, NE)	42	15 (35.7)	5.6 (2.3, NE)	0.638 (0.310, 1.312)	0.2158
Interaction								0.4384

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	28 (35.0)	19.4 (8.3, NE)	60	29 (48.3)	2.8 (1.0, NE)	0.453 (0.263, 0.780)	0.0032
vCPS < 10%	100	33 (33.0)	NR (4.9, NE)	119	59 (49.6)	2.6 (1.0, NE)	0.499 (0.324, 0.768)	0.0012
Missing	75	19 (25.3)	21.4 (11.0, NE)	61	21 (34.4)	NR (2.1, NE)	0.473 (0.242, 0.923)	0.0237
Interaction								0.9080

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	152	0 (0.0)	--	146	7 (4.8)	--	--	--
>= 65 Years	103	0 (0.0)	--	94	5 (5.3)	--	--	--
Interaction								--
Gender								
Male	216	0 (0.0)	NR (NE, NE)	204	11 (5.4)	NR (NE, NE)	0.000 (0.000, NE)	0.0003
Female	39	0 (0.0)	NR (NE, NE)	36	1 (2.8)	NR (NE, NE)	0.000 (0.000, NE)	0.2980
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

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	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Smoking Status								
Former/Current Smoker	187	0 (0.0)	--	183	9 (4.9)	--	--	--
Non-Smoker	68	0 (0.0)	--	57	3 (5.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

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Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ICC Options								
Paclitaxel	83	0 (0.0)	--	79	0 (0.0)	--	--	--
Docetaxel	56	0 (0.0)	--	50	8 (16.0)	--	--	--
Irinotecan	116	0 (0.0)	--	111	4 (3.6)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	0 (0.0)	--	57	3 (5.3)	--	--	--
1	192	0 (0.0)	--	183	9 (4.9)	--	--	--
Interaction								--
Region #1								
Asia	201	0 (0.0)	NR (NE, NE)	191	10 (5.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0006
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	2 (4.1)	NR (NE, NE)	0.000 (0.000, NE)	0.1356
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	0 (0.0)	--	168	8 (4.8)	--	--	--
Japan	25	0 (0.0)	--	23	2 (8.7)	--	--	--
Europe/North America	54	0 (0.0)	--	49	2 (4.1)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	203	0 (0.0)	NR (NE, NE)	198	10 (5.1)	NR (NE, NE)	0.000 (0.000, NE)	0.0007
White	52	0 (0.0)	NR (NE, NE)	42	2 (4.8)	NR (NE, NE)	0.000 (0.000, NE)	0.1134
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Safety Analysis Set
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	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	0 (0.0)	--	60	4 (6.7)	--	--	--
vCPS < 10%	100	0 (0.0)	--	119	3 (2.5)	--	--	--
Missing	75	0 (0.0)	--	61	5 (8.2)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	152	8 (5.3)	NR (NE, NE)	146	19 (13.0)	NR (NE, NE)	0.313 (0.133, 0.734)	0.0049
>= 65 Years	103	1 (1.0)	NR (NE, NE)	94	11 (11.7)	NR (NE, NE)	0.067 (0.008, 0.526)	0.0008
Interaction								0.1287
Gender								
Male	216	9 (4.2)	NR (NE, NE)	204	28 (13.7)	NR (NE, NE)	0.234 (0.107, 0.511)	<0.0001
Female	39	0 (0.0)	NR (NE, NE)	36	2 (5.6)	NR (6.3, NE)	0.000 (0.000, NE)	0.0497
Interaction								0.9853

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	6 (3.2)	NR (NE, NE)	183	20 (10.9)	NR (NE, NE)	0.227 (0.087, 0.588)	0.0009
Non-Smoker	68	3 (4.4)	NR (NE, NE)	57	10 (17.5)	NR (6.3, NE)	0.173 (0.045, 0.672)	0.0048
Interaction								0.8597

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Any TEAE: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	1 (1.2)	NR (NE, NE)	79	2 (2.5)	NR (NE, NE)	0.466 (0.042, 5.137)	0.5228
Docetaxel	56	4 (7.1)	NR (NE, NE)	50	10 (20.0)	NR (6.3, NE)	0.300 (0.094, 0.962)	0.0312
Irinotecan	116	4 (3.4)	NR (NE, NE)	111	18 (16.2)	NR (NE, NE)	0.124 (0.036, 0.429)	0.0001
Interaction								0.6842

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

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Any TEAE: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	3 (4.8)	NR (NE, NE)	57	5 (8.8)	NR (NE, NE)	0.350 (0.068, 1.806)	0.1890
1	192	6 (3.1)	NR (NE, NE)	183	25 (13.7)	NR (NE, NE)	0.177 (0.071, 0.441)	<0.0001
Interaction								0.3277
Region #1								
Asia	201	9 (4.5)	NR (NE, NE)	191	29 (15.2)	NR (NE, NE)	0.218 (0.100, 0.475)	<0.0001
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	0.000 (0.000, NE)	0.2888
Interaction								0.9900

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

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Region #2								
Asia (excluding Japan)	176	9 (5.1)	NR (NE, NE)	168	29 (17.3)	NR (NE, NE)	0.218 (0.100, 0.474)	<0.0001
Japan	25	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	0.000 (0.000, NE)	0.2888
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

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Race								
Asian and other	203	9 (4.4)	NR (NE, NE)	198	29 (14.6)	NR (NE, NE)	0.225 (0.103, 0.491)	<0.0001
White	52	0 (0.0)	NR (NE, NE)	42	1 (2.4)	NR (NE, NE)	0.000 (0.000, NE)	0.2601
Interaction								0.9899

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Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Baseline PD-L1 Status								
vCPS >= 10%	80	4 (5.0)	NR (NE, NE)	60	9 (15.0)	NR (6.3, NE)	0.195 (0.056, 0.674)	0.0047
vCPS < 10%	100	2 (2.0)	NR (NE, NE)	119	17 (14.3)	NR (NE, NE)	0.130 (0.030, 0.565)	0.0013
Missing	75	3 (4.0)	NR (NE, NE)	61	4 (6.6)	NR (NE, NE)	0.536 (0.119, 2.423)	0.4099
Interaction								0.3763

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	152	1 (0.7)	NR (NE, NE)	146	14 (9.6)	NR (NE, NE)	0.065 (0.009, 0.497)	0.0004
>= 65 Years	103	1 (1.0)	NR (NE, NE)	94	17 (18.1)	NR (NE, NE)	0.045 (0.006, 0.338)	<0.0001
Interaction								0.8453
Gender								
Male	216	2 (0.9)	NR (NE, NE)	204	28 (13.7)	NR (NE, NE)	0.059 (0.014, 0.248)	<0.0001
Female	39	0 (0.0)	NR (NE, NE)	36	3 (8.3)	NR (NE, NE)	0.000 (0.000, NE)	0.0714
Interaction								0.9889

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	1 (0.5)	NR (NE, NE)	183	20 (10.9)	NR (NE, NE)	0.043 (0.006, 0.324)	<0.0001
Non-Smoker	68	1 (1.5)	NR (NE, NE)	57	11 (19.3)	NR (NE, NE)	0.068 (0.009, 0.528)	0.0006
Interaction								0.7622

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	0 (0.0)	NR (NE, NE)	79	12 (15.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0001
Docetaxel	56	2 (3.6)	NR (NE, NE)	50	9 (18.0)	NR (NE, NE)	0.184 (0.040, 0.852)	0.0142
Irinotecan	116	0 (0.0)	NR (NE, NE)	111	10 (9.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0010
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	2 (3.2)	NR (NE, NE)	57	10 (17.5)	NR (NE, NE)	0.164 (0.036, 0.751)	0.0077
1	192	0 (0.0)	NR (NE, NE)	183	21 (11.5)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9888
Region #1								
Asia	201	2 (1.0)	NR (NE, NE)	191	19 (9.9)	NR (NE, NE)	0.096 (0.022, 0.411)	<0.0001
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	12 (24.5)	NR (4.7, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9891

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	2 (1.1)	NR (NE, NE)	168	19 (11.3)	NR (NE, NE)	0.096 (0.022, 0.410)	<0.0001
Japan	25	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	12 (24.5)	NR (4.7, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	203	2 (1.0)	NR (NE, NE)	198	20 (10.1)	NR (NE, NE)	0.093 (0.022, 0.399)	<0.0001
White	52	0 (0.0)	NR (NE, NE)	42	11 (26.2)	NR (4.7, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9901

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	0 (0.0)	NR (NE, NE)	60	5 (8.3)	NR (NE, NE)	0.000 (0.000, NE)	0.0073
vCPS < 10%	100	1 (1.0)	NR (NE, NE)	119	20 (16.8)	NR (NE, NE)	0.052 (0.007, 0.390)	<0.0001
Missing	75	1 (1.3)	NR (NE, NE)	61	6 (9.8)	NR (NE, NE)	0.118 (0.014, 0.988)	0.0184
Interaction								0.8331

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	26 (17.1)	16.5 (16.1, NE)	146	2 (1.4)	NR (NE, NE)	7.327 (1.724, 31.146)	0.0014
>= 65 Years	103	17 (16.5)	NR (11.6, NE)	94	0 (0.0)	NR (NE, NE)	21791805.760 (0.000, NE)	0.0018
Interaction								0.9858

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Gender								
Male	216	36 (16.7)	18.6 (16.1, NE)	204	2 (1.0)	NR (NE, NE)	10.134 (2.418, 42.467)	<0.0001
Female	39	7 (17.9)	29.9 (9.0, NE)	36	0 (0.0)	NR (NE, NE)	66553994.404 (0.000, NE)	0.0295
Interaction								0.9864

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

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Safety Analysis Set

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	30 (16.0)	18.6 (16.1, NE)	183	2 (1.1)	NR (NE, NE)	9.258 (2.190, 39.148)	0.0002
Non-Smoker	68	13 (19.1)	29.9 (8.3, NE)	57	0 (0.0)	NR (NE, NE)	18446825.797 (0.000, NE)	0.0135
Interaction								0.9894

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Safety Analysis Set

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	20 (24.1)	29.9 (9.0, NE)	79	1 (1.3)	NR (NE, NE)	14.884 (1.976, 112.100)	0.0005
Docetaxel	56	7 (12.5)	18.6 (11.6, NE)	50	0 (0.0)	NR (NE, NE)	54856964.265 (0.000, NE)	0.0399
Irinotecan	116	16 (13.8)	NR (16.1, NE)	111	1 (0.9)	NR (NE, NE)	7.303 (0.949, 56.192)	0.0255
Interaction								0.9001

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	13 (20.6)	16.1 (10.6, NE)	57	0 (0.0)	NR (NE, NE)	19849030.263 (0.000, NE)	0.0138
1	192	30 (15.6)	29.9 (16.2, NE)	183	2 (1.1)	NR (NE, NE)	9.565 (2.272, 40.263)	0.0002
Interaction								0.9883

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #1								
Asia	201	33 (16.4)	18.6 (11.6, NE)	191	2 (1.0)	NR (NE, NE)	8.562 (2.038, 35.969)	0.0004
Europe/North America	54	10 (18.5)	29.9 (16.2, NE)	49	0 (0.0)	NR (NE, NE)	27457612.665 (0.000, NE)	0.0064
Interaction								0.9893

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	26 (14.8)	NR (16.1, NE)	168	2 (1.2)	NR (NE, NE)	7.037 (1.658, 29.867)	0.0020
Japan	25	7 (28.0)	11.6 (4.6, NE)	23	0 (0.0)	NR (NE, NE)	49166268.174 (0.000, NE)	0.0771
Europe/North America	54	10 (18.5)	29.9 (16.2, NE)	49	0 (0.0)	NR (NE, NE)	27457612.665 (0.000, NE)	0.0064
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	33 (16.3)	18.6 (11.6, NE)	198	2 (1.0)	NR (NE, NE)	8.935 (2.127, 37.535)	0.0003
White	52	10 (19.2)	29.9 (16.2, NE)	42	0 (0.0)	NR (NE, NE)	24551917.285 (0.000, NE)	0.0105
Interaction								0.9901

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	13 (16.3)	16.1 (11.6, NE)	60	1 (1.7)	NR (NE, NE)	4.410 (0.570, 34.109)	0.1203
vCPS < 10%	100	18 (18.0)	29.9 (16.5, NE)	119	1 (0.8)	NR (NE, NE)	15.611 (2.068, 117.860)	0.0003
Missing	75	12 (16.0)	NR (10.6, NE)	61	0 (0.0)	NR (NE, NE)	21444275.375 (0.000, NE)	0.0090
Interaction								0.8240

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	20 (13.2)	29.9 (16.1, NE)	146	1 (0.7)	NR (NE, NE)	9.798 (1.302, 73.712)	0.0060
>= 65 Years	103	11 (10.7)	NR (18.6, NE)	94	0 (0.0)	NR (NE, NE)	21920185.482 (0.000, NE)	0.0085
Interaction								0.9886

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Gender								
Male	216	25 (11.6)	NR (16.5, NE)	204	1 (0.5)	NR (NE, NE)	13.333 (1.792, 99.197)	0.0010
Female	39	6 (15.4)	29.9 (NE, NE)	36	0 (0.0)	NR (NE, NE)	64142089.138 (0.000, NE)	0.0521
Interaction								0.9892

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	22 (11.8)	NR (16.5, NE)	183	1 (0.5)	NR (NE, NE)	12.548 (1.678, 93.841)	0.0015
Non-Smoker	68	9 (13.2)	29.9 (10.6, NE)	57	0 (0.0)	NR (NE, NE)	18720464.181 (0.000, NE)	0.0387
Interaction								0.9916

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	14 (16.9)	29.9 (16.5, NE)	79	0 (0.0)	NR (NE, NE)	25104900.386 (0.000, NE)	0.0020
Docetaxel	56	5 (8.9)	18.6 (NE, NE)	50	0 (0.0)	NR (NE, NE)	57484283.130 (0.000, NE)	0.0674
Irinotecan	116	12 (10.3)	NR (16.1, NE)	111	1 (0.9)	NR (NE, NE)	5.426 (0.687, 42.874)	0.0732
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	9 (14.3)	NR (16.1, NE)	57	0 (0.0)	NR (NE, NE)	18314934.177 (0.000, NE)	0.0555
1	192	22 (11.5)	NR (29.9, NE)	183	1 (0.5)	NR (NE, NE)	13.221 (1.771, 98.673)	0.0010
Interaction								0.9906

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #1								
Asia	201	25 (12.4)	NR (16.5, NE)	191	1 (0.5)	NR (NE, NE)	13.038 (1.754, 96.896)	0.0011
Europe/North America	54	6 (11.1)	29.9 (29.9, NE)	49	0 (0.0)	NR (NE, NE)	23801941.369 (0.000, NE)	0.0484
Interaction								0.9915

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	21 (11.9)	NR (16.5, NE)	168	1 (0.6)	NR (NE, NE)	11.222 (1.499, 84.006)	0.0029
Japan	25	4 (16.0)	NR (4.6, NE)	23	0 (0.0)	NR (NE, NE)	47674440.539 (0.000, NE)	0.1771
Europe/North America	54	6 (11.1)	29.9 (29.9, NE)	49	0 (0.0)	NR (NE, NE)	23801941.369 (0.000, NE)	0.0484
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	25 (12.3)	NR (16.5, NE)	198	1 (0.5)	NR (NE, NE)	13.629 (1.834, 101.278)	0.0008
White	52	6 (11.5)	29.9 (29.9, NE)	42	0 (0.0)	NR (NE, NE)	21614353.272 (0.000, NE)	0.0635
Interaction								0.9921

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	8 (10.0)	NR (16.1, NE)	60	0 (0.0)	NR (NE, NE)	14640513.765 (0.000, NE)	0.1035
vCPS < 10%	100	14 (14.0)	29.9 (16.5, NE)	119	1 (0.8)	NR (NE, NE)	10.720 (1.390, 82.666)	0.0043
Missing	75	9 (12.0)	NR (10.6, NE)	61	0 (0.0)	NR (NE, NE)	19687134.325 (0.000, NE)	0.0412
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	91 (59.9)	2.0 (1.2, 5.6)	146	102 (69.9)	0.4 (0.2, 0.9)	0.512 (0.383, 0.685)	<0.0001
>= 65 Years	103	61 (59.2)	3.3 (2.1, 6.3)	94	70 (74.5)	0.3 (0.2, 0.7)	0.401 (0.280, 0.576)	<0.0001
Interaction								0.4570
Gender								
Male	216	125 (57.9)	3.1 (1.9, 5.6)	204	144 (70.6)	0.4 (0.3, 0.7)	0.465 (0.363, 0.595)	<0.0001
Female	39	27 (69.2)	1.4 (0.7, 4.2)	36	28 (77.8)	0.2 (0.1, 1.1)	0.466 (0.266, 0.814)	0.0052
Interaction								0.9522

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	114 (61.0)	2.4 (1.4, 3.7)	183	132 (72.1)	0.3 (0.2, 0.7)	0.490 (0.379, 0.634)	<0.0001
Non-Smoker	68	38 (55.9)	5.8 (1.3, 8.6)	57	40 (70.2)	0.5 (0.2, 1.2)	0.397 (0.247, 0.638)	<0.0001
Interaction								0.8018

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	55 (66.3)	2.0 (1.2, 3.4)	79	50 (63.3)	1.1 (0.5, 2.3)	0.716 (0.483, 1.061)	0.0911
Docetaxel	56	35 (62.5)	2.9 (0.8, 7.2)	50	29 (58.0)	1.1 (0.3, 6.1)	0.709 (0.427, 1.178)	0.1776
Irinotecan	116	62 (53.4)	4.2 (1.3, 6.6)	111	93 (83.8)	0.2 (0.1, 0.3)	0.257 (0.181, 0.366)	<0.0001
Interaction								<0.0001

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	37 (58.7)	5.9 (2.0, 8.6)	57	38 (66.7)	0.8 (0.3, 1.9)	0.461 (0.284, 0.747)	0.0011
1	192	115 (59.9)	2.2 (1.2, 3.4)	183	134 (73.2)	0.3 (0.2, 0.5)	0.463 (0.358, 0.598)	<0.0001
Interaction								0.6263
Region #1								
Asia	201	110 (54.7)	3.4 (2.0, 5.9)	191	134 (70.2)	0.3 (0.2, 0.6)	0.423 (0.326, 0.549)	<0.0001
Europe/North America	54	42 (77.8)	1.3 (0.5, 2.4)	49	38 (77.6)	0.5 (0.3, 1.2)	0.632 (0.399, 1.002)	0.0451
Interaction								0.0337

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	98 (55.7)	3.4 (1.5, 5.8)	168	119 (70.8)	0.3 (0.1, 0.5)	0.421 (0.319, 0.555)	<0.0001
Japan	25	12 (48.0)	9.8 (1.5, NE)	23	15 (65.2)	1.1 (0.3, NE)	0.422 (0.187, 0.953)	0.0317
Europe/North America	54	42 (77.8)	1.3 (0.5, 2.4)	49	38 (77.6)	0.5 (0.3, 1.2)	0.632 (0.399, 1.002)	0.0451
Interaction								0.1008

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

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Any TEAE: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	112 (55.2)	3.4 (2.0, 5.9)	198	139 (70.2)	0.3 (0.2, 0.7)	0.433 (0.335, 0.560)	<0.0001
White	52	40 (76.9)	1.3 (0.5, 2.5)	42	33 (78.6)	0.4 (0.3, 1.2)	0.578 (0.355, 0.940)	0.0226
Interaction								0.1119

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	52 (65.0)	3.0 (1.3, 6.0)	60	48 (80.0)	0.2 (0.1, 0.4)	0.353 (0.232, 0.538)	<0.0001
vCPS < 10%	100	65 (65.0)	1.4 (0.8, 3.7)	119	87 (73.1)	0.4 (0.3, 0.9)	0.526 (0.377, 0.734)	<0.0001
Missing	75	35 (46.7)	4.2 (2.5, NE)	61	37 (60.7)	0.5 (0.1, NE)	0.490 (0.306, 0.784)	0.0021
Interaction								0.2745

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Gastrointestinal disorders / PT - Abdominal pain upper

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	152	5 (3.3)	NR (NE, NE)	146	9 (6.2)	NR (NE, NE)	0.471 (0.157, 1.418)	0.1704
>= 65 Years	103	4 (3.9)	NR (NE, NE)	94	7 (7.4)	NR (6.9, NE)	0.390 (0.110, 1.380)	0.1310
Interaction								0.9334
Gender								
Male	216	9 (4.2)	NR (NE, NE)	204	11 (5.4)	NR (NE, NE)	0.634 (0.259, 1.550)	0.3134
Female	39	0 (0.0)	NR (NE, NE)	36	5 (13.9)	NR (NE, NE)	0.000 (0.000, NE)	0.0141
Interaction								0.9869

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Abdominal pain upper

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	7 (3.7)	NR (NE, NE)	183	10 (5.5)	NR (NE, NE)	0.586 (0.221, 1.555)	0.2771
Non-Smoker	68	2 (2.9)	NR (NE, NE)	57	6 (10.5)	NR (6.9, NE)	0.202 (0.039, 1.059)	0.0385
Interaction								0.3501

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Abdominal pain upper

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	0 (0.0)	NR (NE, NE)	79	7 (8.9)	NR (NE, NE)	0.000 (0.000, NE)	0.0054
Docetaxel	56	3 (5.4)	NR (NE, NE)	50	3 (6.0)	NR (6.9, NE)	0.700 (0.138, 3.536)	0.6635
Irinotecan	116	6 (5.2)	NR (NE, NE)	111	6 (5.4)	NR (NE, NE)	0.713 (0.221, 2.302)	0.5703
Interaction								0.9997

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Abdominal pain upper

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	2 (3.2)	NR (NE, NE)	57	8 (14.0)	NR (6.9, NE)	0.183 (0.038, 0.874)	0.0172
1	192	7 (3.6)	NR (NE, NE)	183	8 (4.4)	NR (NE, NE)	0.698 (0.250, 1.950)	0.4895
Interaction								0.1502
Region #1								
Asia	201	8 (4.0)	NR (NE, NE)	191	9 (4.7)	NR (NE, NE)	0.710 (0.271, 1.866)	0.4854
Europe/North America	54	1 (1.9)	NR (NE, NE)	49	7 (14.3)	NR (6.9, NE)	0.105 (0.013, 0.870)	0.0111
Interaction								0.1179

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Abdominal pain upper

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	8 (4.5)	NR (NE, NE)	168	9 (5.4)	NR (NE, NE)	0.711 (0.271, 1.868)	0.4864
Japan	25	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Europe/North America	54	1 (1.9)	NR (NE, NE)	49	7 (14.3)	NR (6.9, NE)	0.105 (0.013, 0.870)	0.0111
Interaction								0.2920

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Abdominal pain upper

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	8 (3.9)	NR (NE, NE)	198	9 (4.5)	NR (NE, NE)	0.735 (0.280, 1.929)	0.5302
White	52	1 (1.9)	NR (NE, NE)	42	7 (16.7)	NR (6.9, NE)	0.095 (0.012, 0.780)	0.0065
Interaction								0.0880

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Abdominal pain upper

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	4 (5.0)	NR (NE, NE)	60	6 (10.0)	NR (NE, NE)	0.357 (0.096, 1.322)	0.1078
vCPS < 10%	100	3 (3.0)	NR (NE, NE)	119	8 (6.7)	NR (NE, NE)	0.415 (0.110, 1.567)	0.1803
Missing	75	2 (2.7)	NR (NE, NE)	61	2 (3.3)	NR (6.9, NE)	0.638 (0.088, 4.622)	0.6532
Interaction								0.8184

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	14 (9.2)	NR (NE, NE)	146	42 (28.8)	NR (NE, NE)	0.253 (0.137, 0.464)	<0.0001
>= 65 Years	103	18 (17.5)	NR (NE, NE)	94	34 (36.2)	NR (3.3, NE)	0.354 (0.198, 0.633)	0.0002
Interaction								0.3825
Gender								
Male	216	24 (11.1)	NR (NE, NE)	204	64 (31.4)	NR (NE, NE)	0.272 (0.169, 0.436)	<0.0001
Female	39	8 (20.5)	NR (7.5, NE)	36	12 (33.3)	NR (1.7, NE)	0.451 (0.180, 1.128)	0.0801
Interaction								0.2155

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	27 (14.4)	NR (NE, NE)	183	62 (33.9)	NR (NE, NE)	0.314 (0.199, 0.496)	<0.0001
Non-Smoker	68	5 (7.4)	NR (NE, NE)	57	14 (24.6)	NR (NE, NE)	0.268 (0.096, 0.744)	0.0066
Interaction								0.6577

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	13 (15.7)	NR (NE, NE)	79	14 (17.7)	NR (NE, NE)	0.761 (0.356, 1.624)	0.4771
Docetaxel	56	6 (10.7)	NR (NE, NE)	50	8 (16.0)	NR (NE, NE)	0.553 (0.191, 1.607)	0.2696
Irinotecan	116	13 (11.2)	NR (NE, NE)	111	54 (48.6)	4.4 (0.4, NE)	0.140 (0.074, 0.266)	<0.0001
Interaction								0.0014

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	4 (6.3)	NR (NE, NE)	57	15 (26.3)	NR (NE, NE)	0.175 (0.057, 0.540)	0.0007
1	192	28 (14.6)	NR (NE, NE)	183	61 (33.3)	NR (4.4, NE)	0.332 (0.211, 0.521)	<0.0001
Interaction								0.3306
Region #1								
Asia	201	16 (8.0)	NR (NE, NE)	191	55 (28.8)	NR (NE, NE)	0.217 (0.124, 0.380)	<0.0001
Europe/North America	54	16 (29.6)	NR (7.5, NE)	49	21 (42.9)	NR (0.5, NE)	0.486 (0.250, 0.944)	0.0290
Interaction								0.0319

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	14 (8.0)	NR (NE, NE)	168	52 (31.0)	NR (NE, NE)	0.199 (0.110, 0.360)	<0.0001
Japan	25	2 (8.0)	NR (NE, NE)	23	3 (13.0)	NR (2.6, NE)	0.539 (0.089, 3.271)	0.4952
Europe/North America	54	16 (29.6)	NR (7.5, NE)	49	21 (42.9)	NR (0.5, NE)	0.486 (0.250, 0.944)	0.0290
Interaction								0.0625

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	17 (8.4)	NR (NE, NE)	198	55 (27.8)	NR (NE, NE)	0.241 (0.139, 0.416)	<0.0001
White	52	15 (28.8)	NR (7.5, NE)	42	21 (50.0)	1.7 (0.4, NE)	0.373 (0.189, 0.733)	0.0028
Interaction								0.1778

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

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Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	12 (15.0)	NR (NE, NE)	60	19 (31.7)	NR (3.3, NE)	0.347 (0.167, 0.722)	0.0030
vCPS < 10%	100	16 (16.0)	NR (NE, NE)	119	42 (35.3)	NR (NE, NE)	0.333 (0.186, 0.597)	<0.0001
Missing	75	4 (5.3)	NR (NE, NE)	61	15 (24.6)	NR (4.4, NE)	0.184 (0.061, 0.557)	0.0008
Interaction								0.5012

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Nausea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	24 (15.8)	NR (25.1, NE)	146	45 (30.8)	NR (5.1, NE)	0.406 (0.245, 0.673)	0.0003
>= 65 Years	103	13 (12.6)	NR (NE, NE)	94	27 (28.7)	NR (3.8, NE)	0.314 (0.160, 0.614)	0.0004
Interaction								0.7042
Gender								
Male	216	28 (13.0)	NR (NE, NE)	204	58 (28.4)	NR (5.1, NE)	0.358 (0.227, 0.565)	<0.0001
Female	39	9 (23.1)	25.1 (4.7, NE)	36	14 (38.9)	NR (1.1, NE)	0.363 (0.148, 0.890)	0.0212
Interaction								0.6111

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Nausea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	29 (15.5)	NR (NE, NE)	183	54 (29.5)	NR (5.0, NE)	0.406 (0.257, 0.641)	<0.0001
Non-Smoker	68	8 (11.8)	25.1 (NE, NE)	57	18 (31.6)	NR (3.8, NE)	0.261 (0.109, 0.629)	0.0013
Interaction								0.4955

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

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Any TEAE: SOC - Gastrointestinal disorders / PT - Nausea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	16 (19.3)	NR (25.1, NE)	79	14 (17.7)	NR (NE, NE)	0.924 (0.445, 1.919)	0.8328
Docetaxel	56	7 (12.5)	NR (NE, NE)	50	5 (10.0)	NR (4.2, NE)	1.090 (0.342, 3.469)	0.8841
Irinotecan	116	14 (12.1)	NR (NE, NE)	111	53 (47.7)	2.4 (1.1, 5.1)	0.159 (0.087, 0.292)	<0.0001
Interaction								<0.0001

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	3 (4.8)	NR (NE, NE)	57	10 (17.5)	NR (NE, NE)	0.233 (0.064, 0.851)	0.0163
1	192	34 (17.7)	NR (25.1, NE)	183	62 (33.9)	5.1 (3.0, NE)	0.377 (0.246, 0.579)	<0.0001
Interaction								0.3803
Region #1								
Asia	201	25 (12.4)	NR (NE, NE)	191	57 (29.8)	NR (5.1, NE)	0.321 (0.200, 0.517)	<0.0001
Europe/North America	54	12 (22.2)	25.1 (25.1, NE)	49	15 (30.6)	NR (2.6, NE)	0.544 (0.248, 1.194)	0.1228
Interaction								0.1259

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Region #2								
Asia (excluding Japan)	176	21 (11.9)	NR (NE, NE)	168	56 (33.3)	NR (3.8, NE)	0.268 (0.162, 0.445)	<0.0001
Japan	25	4 (16.0)	NR (NE, NE)	23	1 (4.3)	NR (NE, NE)	3.318 (0.369, 29.832)	0.2564
Europe/North America	54	12 (22.2)	25.1 (25.1, NE)	49	15 (30.6)	NR (2.6, NE)	0.544 (0.248, 1.194)	0.1228
Interaction								0.0236

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Race								
Asian and other	203	25 (12.3)	NR (NE, NE)	198	59 (29.8)	NR (5.1, NE)	0.321 (0.200, 0.515)	<0.0001
White	52	12 (23.1)	25.1 (25.1, NE)	42	13 (31.0)	5.0 (2.6, NE)	0.547 (0.243, 1.235)	0.1403
Interaction								0.1258

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	14 (17.5)	NR (NE, NE)	60	19 (31.7)	NR (3.0, NE)	0.401 (0.198, 0.809)	0.0081
vCPS < 10%	100	14 (14.0)	NR (25.1, NE)	119	37 (31.1)	NR (3.8, NE)	0.329 (0.174, 0.621)	0.0003
Missing	75	9 (12.0)	NR (NE, NE)	61	16 (26.2)	NR (5.0, NE)	0.379 (0.167, 0.861)	0.0155
Interaction								0.9786

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Vomiting

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	20 (13.2)	NR (NE, NE)	146	32 (21.9)	NR (NE, NE)	0.470 (0.266, 0.832)	0.0077
>= 65 Years	103	7 (6.8)	NR (NE, NE)	94	16 (17.0)	NR (NE, NE)	0.352 (0.144, 0.858)	0.0159
Interaction								0.4923
Gender								
Male	216	24 (11.1)	NR (NE, NE)	204	38 (18.6)	NR (NE, NE)	0.476 (0.283, 0.803)	0.0042
Female	39	3 (7.7)	NR (NE, NE)	36	10 (27.8)	NR (2.7, NE)	0.239 (0.066, 0.869)	0.0178
Interaction								0.2650

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Vomiting

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	19 (10.2)	NR (NE, NE)	183	34 (18.6)	NR (NE, NE)	0.447 (0.252, 0.792)	0.0045
Non-Smoker	68	8 (11.8)	NR (NE, NE)	57	14 (24.6)	NR (3.0, NE)	0.374 (0.155, 0.900)	0.0222
Interaction								0.8050

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Vomiting

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	8 (9.6)	NR (NE, NE)	79	6 (7.6)	NR (NE, NE)	1.201 (0.416, 3.469)	0.7349
Docetaxel	56	4 (7.1)	NR (NE, NE)	50	5 (10.0)	NR (NE, NE)	0.611 (0.163, 2.282)	0.4576
Irinotecan	116	15 (12.9)	NR (NE, NE)	111	37 (33.3)	NR (3.5, NE)	0.264 (0.141, 0.493)	<0.0001
Interaction								0.0465

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Vomiting

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	3 (4.8)	NR (14.0, NE)	57	4 (7.0)	NR (NE, NE)	0.393 (0.072, 2.165)	0.2668
1	192	24 (12.5)	NR (NE, NE)	183	44 (24.0)	NR (NE, NE)	0.421 (0.255, 0.695)	0.0005
Interaction								0.6614
Region #1								
Asia	201	21 (10.4)	NR (NE, NE)	191	41 (21.5)	NR (NE, NE)	0.380 (0.222, 0.650)	0.0002
Europe/North America	54	6 (11.1)	NR (NE, NE)	49	7 (14.3)	NR (5.7, NE)	0.727 (0.244, 2.165)	0.5640
Interaction								0.3273

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Vomiting

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	20 (11.4)	NR (NE, NE)	168	40 (23.8)	NR (NE, NE)	0.365 (0.211, 0.631)	0.0002
Japan	25	1 (4.0)	NR (NE, NE)	23	1 (4.3)	NR (NE, NE)	0.895 (0.056, 14.318)	0.9378
Europe/North America	54	6 (11.1)	NR (NE, NE)	49	7 (14.3)	NR (5.7, NE)	0.727 (0.244, 2.165)	0.5640
Interaction								0.5287

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Vomiting

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	21 (10.3)	NR (NE, NE)	198	42 (21.2)	NR (NE, NE)	0.383 (0.225, 0.654)	0.0002
White	52	6 (11.5)	NR (NE, NE)	42	6 (14.3)	NR (5.7, NE)	0.753 (0.242, 2.337)	0.6214
Interaction								0.3215

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Vomiting

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	7 (8.8)	NR (NE, NE)	60	12 (20.0)	NR (5.7, NE)	0.298 (0.114, 0.780)	0.0091
vCPS < 10%	100	15 (15.0)	NR (NE, NE)	119	25 (21.0)	NR (NE, NE)	0.616 (0.324, 1.172)	0.1344
Missing	75	5 (6.7)	NR (NE, NE)	61	11 (18.0)	NR (NE, NE)	0.340 (0.118, 0.980)	0.0356
Interaction								0.4364

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	59 (38.8)	10.3 (7.7, NE)	146	89 (61.0)	1.0 (0.7, 1.7)	0.405 (0.287, 0.572)	<0.0001
>= 65 Years	103	60 (58.3)	3.6 (2.1, 7.0)	94	60 (63.8)	1.1 (0.7, 2.0)	0.574 (0.393, 0.838)	0.0032
Interaction								0.0788
Gender								
Male	216	97 (44.9)	7.7 (5.5, 11.0)	204	125 (61.3)	1.0 (0.8, 1.6)	0.457 (0.346, 0.604)	<0.0001
Female	39	22 (56.4)	2.4 (1.0, 8.5)	36	24 (66.7)	1.3 (0.5, 2.6)	0.563 (0.305, 1.039)	0.0588
Interaction								0.3482

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	89 (47.6)	7.6 (2.8, 11.0)	183	120 (65.6)	1.0 (0.7, 1.3)	0.460 (0.345, 0.614)	<0.0001
Non-Smoker	68	30 (44.1)	7.0 (2.8, 14.5)	57	29 (50.9)	1.9 (0.7, NE)	0.520 (0.301, 0.898)	0.0165
Interaction								0.3686

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	47 (56.6)	3.5 (1.9, 9.9)	79	51 (64.6)	1.7 (0.8, 2.5)	0.571 (0.374, 0.871)	0.0079
Docetaxel	56	27 (48.2)	5.5 (2.9, 8.6)	50	28 (56.0)	1.3 (0.8, NE)	0.548 (0.315, 0.951)	0.0281
Irinotecan	116	45 (38.8)	13.8 (6.1, NE)	111	70 (63.1)	0.8 (0.5, 1.5)	0.395 (0.266, 0.586)	<0.0001
Interaction								0.1520

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	36 (57.1)	6.1 (2.2, 8.5)	57	34 (59.6)	2.0 (0.9, 3.0)	0.591 (0.357, 0.979)	0.0370
1	192	83 (43.2)	7.6 (3.5, 12.7)	183	115 (62.8)	0.9 (0.6, 1.6)	0.436 (0.325, 0.586)	<0.0001
Interaction								0.1045
Region #1								
Asia	201	79 (39.3)	9.9 (6.4, 17.5)	191	113 (59.2)	1.1 (0.8, 2.0)	0.399 (0.294, 0.542)	<0.0001
Europe/North America	54	40 (74.1)	1.0 (0.6, 2.5)	49	36 (73.5)	1.0 (0.5, 1.9)	0.757 (0.475, 1.206)	0.2312
Interaction								0.0122

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	66 (37.5)	11.0 (6.4, NE)	168	99 (58.9)	1.0 (0.8, 2.0)	0.394 (0.284, 0.548)	<0.0001
Japan	25	13 (52.0)	6.9 (1.9, NE)	23	14 (60.9)	1.7 (0.4, NE)	0.432 (0.187, 1.000)	0.0431
Europe/North America	54	40 (74.1)	1.0 (0.6, 2.5)	49	36 (73.5)	1.0 (0.5, 1.9)	0.757 (0.475, 1.206)	0.2312
Interaction								0.0325

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	79 (38.9)	9.9 (6.4, 17.5)	198	117 (59.1)	1.1 (0.8, 2.0)	0.395 (0.291, 0.535)	<0.0001
White	52	40 (76.9)	0.8 (0.5, 2.5)	42	32 (76.2)	0.8 (0.5, 1.5)	0.751 (0.465, 1.213)	0.2305
Interaction								0.0189

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	41 (51.3)	6.4 (2.1, 8.5)	60	46 (76.7)	0.7 (0.3, 1.1)	0.339 (0.216, 0.533)	<0.0001
vCPS < 10%	100	49 (49.0)	7.7 (2.2, 11.0)	119	65 (54.6)	1.9 (0.9, 2.7)	0.590 (0.397, 0.877)	0.0077
Missing	75	29 (38.7)	9.9 (2.8, NE)	61	38 (62.3)	0.9 (0.5, 1.7)	0.425 (0.259, 0.698)	0.0004
Interaction								0.1363

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	15 (9.9)	37.2 (17.5, NE)	146	23 (15.8)	NR (9.0, NE)	0.411 (0.203, 0.830)	0.0105
>= 65 Years	103	14 (13.6)	NR (NE, NE)	94	14 (14.9)	NR (NE, NE)	0.735 (0.344, 1.571)	0.4245
Interaction								0.4571
Gender								
Male	216	26 (12.0)	37.2 (37.2, NE)	204	31 (15.2)	NR (NE, NE)	0.587 (0.340, 1.011)	0.0515
Female	39	3 (7.7)	NR (14.5, NE)	36	6 (16.7)	9.0 (9.0, NE)	0.320 (0.077, 1.331)	0.1004
Interaction								0.5559

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	24 (12.8)	NR (37.2, NE)	183	33 (18.0)	NR (9.0, NE)	0.521 (0.302, 0.901)	0.0173
Non-Smoker	68	5 (7.4)	NR (14.5, NE)	57	4 (7.0)	NR (NE, NE)	0.786 (0.202, 3.063)	0.7282
Interaction								0.4648

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	13 (15.7)	NR (37.2, NE)	79	8 (10.1)	NR (9.0, NE)	1.305 (0.529, 3.216)	0.5613
Docetaxel	56	6 (10.7)	17.5 (8.6, NE)	50	10 (20.0)	NR (4.1, NE)	0.377 (0.133, 1.067)	0.0564
Irinotecan	116	10 (8.6)	NR (14.5, NE)	111	19 (17.1)	NR (NE, NE)	0.343 (0.150, 0.787)	0.0080
Interaction								0.1505

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	8 (12.7)	NR (14.5, NE)	57	7 (12.3)	NR (NE, NE)	0.664 (0.222, 1.988)	0.4602
1	192	21 (10.9)	37.2 (37.2, NE)	183	30 (16.4)	NR (9.0, NE)	0.497 (0.278, 0.888)	0.0158
Interaction								0.4187
Region #1								
Asia	201	12 (6.0)	NR (37.2, NE)	191	26 (13.6)	NR (9.0, NE)	0.291 (0.139, 0.611)	0.0006
Europe/North America	54	17 (31.5)	14.5 (8.6, NE)	49	11 (22.4)	NR (4.1, NE)	1.136 (0.524, 2.464)	0.7461
Interaction								0.0103

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	12 (6.8)	37.2 (37.2, NE)	168	26 (15.5)	NR (9.0, NE)	0.292 (0.140, 0.611)	0.0005
Japan	25	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Europe/North America	54	17 (31.5)	14.5 (8.6, NE)	49	11 (22.4)	NR (4.1, NE)	1.136 (0.524, 2.464)	0.7461
Interaction								0.0389

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	12 (5.9)	NR (37.2, NE)	198	26 (13.1)	NR (9.0, NE)	0.300 (0.143, 0.630)	0.0008
White	52	17 (32.7)	14.5 (8.6, NE)	42	11 (26.2)	NR (3.0, NE)	0.985 (0.454, 2.137)	0.9695
Interaction								0.0260

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	9 (11.3)	NR (14.5, NE)	60	12 (20.0)	NR (9.0, NE)	0.396 (0.163, 0.961)	0.0340
vCPS < 10%	100	15 (15.0)	37.2 (14.5, NE)	119	16 (13.4)	NR (NE, NE)	0.755 (0.355, 1.608)	0.4644
Missing	75	5 (6.7)	NR (NE, NE)	61	9 (14.8)	NR (NE, NE)	0.417 (0.140, 1.244)	0.1048
Interaction								0.2496

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - General disorders and administration site conditions / PT - Malaise

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	6 (3.9)	NR (NE, NE)	146	24 (16.4)	NR (NE, NE)	0.167 (0.063, 0.441)	<0.0001
>= 65 Years	103	10 (9.7)	NR (NE, NE)	94	12 (12.8)	NR (NE, NE)	0.602 (0.255, 1.421)	0.2414
Interaction								0.0634
Gender								
Male	216	12 (5.6)	NR (NE, NE)	204	32 (15.7)	NR (NE, NE)	0.272 (0.136, 0.542)	<0.0001
Female	39	4 (10.3)	NR (7.7, NE)	36	4 (11.1)	NR (NE, NE)	0.632 (0.151, 2.641)	0.5258
Interaction								0.1816

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - General disorders and administration site conditions / PT - Malaise

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Smoking Status								
Former/Current Smoker	187	10 (5.3)	NR (NE, NE)	183	26 (14.2)	NR (NE, NE)	0.288 (0.134, 0.618)	0.0007
Non-Smoker	68	6 (8.8)	NR (8.5, NE)	57	10 (17.5)	NR (NE, NE)	0.346 (0.121, 0.994)	0.0400
Interaction								0.6415

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - General disorders and administration site conditions / PT - Malaise

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	6 (7.2)	NR (NE, NE)	79	5 (6.3)	NR (NE, NE)	0.794 (0.233, 2.709)	0.7119
Docetaxel	56	5 (8.9)	NR (13.3, NE)	50	7 (14.0)	NR (NE, NE)	0.532 (0.166, 1.705)	0.2784
Irinotecan	116	5 (4.3)	NR (NE, NE)	111	24 (21.6)	NR (NE, NE)	0.156 (0.059, 0.415)	<0.0001
Interaction								0.0370

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - General disorders and administration site conditions / PT - Malaise

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	5 (7.9)	NR (13.3, NE)	57	10 (17.5)	NR (NE, NE)	0.249 (0.075, 0.824)	0.0147
1	192	11 (5.7)	NR (NE, NE)	183	26 (14.2)	NR (NE, NE)	0.341 (0.167, 0.695)	0.0019
Interaction								0.9714
Region #1								
Asia	201	16 (8.0)	NR (NE, NE)	191	35 (18.3)	NR (NE, NE)	0.313 (0.169, 0.578)	<0.0001
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	0.000 (0.000, NE)	0.2888
Interaction								0.9879

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - General disorders and administration site conditions / PT - Malaise

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	11 (6.3)	NR (NE, NE)	168	31 (18.5)	NR (NE, NE)	0.268 (0.132, 0.542)	<0.0001
Japan	25	5 (20.0)	NR (7.7, NE)	23	4 (17.4)	NR (2.6, NE)	0.596 (0.144, 2.472)	0.4708
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	0.000 (0.000, NE)	0.2888
Interaction								0.2655

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - General disorders and administration site conditions / PT - Malaise

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	203	16 (7.9)	NR (NE, NE)	198	35 (17.7)	NR (NE, NE)	0.322 (0.174, 0.597)	0.0002
White	52	0 (0.0)	NR (NE, NE)	42	1 (2.4)	NR (NE, NE)	0.000 (0.000, NE)	0.2601
Interaction								0.9878

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - General disorders and administration site conditions / PT - Malaise

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	7 (8.8)	NR (NE, NE)	60	11 (18.3)	NR (NE, NE)	0.351 (0.133, 0.925)	0.0269
vCPS < 10%	100	3 (3.0)	NR (13.3, NE)	119	14 (11.8)	NR (NE, NE)	0.156 (0.035, 0.685)	0.0046
Missing	75	6 (8.0)	NR (NE, NE)	61	11 (18.0)	NR (NE, NE)	0.356 (0.130, 0.975)	0.0355
Interaction								0.7745

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	50 (32.9)	15.8 (5.6, NE)	146	44 (30.1)	8.0 (4.9, NE)	0.853 (0.564, 1.290)	0.4501
>= 65 Years	103	30 (29.1)	13.7 (9.5, 27.0)	94	33 (35.1)	9.2 (2.8, NE)	0.487 (0.283, 0.839)	0.0080
Interaction								0.3728
Gender								
Male	216	69 (31.9)	13.7 (9.5, NE)	204	63 (30.9)	8.0 (4.9, NE)	0.752 (0.528, 1.071)	0.1125
Female	39	11 (28.2)	11.3 (2.7, NE)	36	14 (38.9)	3.0 (2.4, NE)	0.459 (0.195, 1.080)	0.0668
Interaction								0.2755

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	57 (30.5)	13.8 (9.5, 27.0)	183	62 (33.9)	8.0 (3.3, NE)	0.608 (0.417, 0.887)	0.0090
Non-Smoker	68	23 (33.8)	10.5 (2.8, NE)	57	15 (26.3)	NR (3.1, NE)	1.037 (0.536, 2.006)	0.9141
Interaction								0.2061

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Safety Analysis Set

Any TEAE: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	29 (34.9)	13.8 (5.3, NE)	79	26 (32.9)	8.0 (3.3, NE)	0.851 (0.491, 1.475)	0.5644
Docetaxel	56	18 (32.1)	9.5 (3.2, NE)	50	22 (44.0)	3.1 (1.4, NE)	0.479 (0.251, 0.914)	0.0223
Irinotecan	116	33 (28.4)	15.8 (11.3, NE)	111	29 (26.1)	9.2 (5.8, NE)	0.748 (0.443, 1.264)	0.2758
Interaction								0.6137

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	19 (30.2)	13.8 (11.3, NE)	57	14 (24.6)	8.0 (5.3, NE)	0.806 (0.387, 1.677)	0.5627
1	192	61 (31.8)	13.7 (5.6, NE)	183	63 (34.4)	5.8 (2.8, NE)	0.659 (0.457, 0.949)	0.0236
Interaction								0.2796
Region #1								
Asia	201	62 (30.8)	13.7 (6.3, NE)	191	56 (29.3)	NR (3.4, NE)	0.731 (0.503, 1.063)	0.0991
Europe/North America	54	18 (33.3)	22.1 (7.3, NE)	49	21 (42.9)	4.9 (2.5, 9.2)	0.578 (0.296, 1.131)	0.1049
Interaction								0.6794

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	53 (30.1)	13.7 (6.3, NE)	168	47 (28.0)	NR (5.8, NE)	0.748 (0.499, 1.121)	0.1578
Japan	25	9 (36.0)	11.5 (2.8, NE)	23	9 (39.1)	3.4 (3.0, NE)	0.636 (0.235, 1.723)	0.3687
Europe/North America	54	18 (33.3)	22.1 (7.3, NE)	49	21 (42.9)	4.9 (2.5, 9.2)	0.578 (0.296, 1.131)	0.1049
Interaction								0.9137

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	63 (31.0)	11.5 (6.3, NE)	198	59 (29.8)	NR (3.4, NE)	0.732 (0.507, 1.058)	0.0949
White	52	17 (32.7)	22.1 (7.3, NE)	42	18 (42.9)	5.3 (2.5, 9.2)	0.560 (0.277, 1.135)	0.1024
Interaction								0.6479

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	23 (28.8)	15.8 (9.5, 27.0)	60	21 (35.0)	8.0 (2.6, NE)	0.442 (0.230, 0.848)	0.0117
vCPS < 10%	100	40 (40.0)	7.3 (3.8, NE)	119	42 (35.3)	5.3 (3.4, NE)	0.926 (0.596, 1.438)	0.7307
Missing	75	17 (22.7)	13.7 (11.5, NE)	61	14 (23.0)	NR (3.3, NE)	0.730 (0.351, 1.518)	0.3966
Interaction								0.2402

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	77 (50.7)	2.8 (2.1, 7.6)	146	99 (67.8)	0.5 (0.5, 0.8)	0.470 (0.346, 0.638)	<0.0001
>= 65 Years	103	56 (54.4)	3.5 (2.2, 9.2)	94	67 (71.3)	0.5 (0.4, 1.0)	0.390 (0.267, 0.569)	<0.0001
Interaction								0.5597
Gender								
Male	216	116 (53.7)	2.9 (2.1, 7.0)	204	146 (71.6)	0.5 (0.5, 0.7)	0.427 (0.331, 0.551)	<0.0001
Female	39	17 (43.6)	2.8 (2.2, NE)	36	20 (55.6)	1.0 (0.3, NE)	0.522 (0.271, 1.004)	0.0439
Interaction								0.6288

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	97 (51.9)	3.5 (2.1, 9.7)	183	125 (68.3)	0.7 (0.5, 0.9)	0.433 (0.329, 0.572)	<0.0001
Non-Smoker	68	36 (52.9)	2.8 (1.2, 6.6)	57	41 (71.9)	0.5 (0.3, 0.7)	0.440 (0.278, 0.697)	0.0002
Interaction								0.9731

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	31 (37.3)	26.9 (4.4, NE)	79	45 (57.0)	1.2 (0.5, 3.5)	0.396 (0.245, 0.640)	<0.0001
Docetaxel	56	31 (55.4)	2.2 (1.2, 7.7)	50	39 (78.0)	0.3 (0.3, 0.7)	0.356 (0.217, 0.583)	<0.0001
Irinotecan	116	71 (61.2)	2.1 (1.0, 2.8)	111	82 (73.9)	0.5 (0.5, 0.7)	0.476 (0.342, 0.663)	<0.0001
Interaction								0.4589

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

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Safety Analysis Set

Any TEAE: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	28 (44.4)	15.8 (2.2, NE)	57	36 (63.2)	0.5 (0.5, 3.5)	0.402 (0.240, 0.674)	0.0002
1	192	105 (54.7)	2.8 (1.7, 4.9)	183	130 (71.0)	0.5 (0.5, 0.7)	0.450 (0.345, 0.588)	<0.0001
Interaction								0.6188
Region #1								
Asia	201	120 (59.7)	2.1 (1.7, 2.9)	191	148 (77.5)	0.5 (0.4, 0.5)	0.387 (0.300, 0.500)	<0.0001
Europe/North America	54	13 (24.1)	16.2 (16.2, NE)	49	18 (36.7)	3.3 (2.4, NE)	0.486 (0.233, 1.015)	0.0484
Interaction								0.5568

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	108 (61.4)	2.1 (1.4, 2.7)	168	132 (78.6)	0.5 (0.4, 0.5)	0.410 (0.314, 0.535)	<0.0001
Japan	25	12 (48.0)	4.4 (2.8, NE)	23	16 (69.6)	0.5 (0.3, 1.7)	0.217 (0.084, 0.561)	0.0004
Europe/North America	54	13 (24.1)	16.2 (16.2, NE)	49	18 (36.7)	3.3 (2.4, NE)	0.486 (0.233, 1.015)	0.0484
Interaction								0.5986

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Any TEAE: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	120 (59.1)	2.2 (2.0, 2.9)	198	151 (76.3)	0.5 (0.4, 0.5)	0.399 (0.310, 0.514)	<0.0001
White	52	13 (25.0)	16.2 (16.2, NE)	42	15 (35.7)	3.3 (2.4, NE)	0.525 (0.244, 1.128)	0.0913
Interaction								0.4812

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	41 (51.3)	3.5 (2.2, 16.2)	60	39 (65.0)	0.7 (0.4, 1.4)	0.390 (0.245, 0.619)	<0.0001
vCPS < 10%	100	55 (55.0)	2.2 (1.4, 6.2)	119	83 (69.7)	0.5 (0.5, 0.9)	0.514 (0.362, 0.728)	<0.0001
Missing	75	37 (49.3)	2.8 (2.1, 13.8)	61	44 (72.1)	0.5 (0.3, 0.9)	0.388 (0.244, 0.615)	<0.0001
Interaction								0.7121

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	27 (17.8)	NR (14.9, NE)	146	5 (3.4)	NR (NE, NE)	4.027 (1.538, 10.539)	0.0021
>= 65 Years	103	10 (9.7)	NR (30.4, NE)	94	6 (6.4)	NR (NE, NE)	1.098 (0.384, 3.139)	0.8619
Interaction								0.0652

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Gender								
Male	216	32 (14.8)	NR (30.4, NE)	204	11 (5.4)	NR (NE, NE)	2.128 (1.060, 4.272)	0.0295
Female	39	5 (12.8)	NR (4.9, NE)	36	0 (0.0)	NR (NE, NE)	54752211.366 (0.000, NE)	0.0768
Interaction								0.9831

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	27 (14.4)	NR (30.4, NE)	183	9 (4.9)	NR (NE, NE)	2.239 (1.041, 4.819)	0.0340
Non-Smoker	68	10 (14.7)	NR (11.0, NE)	57	2 (3.5)	NR (NE, NE)	3.386 (0.732, 15.656)	0.0976
Interaction								0.5867

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	9 (10.8)	NR (30.4, NE)	79	2 (2.5)	NR (NE, NE)	3.494 (0.740, 16.499)	0.0914
Docetaxel	56	5 (8.9)	NR (NE, NE)	50	1 (2.0)	NR (NE, NE)	3.683 (0.426, 31.829)	0.2040
Irinotecan	116	23 (19.8)	NR (11.0, NE)	111	8 (7.2)	NR (NE, NE)	1.836 (0.804, 4.193)	0.1426
Interaction								0.7101

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

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Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	11 (17.5)	30.4 (14.9, NE)	57	0 (0.0)	NR (NE, NE)	22644564.370 (0.000, NE)	0.0102
1	192	26 (13.5)	NR (NE, NE)	183	11 (6.0)	NR (NE, NE)	1.807 (0.886, 3.687)	0.0986
Interaction								0.9852

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #1								
Asia	201	34 (16.9)	NR (30.4, NE)	191	10 (5.2)	NR (NE, NE)	2.433 (1.189, 4.977)	0.0118
Europe/North America	54	3 (5.6)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	2.322 (0.240, 22.447)	0.4539
Interaction								0.9504

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	31 (17.6)	NR (14.9, NE)	168	10 (6.0)	NR (NE, NE)	2.288 (1.112, 4.708)	0.0207
Japan	25	3 (12.0)	30.4 (NE, NE)	23	0 (0.0)	NR (NE, NE)	64906194.808 (0.000, NE)	0.2144
Europe/North America	54	3 (5.6)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	2.322 (0.240, 22.447)	0.4539
Interaction								0.9998

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

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	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	34 (16.7)	NR (30.4, NE)	198	10 (5.1)	NR (NE, NE)	2.514 (1.229, 5.142)	0.0089
White	52	3 (5.8)	NR (NE, NE)	42	1 (2.4)	NR (NE, NE)	2.083 (0.216, 20.125)	0.5169
Interaction								0.8493

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	16 (20.0)	30.4 (14.9, NE)	60	5 (8.3)	NR (NE, NE)	1.552 (0.556, 4.327)	0.3960
vCPS < 10%	100	11 (11.0)	NR (NE, NE)	119	3 (2.5)	NR (NE, NE)	3.561 (0.981, 12.926)	0.0397
Missing	75	10 (13.3)	NR (NE, NE)	61	3 (4.9)	NR (NE, NE)	2.429 (0.666, 8.861)	0.1642
Interaction								0.6790

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Investigations / PT - Blood alkaline phosphatase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	152	14 (9.2)	NR (NE, NE)	146	3 (2.1)	NR (NE, NE)	3.805 (1.087, 13.317)	0.0246
>= 65 Years	103	3 (2.9)	NR (NE, NE)	94	2 (2.1)	NR (NE, NE)	1.239 (0.205, 7.470)	0.8148
Interaction								0.2981

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Blood alkaline phosphatase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Gender								
Male	216	16 (7.4)	NR (NE, NE)	204	5 (2.5)	NR (NE, NE)	2.669 (0.974, 7.314)	0.0468
Female	39	1 (2.6)	NR (NE, NE)	36	0 (0.0)	NR (NE, NE)	15114368.536 (0.000, NE)	0.5351
Interaction								0.9894

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Investigations / PT - Blood alkaline phosphatase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	16 (8.6)	NR (NE, NE)	183	4 (2.2)	NR (NE, NE)	3.315 (1.103, 9.966)	0.0235
Non-Smoker	68	1 (1.5)	NR (NE, NE)	57	1 (1.8)	NR (NE, NE)	0.868 (0.054, 13.879)	0.9200
Interaction								0.3255

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Blood alkaline phosphatase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	4 (4.8)	NR (NE, NE)	79	2 (2.5)	NR (NE, NE)	1.656 (0.301, 9.117)	0.5581
Docetaxel	56	4 (7.1)	NR (NE, NE)	50	0 (0.0)	NR (NE, NE)	23406417.934 (0.000, NE)	0.0807
Irinotecan	116	9 (7.8)	NR (NE, NE)	111	3 (2.7)	NR (NE, NE)	2.545 (0.683, 9.479)	0.1485
Interaction								0.9776

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Blood alkaline phosphatase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	4 (6.3)	NR (NE, NE)	57	0 (0.0)	NR (NE, NE)	20169752.646 (0.000, NE)	0.1181
1	192	13 (6.8)	NR (NE, NE)	183	5 (2.7)	NR (NE, NE)	2.271 (0.807, 6.388)	0.1093
Interaction								0.9902

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Blood alkaline phosphatase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #1								
Asia	201	16 (8.0)	NR (NE, NE)	191	4 (2.1)	NR (NE, NE)	3.313 (1.103, 9.955)	0.0235
Europe/North America	54	1 (1.9)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	0.735 (0.045, 11.895)	0.8279
Interaction								0.3733

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Blood alkaline phosphatase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	14 (8.0)	NR (NE, NE)	168	4 (2.4)	NR (NE, NE)	2.999 (0.983, 9.147)	0.0422
Japan	25	2 (8.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	59628177.664 (0.000, NE)	0.2639
Europe/North America	54	1 (1.9)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	0.735 (0.045, 11.895)	0.8279
Interaction								0.7242

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Blood alkaline phosphatase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	16 (7.9)	NR (NE, NE)	198	5 (2.5)	NR (NE, NE)	2.748 (1.002, 7.535)	0.0403
White	52	1 (1.9)	NR (NE, NE)	42	0 (0.0)	NR (NE, NE)	50251318.483 (0.000, NE)	0.4561
Interaction								0.9926

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Blood alkaline phosphatase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	4 (5.0)	NR (NE, NE)	60	1 (1.7)	NR (NE, NE)	2.523 (0.276, 23.072)	0.3966
vCPS < 10%	100	9 (9.0)	NR (NE, NE)	119	3 (2.5)	NR (NE, NE)	3.073 (0.827, 11.420)	0.0775
Missing	75	4 (5.3)	NR (NE, NE)	61	1 (1.6)	NR (NE, NE)	3.078 (0.344, 27.567)	0.2890
Interaction								0.9789

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Investigations / PT - Blood creatine phosphokinase MB increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	152	6 (3.9)	--	146	1 (0.7)	--	--	--
>= 65 Years	103	5 (4.9)	--	94	0 (0.0)	--	--	--
Interaction								--
Gender								
Male	216	11 (5.1)	NR (NE, NE)	204	1 (0.5)	NR (NE, NE)	7.964 (1.019, 62.270)	0.0193
Female	39	0 (0.0)	NR (NE, NE)	36	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9995

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Blood creatine phosphokinase MB increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	6 (3.2)	--	183	1 (0.5)	--	--	--
Non-Smoker	68	5 (7.4)	--	57	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Investigations / PT - Blood creatine phosphokinase MB increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ICC Options								
Paclitaxel	83	2 (2.4)	--	79	0 (0.0)	--	--	--
Docetaxel	56	1 (1.8)	--	50	0 (0.0)	--	--	--
Irinotecan	116	8 (6.9)	--	111	1 (0.9)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Safety Analysis Set
Any TEAE: SOC - Investigations / PT - Blood creatine phosphokinase MB increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	3 (4.8)	--	57	0 (0.0)	--	--	--
1	192	8 (4.2)	--	183	1 (0.5)	--	--	--
Interaction								--
Region #1								
Asia	201	11 (5.5)	NR (NE, NE)	191	1 (0.5)	NR (NE, NE)	7.811 (0.997, 61.192)	0.0211
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9994

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	10 (5.7)	NR (NE, NE)	168	1 (0.6)	NR (NE, NE)	7.309 (0.924, 57.782)	0.0279
Japan	25	1 (4.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	50648531.709 (0.000, NE)	0.4533
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

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Safety Analysis Set
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	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	11 (5.4)	NR (NE, NE)	198	1 (0.5)	NR (NE, NE)	8.078 (1.031, 63.260)	0.0184
White	52	0 (0.0)	NR (NE, NE)	42	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9994

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Any TEAE: SOC - Investigations / PT - Blood creatine phosphokinase MB increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	1 (1.3)	--	60	0 (0.0)	--	--	--
vCPS < 10%	100	4 (4.0)	--	119	1 (0.8)	--	--	--
Missing	75	6 (8.0)	--	61	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

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	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	152	7 (4.6)	--	146	0 (0.0)	--	--	--
>= 65 Years	103	3 (2.9)	--	94	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

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	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Gender								
Male	216	10 (4.6)	NR (NE, NE)	204	0 (0.0)	NR (NE, NE)	25050718.902 (0.000, NE)	0.0066
Female	39	0 (0.0)	NR (NE, NE)	36	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9979

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Smoking Status								
Former/Current Smoker	187	7 (3.7)	--	183	0 (0.0)	--	--	--
Non-Smoker	68	3 (4.4)	--	57	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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ICC Options								
Paclitaxel	83	2 (2.4)	--	79	0 (0.0)	--	--	--
Docetaxel	56	1 (1.8)	--	50	0 (0.0)	--	--	--
Irinotecan	116	7 (6.0)	--	111	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

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ECOG Performance Score								
0	63	3 (4.8)	--	57	0 (0.0)	--	--	--
1	192	7 (3.6)	--	183	0 (0.0)	--	--	--
Interaction								--
Region #1								
Asia	201	9 (4.5)	--	191	0 (0.0)	--	--	--
Europe/North America	54	1 (1.9)	--	49	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

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Region #2								
Asia (excluding Japan)	176	8 (4.5)	--	168	0 (0.0)	--	--	--
Japan	25	1 (4.0)	--	23	0 (0.0)	--	--	--
Europe/North America	54	1 (1.9)	--	49	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

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Race								
Asian and other	203	9 (4.4)	--	198	0 (0.0)	--	--	--
White	52	1 (1.9)	--	42	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Blood creatine phosphokinase increased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	3 (3.8)	--	60	0 (0.0)	--	--	--
vCPS < 10%	100	4 (4.0)	--	119	0 (0.0)	--	--	--
Missing	75	3 (4.0)	--	61	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	8 (5.3)	NR (18.6, NE)	146	10 (6.8)	NR (NE, NE)	0.586 (0.222, 1.547)	0.2737
>= 65 Years	103	4 (3.9)	NR (NE, NE)	94	12 (12.8)	NR (NE, NE)	0.268 (0.086, 0.835)	0.0147
Interaction								0.2057
Gender								
Male	216	9 (4.2)	NR (NE, NE)	204	19 (9.3)	NR (NE, NE)	0.349 (0.152, 0.801)	0.0092
Female	39	3 (7.7)	NR (NE, NE)	36	3 (8.3)	NR (NE, NE)	0.824 (0.165, 4.110)	0.8133
Interaction								0.3838

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	9 (4.8)	NR (NE, NE)	183	15 (8.2)	NR (NE, NE)	0.523 (0.228, 1.200)	0.1185
Non-Smoker	68	3 (4.4)	NR (18.6, NE)	57	7 (12.3)	NR (NE, NE)	0.264 (0.066, 1.051)	0.0436
Interaction								0.5832

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	1 (1.2)	NR (NE, NE)	79	4 (5.1)	NR (NE, NE)	0.232 (0.026, 2.074)	0.1520
Docetaxel	56	2 (3.6)	NR (NE, NE)	50	6 (12.0)	NR (NE, NE)	0.262 (0.053, 1.305)	0.0777
Irinotecan	116	9 (7.8)	NR (18.6, NE)	111	12 (10.8)	NR (NE, NE)	0.496 (0.199, 1.234)	0.1236
Interaction								0.5234

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	2 (3.2)	NR (NE, NE)	57	6 (10.5)	NR (NE, NE)	0.241 (0.048, 1.210)	0.0613
1	192	10 (5.2)	NR (NE, NE)	183	16 (8.7)	NR (NE, NE)	0.492 (0.219, 1.103)	0.0784
Interaction								0.4530
Region #1								
Asia	201	10 (5.0)	NR (NE, NE)	191	18 (9.4)	NR (NE, NE)	0.411 (0.186, 0.909)	0.0233
Europe/North America	54	2 (3.7)	NR (NE, NE)	49	4 (8.2)	NR (NE, NE)	0.428 (0.078, 2.337)	0.3104
Interaction								0.8833

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	10 (5.7)	NR (NE, NE)	168	16 (9.5)	NR (NE, NE)	0.458 (0.204, 1.030)	0.0530
Japan	25	0 (0.0)	NR (NE, NE)	23	2 (8.7)	NR (NE, NE)	0.000 (0.000, NE)	0.1361
Europe/North America	54	2 (3.7)	NR (NE, NE)	49	4 (8.2)	NR (NE, NE)	0.428 (0.078, 2.337)	0.3104
Interaction								0.9605

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	10 (4.9)	NR (NE, NE)	198	19 (9.6)	NR (NE, NE)	0.402 (0.183, 0.883)	0.0189
White	52	2 (3.8)	NR (NE, NE)	42	3 (7.1)	NR (NE, NE)	0.510 (0.085, 3.055)	0.4497
Interaction								0.9567

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	2 (2.5)	NR (NE, NE)	60	4 (6.7)	NR (NE, NE)	0.342 (0.062, 1.869)	0.1936
vCPS < 10%	100	6 (6.0)	NR (NE, NE)	119	14 (11.8)	NR (NE, NE)	0.444 (0.170, 1.159)	0.0872
Missing	75	4 (5.3)	NR (18.6, NE)	61	4 (6.6)	NR (NE, NE)	0.489 (0.107, 2.224)	0.3451
Interaction								0.7492

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	152	5 (3.3)	NR (NE, NE)	146	55 (37.7)	NR (2.4, NE)	0.066 (0.026, 0.166)	<0.0001
>= 65 Years	103	1 (1.0)	NR (NE, NE)	94	39 (41.5)	NR (1.3, NE)	0.018 (0.002, 0.131)	<0.0001
Interaction								0.2361
Gender								
Male	216	4 (1.9)	NR (NE, NE)	204	83 (40.7)	NR (2.4, NE)	0.033 (0.012, 0.092)	<0.0001
Female	39	2 (5.1)	NR (NE, NE)	36	11 (30.6)	NR (NE, NE)	0.147 (0.033, 0.666)	0.0036
Interaction								0.1265

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	3 (1.6)	NR (NE, NE)	183	71 (38.8)	NR (2.8, NE)	0.030 (0.009, 0.096)	<0.0001
Non-Smoker	68	3 (4.4)	NR (NE, NE)	57	23 (40.4)	NR (1.2, NE)	0.091 (0.027, 0.304)	<0.0001
Interaction								0.2274

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	1 (1.2)	NR (NE, NE)	79	30 (38.0)	NR (2.4, NE)	0.025 (0.003, 0.182)	<0.0001
Docetaxel	56	0 (0.0)	NR (NE, NE)	50	25 (50.0)	2.8 (0.3, NE)	0.000 (0.000, NE)	<0.0001
Irinotecan	116	5 (4.3)	NR (NE, NE)	111	39 (35.1)	NR (2.1, NE)	0.098 (0.038, 0.249)	<0.0001
Interaction								0.4746

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	2 (3.2)	NR (NE, NE)	57	22 (38.6)	NR (1.3, NE)	0.063 (0.015, 0.268)	<0.0001
1	192	4 (2.1)	NR (NE, NE)	183	72 (39.3)	NR (2.8, NE)	0.040 (0.015, 0.110)	<0.0001
Interaction								0.6084
Region #1								
Asia	201	5 (2.5)	NR (NE, NE)	191	89 (46.6)	2.8 (1.2, NE)	0.038 (0.015, 0.094)	<0.0001
Europe/North America	54	1 (1.9)	NR (NE, NE)	49	5 (10.2)	NR (NE, NE)	0.159 (0.019, 1.364)	0.0543
Interaction								0.2087

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	5 (2.8)	NR (NE, NE)	168	76 (45.2)	2.8 (1.2, NE)	0.045 (0.018, 0.112)	<0.0001
Japan	25	0 (0.0)	NR (NE, NE)	23	13 (56.5)	0.8 (0.5, NE)	0.000 (0.000, NE)	<0.0001
Europe/North America	54	1 (1.9)	NR (NE, NE)	49	5 (10.2)	NR (NE, NE)	0.159 (0.019, 1.364)	0.0543
Interaction								0.5434

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	5 (2.5)	NR (NE, NE)	198	90 (45.5)	3.0 (1.2, NE)	0.039 (0.016, 0.097)	<0.0001
White	52	1 (1.9)	NR (NE, NE)	42	4 (9.5)	NR (NE, NE)	0.173 (0.019, 1.554)	0.0756
Interaction								0.1949

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	2 (2.5)	NR (NE, NE)	60	27 (45.0)	2.8 (1.0, NE)	0.036 (0.008, 0.152)	<0.0001
vCPS < 10%	100	2 (2.0)	NR (NE, NE)	119	43 (36.1)	NR (NE, NE)	0.043 (0.010, 0.180)	<0.0001
Missing	75	2 (2.7)	NR (NE, NE)	61	24 (39.3)	NR (1.0, NE)	0.057 (0.013, 0.242)	<0.0001
Interaction								0.9672

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	152	8 (5.3)	NR (NE, NE)	146	61 (41.8)	NR (1.0, NE)	0.081 (0.037, 0.178)	<0.0001
>= 65 Years	103	3 (2.9)	NR (NE, NE)	94	38 (40.4)	NR (1.2, NE)	0.057 (0.018, 0.185)	<0.0001
Interaction								0.3767
Gender								
Male	216	9 (4.2)	NR (NE, NE)	204	86 (42.2)	NR (1.5, NE)	0.065 (0.031, 0.135)	<0.0001
Female	39	2 (5.1)	NR (NE, NE)	36	13 (36.1)	NR (0.5, NE)	0.120 (0.027, 0.532)	0.0007
Interaction								0.6441

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	6 (3.2)	NR (NE, NE)	183	70 (38.3)	NR (NE, NE)	0.064 (0.028, 0.147)	<0.0001
Non-Smoker	68	5 (7.4)	NR (13.5, NE)	57	29 (50.9)	1.2 (0.5, NE)	0.086 (0.030, 0.246)	<0.0001
Interaction								0.4613

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ICC Options								
Paclitaxel	83	0 (0.0)	NR (NE, NE)	79	22 (27.8)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Docetaxel	56	4 (7.1)	NR (NE, NE)	50	27 (54.0)	0.8 (0.3, NE)	0.091 (0.031, 0.262)	<0.0001
Irinotecan	116	7 (6.0)	NR (NE, NE)	111	50 (45.0)	NR (0.9, NE)	0.082 (0.035, 0.191)	<0.0001
Interaction								0.9821

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Safety Analysis Set

Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	3 (4.8)	NR (NE, NE)	57	26 (45.6)	NR (0.7, NE)	0.076 (0.023, 0.252)	<0.0001
1	192	8 (4.2)	NR (NE, NE)	183	73 (39.9)	NR (NE, NE)	0.071 (0.033, 0.154)	<0.0001
Interaction								0.9751
Region #1								
Asia	201	11 (5.5)	NR (NE, NE)	191	97 (50.8)	1.2 (0.7, NE)	0.067 (0.035, 0.129)	<0.0001
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	2 (4.1)	NR (NE, NE)	0.000 (0.000, NE)	0.1344
Interaction								0.9810

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Region #2								
Asia (excluding Japan)	176	10 (5.7)	NR (NE, NE)	168	85 (50.6)	1.2 (0.7, NE)	0.068 (0.034, 0.135)	<0.0001
Japan	25	1 (4.0)	NR (NE, NE)	23	12 (52.2)	0.8 (0.5, NE)	0.060 (0.008, 0.464)	0.0002
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	2 (4.1)	NR (NE, NE)	0.000 (0.000, NE)	0.1344
Interaction								0.9291

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Safety Analysis Set

Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	11 (5.4)	NR (NE, NE)	198	98 (49.5)	1.5 (0.7, NE)	0.069 (0.036, 0.133)	<0.0001
White	52	0 (0.0)	NR (NE, NE)	42	1 (2.4)	NR (NE, NE)	0.000 (0.000, NE)	0.2611
Interaction								0.9820

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	7 (8.8)	NR (NE, NE)	60	22 (36.7)	NR (1.5, NE)	0.147 (0.059, 0.365)	<0.0001
vCPS < 10%	100	3 (3.0)	NR (NE, NE)	119	47 (39.5)	NR (NE, NE)	0.057 (0.018, 0.185)	<0.0001
Missing	75	1 (1.3)	NR (NE, NE)	61	30 (49.2)	NR (0.5, NE)	0.021 (0.003, 0.157)	<0.0001
Interaction								0.0868

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	75 (49.3)	4.3 (2.2, 13.8)	146	84 (57.5)	1.2 (0.7, 2.3)	0.582 (0.422, 0.802)	0.0007
>= 65 Years	103	48 (46.6)	8.6 (2.9, 16.2)	94	57 (60.6)	1.3 (0.5, 3.5)	0.482 (0.323, 0.718)	0.0002
Interaction								0.4338
Gender								
Male	216	105 (48.6)	5.4 (3.4, 9.0)	204	121 (59.3)	1.2 (0.7, 2.2)	0.531 (0.405, 0.695)	<0.0001
Female	39	18 (46.2)	2.8 (1.4, NE)	36	20 (55.6)	1.2 (0.5, NE)	0.654 (0.343, 1.245)	0.1865
Interaction								0.9427

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	94 (50.3)	4.9 (2.9, 10.2)	183	110 (60.1)	1.2 (0.7, 2.2)	0.542 (0.408, 0.721)	<0.0001
Non-Smoker	68	29 (42.6)	8.6 (2.3, NE)	57	31 (54.4)	1.2 (0.5, 5.7)	0.561 (0.335, 0.940)	0.0246
Interaction								0.8572

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	32 (38.6)	13.8 (4.9, NE)	79	36 (45.6)	4.8 (2.3, NE)	0.649 (0.395, 1.066)	0.0825
Docetaxel	56	31 (55.4)	3.7 (1.3, 9.0)	50	31 (62.0)	1.2 (0.5, 3.7)	0.559 (0.332, 0.942)	0.0236
Irinotecan	116	60 (51.7)	3.3 (2.1, 13.8)	111	74 (66.7)	0.7 (0.5, 1.1)	0.419 (0.293, 0.599)	<0.0001
Interaction								0.3602

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	22 (34.9)	14.0 (8.6, NE)	57	32 (56.1)	3.7 (0.7, 6.6)	0.366 (0.206, 0.652)	0.0003
1	192	101 (52.6)	3.4 (2.1, 7.7)	183	109 (59.6)	1.2 (0.7, 2.0)	0.597 (0.452, 0.789)	0.0002
Interaction								0.1498
Region #1								
Asia	201	100 (49.8)	4.1 (2.8, 10.2)	191	120 (62.8)	0.9 (0.6, 1.3)	0.488 (0.370, 0.642)	<0.0001
Europe/North America	54	23 (42.6)	8.6 (4.2, NE)	49	21 (42.9)	4.2 (2.8, 6.6)	0.777 (0.422, 1.430)	0.4122
Interaction								0.0907

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	93 (52.8)	3.4 (2.1, 7.7)	168	109 (64.9)	0.7 (0.5, 1.2)	0.505 (0.380, 0.671)	<0.0001
Japan	25	7 (28.0)	29.0 (10.2, NE)	23	11 (47.8)	NR (0.7, NE)	0.258 (0.082, 0.817)	0.0122
Europe/North America	54	23 (42.6)	8.6 (4.2, NE)	49	21 (42.9)	4.2 (2.8, 6.6)	0.777 (0.422, 1.430)	0.4122
Interaction								0.1922

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	101 (49.8)	4.1 (2.8, 10.2)	198	121 (61.1)	1.0 (0.7, 1.4)	0.516 (0.392, 0.678)	<0.0001
White	52	22 (42.3)	8.6 (4.2, NE)	42	20 (47.6)	3.7 (1.9, 6.6)	0.670 (0.359, 1.252)	0.2024
Interaction								0.3071

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	33 (41.3)	14.0 (4.1, 21.4)	60	37 (61.7)	1.1 (0.5, 2.3)	0.341 (0.205, 0.567)	<0.0001
vCPS < 10%	100	54 (54.0)	3.7 (1.5, 8.6)	119	66 (55.5)	1.9 (0.8, 4.2)	0.739 (0.513, 1.064)	0.1000
Missing	75	36 (48.0)	4.1 (2.3, NE)	61	38 (62.3)	1.2 (0.5, 3.5)	0.536 (0.337, 0.851)	0.0066
Interaction								0.0674

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	30 (19.7)	26.9 (14.0, NE)	146	50 (34.2)	6.6 (3.7, NE)	0.392 (0.245, 0.628)	<0.0001
>= 65 Years	103	12 (11.7)	NR (NE, NE)	94	34 (36.2)	5.7 (3.4, NE)	0.230 (0.118, 0.450)	<0.0001
Interaction								0.1429
Gender								
Male	216	36 (16.7)	NR (26.9, NE)	204	74 (36.3)	5.7 (3.7, NE)	0.311 (0.206, 0.470)	<0.0001
Female	39	6 (15.4)	NR (NE, NE)	36	10 (27.8)	NR (2.8, NE)	0.422 (0.150, 1.193)	0.0932
Interaction								0.6234

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	37 (19.8)	NR (26.9, NE)	183	71 (38.8)	5.7 (3.5, NE)	0.343 (0.227, 0.518)	<0.0001
Non-Smoker	68	5 (7.4)	NR (NE, NE)	57	13 (22.8)	NR (3.4, NE)	0.240 (0.085, 0.683)	0.0037
Interaction								0.5166

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	17 (20.5)	NR (26.9, NE)	79	23 (29.1)	6.6 (5.7, NE)	0.539 (0.283, 1.026)	0.0554
Docetaxel	56	12 (21.4)	NR (9.0, NE)	50	16 (32.0)	NR (3.2, NE)	0.478 (0.221, 1.033)	0.0534
Irinotecan	116	13 (11.2)	NR (NE, NE)	111	45 (40.5)	3.4 (2.0, NE)	0.168 (0.088, 0.322)	<0.0001
Interaction								0.0112

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	9 (14.3)	NR (14.0, NE)	57	21 (36.8)	6.6 (3.7, NE)	0.247 (0.108, 0.565)	0.0003
1	192	33 (17.2)	NR (26.9, NE)	183	63 (34.4)	5.7 (3.4, NE)	0.351 (0.228, 0.541)	<0.0001
Interaction								0.5254
Region #1								
Asia	201	31 (15.4)	NR (26.9, NE)	191	65 (34.0)	NR (3.5, NE)	0.314 (0.202, 0.488)	<0.0001
Europe/North America	54	11 (20.4)	NR (9.0, NE)	49	19 (38.8)	5.7 (2.8, NE)	0.375 (0.175, 0.802)	0.0084
Interaction								0.4906

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	30 (17.0)	NR (26.9, NE)	168	60 (35.7)	NR (3.4, NE)	0.328 (0.208, 0.515)	<0.0001
Japan	25	1 (4.0)	NR (NE, NE)	23	5 (21.7)	NR (NE, NE)	0.179 (0.021, 1.537)	0.0740
Europe/North America	54	11 (20.4)	NR (9.0, NE)	49	19 (38.8)	5.7 (2.8, NE)	0.375 (0.175, 0.802)	0.0084
Interaction								0.5609

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	31 (15.3)	NR (26.9, NE)	198	66 (33.3)	NR (5.7, NE)	0.318 (0.205, 0.495)	<0.0001
White	52	11 (21.2)	NR (9.0, NE)	42	18 (42.9)	4.2 (2.6, NE)	0.348 (0.162, 0.749)	0.0047
Interaction								0.6843

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	12 (15.0)	NR (NE, NE)	60	23 (38.3)	5.7 (2.9, NE)	0.253 (0.123, 0.521)	<0.0001
vCPS < 10%	100	23 (23.0)	26.9 (9.0, NE)	119	40 (33.6)	5.7 (3.7, NE)	0.482 (0.285, 0.818)	0.0055
Missing	75	7 (9.3)	NR (NE, NE)	61	21 (34.4)	NR (3.5, NE)	0.214 (0.091, 0.507)	0.0001
Interaction								0.0711

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Metabolism and nutrition disorders / PT - Hyponatraemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	152	19 (12.5)	NR (14.5, NE)	146	19 (13.0)	NR (NE, NE)	0.701 (0.364, 1.350)	0.2841
>= 65 Years	103	13 (12.6)	NR (NE, NE)	94	14 (14.9)	NR (6.9, NE)	0.632 (0.286, 1.394)	0.2495
Interaction								0.6615
Gender								
Male	216	28 (13.0)	NR (NE, NE)	204	26 (12.7)	NR (NE, NE)	0.728 (0.418, 1.267)	0.2577
Female	39	4 (10.3)	NR (NE, NE)	36	7 (19.4)	NR (NE, NE)	0.492 (0.144, 1.685)	0.2448
Interaction								0.2990

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Metabolism and nutrition disorders / PT - Hyponatraemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	24 (12.8)	NR (NE, NE)	183	21 (11.5)	NR (NE, NE)	0.825 (0.450, 1.513)	0.5317
Non-Smoker	68	8 (11.8)	NR (10.4, NE)	57	12 (21.1)	NR (4.8, NE)	0.406 (0.160, 1.032)	0.0499
Interaction								0.2116

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders / PT - Hyponatraemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	3 (3.6)	NR (NE, NE)	79	3 (3.8)	NR (NE, NE)	0.860 (0.172, 4.291)	0.8540
Docetaxel	56	9 (16.1)	NR (9.0, NE)	50	5 (10.0)	NR (NE, NE)	1.040 (0.327, 3.301)	0.9472
Irinotecan	116	20 (17.2)	NR (13.8, NE)	111	25 (22.5)	NR (3.9, NE)	0.502 (0.269, 0.936)	0.0259
Interaction								0.4021

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders / PT - Hyponatraemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	5 (7.9)	NR (14.5, NE)	57	5 (8.8)	NR (NE, NE)	0.524 (0.136, 2.012)	0.3389
1	192	27 (14.1)	NR (NE, NE)	183	28 (15.3)	NR (6.9, NE)	0.693 (0.402, 1.196)	0.1830
Interaction								0.9917
Region #1								
Asia	201	30 (14.9)	NR (14.5, NE)	191	32 (16.8)	NR (NE, NE)	0.623 (0.370, 1.048)	0.0710
Europe/North America	54	2 (3.7)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	1.552 (0.139, 17.293)	0.7178
Interaction								0.4862

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Any TEAE: SOC - Metabolism and nutrition disorders / PT - Hyponatraemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	28 (15.9)	NR (14.5, NE)	168	30 (17.9)	NR (6.9, NE)	0.626 (0.366, 1.071)	0.0833
Japan	25	2 (8.0)	NR (10.6, NE)	23	2 (8.7)	NR (NE, NE)	0.589 (0.073, 4.782)	0.6172
Europe/North America	54	2 (3.7)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	1.552 (0.139, 17.293)	0.7178
Interaction								0.7868

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Metabolism and nutrition disorders / PT - Hyponatraemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	31 (15.3)	NR (14.5, NE)	198	32 (16.2)	NR (NE, NE)	0.672 (0.402, 1.125)	0.1262
White	52	1 (1.9)	NR (NE, NE)	42	1 (2.4)	NR (4.8, NE)	0.644 (0.040, 10.446)	0.7552
Interaction								0.9920

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders / PT - Hyponatraemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	7 (8.8)	NR (14.5, NE)	60	7 (11.7)	NR (NE, NE)	0.474 (0.155, 1.446)	0.1787
vCPS < 10%	100	15 (15.0)	NR (NE, NE)	119	17 (14.3)	NR (NE, NE)	0.883 (0.438, 1.780)	0.7268
Missing	75	10 (13.3)	NR (13.8, NE)	61	9 (14.8)	NR (6.9, NE)	0.627 (0.240, 1.637)	0.3345
Interaction								0.7095

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Musculoskeletal and connective tissue disorders / PT - Myalgia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	5 (3.3)	NR (NE, NE)	146	7 (4.8)	NR (NE, NE)	0.672 (0.213, 2.116)	0.4930
>= 65 Years	103	3 (2.9)	NR (19.9, NE)	94	7 (7.4)	NR (NE, NE)	0.194 (0.043, 0.868)	0.0213
Interaction								0.4805
Gender								
Male	216	7 (3.2)	NR (NE, NE)	204	12 (5.9)	NR (NE, NE)	0.428 (0.159, 1.151)	0.0830
Female	39	1 (2.6)	NR (19.9, NE)	36	2 (5.6)	NR (NE, NE)	0.281 (0.023, 3.455)	0.2967
Interaction								0.9155

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Musculoskeletal and connective tissue disorders / PT - Myalgia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	8 (4.3)	NR (NE, NE)	183	14 (7.7)	NR (NE, NE)	0.377 (0.144, 0.990)	0.0393
Non-Smoker	68	0 (0.0)	NR (NE, NE)	57	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9998

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Musculoskeletal and connective tissue disorders / PT - Myalgia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	5 (6.0)	NR (19.9, NE)	79	11 (13.9)	NR (NE, NE)	0.302 (0.095, 0.959)	0.0309
Docetaxel	56	0 (0.0)	NR (NE, NE)	50	3 (6.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0631
Irinotecan	116	3 (2.6)	NR (NE, NE)	111	0 (0.0)	NR (NE, NE)	28387187.655 (0.000, NE)	0.1661
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Musculoskeletal and connective tissue disorders / PT - Myalgia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	1 (1.6)	NR (NE, NE)	57	2 (3.5)	NR (NE, NE)	0.444 (0.040, 4.901)	0.4962
1	192	7 (3.6)	NR (NE, NE)	183	12 (6.6)	NR (NE, NE)	0.386 (0.142, 1.051)	0.0543
Interaction								0.7886

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Musculoskeletal and connective tissue disorders / PT - Myalgia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #1								
Asia	201	5 (2.5)	NR (NE, NE)	191	14 (7.3)	NR (NE, NE)	0.300 (0.107, 0.845)	0.0157
Europe/North America	54	3 (5.6)	19.9 (13.2, NE)	49	0 (0.0)	NR (NE, NE)	26442990.647 (0.000, NE)	0.3458
Interaction								0.9909

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Musculoskeletal and connective tissue disorders / PT - Myalgia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	5 (2.8)	NR (NE, NE)	168	11 (6.5)	NR (NE, NE)	0.383 (0.131, 1.119)	0.0683
Japan	25	0 (0.0)	NR (NE, NE)	23	3 (13.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0648
Europe/North America	54	3 (5.6)	19.9 (13.2, NE)	49	0 (0.0)	NR (NE, NE)	26442990.647 (0.000, NE)	0.3458
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Musculoskeletal and connective tissue disorders / PT - Myalgia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	5 (2.5)	NR (NE, NE)	198	14 (7.1)	NR (NE, NE)	0.310 (0.110, 0.871)	0.0189
White	52	3 (5.8)	19.9 (13.2, NE)	42	0 (0.0)	NR (NE, NE)	23828168.306 (0.000, NE)	0.3746
Interaction								0.9868

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Musculoskeletal and connective tissue disorders / PT - Myalgia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Baseline PD-L1 Status								
vCPS >= 10%	80	5 (6.3)	--	60	4 (6.7)	--	--	--
vCPS < 10%	100	2 (2.0)	--	119	6 (5.0)	--	--	--
Missing	75	1 (1.3)	--	61	4 (6.6)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Neoplasms benign, malignant and unspecified (incl cysts and polyps)

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	11 (7.2)	NR (NE, NE)	146	5 (3.4)	NR (NE, NE)	1.706 (0.588, 4.950)	0.3197
>= 65 Years	103	12 (11.7)	NR (NE, NE)	94	3 (3.2)	NR (NE, NE)	3.477 (0.980, 12.344)	0.0400
Interaction								0.4544
Gender								
Male	216	18 (8.3)	NR (NE, NE)	204	6 (2.9)	NR (NE, NE)	2.334 (0.920, 5.918)	0.0661
Female	39	5 (12.8)	NR (NE, NE)	36	2 (5.6)	NR (NE, NE)	2.421 (0.470, 12.481)	0.2750
Interaction								0.9515

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Neoplasms benign, malignant and unspecified (incl cysts and polyps)

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	16 (8.6)	NR (NE, NE)	183	5 (2.7)	NR (NE, NE)	2.611 (0.950, 7.177)	0.0535
Non-Smoker	68	7 (10.3)	NR (NE, NE)	57	3 (5.3)	NR (NE, NE)	1.886 (0.487, 7.306)	0.3504
Interaction								0.6597

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Neoplasms benign, malignant and unspecified (incl cysts and polyps)

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	9 (10.8)	NR (NE, NE)	79	3 (3.8)	NR (NE, NE)	2.890 (0.782, 10.685)	0.0953
Docetaxel	56	5 (8.9)	NR (NE, NE)	50	1 (2.0)	NR (NE, NE)	4.017 (0.468, 34.460)	0.1700
Irinotecan	116	9 (7.8)	NR (NE, NE)	111	4 (3.6)	NR (NE, NE)	1.501 (0.451, 4.997)	0.5054
Interaction								0.7549

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Neoplasms benign, malignant and unspecified (incl cysts and polyps)

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	4 (6.3)	NR (NE, NE)	57	2 (3.5)	NR (NE, NE)	1.801 (0.330, 9.832)	0.4909
1	192	19 (9.9)	NR (NE, NE)	183	6 (3.3)	NR (NE, NE)	2.523 (1.001, 6.362)	0.0423
Interaction								0.6368
Region #1								
Asia	201	14 (7.0)	NR (NE, NE)	191	6 (3.1)	NR (NE, NE)	1.737 (0.660, 4.570)	0.2574
Europe/North America	54	9 (16.7)	NR (NE, NE)	49	2 (4.1)	NR (NE, NE)	4.225 (0.913, 19.556)	0.0448
Interaction								0.3925

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Neoplasms benign, malignant and unspecified (incl cysts and polyps)

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	10 (5.7)	NR (NE, NE)	168	5 (3.0)	NR (NE, NE)	1.450 (0.488, 4.303)	0.5012
Japan	25	4 (16.0)	NR (NE, NE)	23	1 (4.3)	NR (4.3, NE)	3.227 (0.354, 29.446)	0.2731
Europe/North America	54	9 (16.7)	NR (NE, NE)	49	2 (4.1)	NR (NE, NE)	4.225 (0.913, 19.556)	0.0448
Interaction								0.5737

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Neoplasms benign, malignant and unspecified (incl cysts and polyps)

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	203	14 (6.9)	NR (NE, NE)	198	6 (3.0)	NR (NE, NE)	1.797 (0.683, 4.727)	0.2284
White	52	9 (17.3)	NR (NE, NE)	42	2 (4.8)	NR (NE, NE)	3.737 (0.807, 17.296)	0.0701
Interaction								0.4915

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Neoplasms benign, malignant and unspecified (incl cysts and polyps)

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	9 (11.3)	NR (NE, NE)	60	1 (1.7)	NR (NE, NE)	6.120 (0.774, 48.373)	0.0499
vCPS < 10%	100	7 (7.0)	NR (NE, NE)	119	4 (3.4)	NR (NE, NE)	1.759 (0.512, 6.044)	0.3639
Missing	75	7 (9.3)	NR (NE, NE)	61	3 (4.9)	NR (NE, NE)	1.485 (0.369, 5.977)	0.5755
Interaction								0.6053

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	16 (10.5)	NR (17.8, NE)	146	34 (23.3)	9.7 (9.7, NE)	0.302 (0.160, 0.569)	<0.0001
>= 65 Years	103	15 (14.6)	NR (20.6, NE)	94	28 (29.8)	7.4 (5.3, NE)	0.311 (0.162, 0.599)	0.0002
Interaction								0.8992
Gender								
Male	216	22 (10.2)	NR (20.6, NE)	204	49 (24.0)	9.7 (7.4, NE)	0.252 (0.146, 0.435)	<0.0001
Female	39	9 (23.1)	NR (8.3, NE)	36	13 (36.1)	NR (2.2, NE)	0.487 (0.205, 1.158)	0.0958
Interaction								0.2393

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	22 (11.8)	NR (22.6, NE)	183	46 (25.1)	7.4 (5.3, NE)	0.303 (0.177, 0.520)	<0.0001
Non-Smoker	68	9 (13.2)	17.8 (8.3, NE)	57	16 (28.1)	NR (2.2, NE)	0.310 (0.134, 0.719)	0.0041
Interaction								0.7933

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	13 (15.7)	NR (NE, NE)	79	35 (44.3)	3.5 (2.3, NE)	0.237 (0.124, 0.454)	<0.0001
Docetaxel	56	8 (14.3)	20.6 (17.8, NE)	50	7 (14.0)	NR (NE, NE)	0.827 (0.297, 2.306)	0.7163
Irinotecan	116	10 (8.6)	NR (22.6, NE)	111	20 (18.0)	7.4 (5.3, NE)	0.255 (0.109, 0.594)	0.0008
Interaction								0.0814

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Safety Analysis Set

Any TEAE: SOC - Nervous system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	4 (6.3)	NR (20.6, NE)	57	20 (35.1)	7.4 (2.8, NE)	0.083 (0.024, 0.287)	<0.0001
1	192	27 (14.1)	NR (22.6, NE)	183	42 (23.0)	9.7 (5.3, NE)	0.420 (0.254, 0.694)	0.0005
Interaction								0.0174
Region #1								
Asia	201	16 (8.0)	NR (22.6, NE)	191	43 (22.5)	9.7 (5.3, NE)	0.218 (0.119, 0.399)	<0.0001
Europe/North America	54	15 (27.8)	NR (6.2, NE)	49	19 (38.8)	7.4 (1.4, NE)	0.496 (0.244, 1.005)	0.0468
Interaction								0.0637

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	15 (8.5)	NR (20.6, NE)	168	34 (20.2)	NR (5.3, NE)	0.270 (0.143, 0.510)	<0.0001
Japan	25	1 (4.0)	NR (NE, NE)	23	9 (39.1)	2.8 (1.0, NE)	0.060 (0.007, 0.486)	0.0005
Europe/North America	54	15 (27.8)	NR (6.2, NE)	49	19 (38.8)	7.4 (1.4, NE)	0.496 (0.244, 1.005)	0.0468
Interaction								0.0653

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	16 (7.9)	NR (22.6, NE)	198	44 (22.2)	9.7 (5.3, NE)	0.220 (0.120, 0.401)	<0.0001
White	52	15 (28.8)	NR (6.2, NE)	42	18 (42.9)	7.4 (1.0, NE)	0.452 (0.221, 0.922)	0.0249
Interaction								0.1113

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	9 (11.3)	NR (NE, NE)	60	12 (20.0)	9.7 (9.7, NE)	0.373 (0.151, 0.921)	0.0265
vCPS < 10%	100	15 (15.0)	17.8 (8.3, NE)	119	29 (24.4)	NR (7.4, NE)	0.431 (0.225, 0.823)	0.0086
Missing	75	7 (9.3)	NR (20.6, NE)	61	21 (34.4)	5.3 (2.8, NE)	0.130 (0.048, 0.351)	<0.0001
Interaction								0.1202

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders / PT - Dizziness

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	4 (2.6)	NR (NE, NE)	146	13 (8.9)	NR (NE, NE)	0.247 (0.080, 0.765)	0.0089
>= 65 Years	103	7 (6.8)	NR (NE, NE)	94	6 (6.4)	NR (NE, NE)	0.808 (0.264, 2.478)	0.7087
Interaction								0.1111
Gender								
Male	216	7 (3.2)	NR (NE, NE)	204	14 (6.9)	NR (NE, NE)	0.387 (0.154, 0.974)	0.0367
Female	39	4 (10.3)	NR (8.3, NE)	36	5 (13.9)	NR (NE, NE)	0.583 (0.153, 2.213)	0.4226
Interaction								0.5156

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders / PT - Dizziness

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	6 (3.2)	NR (NE, NE)	183	13 (7.1)	NR (NE, NE)	0.371 (0.139, 0.988)	0.0391
Non-Smoker	68	5 (7.4)	NR (NE, NE)	57	6 (10.5)	NR (NE, NE)	0.507 (0.150, 1.719)	0.2670
Interaction								0.5462

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders / PT - Dizziness

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	6 (7.2)	NR (NE, NE)	79	5 (6.3)	NR (NE, NE)	0.946 (0.284, 3.150)	0.9281
Docetaxel	56	2 (3.6)	NR (NE, NE)	50	2 (4.0)	NR (NE, NE)	0.669 (0.093, 4.800)	0.6872
Irinotecan	116	3 (2.6)	NR (NE, NE)	111	12 (10.8)	NR (NE, NE)	0.167 (0.046, 0.616)	0.0027
Interaction								0.1396

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders / PT - Dizziness

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	2 (3.2)	NR (NE, NE)	57	5 (8.8)	NR (NE, NE)	0.267 (0.050, 1.414)	0.0975
1	192	9 (4.7)	NR (NE, NE)	183	14 (7.7)	NR (NE, NE)	0.489 (0.208, 1.149)	0.0941
Interaction								0.5661
Region #1								
Asia	201	4 (2.0)	NR (NE, NE)	191	16 (8.4)	NR (NE, NE)	0.196 (0.064, 0.597)	0.0015
Europe/North America	54	7 (13.0)	NR (8.3, NE)	49	3 (6.1)	NR (NE, NE)	1.753 (0.449, 6.848)	0.4131
Interaction								0.0088

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Safety Analysis Set

Any TEAE: SOC - Nervous system disorders / PT - Dizziness

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	4 (2.3)	NR (NE, NE)	168	15 (8.9)	NR (NE, NE)	0.216 (0.071, 0.662)	0.0033
Japan	25	0 (0.0)	NR (NE, NE)	23	1 (4.3)	NR (2.4, NE)	0.000 (0.000, NE)	0.1573
Europe/North America	54	7 (13.0)	NR (8.3, NE)	49	3 (6.1)	NR (NE, NE)	1.753 (0.449, 6.848)	0.4131
Interaction								0.0408

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Race								
Asian and other	203	4 (2.0)	NR (NE, NE)	198	16 (8.1)	NR (NE, NE)	0.202 (0.066, 0.615)	0.0019
White	52	7 (13.5)	NR (8.3, NE)	42	3 (7.1)	NR (NE, NE)	1.552 (0.398, 6.053)	0.5236
Interaction								0.0146

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	6 (7.5)	NR (NE, NE)	60	2 (3.3)	NR (NE, NE)	1.850 (0.368, 9.292)	0.4483
vCPS < 10%	100	4 (4.0)	NR (NE, NE)	119	12 (10.1)	NR (NE, NE)	0.303 (0.096, 0.954)	0.0312
Missing	75	1 (1.3)	NR (NE, NE)	61	5 (8.2)	NR (NE, NE)	0.132 (0.015, 1.150)	0.0321
Interaction								0.1148

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders / PT - Peripheral sensory neuropathy

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	1 (0.7)	NR (NE, NE)	146	10 (6.8)	NR (9.7, NE)	0.070 (0.009, 0.560)	0.0013
>= 65 Years	103	1 (1.0)	NR (NE, NE)	94	13 (13.8)	NR (NE, NE)	0.057 (0.007, 0.435)	0.0001
Interaction								0.8252
Gender								
Male	216	0 (0.0)	NR (NE, NE)	204	19 (9.3)	NR (9.7, NE)	0.000 (0.000, NE)	<0.0001
Female	39	2 (5.1)	NR (NE, NE)	36	4 (11.1)	NR (NE, NE)	0.389 (0.071, 2.149)	0.2622
Interaction								0.9885

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Nervous system disorders / PT - Peripheral sensory neuropathy

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	2 (1.1)	NR (NE, NE)	183	19 (10.4)	NR (9.7, NE)	0.070 (0.016, 0.306)	<0.0001
Non-Smoker	68	0 (0.0)	NR (NE, NE)	57	4 (7.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0262
Interaction								0.9913

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Nervous system disorders / PT - Peripheral sensory neuropathy

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	1 (1.2)	NR (NE, NE)	79	19 (24.1)	9.7 (9.7, NE)	0.035 (0.005, 0.266)	<0.0001
Docetaxel	56	0 (0.0)	NR (NE, NE)	50	3 (6.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0608
Irinotecan	116	1 (0.9)	NR (NE, NE)	111	1 (0.9)	NR (NE, NE)	0.950 (0.059, 15.190)	0.9711
Interaction								0.2390

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

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Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders / PT - Peripheral sensory neuropathy

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	0 (0.0)	NR (NE, NE)	57	8 (14.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0014
1	192	2 (1.0)	NR (NE, NE)	183	15 (8.2)	NR (9.7, NE)	0.081 (0.018, 0.370)	<0.0001
Interaction								0.9908
Region #1								
Asia	201	0 (0.0)	NR (NE, NE)	191	14 (7.3)	NR (9.7, NE)	0.000 (0.000, NE)	<0.0001
Europe/North America	54	2 (3.7)	NR (NE, NE)	49	9 (18.4)	NR (NE, NE)	0.176 (0.038, 0.815)	0.0122
Interaction								0.9889

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Nervous system disorders / PT - Peripheral sensory neuropathy

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	0 (0.0)	NR (NE, NE)	168	7 (4.2)	NR (9.7, NE)	0.000 (0.000, NE)	0.0003
Japan	25	0 (0.0)	NR (NE, NE)	23	7 (30.4)	NR (1.0, NE)	0.000 (0.000, NE)	0.0015
Europe/North America	54	2 (3.7)	NR (NE, NE)	49	9 (18.4)	NR (NE, NE)	0.176 (0.038, 0.815)	0.0122
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

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Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set
Any TEAE: SOC - Nervous system disorders / PT - Peripheral sensory neuropathy

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	0 (0.0)	NR (NE, NE)	198	15 (7.6)	NR (9.7, NE)	0.000 (0.000, NE)	<0.0001
White	52	2 (3.8)	NR (NE, NE)	42	8 (19.0)	NR (NE, NE)	0.175 (0.037, 0.827)	0.0130
Interaction								0.9889

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders / PT - Peripheral sensory neuropathy

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	2 (2.5)	NR (NE, NE)	60	3 (5.0)	NR (9.7, NE)	0.325 (0.051, 2.081)	0.2150
vCPS < 10%	100	0 (0.0)	NR (NE, NE)	119	11 (9.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0010
Missing	75	0 (0.0)	NR (NE, NE)	61	9 (14.8)	NR (3.5, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Skin and subcutaneous tissue disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	33 (21.7)	NR (NE, NE)	146	38 (26.0)	NR (NE, NE)	0.722 (0.451, 1.156)	0.1712
>= 65 Years	103	29 (28.2)	21.3 (9.6, NE)	94	29 (30.9)	5.3 (5.1, NE)	0.642 (0.376, 1.096)	0.1009
Interaction								0.7699
Gender								
Male	216	50 (23.1)	30.5 (10.7, NE)	204	49 (24.0)	NR (5.3, NE)	0.750 (0.500, 1.124)	0.1603
Female	39	12 (30.8)	NR (2.6, NE)	36	18 (50.0)	1.9 (0.9, NE)	0.421 (0.199, 0.888)	0.0192
Interaction								0.2091

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

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Safety Analysis Set

Any TEAE: SOC - Skin and subcutaneous tissue disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	45 (24.1)	30.5 (10.7, NE)	183	53 (29.0)	NR (5.3, NE)	0.629 (0.417, 0.949)	0.0255
Non-Smoker	68	17 (25.0)	NR (4.9, NE)	57	14 (24.6)	NR (3.0, NE)	0.830 (0.407, 1.693)	0.6074
Interaction								0.4478

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Safety Analysis Set

Any TEAE: SOC - Skin and subcutaneous tissue disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	24 (28.9)	NR (4.9, NE)	79	37 (46.8)	3.0 (1.3, NE)	0.533 (0.318, 0.894)	0.0149
Docetaxel	56	14 (25.0)	10.3 (7.0, NE)	50	12 (24.0)	NR (NE, NE)	0.783 (0.358, 1.712)	0.5374
Irinotecan	116	24 (20.7)	30.5 (21.3, NE)	111	18 (16.2)	NR (5.3, NE)	0.898 (0.474, 1.702)	0.7405
Interaction								0.2558

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

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Safety Analysis Set

Any TEAE: SOC - Skin and subcutaneous tissue disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	18 (28.6)	NR (7.0, NE)	57	21 (36.8)	NR (3.0, NE)	0.598 (0.317, 1.131)	0.1091
1	192	44 (22.9)	30.5 (10.7, NE)	183	46 (25.1)	NR (5.1, NE)	0.717 (0.470, 1.095)	0.1215
Interaction								0.5800
Region #1								
Asia	201	46 (22.9)	30.5 (10.7, NE)	191	49 (25.7)	NR (NE, NE)	0.680 (0.450, 1.027)	0.0646
Europe/North America	54	16 (29.6)	21.3 (4.9, NE)	49	18 (36.7)	5.3 (2.4, NE)	0.687 (0.346, 1.366)	0.2804
Interaction								0.9602

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Skin and subcutaneous tissue disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	40 (22.7)	30.5 (10.7, NE)	168	36 (21.4)	NR (NE, NE)	0.837 (0.528, 1.325)	0.4457
Japan	25	6 (24.0)	NR (10.3, NE)	23	13 (56.5)	0.7 (0.5, NE)	0.222 (0.078, 0.629)	0.0020
Europe/North America	54	16 (29.6)	21.3 (4.9, NE)	49	18 (36.7)	5.3 (2.4, NE)	0.687 (0.346, 1.366)	0.2804
Interaction								0.0661

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Skin and subcutaneous tissue disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	46 (22.7)	30.5 (10.7, NE)	198	53 (26.8)	NR (5.1, NE)	0.639 (0.426, 0.959)	0.0288
White	52	16 (30.8)	21.3 (4.9, NE)	42	14 (33.3)	NR (2.4, NE)	0.804 (0.387, 1.667)	0.5555
Interaction								0.6088

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Skin and subcutaneous tissue disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	18 (22.5)	21.3 (10.3, NE)	60	17 (28.3)	NR (5.1, NE)	0.530 (0.269, 1.042)	0.0607
vCPS < 10%	100	32 (32.0)	NR (5.1, NE)	119	33 (27.7)	NR (5.3, NE)	1.091 (0.669, 1.781)	0.7260
Missing	75	12 (16.0)	30.5 (9.6, NE)	61	17 (27.9)	NR (NE, NE)	0.374 (0.170, 0.822)	0.0107
Interaction								0.0855

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Skin and subcutaneous tissue disorders / PT - Alopecia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	0 (0.0)	NR (NE, NE)	146	24 (16.4)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
>= 65 Years	103	1 (1.0)	NR (NE, NE)	94	18 (19.1)	NR (NE, NE)	0.033 (0.004, 0.259)	<0.0001
Interaction								0.9893
Gender								
Male	216	0 (0.0)	NR (NE, NE)	204	29 (14.2)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Female	39	1 (2.6)	NR (18.0, NE)	36	13 (36.1)	NR (1.9, NE)	0.049 (0.006, 0.381)	<0.0001
Interaction								0.9881

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Skin and subcutaneous tissue disorders / PT - Alopecia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	1 (0.5)	NR (NE, NE)	183	34 (18.6)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Non-Smoker	68	0 (0.0)	NR (NE, NE)	57	8 (14.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0009
Interaction								0.9900

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Skin and subcutaneous tissue disorders / PT - Alopecia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	1 (1.2)	NR (18.0, NE)	79	24 (30.4)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Docetaxel	56	0 (0.0)	NR (NE, NE)	50	10 (20.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0002
Irinotecan	116	0 (0.0)	NR (NE, NE)	111	8 (7.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0027
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Skin and subcutaneous tissue disorders / PT - Alopecia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	0 (0.0)	NR (NE, NE)	57	16 (28.1)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
1	192	1 (0.5)	NR (NE, NE)	183	26 (14.2)	NR (NE, NE)	0.023 (0.003, 0.182)	<0.0001
Interaction								0.9855
Region #1								
Asia	201	0 (0.0)	NR (NE, NE)	191	31 (16.2)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Europe/North America	54	1 (1.9)	NR (18.0, NE)	49	11 (22.4)	NR (NE, NE)	0.000 (0.000, NE)	0.0002
Interaction								0.9874

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Skin and subcutaneous tissue disorders / PT - Alopecia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	0 (0.0)	NR (NE, NE)	168	20 (11.9)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Japan	25	0 (0.0)	NR (NE, NE)	23	11 (47.8)	NR (0.7, NE)	0.000 (0.000, NE)	<0.0001
Europe/North America	54	1 (1.9)	NR (18.0, NE)	49	11 (22.4)	NR (NE, NE)	0.000 (0.000, NE)	0.0002
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Skin and subcutaneous tissue disorders / PT - Alopecia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	0 (0.0)	NR (NE, NE)	198	33 (16.7)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
White	52	1 (1.9)	NR (18.0, NE)	42	9 (21.4)	NR (NE, NE)	0.000 (0.000, NE)	0.0003
Interaction								0.9872

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Safety Analysis Set

Any TEAE: SOC - Skin and subcutaneous tissue disorders / PT - Alopecia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	1 (1.3)	NR (18.0, NE)	60	10 (16.7)	NR (NE, NE)	0.052 (0.006, 0.418)	0.0002
vCPS < 10%	100	0 (0.0)	NR (NE, NE)	119	23 (19.3)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Missing	75	0 (0.0)	NR (NE, NE)	61	9 (14.8)	NR (NE, NE)	0.000 (0.000, NE)	0.0003
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	28 (36.8)	NR (4.3, NE)	69	40 (58.0)	1.4 (0.9, 5.6)	0.495 (0.304, 0.805)	0.0033
>= 65 Years	63	18 (28.6)	NR (21.4, NE)	60	33 (55.0)	1.5 (0.8, NE)	0.351 (0.192, 0.642)	0.0003
Interaction								0.4499
Gender								
Male	118	42 (35.6)	21.4 (8.9, NE)	106	63 (59.4)	1.3 (1.0, 2.8)	0.434 (0.291, 0.646)	<0.0001
Female	21	4 (19.0)	NR (NE, NE)	23	10 (43.5)	NR (0.5, NE)	0.377 (0.118, 1.203)	0.0797
Interaction								0.5908

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	35 (33.7)	NR (8.9, NE)	101	56 (55.4)	1.7 (1.0, 4.7)	0.444 (0.288, 0.683)	0.0001
Non-Smoker	35	11 (31.4)	NR (2.1, NE)	28	17 (60.7)	1.2 (0.5, NE)	0.395 (0.183, 0.853)	0.0129
Interaction								0.7013
ICC Options								
Paclitaxel	83	24 (28.9)	NR (21.4, NE)	79	36 (45.6)	4.1 (1.2, NE)	0.515 (0.303, 0.872)	0.0112
Docetaxel	56	22 (39.3)	NR (3.4, NE)	50	37 (74.0)	0.9 (0.3, 1.3)	0.313 (0.181, 0.542)	<0.0001
Interaction								0.2254

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	8 (18.6)	NR (21.4, NE)	37	17 (45.9)	5.6 (1.7, NE)	0.296 (0.122, 0.718)	0.0037
1	96	38 (39.6)	8.9 (3.4, NE)	92	56 (60.9)	1.0 (0.5, 1.4)	0.457 (0.300, 0.696)	0.0001
Interaction								0.5056
Region #1								
Asia	103	35 (34.0)	NR (6.9, NE)	99	55 (55.6)	1.4 (1.0, 4.1)	0.450 (0.292, 0.693)	0.0002
Europe/North America	36	11 (30.6)	NR (8.9, NE)	30	18 (60.0)	1.5 (0.5, 5.6)	0.386 (0.180, 0.828)	0.0102
Interaction								0.8329

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	33 (42.3)	NR (2.1, NE)	76	49 (64.5)	1.0 (0.5, 1.4)	0.480 (0.306, 0.751)	0.0008
Japan	25	2 (8.0)	NR (21.4, NE)	23	6 (26.1)	NR (2.8, NE)	0.122 (0.015, 1.026)	0.0203
Europe/North America	36	11 (30.6)	NR (8.9, NE)	30	18 (60.0)	1.5 (0.5, 5.6)	0.386 (0.180, 0.828)	0.0102
Interaction								0.7231

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	36 (34.3)	NR (6.9, NE)	106	57 (53.8)	1.4 (1.0, NE)	0.480 (0.314, 0.735)	0.0004
White	34	10 (29.4)	NR (8.9, NE)	23	16 (69.6)	1.0 (0.5, 5.6)	0.304 (0.137, 0.677)	0.0017
Interaction								0.3879

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	15 (33.3)	NR (3.4, NE)	34	20 (58.8)	1.1 (0.5, NE)	0.407 (0.207, 0.803)	0.0069
vCPS < 10%	53	18 (34.0)	NR (4.3, NE)	54	36 (66.7)	1.0 (0.5, 2.2)	0.345 (0.194, 0.615)	0.0001
Missing	41	13 (31.7)	21.4 (6.9, NE)	41	17 (41.5)	4.7 (1.4, NE)	0.612 (0.290, 1.291)	0.1814
Interaction								0.4145

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	22 (28.9)	NR (8.3, NE)	69	31 (44.9)	5.6 (1.4, NE)	0.533 (0.308, 0.924)	0.0218
>= 65 Years	63	16 (25.4)	NR (21.4, NE)	60	22 (36.7)	5.1 (4.1, NE)	0.487 (0.248, 0.958)	0.0321
Interaction								0.9086
Gender								
Male	118	34 (28.8)	NR (21.4, NE)	106	46 (43.4)	5.1 (2.0, NE)	0.501 (0.318, 0.789)	0.0022
Female	21	4 (19.0)	NR (NE, NE)	23	7 (30.4)	NR (0.5, NE)	0.555 (0.162, 1.897)	0.3323
Interaction								0.8478

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	30 (28.8)	NR (21.4, NE)	101	45 (44.6)	4.1 (1.4, NE)	0.479 (0.298, 0.770)	0.0018
Non-Smoker	35	8 (22.9)	NR (4.3, NE)	28	8 (28.6)	NR (2.1, NE)	0.727 (0.272, 1.943)	0.5216
Interaction								0.5765
ICC Options								
Paclitaxel	83	21 (25.3)	NR (21.4, NE)	79	27 (34.2)	NR (4.1, NE)	0.639 (0.357, 1.141)	0.1239
Docetaxel	56	17 (30.4)	NR (8.3, NE)	50	26 (52.0)	2.0 (1.0, NE)	0.353 (0.185, 0.673)	0.0009
Interaction								0.3068

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	5 (11.6)	NR (21.4, NE)	37	8 (21.6)	NR (5.6, NE)	0.388 (0.116, 1.296)	0.1096
1	96	33 (34.4)	NR (8.3, NE)	92	45 (48.9)	2.1 (1.1, NE)	0.512 (0.323, 0.811)	0.0034
Interaction								0.8962
Region #1								
Asia	103	27 (26.2)	NR (21.4, NE)	99	41 (41.4)	4.1 (2.0, NE)	0.470 (0.286, 0.774)	0.0022
Europe/North America	36	11 (30.6)	NR (8.9, NE)	30	12 (40.0)	5.6 (1.0, NE)	0.645 (0.281, 1.479)	0.2922
Interaction								0.4815

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	25 (32.1)	NR (8.3, NE)	76	37 (48.7)	2.0 (1.1, NE)	0.493 (0.294, 0.826)	0.0057
Japan	25	2 (8.0)	NR (21.4, NE)	23	4 (17.4)	NR (2.8, NE)	0.194 (0.021, 1.743)	0.1014
Europe/North America	36	11 (30.6)	NR (8.9, NE)	30	12 (40.0)	5.6 (1.0, NE)	0.645 (0.281, 1.479)	0.2922
Interaction								0.7347

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	28 (26.7)	NR (21.4, NE)	106	42 (39.6)	NR (2.0, NE)	0.516 (0.316, 0.842)	0.0066
White	34	10 (29.4)	NR (8.9, NE)	23	11 (47.8)	5.1 (0.5, NE)	0.485 (0.204, 1.155)	0.0914
Interaction								0.9670

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	14 (31.1)	NR (8.3, NE)	34	17 (50.0)	4.1 (0.8, NE)	0.457 (0.223, 0.937)	0.0278
vCPS < 10%	53	16 (30.2)	NR (8.9, NE)	54	24 (44.4)	5.6 (1.1, NE)	0.529 (0.278, 1.008)	0.0480
Missing	41	8 (19.5)	21.4 (21.4, NE)	41	12 (29.3)	NR (5.1, NE)	0.521 (0.205, 1.327)	0.1579
Interaction								0.9059

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	4 (5.3)	NR (NE, NE)	69	7 (10.1)	NR (NE, NE)	0.483 (0.141, 1.651)	0.2349
>= 65 Years	63	1 (1.6)	NR (NE, NE)	60	5 (8.3)	NR (6.3, NE)	0.143 (0.016, 1.273)	0.0456
Interaction								0.4001
Gender								
Male	118	5 (4.2)	NR (NE, NE)	106	11 (10.4)	NR (NE, NE)	0.377 (0.131, 1.086)	0.0597
Female	21	0 (0.0)	NR (NE, NE)	23	1 (4.3)	NR (6.3, NE)	0.000 (0.000, NE)	0.1573
Interaction								0.9936

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	3 (2.9)	NR (NE, NE)	101	7 (6.9)	NR (NE, NE)	0.391 (0.101, 1.514)	0.1578
Non-Smoker	35	2 (5.7)	NR (NE, NE)	28	5 (17.9)	NR (6.3, NE)	0.284 (0.055, 1.468)	0.1064
Interaction								0.8346
ICC Options								
Paclitaxel	83	1 (1.2)	NR (NE, NE)	79	2 (2.5)	NR (NE, NE)	0.466 (0.042, 5.137)	0.5228
Docetaxel	56	4 (7.1)	NR (NE, NE)	50	10 (20.0)	NR (6.3, NE)	0.300 (0.094, 0.962)	0.0312
Interaction								0.7942

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Any TEAE: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	2 (4.7)	NR (NE, NE)	37	4 (10.8)	NR (NE, NE)	0.413 (0.076, 2.258)	0.2912
1	96	3 (3.1)	NR (NE, NE)	92	8 (8.7)	NR (NE, NE)	0.308 (0.081, 1.172)	0.0678
Interaction								0.8602
Region #1								
Asia	103	5 (4.9)	NR (NE, NE)	99	11 (11.1)	NR (NE, NE)	0.387 (0.134, 1.119)	0.0686
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	1 (3.3)	NR (NE, NE)	0.000 (0.000, NE)	0.2733
Interaction								0.9917

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

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	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	5 (6.4)	NR (NE, NE)	76	11 (14.5)	NR (NE, NE)	0.392 (0.136, 1.131)	0.0717
Japan	25	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	1 (3.3)	NR (NE, NE)	0.000 (0.000, NE)	0.2733
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	5 (4.8)	NR (NE, NE)	106	11 (10.4)	NR (NE, NE)	0.411 (0.142, 1.186)	0.0887
White	34	0 (0.0)	NR (NE, NE)	23	1 (4.3)	NR (NE, NE)	0.000 (0.000, NE)	0.2240
Interaction								0.9916

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	2 (4.4)	--	34	5 (14.7)	--	--	--
vCPS < 10%	53	1 (1.9)	--	54	6 (11.1)	--	--	--
Missing	41	2 (4.9)	--	41	1 (2.4)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Any TEAE: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	1 (1.3)	NR (NE, NE)	69	8 (11.6)	NR (NE, NE)	0.106 (0.013, 0.850)	0.0097
>= 65 Years	63	1 (1.6)	NR (NE, NE)	60	13 (21.7)	NR (4.7, NE)	0.060 (0.008, 0.462)	0.0003
Interaction								0.7384
Gender								
Male	118	2 (1.7)	NR (NE, NE)	106	18 (17.0)	NR (NE, NE)	0.087 (0.020, 0.375)	<0.0001
Female	21	0 (0.0)	NR (NE, NE)	23	3 (13.0)	NR (NE, NE)	0.000 (0.000, NE)	0.1022
Interaction								0.9901

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

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Any TEAE: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Smoking Status								
Former/Current Smoker	104	1 (1.0)	NR (NE, NE)	101	13 (12.9)	NR (NE, NE)	0.065 (0.009, 0.502)	0.0005
Non-Smoker	35	1 (2.9)	NR (NE, NE)	28	8 (28.6)	NR (2.2, NE)	0.090 (0.011, 0.717)	0.0041
Interaction								0.8583
ICC Options								
Paclitaxel	83	0 (0.0)	NR (NE, NE)	79	12 (15.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0001
Docetaxel	56	2 (3.6)	NR (NE, NE)	50	9 (18.0)	NR (NE, NE)	0.184 (0.040, 0.852)	0.0142
Interaction								0.9911

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	43	2 (4.7)	NR (NE, NE)	37	7 (18.9)	NR (NE, NE)	0.232 (0.048, 1.115)	0.0453
1	96	0 (0.0)	NR (NE, NE)	92	14 (15.2)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9903
Region #1								
Asia	103	2 (1.9)	NR (NE, NE)	99	9 (9.1)	NR (NE, NE)	0.204 (0.044, 0.946)	0.0239
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	12 (40.0)	4.7 (1.5, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9910

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	2 (2.6)	NR (NE, NE)	76	9 (11.8)	NR (NE, NE)	0.205 (0.044, 0.947)	0.0238
Japan	25	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	12 (40.0)	4.7 (1.5, NE)	0.000 (0.000, NE)	<0.0001
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	2 (1.9)	NR (NE, NE)	106	10 (9.4)	NR (NE, NE)	0.193 (0.042, 0.880)	0.0173
White	34	0 (0.0)	NR (NE, NE)	23	11 (47.8)	4.7 (1.0, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9886

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	0 (0.0)	NR (NE, NE)	34	3 (8.8)	NR (NE, NE)	0.000 (0.000, NE)	0.0436
vCPS < 10%	53	1 (1.9)	NR (NE, NE)	54	14 (25.9)	NR (NE, NE)	0.060 (0.008, 0.460)	0.0002
Missing	41	1 (2.4)	NR (NE, NE)	41	4 (9.8)	NR (4.7, NE)	0.226 (0.025, 2.038)	0.1457
Interaction								0.6493

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	15 (19.7)	16.5 (9.0, NE)	69	1 (1.4)	NR (NE, NE)	10.339 (1.351, 79.103)	0.0049
>= 65 Years	63	12 (19.0)	18.6 (10.6, NE)	60	0 (0.0)	NR (NE, NE)	24064375.674 (0.000, NE)	0.0056
Interaction								0.9926

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Gender								
Male	118	22 (18.6)	18.6 (11.6, NE)	106	1 (0.9)	NR (NE, NE)	13.923 (1.858, 104.346)	0.0008
Female	21	5 (23.8)	9.0 (2.3, NE)	23	0 (0.0)	NR (NE, NE)	101665480.621 (0.000, NE)	0.0290
Interaction								0.9923

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	17 (16.3)	NR (16.5, NE)	101	1 (1.0)	NR (NE, NE)	12.460 (1.639, 94.706)	0.0017
Non-Smoker	35	10 (28.6)	9.0 (4.2, NE)	28	0 (0.0)	NR (NE, NE)	58638083.153 (0.000, NE)	0.0175
Interaction								0.9921

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	20 (24.1)	29.9 (9.0, NE)	79	1 (1.3)	NR (NE, NE)	14.884 (1.976, 112.100)	0.0005
Docetaxel	56	7 (12.5)	18.6 (11.6, NE)	50	0 (0.0)	NR (NE, NE)	54856964.265 (0.000, NE)	0.0399
Interaction								0.9908

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	11 (25.6)	11.6 (8.3, NE)	37	0 (0.0)	NR (NE, NE)	20986149.621 (0.000, NE)	0.0166
1	96	16 (16.7)	29.9 (16.5, NE)	92	1 (1.1)	NR (NE, NE)	12.267 (1.616, 93.123)	0.0018
Interaction								0.9901

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #1								
Asia	103	20 (19.4)	16.5 (10.6, NE)	99	1 (1.0)	NR (NE, NE)	12.205 (1.624, 91.730)	0.0019
Europe/North America	36	7 (19.4)	29.9 (NE, NE)	30	0 (0.0)	NR (NE, NE)	27780792.374 (0.000, NE)	0.0176
Interaction								0.9915

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	13 (16.7)	18.6 (16.5, NE)	76	1 (1.3)	NR (NE, NE)	9.219 (1.196, 71.068)	0.0094
Japan	25	7 (28.0)	11.6 (4.6, NE)	23	0 (0.0)	NR (NE, NE)	49166268.174 (0.000, NE)	0.0771
Europe/North America	36	7 (19.4)	29.9 (NE, NE)	30	0 (0.0)	NR (NE, NE)	27780792.374 (0.000, NE)	0.0176
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	20 (19.0)	16.5 (10.6, NE)	106	1 (0.9)	NR (NE, NE)	12.976 (1.726, 97.567)	0.0013
White	34	7 (20.6)	29.9 (NE, NE)	23	0 (0.0)	NR (NE, NE)	23426153.693 (0.000, NE)	0.0313
Interaction								0.9924

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Endocrine disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	6 (13.3)	NR (9.0, NE)	34	1 (2.9)	NR (NE, NE)	2.930 (0.348, 24.669)	0.3003
vCPS < 10%	53	12 (22.6)	29.9 (16.5, NE)	54	0 (0.0)	NR (NE, NE)	28223232.083 (0.000, NE)	0.0019
Missing	41	9 (22.0)	18.6 (4.6, NE)	41	0 (0.0)	NR (NE, NE)	76459732.458 (0.000, NE)	0.0102
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	76	12 (15.8)	29.9 (4.9, NE)	69	0 (0.0)	NR (NE, NE)	23397342.626 (0.000, NE)	0.0053
>= 65 Years	63	7 (11.1)	NR (18.6, NE)	60	0 (0.0)	NR (NE, NE)	24186539.945 (0.000, NE)	0.0296
Interaction								0.9998

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Gender								
Male	118	15 (12.7)	NR (16.5, NE)	106	0 (0.0)	NR (NE, NE)	22555386.209 (0.000, NE)	0.0024
Female	21	4 (19.0)	29.9 (2.3, NE)	23	0 (0.0)	NR (NE, NE)	92609463.806 (0.000, NE)	0.0744
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	13 (12.5)	NR (16.5, NE)	101	0 (0.0)	NR (NE, NE)	23958115.109 (0.000, NE)	0.0032
Non-Smoker	35	6 (17.1)	29.9 (4.2, NE)	28	0 (0.0)	NR (NE, NE)	57917086.256 (0.000, NE)	0.0728
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ICC Options								
Paclitaxel	83	14 (16.9)	29.9 (16.5, NE)	79	0 (0.0)	NR (NE, NE)	25104900.386 (0.000, NE)	0.0020
Docetaxel	56	5 (8.9)	18.6 (NE, NE)	50	0 (0.0)	NR (NE, NE)	57484283.130 (0.000, NE)	0.0674
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	43	8 (18.6)	18.6 (10.6, NE)	37	0 (0.0)	NR (NE, NE)	21206999.553 (0.000, NE)	0.0376
1	96	11 (11.5)	29.9 (16.5, NE)	92	0 (0.0)	NR (NE, NE)	23968338.434 (0.000, NE)	0.0058
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Region #1								
Asia	103	14 (13.6)	NR (16.5, NE)	99	0 (0.0)	NR (NE, NE)	21617628.784 (0.000, NE)	0.0030
Europe/North America	36	5 (13.9)	29.9 (4.9, NE)	30	0 (0.0)	NR (NE, NE)	68856680.107 (0.000, NE)	0.0661
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Region #2								
Asia (excluding Japan)	78	10 (12.8)	NR (16.5, NE)	76	0 (0.0)	NR (NE, NE)	22973526.583 (0.000, NE)	0.0083
Japan	25	4 (16.0)	NR (4.6, NE)	23	0 (0.0)	NR (NE, NE)	47674440.539 (0.000, NE)	0.1771
Europe/North America	36	5 (13.9)	29.9 (4.9, NE)	30	0 (0.0)	NR (NE, NE)	68856680.107 (0.000, NE)	0.0661
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
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Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	105	14 (13.3)	NR (16.5, NE)	106	0 (0.0)	NR (NE, NE)	22788639.853 (0.000, NE)	0.0022
White	34	5 (14.7)	29.9 (4.9, NE)	23	0 (0.0)	NR (NE, NE)	59592827.394 (0.000, NE)	0.0928
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Endocrine disorders / PT - Hypothyroidism

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Baseline PD-L1 Status								
vCPS >= 10%	45	3 (6.7)	--	34	0 (0.0)	--	--	--
vCPS < 10%	53	9 (17.0)	--	54	0 (0.0)	--	--	--
Missing	41	7 (17.1)	--	41	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Gastrointestinal disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	48 (63.2)	2.0 (0.8, 3.7)	69	40 (58.0)	1.1 (0.5, 2.6)	0.803 (0.524, 1.230)	0.3075
>= 65 Years	63	42 (66.7)	2.9 (1.4, 4.1)	60	39 (65.0)	1.1 (0.3, 2.1)	0.619 (0.392, 0.976)	0.0355
Interaction								0.5209
Gender								
Male	118	76 (64.4)	2.4 (1.4, 3.4)	106	62 (58.5)	1.2 (0.7, 2.6)	0.763 (0.541, 1.076)	0.1189
Female	21	14 (66.7)	2.1 (0.3, 6.2)	23	17 (73.9)	1.0 (0.1, 2.1)	0.512 (0.242, 1.081)	0.0709
Interaction								0.3784

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Gastrointestinal disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	71 (68.3)	2.0 (1.2, 3.1)	101	61 (60.4)	1.1 (0.4, 2.3)	0.775 (0.546, 1.099)	0.1473
Non-Smoker	35	19 (54.3)	2.9 (0.8, NE)	28	18 (64.3)	1.2 (0.5, 5.1)	0.538 (0.273, 1.061)	0.0684
Interaction								0.4833
ICC Options								
Paclitaxel	83	55 (66.3)	2.0 (1.2, 3.4)	79	50 (63.3)	1.1 (0.5, 2.3)	0.716 (0.483, 1.061)	0.0911
Docetaxel	56	35 (62.5)	2.9 (0.8, 7.2)	50	29 (58.0)	1.1 (0.3, 6.1)	0.709 (0.427, 1.178)	0.1776
Interaction								0.8913

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Gastrointestinal disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	24 (55.8)	5.9 (2.0, 9.8)	37	24 (64.9)	1.3 (0.4, 5.1)	0.482 (0.265, 0.876)	0.0137
1	96	66 (68.8)	1.4 (0.8, 2.9)	92	55 (59.8)	1.1 (0.5, 2.3)	0.840 (0.584, 1.210)	0.3444
Interaction								0.1262
Region #1								
Asia	103	62 (60.2)	3.0 (1.8, 4.1)	99	56 (56.6)	1.1 (0.5, 2.3)	0.685 (0.472, 0.992)	0.0425
Europe/North America	36	28 (77.8)	1.2 (0.3, 2.5)	30	23 (76.7)	1.1 (0.4, 2.3)	0.768 (0.433, 1.362)	0.3580
Interaction								0.5525

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Gastrointestinal disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	50 (64.1)	2.2 (1.2, 3.4)	76	41 (53.9)	1.2 (0.3, NE)	0.799 (0.524, 1.217)	0.2899
Japan	25	12 (48.0)	9.8 (1.5, NE)	23	15 (65.2)	1.1 (0.3, NE)	0.422 (0.187, 0.953)	0.0317
Europe/North America	36	28 (77.8)	1.2 (0.3, 2.5)	30	23 (76.7)	1.1 (0.4, 2.3)	0.768 (0.433, 1.362)	0.3580
Interaction								0.2022

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Gastrointestinal disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	64 (61.0)	2.9 (1.8, 3.7)	106	61 (57.5)	1.1 (0.6, 2.3)	0.697 (0.486, 0.998)	0.0460
White	34	26 (76.5)	1.2 (0.3, 2.5)	23	18 (78.3)	1.2 (0.2, 2.3)	0.696 (0.372, 1.301)	0.2450
Interaction								0.8281

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Gastrointestinal disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	35 (77.8)	1.9 (0.6, 3.3)	34	25 (73.5)	0.4 (0.1, 1.9)	0.581 (0.340, 0.993)	0.0417
vCPS < 10%	53	38 (71.7)	1.5 (0.8, 3.7)	54	32 (59.3)	1.5 (0.7, 2.6)	0.874 (0.536, 1.425)	0.5858
Missing	41	17 (41.5)	4.1 (2.5, NE)	41	22 (53.7)	1.0 (0.3, NE)	0.562 (0.297, 1.063)	0.0698
Interaction								0.2249

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Gastrointestinal disorders / PT - Abdominal pain upper

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	76	1 (1.3)	--	69	4 (5.8)	--	--	--
>= 65 Years	63	2 (3.2)	--	60	6 (10.0)	--	--	--
Interaction								--
Gender								
Male	118	3 (2.5)	--	106	6 (5.7)	--	--	--
Female	21	0 (0.0)	--	23	4 (17.4)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Gastrointestinal disorders / PT - Abdominal pain upper

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	1 (1.0)	--	101	5 (5.0)	--	--	--
Non-Smoker	35	2 (5.7)	--	28	5 (17.9)	--	--	--
Interaction								--
ICC Options								
Paclitaxel	83	0 (0.0)	--	79	7 (8.9)	--	--	--
Docetaxel	56	3 (5.4)	--	50	3 (6.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Gastrointestinal disorders / PT - Abdominal pain upper

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	43	0 (0.0)	--	37	5 (13.5)	--	--	--
1	96	3 (3.1)	--	92	5 (5.4)	--	--	--
Interaction								--
Region #1								
Asia	103	3 (2.9)	--	99	6 (6.1)	--	--	--
Europe/North America	36	0 (0.0)	--	30	4 (13.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Gastrointestinal disorders / PT - Abdominal pain upper

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Region #2								
Asia (excluding Japan)	78	3 (3.8)	--	76	6 (7.9)	--	--	--
Japan	25	0 (0.0)	--	23	0 (0.0)	--	--	--
Europe/North America	36	0 (0.0)	--	30	4 (13.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Gastrointestinal disorders / PT - Abdominal pain upper

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	105	3 (2.9)	--	106	6 (5.7)	--	--	--
White	34	0 (0.0)	--	23	4 (17.4)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
Adverse events were classified based on MedDRA v25.0.
System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.
Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.
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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Gastrointestinal disorders / PT - Abdominal pain upper

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	2 (4.4)	--	34	5 (14.7)	--	--	--
vCPS < 10%	53	0 (0.0)	--	54	3 (5.6)	--	--	--
Missing	41	1 (2.4)	--	41	2 (4.9)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - General disorders and administration site conditions

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	35 (46.1)	8.5 (2.5, 17.5)	69	40 (58.0)	1.3 (0.9, 3.0)	0.508 (0.315, 0.819)	0.0044
>= 65 Years	63	39 (61.9)	3.5 (1.3, 7.6)	60	39 (65.0)	1.1 (0.5, 2.6)	0.603 (0.377, 0.963)	0.0304
Interaction								0.5402
Gender								
Male	118	63 (53.4)	6.9 (2.7, 8.6)	106	63 (59.4)	1.3 (0.9, 2.6)	0.555 (0.384, 0.801)	0.0013
Female	21	11 (52.4)	2.2 (0.3, NE)	23	16 (69.6)	1.8 (0.3, 2.7)	0.595 (0.269, 1.317)	0.1908
Interaction								0.9756

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - General disorders and administration site conditions

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	57 (54.8)	3.6 (2.2, 8.6)	101	64 (63.4)	1.3 (0.9, 2.3)	0.538 (0.370, 0.783)	0.0009
Non-Smoker	35	17 (48.6)	7.7 (2.1, 17.5)	28	15 (53.6)	1.9 (0.4, NE)	0.594 (0.283, 1.247)	0.1611
Interaction								0.7151
ICC Options								
Paclitaxel	83	47 (56.6)	3.5 (1.9, 9.9)	79	51 (64.6)	1.7 (0.8, 2.5)	0.571 (0.374, 0.871)	0.0079
Docetaxel	56	27 (48.2)	5.5 (2.9, 8.6)	50	28 (56.0)	1.3 (0.8, NE)	0.548 (0.315, 0.951)	0.0281
Interaction								0.9554

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - General disorders and administration site conditions

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	22 (51.2)	7.7 (2.7, 9.9)	37	21 (56.8)	2.1 (1.0, NE)	0.556 (0.293, 1.055)	0.0673
1	96	52 (54.2)	3.5 (2.0, 10.3)	92	58 (63.0)	1.2 (0.6, 1.9)	0.543 (0.366, 0.804)	0.0018
Interaction								0.6506
Region #1								
Asia	103	48 (46.6)	7.7 (3.6, 11.0)	99	57 (57.6)	1.6 (0.9, 2.6)	0.491 (0.326, 0.740)	0.0005
Europe/North America	36	26 (72.2)	2.2 (0.7, 3.5)	30	22 (73.3)	1.0 (0.4, 2.7)	0.670 (0.372, 1.209)	0.1753
Interaction								0.3045

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - General disorders and administration site conditions

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	35 (44.9)	7.7 (3.4, 12.7)	76	43 (56.6)	1.6 (0.9, 3.0)	0.503 (0.313, 0.809)	0.0035
Japan	25	13 (52.0)	6.9 (1.9, NE)	23	14 (60.9)	1.7 (0.4, NE)	0.432 (0.187, 1.000)	0.0431
Europe/North America	36	26 (72.2)	2.2 (0.7, 3.5)	30	22 (73.3)	1.0 (0.4, 2.7)	0.670 (0.372, 1.209)	0.1753
Interaction								0.5878

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - General disorders and administration site conditions

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	48 (45.7)	7.7 (3.6, 11.0)	106	61 (57.5)	1.7 (0.9, 2.6)	0.479 (0.319, 0.718)	0.0002
White	34	26 (76.5)	1.7 (0.5, 2.8)	23	18 (78.3)	0.9 (0.2, 1.9)	0.655 (0.352, 1.217)	0.1715
Interaction								0.3896

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - General disorders and administration site conditions

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	29 (64.4)	2.9 (1.2, 7.0)	34	25 (73.5)	1.0 (0.2, 2.0)	0.487 (0.277, 0.856)	0.0100
vCPS < 10%	53	31 (58.5)	7.7 (1.2, 11.0)	54	30 (55.6)	2.1 (0.9, 3.0)	0.669 (0.390, 1.147)	0.1380
Missing	41	14 (34.1)	9.9 (2.5, NE)	41	24 (58.5)	1.1 (0.8, NE)	0.413 (0.208, 0.818)	0.0084
Interaction								0.4075

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Infections and infestations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	28 (36.8)	10.5 (3.2, NE)	69	24 (34.8)	8.0 (3.4, NE)	0.878 (0.505, 1.527)	0.6439
>= 65 Years	63	19 (30.2)	11.5 (5.3, NE)	60	24 (40.0)	3.1 (2.6, NE)	0.482 (0.251, 0.925)	0.0246
Interaction								0.2736
Gender								
Male	118	42 (35.6)	10.5 (5.3, NE)	106	40 (37.7)	5.3 (3.1, NE)	0.727 (0.466, 1.134)	0.1572
Female	21	5 (23.8)	27.0 (2.1, NE)	23	8 (34.8)	3.1 (2.4, NE)	0.468 (0.135, 1.618)	0.2195
Interaction								0.4506

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Infections and infestations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	35 (33.7)	11.5 (5.3, NE)	101	40 (39.6)	5.3 (2.8, NE)	0.614 (0.383, 0.984)	0.0402
Non-Smoker	35	12 (34.3)	10.5 (2.6, NE)	28	8 (28.6)	4.9 (3.1, NE)	1.059 (0.426, 2.637)	0.9008
Interaction								0.3190
ICC Options								
Paclitaxel	83	29 (34.9)	13.8 (5.3, NE)	79	26 (32.9)	8.0 (3.3, NE)	0.851 (0.491, 1.475)	0.5644
Docetaxel	56	18 (32.1)	9.5 (3.2, NE)	50	22 (44.0)	3.1 (1.4, NE)	0.479 (0.251, 0.914)	0.0223
Interaction								0.2738

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Infections and infestations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	11 (25.6)	13.8 (7.3, NE)	37	10 (27.0)	8.0 (4.9, NE)	0.656 (0.263, 1.633)	0.3609
1	96	36 (37.5)	5.6 (3.2, 27.0)	92	38 (41.3)	3.1 (2.4, NE)	0.673 (0.421, 1.077)	0.0957
Interaction								0.7127
Region #1								
Asia	103	36 (35.0)	9.5 (4.9, NE)	99	36 (36.4)	NR (2.8, NE)	0.681 (0.423, 1.098)	0.1115
Europe/North America	36	11 (30.6)	27.0 (7.3, NE)	30	12 (40.0)	5.3 (2.8, NE)	0.679 (0.291, 1.586)	0.3681
Interaction								0.9702

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Infections and infestations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	27 (34.6)	9.5 (3.8, NE)	76	27 (35.5)	NR (2.4, NE)	0.692 (0.402, 1.193)	0.1816
Japan	25	9 (36.0)	11.5 (2.8, NE)	23	9 (39.1)	3.4 (3.0, NE)	0.636 (0.235, 1.723)	0.3687
Europe/North America	36	11 (30.6)	27.0 (7.3, NE)	30	12 (40.0)	5.3 (2.8, NE)	0.679 (0.291, 1.586)	0.3681
Interaction								0.9895

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Infections and infestations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	37 (35.2)	9.5 (4.9, NE)	106	39 (36.8)	NR (2.8, NE)	0.692 (0.435, 1.102)	0.1183
White	34	10 (29.4)	27.0 (7.3, NE)	23	9 (39.1)	5.3 (2.8, NE)	0.689 (0.272, 1.748)	0.4303
Interaction								0.9581

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Infections and infestations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	13 (28.9)	13.8 (5.3, NE)	34	15 (44.1)	2.8 (2.2, NE)	0.337 (0.148, 0.769)	0.0069
vCPS < 10%	53	24 (45.3)	5.6 (2.6, NE)	54	22 (40.7)	4.9 (2.0, NE)	0.917 (0.509, 1.654)	0.7738
Missing	41	10 (24.4)	11.5 (3.2, NE)	41	11 (26.8)	NR (3.3, NE)	0.751 (0.311, 1.813)	0.5209
Interaction								0.2835

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	31 (40.8)	7.6 (2.2, NE)	69	46 (66.7)	0.5 (0.4, 1.2)	0.376 (0.235, 0.602)	<0.0001
>= 65 Years	63	31 (49.2)	7.7 (2.8, 15.8)	60	38 (63.3)	0.7 (0.3, 3.0)	0.407 (0.245, 0.677)	0.0003
Interaction								0.7036
Gender								
Male	118	55 (46.6)	7.6 (2.8, 15.8)	106	73 (68.9)	0.5 (0.4, 1.2)	0.380 (0.263, 0.549)	<0.0001
Female	21	7 (33.3)	NR (2.2, NE)	23	11 (47.8)	NR (0.3, NE)	0.490 (0.189, 1.271)	0.1281
Interaction								0.8097

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	48 (46.2)	7.6 (2.8, 26.9)	101	66 (65.3)	0.7 (0.5, 1.4)	0.397 (0.269, 0.588)	<0.0001
Non-Smoker	35	14 (40.0)	9.2 (2.2, NE)	28	18 (64.3)	0.5 (0.3, NE)	0.385 (0.187, 0.791)	0.0056
Interaction								0.7884
ICC Options								
Paclitaxel	83	31 (37.3)	26.9 (4.4, NE)	79	45 (57.0)	1.2 (0.5, 3.5)	0.396 (0.245, 0.640)	<0.0001
Docetaxel	56	31 (55.4)	2.2 (1.2, 7.7)	50	39 (78.0)	0.3 (0.3, 0.7)	0.356 (0.217, 0.583)	<0.0001
Interaction								0.8824

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

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Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	14 (32.6)	15.8 (9.2, NE)	37	22 (59.5)	0.7 (0.3, NE)	0.307 (0.149, 0.630)	0.0005
1	96	48 (50.0)	3.1 (2.1, 7.7)	92	62 (67.4)	0.5 (0.4, 1.2)	0.434 (0.294, 0.642)	<0.0001
Interaction								0.3952
Region #1								
Asia	103	55 (53.4)	3.5 (2.1, 9.2)	99	74 (74.7)	0.5 (0.3, 0.5)	0.347 (0.239, 0.503)	<0.0001
Europe/North America	36	7 (19.4)	NR (NE, NE)	30	10 (33.3)	NR (3.0, NE)	0.504 (0.191, 1.328)	0.1548
Interaction								0.6614

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Any TEAE: SOC - Investigations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	43 (55.1)	2.8 (1.7, 7.7)	76	58 (76.3)	0.4 (0.3, 0.7)	0.379 (0.251, 0.574)	<0.0001
Japan	25	12 (48.0)	4.4 (2.8, NE)	23	16 (69.6)	0.5 (0.3, 1.7)	0.217 (0.084, 0.561)	0.0004
Europe/North America	36	7 (19.4)	NR (NE, NE)	30	10 (33.3)	NR (3.0, NE)	0.504 (0.191, 1.328)	0.1548
Interaction								0.8276

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	55 (52.4)	3.5 (2.1, 9.2)	106	77 (72.6)	0.5 (0.3, 0.7)	0.362 (0.251, 0.523)	<0.0001
White	34	7 (20.6)	NR (NE, NE)	23	7 (30.4)	NR (3.0, NE)	0.613 (0.214, 1.755)	0.3535
Interaction								0.4945

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	19 (42.2)	7.6 (3.1, NE)	34	22 (64.7)	0.6 (0.3, 1.5)	0.370 (0.196, 0.699)	0.0012
vCPS < 10%	53	25 (47.2)	4.4 (2.1, NE)	54	34 (63.0)	0.6 (0.3, 3.3)	0.462 (0.270, 0.792)	0.0032
Missing	41	18 (43.9)	9.2 (2.1, NE)	41	28 (68.3)	0.5 (0.3, 1.7)	0.359 (0.190, 0.677)	0.0007
Interaction								0.9116

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	8 (10.5)	--	69	1 (1.4)	--	--	--
>= 65 Years	63	6 (9.5)	--	60	2 (3.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Gender								
Male	118	11 (9.3)	NR (30.4, NE)	106	3 (2.8)	NR (NE, NE)	2.729 (0.748, 9.961)	0.1118
Female	21	3 (14.3)	NR (2.8, NE)	23	0 (0.0)	NR (NE, NE)	74428493.556 (0.000, NE)	0.1010
Interaction								0.9932

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	11 (10.6)	NR (30.4, NE)	101	2 (2.0)	NR (NE, NE)	4.164 (0.907, 19.126)	0.0460
Non-Smoker	35	3 (8.6)	NR (NE, NE)	28	1 (3.6)	NR (NE, NE)	2.217 (0.230, 21.341)	0.4794
Interaction								0.6176
ICC Options								
Paclitaxel	83	9 (10.8)	NR (30.4, NE)	79	2 (2.5)	NR (NE, NE)	3.494 (0.740, 16.499)	0.0914
Docetaxel	56	5 (8.9)	NR (NE, NE)	50	1 (2.0)	NR (NE, NE)	3.683 (0.426, 31.829)	0.2040
Interaction								0.9534

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	43	5 (11.6)	30.4 (30.4, NE)	37	0 (0.0)	NR (NE, NE)	22891617.564 (0.000, NE)	0.0846
1	96	9 (9.4)	NR (NE, NE)	92	3 (3.3)	NR (NE, NE)	2.596 (0.699, 9.646)	0.1380
Interaction								0.9908

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Region #1								
Asia	103	11 (10.7)	NR (30.4, NE)	99	3 (3.0)	NR (NE, NE)	2.833 (0.776, 10.342)	0.0981
Europe/North America	36	3 (8.3)	NR (NE, NE)	30	0 (0.0)	NR (NE, NE)	62814472.592 (0.000, NE)	0.1317
Interaction								0.9921

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	8 (10.3)	NR (NE, NE)	76	3 (3.9)	NR (NE, NE)	2.307 (0.609, 8.743)	0.2031
Japan	25	3 (12.0)	30.4 (NE, NE)	23	0 (0.0)	NR (NE, NE)	64906194.808 (0.000, NE)	0.2144
Europe/North America	36	3 (8.3)	NR (NE, NE)	30	0 (0.0)	NR (NE, NE)	62814472.592 (0.000, NE)	0.1317
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	11 (10.5)	NR (30.4, NE)	106	3 (2.8)	NR (NE, NE)	2.987 (0.818, 10.906)	0.0809
White	34	3 (8.8)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	55484688.828 (0.000, NE)	0.1646
Interaction								0.9929

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - Aspartate aminotransferase increased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	6 (13.3)	--	34	1 (2.9)	--	--	--
vCPS < 10%	53	3 (5.7)	--	54	1 (1.9)	--	--	--
Missing	41	5 (12.2)	--	41	1 (2.4)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	2 (2.6)	--	69	3 (4.3)	--	--	--
>= 65 Years	63	1 (1.6)	--	60	7 (11.7)	--	--	--
Interaction								--
Gender								
Male	118	2 (1.7)	NR (NE, NE)	106	9 (8.5)	NR (NE, NE)	0.186 (0.040, 0.860)	0.0153
Female	21	1 (4.8)	NR (NE, NE)	23	1 (4.3)	NR (NE, NE)	1.047 (0.065, 16.744)	0.9743
Interaction								0.2665

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	3 (2.9)	NR (NE, NE)	101	9 (8.9)	NR (NE, NE)	0.302 (0.082, 1.118)	0.0558
Non-Smoker	35	0 (0.0)	NR (NE, NE)	28	1 (3.6)	NR (NE, NE)	0.000 (0.000, NE)	0.2618
Interaction								0.9930
ICC Options								
Paclitaxel	83	1 (1.2)	--	79	4 (5.1)	--	--	--
Docetaxel	56	2 (3.6)	--	50	6 (12.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	1 (2.3)	--	37	3 (8.1)	--	--	--
1	96	2 (2.1)	--	92	7 (7.6)	--	--	--
Interaction								--
Region #1								
Asia	103	2 (1.9)	--	99	6 (6.1)	--	--	--
Europe/North America	36	1 (2.8)	--	30	4 (13.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	2 (2.6)	--	76	4 (5.3)	--	--	--
Japan	25	0 (0.0)	--	23	2 (8.7)	--	--	--
Europe/North America	36	1 (2.8)	--	30	4 (13.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	105	2 (1.9)	--	106	7 (6.6)	--	--	--
White	34	1 (2.9)	--	23	3 (13.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
Adverse events were classified based on MedDRA v25.0.
System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.
Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.
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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	1 (2.2)	--	34	2 (5.9)	--	--	--
vCPS < 10%	53	2 (3.8)	--	54	6 (11.1)	--	--	--
Missing	41	0 (0.0)	--	41	2 (4.9)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	76	1 (1.3)	NR (NE, NE)	69	33 (47.8)	2.4 (0.5, NE)	0.019 (0.003, 0.142)	<0.0001
>= 65 Years	63	0 (0.0)	NR (NE, NE)	60	22 (36.7)	NR (2.8, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9853
Gender								
Male	118	0 (0.0)	NR (NE, NE)	106	48 (45.3)	3.0 (1.0, NE)	0.000 (0.000, NE)	<0.0001
Female	21	1 (4.8)	NR (NE, NE)	23	7 (30.4)	NR (0.5, NE)	0.137 (0.017, 1.114)	0.0288
Interaction								0.9846

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	1 (1.0)	NR (NE, NE)	101	44 (43.6)	3.0 (1.2, NE)	0.016 (0.002, 0.116)	<0.0001
Non-Smoker	35	0 (0.0)	NR (NE, NE)	28	11 (39.3)	NR (0.5, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9888
ICC Options								
Paclitaxel	83	1 (1.2)	NR (NE, NE)	79	30 (38.0)	NR (2.4, NE)	0.025 (0.003, 0.182)	<0.0001
Docetaxel	56	0 (0.0)	NR (NE, NE)	50	25 (50.0)	2.8 (0.3, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9860

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	43	1 (2.3)	NR (NE, NE)	37	18 (48.6)	2.4 (0.5, NE)	0.036 (0.005, 0.273)	<0.0001
1	96	0 (0.0)	NR (NE, NE)	92	37 (40.2)	NR (1.4, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9873
Region #1								
Asia	103	0 (0.0)	NR (NE, NE)	99	52 (52.5)	1.2 (0.5, NE)	0.000 (0.000, NE)	<0.0001
Europe/North America	36	1 (2.8)	NR (NE, NE)	30	3 (10.0)	NR (NE, NE)	0.270 (0.028, 2.598)	0.2223
Interaction								0.9869

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	0 (0.0)	NR (NE, NE)	76	39 (51.3)	1.4 (0.5, NE)	0.000 (0.000, NE)	<0.0001
Japan	25	0 (0.0)	NR (NE, NE)	23	13 (56.5)	0.8 (0.5, NE)	0.000 (0.000, NE)	<0.0001
Europe/North America	36	1 (2.8)	NR (NE, NE)	30	3 (10.0)	NR (NE, NE)	0.270 (0.028, 2.598)	0.2223
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	105	0 (0.0)	NR (NE, NE)	106	53 (50.0)	2.4 (0.7, NE)	0.000 (0.000, NE)	<0.0001
White	34	1 (2.9)	NR (NE, NE)	23	2 (8.7)	NR (NE, NE)	0.337 (0.031, 3.712)	0.3476
Interaction								0.9859

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
Adverse events were classified based on MedDRA v25.0.
System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.
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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.
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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	0 (0.0)	NR (NE, NE)	34	16 (47.1)	3.0 (0.7, NE)	0.000 (0.000, NE)	<0.0001
vCPS < 10%	53	1 (1.9)	NR (NE, NE)	54	19 (35.2)	NR (2.4, NE)	0.042 (0.006, 0.318)	<0.0001
Missing	41	0 (0.0)	NR (NE, NE)	41	20 (48.8)	1.2 (0.5, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	1 (1.3)	NR (NE, NE)	69	31 (44.9)	NR (0.5, NE)	0.023 (0.003, 0.167)	<0.0001
>= 65 Years	63	3 (4.8)	NR (NE, NE)	60	18 (30.0)	NR (NE, NE)	0.135 (0.040, 0.458)	0.0001
Interaction								0.1499
Gender								
Male	118	2 (1.7)	NR (NE, NE)	106	43 (40.6)	NR (1.5, NE)	0.033 (0.008, 0.136)	<0.0001
Female	21	2 (9.5)	NR (NE, NE)	23	6 (26.1)	NR (NE, NE)	0.336 (0.068, 1.666)	0.1554
Interaction								0.0381

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	2 (1.9)	NR (NE, NE)	101	38 (37.6)	NR (NE, NE)	0.041 (0.010, 0.170)	<0.0001
Non-Smoker	35	2 (5.7)	NR (NE, NE)	28	11 (39.3)	NR (0.5, NE)	0.122 (0.027, 0.550)	0.0009
Interaction								0.3260
ICC Options								
Paclitaxel	83	0 (0.0)	NR (NE, NE)	79	22 (27.8)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Docetaxel	56	4 (7.1)	NR (NE, NE)	50	27 (54.0)	0.8 (0.3, NE)	0.091 (0.031, 0.262)	<0.0001
Interaction								0.9845

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	2 (4.7)	NR (NE, NE)	37	15 (40.5)	NR (0.5, NE)	0.090 (0.020, 0.397)	<0.0001
1	96	2 (2.1)	NR (NE, NE)	92	34 (37.0)	NR (NE, NE)	0.046 (0.011, 0.193)	<0.0001
Interaction								0.4791
Region #1								
Asia	103	4 (3.9)	NR (NE, NE)	99	48 (48.5)	NR (0.5, NE)	0.059 (0.021, 0.164)	<0.0001
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	1 (3.3)	NR (NE, NE)	0.000 (0.000, NE)	0.2733
Interaction								0.9910

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	3 (3.8)	NR (NE, NE)	76	36 (47.4)	NR (0.4, NE)	0.059 (0.018, 0.192)	<0.0001
Japan	25	1 (4.0)	NR (NE, NE)	23	12 (52.2)	0.8 (0.5, NE)	0.060 (0.008, 0.464)	0.0002
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	1 (3.3)	NR (NE, NE)	0.000 (0.000, NE)	0.2733
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	105	4 (3.8)	NR (NE, NE)	106	49 (46.2)	NR (0.5, NE)	0.061 (0.022, 0.171)	<0.0001
White	34	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9986

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
Adverse events were classified based on MedDRA v25.0.
System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.
Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.
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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	2 (4.4)	NR (NE, NE)	34	11 (32.4)	NR (1.5, NE)	0.118 (0.026, 0.532)	0.0008
vCPS < 10%	53	2 (3.8)	NR (NE, NE)	54	18 (33.3)	NR (NE, NE)	0.084 (0.019, 0.371)	<0.0001
Missing	41	0 (0.0)	NR (NE, NE)	41	20 (48.8)	NR (0.3, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9750

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	38 (50.0)	4.9 (2.0, 13.8)	69	37 (53.6)	1.9 (1.0, 6.6)	0.725 (0.456, 1.154)	0.1671
>= 65 Years	63	25 (39.7)	9.0 (4.1, NE)	60	30 (50.0)	3.5 (1.2, NE)	0.519 (0.295, 0.913)	0.0195
Interaction								0.3969
Gender								
Male	118	56 (47.5)	8.3 (3.6, 10.2)	106	56 (52.8)	2.6 (1.3, 5.7)	0.653 (0.445, 0.959)	0.0267
Female	21	7 (33.3)	NR (1.0, NE)	23	11 (47.8)	2.8 (0.3, NE)	0.598 (0.231, 1.542)	0.2741
Interaction								0.4865

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	52 (50.0)	5.4 (2.3, 13.8)	101	53 (52.5)	2.6 (1.2, 6.6)	0.733 (0.494, 1.087)	0.1160
Non-Smoker	35	11 (31.4)	9.0 (3.6, NE)	28	14 (50.0)	4.8 (0.5, NE)	0.378 (0.162, 0.886)	0.0186
Interaction								0.2405
ICC Options								
Paclitaxel	83	32 (38.6)	13.8 (4.9, NE)	79	36 (45.6)	4.8 (2.3, NE)	0.649 (0.395, 1.066)	0.0825
Docetaxel	56	31 (55.4)	3.7 (1.3, 9.0)	50	31 (62.0)	1.2 (0.5, 3.7)	0.559 (0.332, 0.942)	0.0236
Interaction								0.8037

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	12 (27.9)	29.0 (8.6, NE)	37	20 (54.1)	4.8 (0.7, 6.6)	0.272 (0.124, 0.599)	0.0005
1	96	51 (53.1)	3.6 (1.4, 8.3)	92	47 (51.1)	2.3 (1.2, NE)	0.843 (0.563, 1.264)	0.4016
Interaction								0.0318
Region #1								
Asia	103	47 (45.6)	8.3 (3.4, 26.9)	99	55 (55.6)	1.4 (0.7, 5.7)	0.564 (0.377, 0.844)	0.0042
Europe/North America	36	16 (44.4)	8.6 (1.1, NE)	30	12 (40.0)	4.8 (2.8, NE)	0.956 (0.439, 2.082)	0.9084
Interaction								0.1244

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	40 (51.3)	3.7 (2.0, 9.0)	76	44 (57.9)	1.2 (0.6, 3.5)	0.651 (0.421, 1.007)	0.0484
Japan	25	7 (28.0)	29.0 (10.2, NE)	23	11 (47.8)	NR (0.7, NE)	0.258 (0.082, 0.817)	0.0122
Europe/North America	36	16 (44.4)	8.6 (1.1, NE)	30	12 (40.0)	4.8 (2.8, NE)	0.956 (0.439, 2.082)	0.9084
Interaction								0.1983

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	48 (45.7)	8.3 (3.4, 26.9)	106	56 (52.8)	1.7 (1.2, 5.7)	0.614 (0.412, 0.915)	0.0140
White	34	15 (44.1)	8.6 (1.1, NE)	23	11 (47.8)	4.8 (2.6, NE)	0.771 (0.343, 1.732)	0.5230
Interaction								0.4358

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	17 (37.8)	13.8 (4.1, NE)	34	22 (64.7)	1.0 (0.3, NE)	0.312 (0.157, 0.619)	0.0003
vCPS < 10%	53	32 (60.4)	3.7 (1.2, 8.6)	54	22 (40.7)	4.8 (2.6, NE)	1.273 (0.730, 2.218)	0.3903
Missing	41	14 (34.1)	NR (2.3, NE)	41	23 (56.1)	1.4 (0.6, NE)	0.499 (0.256, 0.972)	0.0349
Interaction								0.0019

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	22 (28.9)	26.9 (5.4, NE)	69	19 (27.5)	NR (3.7, NE)	0.830 (0.444, 1.551)	0.5561
>= 65 Years	63	7 (11.1)	NR (NE, NE)	60	20 (33.3)	5.7 (3.5, NE)	0.242 (0.099, 0.589)	0.0007
Interaction								0.0186
Gender								
Male	118	27 (22.9)	26.9 (9.0, NE)	106	33 (31.1)	6.6 (5.7, NE)	0.552 (0.327, 0.931)	0.0232
Female	21	2 (9.5)	NR (NE, NE)	23	6 (26.1)	NR (2.8, NE)	0.350 (0.071, 1.735)	0.1785
Interaction								0.3952

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	27 (26.0)	26.9 (9.0, NE)	101	35 (34.7)	6.6 (3.5, NE)	0.557 (0.332, 0.933)	0.0236
Non-Smoker	35	2 (5.7)	NR (NE, NE)	28	4 (14.3)	NR (5.7, NE)	0.338 (0.062, 1.855)	0.1903
Interaction								0.5620
ICC Options								
Paclitaxel	83	17 (20.5)	NR (26.9, NE)	79	23 (29.1)	6.6 (5.7, NE)	0.539 (0.283, 1.026)	0.0554
Docetaxel	56	12 (21.4)	NR (9.0, NE)	50	16 (32.0)	NR (3.2, NE)	0.478 (0.221, 1.033)	0.0534
Interaction								0.8815

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	6 (14.0)	NR (NE, NE)	37	12 (32.4)	6.6 (3.7, NE)	0.293 (0.106, 0.808)	0.0121
1	96	23 (24.0)	26.9 (9.0, NE)	92	27 (29.3)	NR (3.5, NE)	0.652 (0.370, 1.150)	0.1343
Interaction								0.1982
Region #1								
Asia	103	20 (19.4)	NR (26.9, NE)	99	28 (28.3)	NR (5.7, NE)	0.521 (0.289, 0.939)	0.0267
Europe/North America	36	9 (25.0)	NR (4.9, NE)	30	11 (36.7)	5.7 (2.8, NE)	0.520 (0.207, 1.304)	0.1547
Interaction								0.7714

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	19 (24.4)	26.9 (9.0, NE)	76	23 (30.3)	NR (5.7, NE)	0.625 (0.336, 1.163)	0.1320
Japan	25	1 (4.0)	NR (NE, NE)	23	5 (21.7)	NR (NE, NE)	0.179 (0.021, 1.537)	0.0740
Europe/North America	36	9 (25.0)	NR (4.9, NE)	30	11 (36.7)	5.7 (2.8, NE)	0.520 (0.207, 1.304)	0.1547
Interaction								0.3582

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

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Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	20 (19.0)	NR (26.9, NE)	106	29 (27.4)	NR (5.7, NE)	0.531 (0.296, 0.952)	0.0302
White	34	9 (26.5)	NR (4.9, NE)	23	10 (43.5)	6.6 (2.6, NE)	0.470 (0.184, 1.200)	0.1046
Interaction								0.9752

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

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Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	7 (15.6)	NR (NE, NE)	34	13 (38.2)	6.6 (0.7, NE)	0.299 (0.118, 0.758)	0.0068
vCPS < 10%	53	20 (37.7)	9.0 (3.9, NE)	54	14 (25.9)	NR (3.7, NE)	1.147 (0.567, 2.317)	0.7021
Missing	41	2 (4.9)	NR (NE, NE)	41	12 (29.3)	NR (3.5, NE)	0.144 (0.032, 0.645)	0.0032
Interaction								0.0034

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Musculoskeletal and connective tissue disorders / PT - Myalgia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	3 (3.9)	NR (NE, NE)	69	7 (10.1)	NR (NE, NE)	0.374 (0.097, 1.445)	0.1362
>= 65 Years	63	2 (3.2)	NR (19.9, NE)	60	7 (11.7)	NR (NE, NE)	0.183 (0.036, 0.928)	0.0238
Interaction								0.7202
Gender								
Male	118	4 (3.4)	NR (NE, NE)	106	12 (11.3)	NR (NE, NE)	0.268 (0.086, 0.835)	0.0146
Female	21	1 (4.8)	NR (19.9, NE)	23	2 (8.7)	NR (NE, NE)	0.347 (0.029, 4.188)	0.3879
Interaction								0.6803

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Musculoskeletal and connective tissue disorders / PT - Myalgia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	5 (4.8)	NR (19.9, NE)	101	14 (13.9)	NR (NE, NE)	0.243 (0.079, 0.745)	0.0072
Non-Smoker	35	0 (0.0)	NR (NE, NE)	28	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9997
ICC Options								
Paclitaxel	83	5 (6.0)	NR (19.9, NE)	79	11 (13.9)	NR (NE, NE)	0.302 (0.095, 0.959)	0.0309
Docetaxel	56	0 (0.0)	NR (NE, NE)	50	3 (6.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0631
Interaction								0.9895

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Musculoskeletal and connective tissue disorders / PT - Myalgia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	0 (0.0)	NR (NE, NE)	37	2 (5.4)	NR (NE, NE)	0.000 (0.000, NE)	0.1248
1	96	5 (5.2)	NR (19.9, NE)	92	12 (13.0)	NR (NE, NE)	0.316 (0.108, 0.922)	0.0262
Interaction								0.9901
Region #1								
Asia	103	4 (3.9)	NR (NE, NE)	99	14 (14.1)	NR (NE, NE)	0.241 (0.079, 0.737)	0.0066
Europe/North America	36	1 (2.8)	NR (19.9, NE)	30	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9919

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.b.s:
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Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Musculoskeletal and connective tissue disorders / PT - Myalgia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	4 (5.1)	NR (NE, NE)	76	11 (14.5)	NR (NE, NE)	0.313 (0.099, 0.989)	0.0357
Japan	25	0 (0.0)	NR (NE, NE)	23	3 (13.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0648
Europe/North America	36	1 (2.8)	NR (19.9, NE)	30	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Musculoskeletal and connective tissue disorders / PT - Myalgia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	4 (3.8)	NR (NE, NE)	106	14 (13.2)	NR (NE, NE)	0.255 (0.083, 0.780)	0.0096
White	34	1 (2.9)	NR (19.9, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9887

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Musculoskeletal and connective tissue disorders / PT - Myalgia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	3 (6.7)	--	34	4 (11.8)	--	--	--
vCPS < 10%	53	2 (3.8)	--	54	6 (11.1)	--	--	--
Missing	41	0 (0.0)	--	41	4 (9.8)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Neoplasms benign, malignant and unspecified (incl cysts and polyps)

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	5 (6.6)	NR (NE, NE)	69	2 (2.9)	NR (NE, NE)	2.265 (0.440, 11.677)	0.3150
>= 65 Years	63	9 (14.3)	NR (NE, NE)	60	2 (3.3)	NR (NE, NE)	4.196 (0.905, 19.443)	0.0463
Interaction								0.5678
Gender								
Male	118	11 (9.3)	NR (NE, NE)	106	2 (1.9)	NR (NE, NE)	4.722 (1.046, 21.315)	0.0259
Female	21	3 (14.3)	NR (NE, NE)	23	2 (8.7)	NR (NE, NE)	1.795 (0.300, 10.757)	0.5158
Interaction								0.3976

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Neoplasms benign, malignant and unspecified (incl cysts and polyps)

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	11 (10.6)	NR (NE, NE)	101	3 (3.0)	NR (NE, NE)	3.407 (0.949, 12.229)	0.0455
Non-Smoker	35	3 (8.6)	NR (NE, NE)	28	1 (3.6)	NR (NE, NE)	2.447 (0.254, 23.540)	0.4231
Interaction								0.7977
ICC Options								
Paclitaxel	83	9 (10.8)	NR (NE, NE)	79	3 (3.8)	NR (NE, NE)	2.890 (0.782, 10.685)	0.0953
Docetaxel	56	5 (8.9)	NR (NE, NE)	50	1 (2.0)	NR (NE, NE)	4.017 (0.468, 34.460)	0.1700
Interaction								0.7889

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Neoplasms benign, malignant and unspecified (incl cysts and polyps)

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	3 (7.0)	NR (NE, NE)	37	1 (2.7)	NR (NE, NE)	2.716 (0.282, 26.118)	0.3674
1	96	11 (11.5)	NR (NE, NE)	92	3 (3.3)	NR (NE, NE)	3.405 (0.949, 12.216)	0.0453
Interaction								0.8306
Region #1								
Asia	103	8 (7.8)	NR (NE, NE)	99	2 (2.0)	NR (NE, NE)	3.577 (0.758, 16.878)	0.0854
Europe/North America	36	6 (16.7)	NR (NE, NE)	30	2 (6.7)	NR (NE, NE)	2.816 (0.568, 13.971)	0.1856
Interaction								0.8181

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Neoplasms benign, malignant and unspecified (incl cysts and polyps)

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	4 (5.1)	--	76	1 (1.3)	--	--	--
Japan	25	4 (16.0)	--	23	1 (4.3)	--	--	--
Europe/North America	36	6 (16.7)	--	30	2 (6.7)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Any TEAE: SOC - Neoplasms benign, malignant and unspecified (incl cysts and polyps)

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	8 (7.6)	NR (NE, NE)	106	2 (1.9)	NR (NE, NE)	3.771 (0.799, 17.795)	0.0716
White	34	6 (17.6)	NR (NE, NE)	23	2 (8.7)	NR (NE, NE)	2.302 (0.464, 11.423)	0.2939
Interaction								0.6518

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	6 (13.3)	--	34	1 (2.9)	--	--	--
vCPS < 10%	53	4 (7.5)	--	54	1 (1.9)	--	--	--
Missing	41	4 (9.8)	--	41	2 (4.9)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Nervous system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	11 (14.5)	NR (17.8, NE)	69	22 (31.9)	9.7 (3.5, NE)	0.324 (0.152, 0.688)	0.0020
>= 65 Years	63	10 (15.9)	NR (20.6, NE)	60	20 (33.3)	NR (2.4, NE)	0.328 (0.151, 0.712)	0.0031
Interaction								0.9639
Gender								
Male	118	16 (13.6)	NR (17.8, NE)	106	31 (29.2)	9.7 (3.5, NE)	0.293 (0.154, 0.558)	<0.0001
Female	21	5 (23.8)	NR (3.5, NE)	23	11 (47.8)	2.4 (0.8, NE)	0.400 (0.138, 1.160)	0.0787
Interaction								0.7541

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Nervous system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	14 (13.5)	NR (20.6, NE)	101	31 (30.7)	9.7 (3.5, NE)	0.302 (0.156, 0.583)	0.0002
Non-Smoker	35	7 (20.0)	17.8 (6.2, NE)	28	11 (39.3)	NR (0.9, NE)	0.362 (0.139, 0.940)	0.0293
Interaction								0.7651
ICC Options								
Paclitaxel	83	13 (15.7)	NR (NE, NE)	79	35 (44.3)	3.5 (2.3, NE)	0.237 (0.124, 0.454)	<0.0001
Docetaxel	56	8 (14.3)	20.6 (17.8, NE)	50	7 (14.0)	NR (NE, NE)	0.827 (0.297, 2.306)	0.7163
Interaction								0.0346

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Nervous system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	3 (7.0)	NR (20.6, NE)	37	15 (40.5)	NR (1.0, NE)	0.083 (0.019, 0.366)	<0.0001
1	96	18 (18.8)	NR (17.8, NE)	92	27 (29.3)	9.7 (3.5, NE)	0.475 (0.259, 0.871)	0.0137
Interaction								0.0195
Region #1								
Asia	103	12 (11.7)	NR (17.8, NE)	99	27 (27.3)	9.7 (3.5, NE)	0.286 (0.142, 0.576)	0.0002
Europe/North America	36	9 (25.0)	NR (3.5, NE)	30	15 (50.0)	2.4 (0.5, NE)	0.337 (0.142, 0.798)	0.0093
Interaction								0.7145

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Nervous system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	11 (14.1)	20.6 (17.8, NE)	76	18 (23.7)	9.7 (9.7, NE)	0.430 (0.200, 0.924)	0.0260
Japan	25	1 (4.0)	NR (NE, NE)	23	9 (39.1)	2.8 (1.0, NE)	0.060 (0.007, 0.486)	0.0005
Europe/North America	36	9 (25.0)	NR (3.5, NE)	30	15 (50.0)	2.4 (0.5, NE)	0.337 (0.142, 0.798)	0.0093
Interaction								0.1502

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Nervous system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	12 (11.4)	NR (17.8, NE)	106	28 (26.4)	9.7 (3.5, NE)	0.292 (0.146, 0.587)	0.0003
White	34	9 (26.5)	NR (3.5, NE)	23	14 (60.9)	0.7 (0.4, NE)	0.263 (0.110, 0.632)	0.0013
Interaction								0.8699

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Nervous system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	8 (17.8)	NR (NE, NE)	34	9 (26.5)	9.7 (2.7, NE)	0.463 (0.174, 1.233)	0.1145
vCPS < 10%	53	10 (18.9)	17.8 (17.8, NE)	54	17 (31.5)	NR (2.4, NE)	0.439 (0.196, 0.988)	0.0403
Missing	41	3 (7.3)	20.6 (20.6, NE)	41	16 (39.0)	3.5 (1.2, NE)	0.089 (0.020, 0.392)	<0.0001
Interaction								0.1525

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Nervous system disorders / PT - Peripheral sensory neuropathy

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	76	0 (0.0)	NR (NE, NE)	69	10 (14.5)	NR (9.7, NE)	0.000 (0.000, NE)	0.0002
>= 65 Years	63	1 (1.6)	NR (NE, NE)	60	12 (20.0)	NR (NE, NE)	0.066 (0.009, 0.512)	0.0005
Interaction								0.9925
Gender								
Male	118	0 (0.0)	NR (NE, NE)	106	18 (17.0)	NR (9.7, NE)	0.000 (0.000, NE)	<0.0001
Female	21	1 (4.8)	NR (2.5, NE)	23	4 (17.4)	NR (2.4, NE)	0.234 (0.026, 2.109)	0.1589
Interaction								0.9894

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Nervous system disorders / PT - Peripheral sensory neuropathy

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	1 (1.0)	NR (NE, NE)	101	18 (17.8)	9.7 (9.7, NE)	0.036 (0.005, 0.277)	<0.0001
Non-Smoker	35	0 (0.0)	NR (NE, NE)	28	4 (14.3)	NR (NE, NE)	0.000 (0.000, NE)	0.0199
Interaction								0.9923
ICC Options								
Paclitaxel	83	1 (1.2)	NR (NE, NE)	79	19 (24.1)	9.7 (9.7, NE)	0.035 (0.005, 0.266)	<0.0001
Docetaxel	56	0 (0.0)	NR (NE, NE)	50	3 (6.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0608
Interaction								0.9927

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Nervous system disorders / PT - Peripheral sensory neuropathy

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	0 (0.0)	NR (NE, NE)	37	8 (21.6)	NR (NE, NE)	0.000 (0.000, NE)	0.0010
1	96	1 (1.0)	NR (NE, NE)	92	14 (15.2)	9.7 (9.7, NE)	0.044 (0.006, 0.346)	<0.0001
Interaction								0.9906
Region #1								
Asia	103	0 (0.0)	NR (NE, NE)	99	14 (14.1)	NR (9.7, NE)	0.000 (0.000, NE)	<0.0001
Europe/North America	36	1 (2.8)	NR (NE, NE)	30	8 (26.7)	NR (NE, NE)	0.088 (0.011, 0.709)	0.0040
Interaction								0.9922

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Nervous system disorders / PT - Peripheral sensory neuropathy

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	0 (0.0)	--	76	7 (9.2)	--	--	--
Japan	25	0 (0.0)	--	23	7 (30.4)	--	--	--
Europe/North America	36	1 (2.8)	--	30	8 (26.7)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
Any TEAE: SOC - Nervous system disorders / PT - Peripheral sensory neuropathy

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	0 (0.0)	NR (NE, NE)	106	15 (14.2)	NR (9.7, NE)	0.000 (0.000, NE)	<0.0001
White	34	1 (2.9)	NR (NE, NE)	23	7 (30.4)	NR (2.4, NE)	0.081 (0.010, 0.657)	0.0026
Interaction								0.9893

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Nervous system disorders / PT - Peripheral sensory neuropathy

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	1 (2.2)	NR (NE, NE)	34	3 (8.8)	NR (9.7, NE)	0.177 (0.018, 1.758)	0.0986
vCPS < 10%	53	0 (0.0)	NR (NE, NE)	54	10 (18.5)	NR (NE, NE)	0.000 (0.000, NE)	0.0006
Missing	41	0 (0.0)	NR (NE, NE)	41	9 (22.0)	NR (3.5, NE)	0.000 (0.000, NE)	0.0004
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Skin and subcutaneous tissue disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	20 (26.3)	NR (7.0, NE)	69	26 (37.7)	NR (1.4, NE)	0.617 (0.343, 1.109)	0.1010
>= 65 Years	63	18 (28.6)	NR (4.9, NE)	60	23 (38.3)	5.1 (1.9, NE)	0.573 (0.305, 1.077)	0.0789
Interaction								0.9201
Gender								
Male	118	34 (28.8)	NR (9.6, NE)	106	34 (32.1)	NR (5.1, NE)	0.766 (0.474, 1.237)	0.2727
Female	21	4 (19.0)	NR (2.2, NE)	23	15 (65.2)	1.4 (0.7, 1.9)	0.196 (0.064, 0.596)	0.0014
Interaction								0.0327

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Skin and subcutaneous tissue disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	27 (26.0)	NR (9.6, NE)	101	38 (37.6)	NR (2.4, NE)	0.556 (0.337, 0.917)	0.0193
Non-Smoker	35	11 (31.4)	NR (2.1, NE)	28	11 (39.3)	NR (1.9, NE)	0.757 (0.328, 1.747)	0.5103
Interaction								0.5409
ICC Options								
Paclitaxel	83	24 (28.9)	NR (4.9, NE)	79	37 (46.8)	3.0 (1.3, NE)	0.533 (0.318, 0.894)	0.0149
Docetaxel	56	14 (25.0)	10.3 (7.0, NE)	50	12 (24.0)	NR (NE, NE)	0.783 (0.358, 1.712)	0.5374
Interaction								0.3064

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Skin and subcutaneous tissue disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	13 (30.2)	NR (7.0, NE)	37	17 (45.9)	NR (0.7, NE)	0.492 (0.237, 1.021)	0.0509
1	96	25 (26.0)	NR (9.6, NE)	92	32 (34.8)	NR (1.9, NE)	0.643 (0.380, 1.090)	0.0977
Interaction								0.5389
Region #1								
Asia	103	29 (28.2)	NR (9.6, NE)	99	37 (37.4)	NR (1.9, NE)	0.605 (0.370, 0.989)	0.0420
Europe/North America	36	9 (25.0)	NR (4.9, NE)	30	12 (40.0)	NR (1.4, NE)	0.580 (0.244, 1.378)	0.2110
Interaction								0.9486

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Skin and subcutaneous tissue disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	23 (29.5)	NR (7.0, NE)	76	24 (31.6)	NR (5.1, NE)	0.822 (0.462, 1.461)	0.5014
Japan	25	6 (24.0)	NR (10.3, NE)	23	13 (56.5)	0.7 (0.5, NE)	0.222 (0.078, 0.629)	0.0020
Europe/North America	36	9 (25.0)	NR (4.9, NE)	30	12 (40.0)	NR (1.4, NE)	0.580 (0.244, 1.378)	0.2110
Interaction								0.0957

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Skin and subcutaneous tissue disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	29 (27.6)	NR (9.6, NE)	106	41 (38.7)	5.1 (1.9, NE)	0.569 (0.351, 0.920)	0.0194
White	34	9 (26.5)	NR (4.9, NE)	23	8 (34.8)	NR (1.4, NE)	0.737 (0.284, 1.911)	0.5284
Interaction								0.6495

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Skin and subcutaneous tissue disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	11 (24.4)	NR (4.9, NE)	34	14 (41.2)	5.1 (1.6, NE)	0.461 (0.208, 1.019)	0.0489
vCPS < 10%	53	22 (41.5)	7.0 (2.1, NE)	54	20 (37.0)	NR (1.4, NE)	1.076 (0.584, 1.980)	0.8143
Missing	41	5 (12.2)	NR (9.6, NE)	41	15 (36.6)	NR (1.9, NE)	0.218 (0.072, 0.658)	0.0029
Interaction								0.0460

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Skin and subcutaneous tissue disorders / PT - Alopecia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	0 (0.0)	NR (NE, NE)	69	18 (26.1)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
>= 65 Years	63	1 (1.6)	NR (18.0, NE)	60	16 (26.7)	NR (NE, NE)	0.040 (0.005, 0.314)	<0.0001
Interaction								0.9906
Gender								
Male	118	0 (0.0)	NR (NE, NE)	106	22 (20.8)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Female	21	1 (4.8)	NR (18.0, NE)	23	12 (52.2)	1.9 (0.9, NE)	0.065 (0.008, 0.506)	0.0005
Interaction								0.9898

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Skin and subcutaneous tissue disorders / PT - Alopecia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	1 (1.0)	NR (18.0, NE)	101	27 (26.7)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Non-Smoker	35	0 (0.0)	NR (NE, NE)	28	7 (25.0)	NR (1.9, NE)	0.000 (0.000, NE)	0.0011
Interaction								0.9908
ICC Options								
Paclitaxel	83	1 (1.2)	NR (18.0, NE)	79	24 (30.4)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Docetaxel	56	0 (0.0)	NR (NE, NE)	50	10 (20.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0002
Interaction								0.9888

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Skin and subcutaneous tissue disorders / PT - Alopecia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	0 (0.0)	NR (NE, NE)	37	13 (35.1)	NR (1.0, NE)	0.000 (0.000, NE)	<0.0001
1	96	1 (1.0)	NR (18.0, NE)	92	21 (22.8)	NR (NE, NE)	0.031 (0.004, 0.236)	<0.0001
Interaction								0.9894
Region #1								
Asia	103	0 (0.0)	NR (NE, NE)	99	25 (25.3)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Europe/North America	36	1 (2.8)	NR (18.0, NE)	30	9 (30.0)	NR (2.4, NE)	0.000 (0.000, NE)	0.0005
Interaction								0.9886

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Skin and subcutaneous tissue disorders / PT - Alopecia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	0 (0.0)	NR (NE, NE)	76	14 (18.4)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Japan	25	0 (0.0)	NR (NE, NE)	23	11 (47.8)	NR (0.7, NE)	0.000 (0.000, NE)	<0.0001
Europe/North America	36	1 (2.8)	NR (18.0, NE)	30	9 (30.0)	NR (2.4, NE)	0.000 (0.000, NE)	0.0005
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Skin and subcutaneous tissue disorders / PT - Alopecia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	0 (0.0)	NR (NE, NE)	106	27 (25.5)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
White	34	1 (2.9)	NR (18.0, NE)	23	7 (30.4)	NR (2.4, NE)	0.000 (0.000, NE)	0.0007
Interaction								0.9885

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.2.1.b.s:
Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Skin and subcutaneous tissue disorders / PT - Alopecia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	1 (2.2)	NR (18.0, NE)	34	10 (29.4)	NR (1.9, NE)	0.060 (0.008, 0.468)	0.0003
vCPS < 10%	53	0 (0.0)	NR (NE, NE)	54	16 (29.6)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Missing	41	0 (0.0)	NR (NE, NE)	41	8 (19.5)	NR (NE, NE)	0.000 (0.000, NE)	0.0024
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0.

System organ classes or preferred terms will only be included if they have occurred in at least 10% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	13 (8.6)	NR (NE, NE)	146	34 (23.3)	NR (NE, NE)	0.260 (0.134, 0.505)	<0.0001
>= 65 Years	103	5 (4.9)	NR (NE, NE)	94	22 (23.4)	9.2 (NE, NE)	0.145 (0.052, 0.404)	<0.0001
Interaction								0.2962
Gender								
Male	216	17 (7.9)	NR (NE, NE)	204	49 (24.0)	NR (9.2, NE)	0.235 (0.133, 0.416)	<0.0001
Female	39	1 (2.6)	NR (NE, NE)	36	7 (19.4)	NR (NE, NE)	0.120 (0.015, 0.978)	0.0173
Interaction								0.4110

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	15 (8.0)	NR (NE, NE)	183	41 (22.4)	NR (9.2, NE)	0.257 (0.139, 0.475)	<0.0001
Non-Smoker	68	3 (4.4)	NR (NE, NE)	57	15 (26.3)	NR (NE, NE)	0.128 (0.036, 0.448)	0.0002
Interaction								0.2679

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	4 (4.8)	NR (NE, NE)	79	12 (15.2)	NR (NE, NE)	0.281 (0.091, 0.872)	0.0188
Docetaxel	56	9 (16.1)	NR (7.6, NE)	50	19 (38.0)	NR (1.3, NE)	0.301 (0.134, 0.676)	0.0018
Irinotecan	116	5 (4.3)	NR (NE, NE)	111	25 (22.5)	NR (9.2, NE)	0.113 (0.039, 0.329)	<0.0001
Interaction								0.5185

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	2 (3.2)	NR (17.5, NE)	57	11 (19.3)	NR (9.2, NE)	0.059 (0.008, 0.464)	0.0003
1	192	16 (8.3)	NR (NE, NE)	183	45 (24.6)	NR (NE, NE)	0.268 (0.151, 0.476)	<0.0001
Interaction								0.3771
Region #1								
Asia	201	15 (7.5)	NR (NE, NE)	191	44 (23.0)	NR (NE, NE)	0.233 (0.127, 0.429)	<0.0001
Europe/North America	54	3 (5.6)	NR (NE, NE)	49	12 (24.5)	NR (9.2, NE)	0.180 (0.050, 0.645)	0.0032
Interaction								0.6939

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	14 (8.0)	NR (NE, NE)	168	39 (23.2)	NR (NE, NE)	0.246 (0.130, 0.465)	<0.0001
Japan	25	1 (4.0)	NR (NE, NE)	23	5 (21.7)	NR (2.8, NE)	0.146 (0.017, 1.262)	0.0427
Europe/North America	54	3 (5.6)	NR (NE, NE)	49	12 (24.5)	NR (9.2, NE)	0.180 (0.050, 0.645)	0.0032
Interaction								0.7894

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	15 (7.4)	NR (NE, NE)	198	45 (22.7)	NR (NE, NE)	0.236 (0.129, 0.433)	<0.0001
White	52	3 (5.8)	NR (NE, NE)	42	11 (26.2)	NR (9.2, NE)	0.173 (0.048, 0.628)	0.0026
Interaction								0.6350

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	7 (8.8)	NR (17.5, NE)	60	16 (26.7)	NR (NE, NE)	0.205 (0.079, 0.530)	0.0003
vCPS < 10%	100	9 (9.0)	NR (NE, NE)	119	32 (26.9)	NR (9.2, NE)	0.252 (0.119, 0.533)	0.0001
Missing	75	2 (2.7)	NR (NE, NE)	61	8 (13.1)	NR (NE, NE)	0.181 (0.038, 0.857)	0.0155
Interaction								0.8466

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	11 (7.2)	NR (NE, NE)	146	17 (11.6)	NR (NE, NE)	0.463 (0.211, 1.018)	0.0498
>= 65 Years	103	4 (3.9)	NR (NE, NE)	94	9 (9.6)	9.2 (9.2, NE)	0.276 (0.080, 0.956)	0.0311
Interaction								0.5235
Gender								
Male	216	14 (6.5)	NR (NE, NE)	204	22 (10.8)	NR (9.2, NE)	0.439 (0.219, 0.880)	0.0171
Female	39	1 (2.6)	NR (NE, NE)	36	4 (11.1)	NR (NE, NE)	0.219 (0.024, 1.958)	0.1354
Interaction								0.4329

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	12 (6.4)	NR (NE, NE)	183	19 (10.4)	NR (9.2, NE)	0.451 (0.212, 0.957)	0.0333
Non-Smoker	68	3 (4.4)	NR (NE, NE)	57	7 (12.3)	NR (NE, NE)	0.290 (0.074, 1.137)	0.0593
Interaction								0.5273

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	4 (4.8)	NR (NE, NE)	79	6 (7.6)	NR (NE, NE)	0.582 (0.164, 2.065)	0.3961
Docetaxel	56	6 (10.7)	NR (NE, NE)	50	4 (8.0)	NR (NE, NE)	1.130 (0.317, 4.034)	0.8505
Irinotecan	116	5 (4.3)	NR (NE, NE)	111	16 (14.4)	NR (9.2, NE)	0.170 (0.055, 0.523)	0.0005
Interaction								0.1251

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	1 (1.6)	NR (17.5, NE)	57	3 (5.3)	NR (9.2, NE)	0.000 (0.000, NE)	0.0169
1	192	14 (7.3)	NR (NE, NE)	183	23 (12.6)	NR (NE, NE)	0.473 (0.242, 0.924)	0.0249
Interaction								0.6024
Region #1								
Asia	201	12 (6.0)	NR (NE, NE)	191	20 (10.5)	NR (NE, NE)	0.434 (0.208, 0.906)	0.0222
Europe/North America	54	3 (5.6)	NR (NE, NE)	49	6 (12.2)	NR (9.2, NE)	0.364 (0.089, 1.489)	0.1436
Interaction								0.8607

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	11 (6.3)	NR (NE, NE)	168	17 (10.1)	NR (NE, NE)	0.472 (0.217, 1.030)	0.0538
Japan	25	1 (4.0)	NR (NE, NE)	23	3 (13.0)	NR (2.8, NE)	0.253 (0.026, 2.451)	0.2007
Europe/North America	54	3 (5.6)	NR (NE, NE)	49	6 (12.2)	NR (9.2, NE)	0.364 (0.089, 1.489)	0.1436
Interaction								0.8153

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	203	12 (5.9)	NR (NE, NE)	198	21 (10.6)	NR (NE, NE)	0.428 (0.207, 0.887)	0.0189
White	52	3 (5.8)	NR (NE, NE)	42	5 (11.9)	NR (9.2, NE)	0.387 (0.091, 1.655)	0.1851
Interaction								0.9361

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Anaemia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	6 (7.5)	NR (17.5, NE)	60	5 (8.3)	NR (NE, NE)	0.596 (0.177, 2.012)	0.3998
vCPS < 10%	100	7 (7.0)	NR (NE, NE)	119	18 (15.1)	NR (9.2, NE)	0.372 (0.154, 0.900)	0.0225
Missing	75	2 (2.7)	NR (NE, NE)	61	3 (4.9)	NR (NE, NE)	0.478 (0.079, 2.892)	0.4111
Interaction								0.7577

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	152	0 (0.0)	--	146	6 (4.1)	--	--	--
>= 65 Years	103	0 (0.0)	--	94	5 (5.3)	--	--	--
Interaction								--
Gender								
Male	216	0 (0.0)	NR (NE, NE)	204	10 (4.9)	NR (NE, NE)	0.000 (0.000, NE)	0.0006
Female	39	0 (0.0)	NR (NE, NE)	36	1 (2.8)	NR (NE, NE)	0.000 (0.000, NE)	0.2980
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	0 (0.0)	--	183	8 (4.4)	--	--	--
Non-Smoker	68	0 (0.0)	--	57	3 (5.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	0 (0.0)	--	79	0 (0.0)	--	--	--
Docetaxel	56	0 (0.0)	--	50	8 (16.0)	--	--	--
Irinotecan	116	0 (0.0)	--	111	3 (2.7)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	0 (0.0)	--	57	2 (3.5)	--	--	--
1	192	0 (0.0)	--	183	9 (4.9)	--	--	--
Interaction								--
Region #1								
Asia	201	0 (0.0)	--	191	9 (4.7)	--	--	--
Europe/North America	54	0 (0.0)	--	49	2 (4.1)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Region #2								
Asia (excluding Japan)	176	0 (0.0)	--	168	7 (4.2)	--	--	--
Japan	25	0 (0.0)	--	23	2 (8.7)	--	--	--
Europe/North America	54	0 (0.0)	--	49	2 (4.1)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	0 (0.0)	--	198	9 (4.5)	--	--	--
White	52	0 (0.0)	--	42	2 (4.8)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	0 (0.0)	--	60	4 (6.7)	--	--	--
vCPS < 10%	100	0 (0.0)	--	119	3 (2.5)	--	--	--
Missing	75	0 (0.0)	--	61	4 (6.6)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	0 (0.0)	NR (NE, NE)	146	11 (7.5)	NR (NE, NE)	0.000 (0.000, NE)	0.0006
>= 65 Years	103	0 (0.0)	NR (NE, NE)	94	6 (6.4)	NR (NE, NE)	0.000 (0.000, NE)	0.0090
Interaction								1.0000
Gender								
Male	216	0 (0.0)	NR (NE, NE)	204	16 (7.8)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Female	39	0 (0.0)	NR (NE, NE)	36	1 (2.8)	NR (NE, NE)	0.000 (0.000, NE)	0.3042
Interaction								0.9998

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	0 (0.0)	NR (NE, NE)	183	11 (6.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0006
Non-Smoker	68	0 (0.0)	NR (NE, NE)	57	6 (10.5)	NR (NE, NE)	0.000 (0.000, NE)	0.0066
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	0 (0.0)	--	79	1 (1.3)	--	--	--
Docetaxel	56	0 (0.0)	--	50	7 (14.0)	--	--	--
Irinotecan	116	0 (0.0)	--	111	9 (8.1)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	0 (0.0)	NR (NE, NE)	57	4 (7.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0330
1	192	0 (0.0)	NR (NE, NE)	183	13 (7.1)	NR (NE, NE)	0.000 (0.000, NE)	0.0002
Interaction								1.0000
Region #1								
Asia	201	0 (0.0)	NR (NE, NE)	191	16 (8.4)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	0.000 (0.000, NE)	0.2888
Interaction								0.9997

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

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Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	0 (0.0)	NR (NE, NE)	168	16 (9.5)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Japan	25	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	0.000 (0.000, NE)	0.2888
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	203	0 (0.0)	NR (NE, NE)	198	16 (8.1)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
White	52	0 (0.0)	NR (NE, NE)	42	1 (2.4)	NR (NE, NE)	0.000 (0.000, NE)	0.2601
Interaction								0.9997

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	0 (0.0)	NR (NE, NE)	60	6 (10.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0033
vCPS < 10%	100	0 (0.0)	NR (NE, NE)	119	10 (8.4)	NR (NE, NE)	0.000 (0.000, NE)	0.0030
Missing	75	0 (0.0)	NR (NE, NE)	61	1 (1.6)	NR (NE, NE)	0.000 (0.000, NE)	0.2668
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	1 (0.7)	--	146	8 (5.5)	--	--	--
>= 65 Years	103	0 (0.0)	--	94	8 (8.5)	--	--	--
Interaction								--
Gender								
Male	216	1 (0.5)	NR (NE, NE)	204	14 (6.9)	NR (NE, NE)	0.056 (0.007, 0.436)	0.0002
Female	39	0 (0.0)	NR (NE, NE)	36	2 (5.6)	NR (NE, NE)	0.000 (0.000, NE)	0.1435
Interaction								0.9917

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	1 (0.5)	NR (NE, NE)	183	11 (6.0)	NR (NE, NE)	0.071 (0.009, 0.563)	0.0013
Non-Smoker	68	0 (0.0)	NR (NE, NE)	57	5 (8.8)	NR (NE, NE)	0.000 (0.000, NE)	0.0130
Interaction								0.9927

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ICC Options								
Paclitaxel	83	0 (0.0)	--	79	5 (6.3)	--	--	--
Docetaxel	56	1 (1.8)	--	50	7 (14.0)	--	--	--
Irinotecan	116	0 (0.0)	--	111	4 (3.6)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	1 (1.6)	NR (NE, NE)	57	4 (7.0)	NR (NE, NE)	0.180 (0.020, 1.653)	0.0894
1	192	0 (0.0)	NR (NE, NE)	183	12 (6.6)	NR (NE, NE)	0.000 (0.000, NE)	0.0003
Interaction								0.9915
Region #1								
Asia	201	1 (0.5)	NR (NE, NE)	191	11 (5.8)	NR (NE, NE)	0.068 (0.009, 0.546)	0.0011
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	5 (10.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0152
Interaction								0.9903

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	1 (0.6)	NR (NE, NE)	168	11 (6.5)	NR (NE, NE)	0.068 (0.008, 0.543)	0.0011
Japan	25	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	5 (10.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0152
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	203	1 (0.5)	NR (NE, NE)	198	11 (5.6)	NR (NE, NE)	0.070 (0.009, 0.559)	0.0013
White	52	0 (0.0)	NR (NE, NE)	42	5 (11.9)	NR (NE, NE)	0.000 (0.000, NE)	0.0096
Interaction								0.9913

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Baseline PD-L1 Status								
vCPS >= 10%	80	0 (0.0)	NR (NE, NE)	60	3 (5.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0416
vCPS < 10%	100	1 (1.0)	NR (NE, NE)	119	10 (8.4)	NR (NE, NE)	0.094 (0.012, 0.756)	0.0065
Missing	75	0 (0.0)	NR (NE, NE)	61	3 (4.9)	NR (NE, NE)	0.000 (0.000, NE)	0.0530
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	26 (17.1)	NR (20.9, NE)	146	27 (18.5)	NR (8.9, NE)	0.634 (0.363, 1.106)	0.1054
>= 65 Years	103	13 (12.6)	NR (NE, NE)	94	18 (19.1)	NR (6.1, NE)	0.526 (0.255, 1.087)	0.0776
Interaction								0.4205
Gender								
Male	216	36 (16.7)	NR (27.6, NE)	204	38 (18.6)	NR (8.9, NE)	0.646 (0.404, 1.033)	0.0659
Female	39	3 (7.7)	NR (NE, NE)	36	7 (19.4)	NR (NE, NE)	0.346 (0.089, 1.342)	0.1077
Interaction								0.2550

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	29 (15.5)	NR (27.6, NE)	183	34 (18.6)	NR (8.9, NE)	0.616 (0.371, 1.024)	0.0589
Non-Smoker	68	10 (14.7)	NR (20.9, NE)	57	11 (19.3)	NR (NE, NE)	0.568 (0.237, 1.360)	0.1984
Interaction								0.9164

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	11 (13.3)	NR (27.6, NE)	79	9 (11.4)	NR (8.9, NE)	0.909 (0.367, 2.254)	0.8372
Docetaxel	56	8 (14.3)	NR (9.7, NE)	50	5 (10.0)	NR (6.1, NE)	1.075 (0.344, 3.359)	0.9010
Irinotecan	116	20 (17.2)	NR (20.9, NE)	111	31 (27.9)	NR (NE, NE)	0.411 (0.229, 0.738)	0.0021
Interaction								0.1142

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	5 (7.9)	NR (NE, NE)	57	9 (15.8)	NR (8.9, NE)	0.381 (0.126, 1.154)	0.0764
1	192	34 (17.7)	NR (20.9, NE)	183	36 (19.7)	NR (NE, NE)	0.653 (0.403, 1.056)	0.0799
Interaction								0.3468
Region #1								
Asia	201	29 (14.4)	NR (27.6, NE)	191	31 (16.2)	NR (NE, NE)	0.644 (0.382, 1.085)	0.0954
Europe/North America	54	10 (18.5)	NR (NE, NE)	49	14 (28.6)	8.9 (6.1, NE)	0.525 (0.232, 1.190)	0.1164
Interaction								0.6055

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	27 (15.3)	NR (20.9, NE)	168	28 (16.7)	NR (NE, NE)	0.659 (0.382, 1.136)	0.1306
Japan	25	2 (8.0)	NR (NE, NE)	23	3 (13.0)	NR (2.4, NE)	0.525 (0.087, 3.174)	0.4757
Europe/North America	54	10 (18.5)	NR (NE, NE)	49	14 (28.6)	8.9 (6.1, NE)	0.525 (0.232, 1.190)	0.1164
Interaction								0.7935

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	30 (14.8)	NR (27.6, NE)	198	32 (16.2)	NR (NE, NE)	0.669 (0.401, 1.117)	0.1214
White	52	9 (17.3)	NR (NE, NE)	42	13 (31.0)	8.9 (6.1, NE)	0.440 (0.187, 1.037)	0.0536
Interaction								0.3526

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	12 (15.0)	NR (NE, NE)	60	16 (26.7)	NR (8.9, NE)	0.331 (0.154, 0.714)	0.0032
vCPS < 10%	100	18 (18.0)	NR (27.6, NE)	119	24 (20.2)	NR (6.1, NE)	0.716 (0.383, 1.338)	0.2924
Missing	75	9 (12.0)	NR (20.9, NE)	61	5 (8.2)	NR (NE, NE)	1.159 (0.377, 3.563)	0.7969
Interaction								0.1751

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	2 (1.3)	--	146	7 (4.8)	--	--	--
>= 65 Years	103	1 (1.0)	--	94	8 (8.5)	--	--	--
Interaction								--
Gender								
Male	216	3 (1.4)	NR (NE, NE)	204	13 (6.4)	NR (NE, NE)	0.192 (0.054, 0.675)	0.0041
Female	39	0 (0.0)	NR (NE, NE)	36	2 (5.6)	NR (NE, NE)	0.000 (0.000, NE)	0.1408
Interaction								0.9900

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	3 (1.6)	NR (NE, NE)	183	11 (6.0)	NR (NE, NE)	0.232 (0.065, 0.835)	0.0148
Non-Smoker	68	0 (0.0)	NR (NE, NE)	57	4 (7.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0283
Interaction								0.9912

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	1 (1.2)	NR (NE, NE)	79	2 (2.5)	NR (NE, NE)	0.464 (0.042, 5.115)	0.5202
Docetaxel	56	0 (0.0)	NR (NE, NE)	50	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Irinotecan	116	2 (1.7)	NR (NE, NE)	111	13 (11.7)	NR (NE, NE)	0.123 (0.028, 0.549)	0.0011
Interaction								0.6492

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	0 (0.0)	NR (NE, NE)	57	2 (3.5)	NR (NE, NE)	0.000 (0.000, NE)	0.1351
1	192	3 (1.6)	NR (NE, NE)	183	13 (7.1)	NR (NE, NE)	0.192 (0.055, 0.677)	0.0042
Interaction								0.9921
Region #1								
Asia	201	3 (1.5)	NR (NE, NE)	191	11 (5.8)	NR (NE, NE)	0.224 (0.062, 0.807)	0.0123
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	4 (8.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0310
Interaction								0.9920

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	3 (1.7)	NR (NE, NE)	168	11 (6.5)	NR (NE, NE)	0.222 (0.062, 0.801)	0.0118
Japan	25	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	4 (8.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0310
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	203	3 (1.5)	NR (NE, NE)	198	11 (5.6)	NR (NE, NE)	0.232 (0.064, 0.834)	0.0148
White	52	0 (0.0)	NR (NE, NE)	42	4 (9.5)	NR (NE, NE)	0.000 (0.000, NE)	0.0215
Interaction								0.9923

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Gastrointestinal disorders / PT - Diarrhoea

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	1 (1.3)	NR (NE, NE)	60	5 (8.3)	NR (NE, NE)	0.117 (0.014, 1.012)	0.0199
vCPS < 10%	100	2 (2.0)	NR (NE, NE)	119	10 (8.4)	NR (NE, NE)	0.218 (0.048, 0.996)	0.0307
Missing	75	0 (0.0)	NR (NE, NE)	61	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9228

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	8 (5.3)	37.2 (NE, NE)	146	12 (8.2)	NR (NE, NE)	0.363 (0.135, 0.977)	0.0370
>= 65 Years	103	8 (7.8)	NR (NE, NE)	94	13 (13.8)	NR (NE, NE)	0.405 (0.162, 1.011)	0.0459
Interaction								0.7910
Gender								
Male	216	14 (6.5)	NR (37.2, NE)	204	19 (9.3)	NR (NE, NE)	0.423 (0.200, 0.897)	0.0209
Female	39	2 (5.1)	NR (NE, NE)	36	6 (16.7)	NR (2.6, NE)	0.238 (0.047, 1.198)	0.0596
Interaction								0.4681

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	9 (4.8)	NR (37.2, NE)	183	17 (9.3)	NR (NE, NE)	0.281 (0.110, 0.716)	0.0046
Non-Smoker	68	7 (10.3)	NR (NE, NE)	57	8 (14.0)	NR (3.7, NE)	0.522 (0.185, 1.470)	0.2112
Interaction								0.4382

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	8 (9.6)	NR (37.2, NE)	79	6 (7.6)	NR (NE, NE)	0.837 (0.268, 2.607)	0.7580
Docetaxel	56	4 (7.1)	NR (13.3, NE)	50	5 (10.0)	NR (3.7, NE)	0.539 (0.141, 2.060)	0.3594
Irinotecan	116	4 (3.4)	NR (NE, NE)	111	14 (12.6)	NR (NE, NE)	0.193 (0.062, 0.603)	0.0018
Interaction								0.1015

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	2 (3.2)	NR (NE, NE)	57	4 (7.0)	NR (5.7, NE)	0.156 (0.017, 1.416)	0.0594
1	192	14 (7.3)	37.2 (37.2, NE)	183	21 (11.5)	NR (NE, NE)	0.425 (0.209, 0.865)	0.0152
Interaction								0.7294
Region #1								
Asia	201	11 (5.5)	NR (37.2, NE)	191	14 (7.3)	NR (NE, NE)	0.441 (0.186, 1.044)	0.0564
Europe/North America	54	5 (9.3)	NR (NE, NE)	49	11 (22.4)	NR (5.6, NE)	0.350 (0.121, 1.010)	0.0422
Interaction								0.6307

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	9 (5.1)	37.2 (37.2, NE)	168	14 (8.3)	NR (NE, NE)	0.347 (0.137, 0.882)	0.0207
Japan	25	2 (8.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	58857345.823 (0.000, NE)	0.2435
Europe/North America	54	5 (9.3)	NR (NE, NE)	49	11 (22.4)	NR (5.6, NE)	0.350 (0.121, 1.010)	0.0422
Interaction								0.9757

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	11 (5.4)	NR (37.2, NE)	198	16 (8.1)	NR (NE, NE)	0.384 (0.165, 0.891)	0.0213
White	52	5 (9.6)	NR (NE, NE)	42	9 (21.4)	NR (5.6, NE)	0.388 (0.130, 1.161)	0.0787
Interaction								0.8227

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - General disorders and administration site conditions

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	5 (6.3)	NR (NE, NE)	60	8 (13.3)	NR (NE, NE)	0.318 (0.101, 0.998)	0.0393
vCPS < 10%	100	5 (5.0)	37.2 (13.3, NE)	119	16 (13.4)	NR (5.7, NE)	0.118 (0.027, 0.517)	0.0007
Missing	75	6 (8.0)	NR (NE, NE)	61	1 (1.6)	NR (NE, NE)	4.314 (0.517, 35.993)	0.1409
Interaction								0.0673

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	16 (10.5)	NR (NE, NE)	146	17 (11.6)	NR (NE, NE)	0.699 (0.347, 1.409)	0.3146
>= 65 Years	103	8 (7.8)	NR (30.4, NE)	94	16 (17.0)	9.2 (9.2, NE)	0.233 (0.088, 0.618)	0.0017
Interaction								0.2005
Gender								
Male	216	23 (10.6)	NR (30.4, NE)	204	29 (14.2)	NR (9.2, NE)	0.506 (0.283, 0.904)	0.0191
Female	39	1 (2.6)	NR (7.3, NE)	36	4 (11.1)	NR (NE, NE)	0.166 (0.018, 1.533)	0.0748
Interaction								0.3224

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	19 (10.2)	NR (30.4, NE)	183	28 (15.3)	NR (9.2, NE)	0.427 (0.228, 0.802)	0.0065
Non-Smoker	68	5 (7.4)	NR (NE, NE)	57	5 (8.8)	NR (4.9, NE)	0.634 (0.180, 2.233)	0.4742
Interaction								0.6193

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	13 (15.7)	NR (30.4, NE)	79	12 (15.2)	NR (NE, NE)	0.804 (0.356, 1.817)	0.5998
Docetaxel	56	3 (5.4)	NR (NE, NE)	50	7 (14.0)	NR (NE, NE)	0.313 (0.081, 1.215)	0.0762
Irinotecan	116	8 (6.9)	NR (15.8, NE)	111	14 (12.6)	NR (9.2, NE)	0.296 (0.110, 0.795)	0.0109
Interaction								0.3459

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	5 (7.9)	30.4 (15.8, NE)	57	6 (10.5)	NR (9.2, NE)	0.320 (0.078, 1.317)	0.0979
1	192	19 (9.9)	NR (NE, NE)	183	27 (14.8)	NR (NE, NE)	0.506 (0.277, 0.924)	0.0240
Interaction								0.8711
Region #1								
Asia	201	18 (9.0)	NR (30.4, NE)	191	21 (11.0)	NR (NE, NE)	0.550 (0.283, 1.071)	0.0747
Europe/North America	54	6 (11.1)	NR (NE, NE)	49	12 (24.5)	9.2 (4.9, NE)	0.371 (0.137, 0.999)	0.0413
Interaction								0.4219

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	16 (9.1)	NR (NE, NE)	168	16 (9.5)	NR (NE, NE)	0.676 (0.329, 1.390)	0.2837
Japan	25	2 (8.0)	30.4 (NE, NE)	23	5 (21.7)	NR (3.4, NE)	0.162 (0.019, 1.393)	0.0585
Europe/North America	54	6 (11.1)	NR (NE, NE)	49	12 (24.5)	9.2 (4.9, NE)	0.371 (0.137, 0.999)	0.0413
Interaction								0.3798

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	19 (9.4)	NR (30.4, NE)	198	23 (11.6)	NR (NE, NE)	0.559 (0.295, 1.062)	0.0718
White	52	5 (9.6)	NR (NE, NE)	42	10 (23.8)	9.2 (4.9, NE)	0.323 (0.109, 0.955)	0.0316
Interaction								0.3355

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	5 (6.3)	NR (15.8, NE)	60	7 (11.7)	NR (NE, NE)	0.281 (0.079, 1.006)	0.0390
vCPS < 10%	100	16 (16.0)	NR (NE, NE)	119	19 (16.0)	NR (9.2, NE)	0.793 (0.402, 1.561)	0.5006
Missing	75	3 (4.0)	NR (13.7, NE)	61	7 (11.5)	NR (NE, NE)	0.190 (0.039, 0.924)	0.0219
Interaction								0.2375

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations / PT - Pneumonia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	10 (6.6)	NR (NE, NE)	146	6 (4.1)	NR (NE, NE)	1.157 (0.409, 3.272)	0.7839
>= 65 Years	103	3 (2.9)	NR (30.4, NE)	94	11 (11.7)	NR (NE, NE)	0.092 (0.018, 0.474)	0.0007
Interaction								0.0202
Gender								
Male	216	13 (6.0)	NR (30.4, NE)	204	15 (7.4)	NR (NE, NE)	0.520 (0.235, 1.151)	0.1012
Female	39	0 (0.0)	NR (NE, NE)	36	2 (5.6)	NR (NE, NE)	0.000 (0.000, NE)	0.1082
Interaction								0.9898

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations / PT - Pneumonia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	9 (4.8)	NR (30.4, NE)	183	14 (7.7)	NR (NE, NE)	0.357 (0.140, 0.912)	0.0249
Non-Smoker	68	4 (5.9)	NR (NE, NE)	57	3 (5.3)	NR (NE, NE)	0.876 (0.191, 4.015)	0.8645
Interaction								0.4056

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations / PT - Pneumonia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	5 (6.0)	NR (30.4, NE)	79	6 (7.6)	NR (NE, NE)	0.496 (0.133, 1.848)	0.2874
Docetaxel	56	3 (5.4)	NR (NE, NE)	50	5 (10.0)	NR (NE, NE)	0.435 (0.104, 1.829)	0.2427
Irinotecan	116	5 (4.3)	NR (15.8, NE)	111	6 (5.4)	NR (NE, NE)	0.434 (0.117, 1.606)	0.2004
Interaction								0.9589

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations / PT - Pneumonia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	2 (3.2)	30.4 (15.8, NE)	57	2 (3.5)	NR (NE, NE)	0.000 (0.000, NE)	0.1342
1	192	11 (5.7)	NR (NE, NE)	183	15 (8.2)	NR (NE, NE)	0.510 (0.230, 1.132)	0.0920
Interaction								0.7837
Region #1								
Asia	201	12 (6.0)	NR (30.4, NE)	191	13 (6.8)	NR (NE, NE)	0.564 (0.244, 1.299)	0.1730
Europe/North America	54	1 (1.9)	NR (NE, NE)	49	4 (8.2)	NR (NE, NE)	0.186 (0.021, 1.669)	0.0922
Interaction								0.2779

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations / PT - Pneumonia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	11 (6.3)	NR (NE, NE)	168	10 (6.0)	NR (NE, NE)	0.718 (0.295, 1.745)	0.4626
Japan	25	1 (4.0)	30.4 (NE, NE)	23	3 (13.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0704
Europe/North America	54	1 (1.9)	NR (NE, NE)	49	4 (8.2)	NR (NE, NE)	0.186 (0.021, 1.669)	0.0922
Interaction								0.3260

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations / PT - Pneumonia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	12 (5.9)	NR (30.4, NE)	198	14 (7.1)	NR (NE, NE)	0.540 (0.237, 1.227)	0.1357
White	52	1 (1.9)	NR (NE, NE)	42	3 (7.1)	NR (NE, NE)	0.217 (0.023, 2.095)	0.1467
Interaction								0.3710

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Infections and infestations / PT - Pneumonia

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	4 (5.0)	NR (15.8, NE)	60	3 (5.0)	NR (NE, NE)	0.439 (0.082, 2.366)	0.3272
vCPS < 10%	100	8 (8.0)	NR (NE, NE)	119	10 (8.4)	NR (NE, NE)	0.717 (0.278, 1.852)	0.4902
Missing	75	1 (1.3)	NR (NE, NE)	61	4 (6.6)	NR (NE, NE)	0.176 (0.019, 1.591)	0.0817
Interaction								0.4184

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	16 (10.5)	NR (NE, NE)	146	49 (33.6)	NR (4.1, NE)	0.211 (0.117, 0.381)	<0.0001
>= 65 Years	103	9 (8.7)	NR (NE, NE)	94	41 (43.6)	NR (1.2, NE)	0.129 (0.060, 0.276)	<0.0001
Interaction								0.2507
Gender								
Male	216	22 (10.2)	NR (NE, NE)	204	82 (40.2)	NR (2.1, NE)	0.162 (0.099, 0.267)	<0.0001
Female	39	3 (7.7)	NR (NE, NE)	36	8 (22.2)	NR (NE, NE)	0.277 (0.073, 1.055)	0.0442
Interaction								0.5203

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	17 (9.1)	NR (NE, NE)	183	68 (37.2)	NR (4.1, NE)	0.153 (0.087, 0.269)	<0.0001
Non-Smoker	68	8 (11.8)	NR (NE, NE)	57	22 (38.6)	NR (1.0, NE)	0.237 (0.105, 0.535)	0.0002
Interaction								0.5944

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	6 (7.2)	NR (NE, NE)	79	24 (30.4)	NR (4.1, NE)	0.185 (0.075, 0.456)	<0.0001
Docetaxel	56	6 (10.7)	NR (13.8, NE)	50	27 (54.0)	1.0 (0.3, NE)	0.108 (0.041, 0.285)	<0.0001
Irinotecan	116	13 (11.2)	NR (NE, NE)	111	39 (35.1)	NR (2.1, NE)	0.208 (0.108, 0.403)	<0.0001
Interaction								0.3980

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	4 (6.3)	NR (NE, NE)	57	19 (33.3)	NR (2.4, NE)	0.105 (0.031, 0.362)	<0.0001
1	192	21 (10.9)	NR (NE, NE)	183	71 (38.8)	NR (2.1, NE)	0.193 (0.117, 0.319)	<0.0001
Interaction								0.4637
Region #1								
Asia	201	21 (10.4)	NR (NE, NE)	191	81 (42.4)	4.1 (2.0, NE)	0.149 (0.090, 0.249)	<0.0001
Europe/North America	54	4 (7.4)	NR (NE, NE)	49	9 (18.4)	NR (NE, NE)	0.347 (0.106, 1.132)	0.0654
Interaction								0.2540

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	19 (10.8)	NR (NE, NE)	168	71 (42.3)	4.1 (1.4, NE)	0.155 (0.090, 0.265)	<0.0001
Japan	25	2 (8.0)	NR (NE, NE)	23	10 (43.5)	NR (0.5, NE)	0.125 (0.026, 0.593)	0.0018
Europe/North America	54	4 (7.4)	NR (NE, NE)	49	9 (18.4)	NR (NE, NE)	0.347 (0.106, 1.132)	0.0654
Interaction								0.4436

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	21 (10.3)	NR (NE, NE)	198	84 (42.4)	4.1 (2.0, NE)	0.149 (0.090, 0.247)	<0.0001
White	52	4 (7.7)	NR (NE, NE)	42	6 (14.3)	NR (NE, NE)	0.469 (0.132, 1.671)	0.2304
Interaction								0.1264

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	7 (8.8)	NR (NE, NE)	60	22 (36.7)	4.1 (2.0, NE)	0.138 (0.057, 0.334)	<0.0001
vCPS < 10%	100	8 (8.0)	NR (13.8, NE)	119	48 (40.3)	NR (1.4, NE)	0.134 (0.061, 0.298)	<0.0001
Missing	75	10 (13.3)	NR (13.8, NE)	61	20 (32.8)	NR (NE, NE)	0.283 (0.127, 0.627)	0.0008
Interaction								0.3515

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	5 (3.3)	NR (NE, NE)	146	7 (4.8)	NR (NE, NE)	0.618 (0.195, 1.954)	0.4070
>= 65 Years	103	1 (1.0)	NR (NE, NE)	94	11 (11.7)	NR (NE, NE)	0.072 (0.009, 0.563)	0.0010
Interaction								0.0796
Gender								
Male	216	5 (2.3)	NR (NE, NE)	204	15 (7.4)	NR (NE, NE)	0.278 (0.101, 0.769)	0.0083
Female	39	1 (2.6)	NR (NE, NE)	36	3 (8.3)	NR (NE, NE)	0.247 (0.025, 2.434)	0.1969
Interaction								0.9868

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	5 (2.7)	NR (NE, NE)	183	13 (7.1)	NR (NE, NE)	0.334 (0.119, 0.942)	0.0291
Non-Smoker	68	1 (1.5)	NR (NE, NE)	57	5 (8.8)	NR (NE, NE)	0.145 (0.017, 1.246)	0.0414
Interaction								0.5258

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	0 (0.0)	NR (NE, NE)	79	3 (3.8)	NR (NE, NE)	0.000 (0.000, NE)	0.0734
Docetaxel	56	2 (3.6)	NR (NE, NE)	50	6 (12.0)	NR (NE, NE)	0.264 (0.053, 1.315)	0.0786
Irinotecan	116	4 (3.4)	NR (NE, NE)	111	9 (8.1)	NR (NE, NE)	0.325 (0.097, 1.086)	0.0556
Interaction								0.9435

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	1 (1.6)	NR (NE, NE)	57	6 (10.5)	NR (NE, NE)	0.125 (0.015, 1.051)	0.0237
1	192	5 (2.6)	NR (NE, NE)	183	12 (6.6)	NR (NE, NE)	0.356 (0.125, 1.015)	0.0431
Interaction								0.4178
Region #1								
Asia	201	5 (2.5)	NR (NE, NE)	191	15 (7.9)	NR (NE, NE)	0.267 (0.096, 0.741)	0.0065
Europe/North America	54	1 (1.9)	NR (NE, NE)	49	3 (6.1)	NR (NE, NE)	0.288 (0.030, 2.768)	0.2492
Interaction								0.9891

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	5 (2.8)	NR (NE, NE)	168	13 (7.7)	NR (NE, NE)	0.305 (0.108, 0.861)	0.0177
Japan	25	0 (0.0)	NR (NE, NE)	23	2 (8.7)	NR (NE, NE)	0.000 (0.000, NE)	0.1361
Europe/North America	54	1 (1.9)	NR (NE, NE)	49	3 (6.1)	NR (NE, NE)	0.288 (0.030, 2.768)	0.2492
Interaction								0.9912

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	5 (2.5)	NR (NE, NE)	198	16 (8.1)	NR (NE, NE)	0.259 (0.094, 0.712)	0.0048
White	52	1 (1.9)	NR (NE, NE)	42	2 (4.8)	NR (NE, NE)	0.386 (0.035, 4.257)	0.4180
Interaction								0.8151

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	0 (0.0)	NR (NE, NE)	60	3 (5.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0355
vCPS < 10%	100	4 (4.0)	NR (NE, NE)	119	12 (10.1)	NR (NE, NE)	0.348 (0.112, 1.082)	0.0556
Missing	75	2 (2.7)	NR (NE, NE)	61	3 (4.9)	NR (NE, NE)	0.452 (0.074, 2.774)	0.3797
Interaction								0.9571

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	0 (0.0)	NR (NE, NE)	146	35 (24.0)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
>= 65 Years	103	0 (0.0)	NR (NE, NE)	94	28 (29.8)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9999
Gender								
Male	216	0 (0.0)	NR (NE, NE)	204	57 (27.9)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Female	39	0 (0.0)	NR (NE, NE)	36	6 (16.7)	NR (NE, NE)	0.000 (0.000, NE)	0.0089
Interaction								0.9998

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	0 (0.0)	NR (NE, NE)	183	50 (27.3)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Non-Smoker	68	0 (0.0)	NR (NE, NE)	57	13 (22.8)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	0 (0.0)	NR (NE, NE)	79	19 (24.1)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Docetaxel	56	0 (0.0)	NR (NE, NE)	50	19 (38.0)	NR (1.0, NE)	0.000 (0.000, NE)	<0.0001
Irinotecan	116	0 (0.0)	NR (NE, NE)	111	25 (22.5)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	0 (0.0)	NR (NE, NE)	57	14 (24.6)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
1	192	0 (0.0)	NR (NE, NE)	183	49 (26.8)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9999
Region #1								
Asia	201	0 (0.0)	NR (NE, NE)	191	58 (30.4)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	5 (10.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0137
Interaction								0.9995

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	0 (0.0)	NR (NE, NE)	168	49 (29.2)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Japan	25	0 (0.0)	NR (NE, NE)	23	9 (39.1)	NR (0.5, NE)	0.000 (0.000, NE)	0.0005
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	5 (10.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0137
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	203	0 (0.0)	NR (NE, NE)	198	59 (29.8)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
White	52	0 (0.0)	NR (NE, NE)	42	4 (9.5)	NR (NE, NE)	0.000 (0.000, NE)	0.0187
Interaction								0.9994

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	0 (0.0)	NR (NE, NE)	60	15 (25.0)	NR (4.1, NE)	0.000 (0.000, NE)	<0.0001
vCPS < 10%	100	0 (0.0)	NR (NE, NE)	119	34 (28.6)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Missing	75	0 (0.0)	NR (NE, NE)	61	14 (23.0)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

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Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	1 (0.7)	NR (NE, NE)	146	29 (19.9)	NR (NE, NE)	0.028 (0.004, 0.208)	<0.0001
>= 65 Years	103	0 (0.0)	NR (NE, NE)	94	19 (20.2)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9859
Gender								
Male	216	1 (0.5)	NR (NE, NE)	204	42 (20.6)	NR (NE, NE)	0.020 (0.003, 0.144)	<0.0001
Female	39	0 (0.0)	NR (NE, NE)	36	6 (16.7)	NR (NE, NE)	0.000 (0.000, NE)	0.0084
Interaction								0.9876

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	0 (0.0)	NR (NE, NE)	183	34 (18.6)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Non-Smoker	68	1 (1.5)	NR (NE, NE)	57	14 (24.6)	NR (NE, NE)	0.050 (0.006, 0.378)	<0.0001
Interaction								0.9874

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	0 (0.0)	NR (NE, NE)	79	8 (10.1)	NR (NE, NE)	0.000 (0.000, NE)	0.0029
Docetaxel	56	0 (0.0)	NR (NE, NE)	50	20 (40.0)	NR (1.0, NE)	0.000 (0.000, NE)	<0.0001
Irinotecan	116	1 (0.9)	NR (NE, NE)	111	20 (18.0)	NR (NE, NE)	0.040 (0.005, 0.300)	<0.0001
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	0 (0.0)	NR (NE, NE)	57	12 (21.1)	NR (NE, NE)	0.000 (0.000, NE)	0.0001
1	192	1 (0.5)	NR (NE, NE)	183	36 (19.7)	NR (NE, NE)	0.023 (0.003, 0.170)	<0.0001
Interaction								0.9890
Region #1								
Asia	201	1 (0.5)	NR (NE, NE)	191	46 (24.1)	NR (NE, NE)	0.018 (0.002, 0.130)	<0.0001
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	2 (4.1)	NR (NE, NE)	0.000 (0.000, NE)	0.1324
Interaction								0.9884

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

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Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	1 (0.6)	NR (NE, NE)	168	37 (22.0)	NR (NE, NE)	0.022 (0.003, 0.164)	<0.0001
Japan	25	0 (0.0)	NR (NE, NE)	23	9 (39.1)	NR (0.5, NE)	0.000 (0.000, NE)	0.0005
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	2 (4.1)	NR (NE, NE)	0.000 (0.000, NE)	0.1324
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	1 (0.5)	NR (NE, NE)	198	47 (23.7)	NR (NE, NE)	0.018 (0.002, 0.131)	<0.0001
White	52	0 (0.0)	NR (NE, NE)	42	1 (2.4)	NR (NE, NE)	0.000 (0.000, NE)	0.2611
Interaction								0.9892

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

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TEAE >= Grade 3: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	1 (1.3)	NR (NE, NE)	60	9 (15.0)	NR (NE, NE)	0.067 (0.008, 0.534)	0.0008
vCPS < 10%	100	0 (0.0)	NR (NE, NE)	119	25 (21.0)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Missing	75	0 (0.0)	NR (NE, NE)	61	14 (23.0)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	14 (9.2)	31.1 (14.5, NE)	146	14 (9.6)	NR (9.6, NE)	0.551 (0.248, 1.226)	0.1384
>= 65 Years	103	15 (14.6)	NR (30.8, NE)	94	17 (18.1)	NR (NE, NE)	0.554 (0.265, 1.158)	0.1110
Interaction								0.5463
Gender								
Male	216	26 (12.0)	31.1 (30.8, NE)	204	23 (11.3)	NR (9.6, NE)	0.637 (0.348, 1.163)	0.1384
Female	39	3 (7.7)	NR (NE, NE)	36	8 (22.2)	NR (3.1, NE)	0.281 (0.073, 1.073)	0.0478
Interaction								0.0994

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	24 (12.8)	31.1 (30.8, NE)	183	20 (10.9)	NR (9.6, NE)	0.707 (0.374, 1.338)	0.2845
Non-Smoker	68	5 (7.4)	NR (NE, NE)	57	11 (19.3)	NR (4.8, NE)	0.258 (0.086, 0.775)	0.0099
Interaction								0.0782

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	10 (12.0)	NR (30.8, NE)	79	5 (6.3)	NR (NE, NE)	1.430 (0.467, 4.380)	0.5288
Docetaxel	56	10 (17.9)	10.2 (6.9, NE)	50	8 (16.0)	9.6 (4.9, NE)	0.645 (0.242, 1.724)	0.3783
Irinotecan	116	9 (7.8)	31.1 (14.5, NE)	111	18 (16.2)	NR (NE, NE)	0.244 (0.096, 0.625)	0.0015
Interaction								0.0586

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	7 (11.1)	30.8 (13.8, NE)	57	8 (14.0)	NR (9.6, NE)	0.319 (0.094, 1.081)	0.0540
1	192	22 (11.5)	NR (31.1, NE)	183	23 (12.6)	NR (NE, NE)	0.643 (0.350, 1.181)	0.1511
Interaction								0.8463
Region #1								
Asia	201	25 (12.4)	31.1 (30.8, NE)	191	24 (12.6)	NR (9.6, NE)	0.564 (0.307, 1.037)	0.0618
Europe/North America	54	4 (7.4)	NR (NE, NE)	49	7 (14.3)	NR (NE, NE)	0.474 (0.138, 1.626)	0.2250
Interaction								0.4366

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	18 (10.2)	NR (31.1, NE)	168	22 (13.1)	NR (9.6, NE)	0.465 (0.237, 0.912)	0.0227
Japan	25	7 (28.0)	13.8 (4.1, NE)	23	2 (8.7)	NR (NE, NE)	1.558 (0.290, 8.369)	0.6023
Europe/North America	54	4 (7.4)	NR (NE, NE)	49	7 (14.3)	NR (NE, NE)	0.474 (0.138, 1.626)	0.2250
Interaction								0.1949

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	25 (12.3)	31.1 (30.8, NE)	198	24 (12.1)	NR (9.6, NE)	0.582 (0.317, 1.071)	0.0784
White	52	4 (7.7)	NR (NE, NE)	42	7 (16.7)	NR (4.8, NE)	0.419 (0.122, 1.437)	0.1538
Interaction								0.3132

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	9 (11.3)	31.1 (14.5, NE)	60	9 (15.0)	NR (4.9, NE)	0.274 (0.089, 0.843)	0.0165
vCPS < 10%	100	11 (11.0)	NR (NE, NE)	119	15 (12.6)	NR (NE, NE)	0.667 (0.303, 1.465)	0.3098
Missing	75	9 (12.0)	NR (13.8, NE)	61	7 (11.5)	9.6 (NE, NE)	0.777 (0.276, 2.194)	0.6332
Interaction								0.6331

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	2 (1.3)	--	146	5 (3.4)	--	--	--
>= 65 Years	103	0 (0.0)	--	94	5 (5.3)	--	--	--
Interaction								--
Gender								
Male	216	2 (0.9)	NR (NE, NE)	204	9 (4.4)	NR (NE, NE)	0.089 (0.011, 0.704)	0.0039
Female	39	0 (0.0)	NR (NE, NE)	36	1 (2.8)	NR (NE, NE)	0.000 (0.000, NE)	0.2980
Interaction								0.9947

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	2 (1.1)	NR (NE, NE)	183	9 (4.9)	NR (NE, NE)	0.097 (0.012, 0.767)	0.0061
Non-Smoker	68	0 (0.0)	NR (NE, NE)	57	1 (1.8)	NR (NE, NE)	0.000 (0.000, NE)	0.1649
Interaction								0.9935

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ICC Options								
Paclitaxel	83	1 (1.2)	--	79	2 (2.5)	--	--	--
Docetaxel	56	1 (1.8)	--	50	2 (4.0)	--	--	--
Irinotecan	116	0 (0.0)	--	111	6 (5.4)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	1 (1.6)	NR (13.3, NE)	57	1 (1.8)	NR (NE, NE)	0.000 (0.000, NE)	0.2963
1	192	1 (0.5)	NR (NE, NE)	183	9 (4.9)	NR (NE, NE)	0.088 (0.011, 0.699)	0.0038
Interaction								0.2557
Region #1								
Asia	201	1 (0.5)	--	191	6 (3.1)	--	--	--
Europe/North America	54	1 (1.9)	--	49	4 (8.2)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	1 (0.6)	--	168	5 (3.0)	--	--	--
Japan	25	0 (0.0)	--	23	1 (4.3)	--	--	--
Europe/North America	54	1 (1.9)	--	49	4 (8.2)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	203	1 (0.5)	--	198	6 (3.0)	--	--	--
White	52	1 (1.9)	--	42	4 (9.5)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

TEAE >= Grade 3: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	1 (1.3)	--	60	4 (6.7)	--	--	--
vCPS < 10%	100	1 (1.0)	--	119	3 (2.5)	--	--	--
Missing	75	0 (0.0)	--	61	3 (4.9)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	10 (13.2)	NR (NE, NE)	69	18 (26.1)	NR (NE, NE)	0.401 (0.184, 0.872)	0.0165
>= 65 Years	63	3 (4.8)	NR (NE, NE)	60	13 (21.7)	NR (NE, NE)	0.195 (0.056, 0.686)	0.0044
Interaction								0.2620
Gender								
Male	118	12 (10.2)	NR (NE, NE)	106	26 (24.5)	NR (NE, NE)	0.335 (0.169, 0.667)	0.0010
Female	21	1 (4.8)	NR (NE, NE)	23	5 (21.7)	NR (NE, NE)	0.209 (0.024, 1.791)	0.1115
Interaction								0.5830

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Smoking Status								
Former/Current Smoker	104	10 (9.6)	NR (NE, NE)	101	25 (24.8)	NR (NE, NE)	0.322 (0.154, 0.673)	0.0014
Non-Smoker	35	3 (8.6)	NR (4.3, NE)	28	6 (21.4)	NR (NE, NE)	0.303 (0.074, 1.232)	0.0774
Interaction								0.9711
ICC Options								
Paclitaxel	83	4 (4.8)	NR (NE, NE)	79	12 (15.2)	NR (NE, NE)	0.281 (0.091, 0.872)	0.0188
Docetaxel	56	9 (16.1)	NR (7.6, NE)	50	19 (38.0)	NR (1.3, NE)	0.301 (0.134, 0.676)	0.0018
Interaction								0.9112

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	1 (2.3)	NR (NE, NE)	37	8 (21.6)	NR (NE, NE)	0.085 (0.010, 0.686)	0.0033
1	96	12 (12.5)	NR (NE, NE)	92	23 (25.0)	NR (NE, NE)	0.413 (0.205, 0.832)	0.0104
Interaction								0.1722
Region #1								
Asia	103	11 (10.7)	NR (NE, NE)	99	23 (23.2)	NR (NE, NE)	0.369 (0.179, 0.762)	0.0048
Europe/North America	36	2 (5.6)	NR (NE, NE)	30	8 (26.7)	NR (NE, NE)	0.183 (0.039, 0.862)	0.0156
Interaction								0.3978

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	10 (12.8)	NR (NE, NE)	76	18 (23.7)	NR (NE, NE)	0.439 (0.201, 0.957)	0.0323
Japan	25	1 (4.0)	NR (NE, NE)	23	5 (21.7)	NR (2.8, NE)	0.146 (0.017, 1.262)	0.0427
Europe/North America	36	2 (5.6)	NR (NE, NE)	30	8 (26.7)	NR (NE, NE)	0.183 (0.039, 0.862)	0.0156
Interaction								0.4333

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	11 (10.5)	NR (NE, NE)	106	24 (22.6)	NR (NE, NE)	0.376 (0.183, 0.771)	0.0053
White	34	2 (5.9)	NR (NE, NE)	23	7 (30.4)	NR (1.0, NE)	0.167 (0.035, 0.806)	0.0110
Interaction								0.3312

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	4 (8.9)	NR (NE, NE)	34	8 (23.5)	NR (NE, NE)	0.310 (0.093, 1.032)	0.0429
vCPS < 10%	53	7 (13.2)	NR (NE, NE)	54	17 (31.5)	NR (NE, NE)	0.302 (0.123, 0.742)	0.0056
Missing	41	2 (4.9)	NR (NE, NE)	41	6 (14.6)	NR (NE, NE)	0.307 (0.062, 1.527)	0.1262
Interaction								0.9874

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	76	0 (0.0)	--	69	4 (5.8)	--	--	--
>= 65 Years	63	0 (0.0)	--	60	4 (6.7)	--	--	--
Interaction								--
Gender								
Male	118	0 (0.0)	--	106	7 (6.6)	--	--	--
Female	21	0 (0.0)	--	23	1 (4.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Smoking Status								
Former/Current Smoker	104	0 (0.0)	--	101	7 (6.9)	--	--	--
Non-Smoker	35	0 (0.0)	--	28	1 (3.6)	--	--	--
Interaction								--
ICC Options								
Paclitaxel	83	0 (0.0)	--	79	0 (0.0)	--	--	--
Docetaxel	56	0 (0.0)	--	50	8 (16.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	43	0 (0.0)	--	37	2 (5.4)	--	--	--
1	96	0 (0.0)	--	92	6 (6.5)	--	--	--
Interaction								--
Region #1								
Asia	103	0 (0.0)	--	99	7 (7.1)	--	--	--
Europe/North America	36	0 (0.0)	--	30	1 (3.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Region #2								
Asia (excluding Japan)	78	0 (0.0)	--	76	5 (6.6)	--	--	--
Japan	25	0 (0.0)	--	23	2 (8.7)	--	--	--
Europe/North America	36	0 (0.0)	--	30	1 (3.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	0 (0.0)	--	106	7 (6.6)	--	--	--
White	34	0 (0.0)	--	23	1 (4.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Febrile neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Baseline PD-L1 Status								
vCPS >= 10%	45	0 (0.0)	--	34	2 (5.9)	--	--	--
vCPS < 10%	53	0 (0.0)	--	54	2 (3.7)	--	--	--
Missing	41	0 (0.0)	--	41	4 (9.8)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	0 (0.0)	--	69	5 (7.2)	--	--	--
>= 65 Years	63	0 (0.0)	--	60	3 (5.0)	--	--	--
Interaction								--
Gender								
Male	118	0 (0.0)	--	106	8 (7.5)	--	--	--
Female	21	0 (0.0)	--	23	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Smoking Status								
Former/Current Smoker	104	0 (0.0)	--	101	6 (5.9)	--	--	--
Non-Smoker	35	0 (0.0)	--	28	2 (7.1)	--	--	--
Interaction								--
ICC Options								
Paclitaxel	83	0 (0.0)	--	79	1 (1.3)	--	--	--
Docetaxel	56	0 (0.0)	--	50	7 (14.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	43	0 (0.0)	--	37	4 (10.8)	--	--	--
1	96	0 (0.0)	--	92	4 (4.3)	--	--	--
Interaction								--
Region #1								
Asia	103	0 (0.0)	--	99	7 (7.1)	--	--	--
Europe/North America	36	0 (0.0)	--	30	1 (3.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

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System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Region #2								
Asia (excluding Japan)	78	0 (0.0)	--	76	7 (9.2)	--	--	--
Japan	25	0 (0.0)	--	23	0 (0.0)	--	--	--
Europe/North America	36	0 (0.0)	--	30	1 (3.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

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Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	105	0 (0.0)	--	106	7 (6.6)	--	--	--
White	34	0 (0.0)	--	23	1 (4.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.
System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.
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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.
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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Leukopenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	0 (0.0)	--	34	2 (5.9)	--	--	--
vCPS < 10%	53	0 (0.0)	--	54	5 (9.3)	--	--	--
Missing	41	0 (0.0)	--	41	1 (2.4)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	1 (1.3)	--	69	5 (7.2)	--	--	--
>= 65 Years	63	0 (0.0)	--	60	7 (11.7)	--	--	--
Interaction								--
Gender								
Male	118	1 (0.8)	NR (NE, NE)	106	10 (9.4)	NR (NE, NE)	0.074 (0.009, 0.589)	0.0015
Female	21	0 (0.0)	NR (NE, NE)	23	2 (8.7)	NR (NE, NE)	0.000 (0.000, NE)	0.1820
Interaction								0.9924

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	1 (1.0)	NR (NE, NE)	101	9 (8.9)	NR (NE, NE)	0.086 (0.011, 0.695)	0.0041
Non-Smoker	35	0 (0.0)	NR (NE, NE)	28	3 (10.7)	NR (NE, NE)	0.000 (0.000, NE)	0.0492
Interaction								0.9936
ICC Options								
Paclitaxel	83	0 (0.0)	--	79	5 (6.3)	--	--	--
Docetaxel	56	1 (1.8)	--	50	7 (14.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	43	1 (2.3)	--	37	3 (8.1)	--	--	--
1	96	0 (0.0)	--	92	9 (9.8)	--	--	--
Interaction								--
Region #1								
Asia	103	1 (1.0)	--	99	7 (7.1)	--	--	--
Europe/North America	36	0 (0.0)	--	30	5 (16.7)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Region #2								
Asia (excluding Japan)	78	1 (1.3)	--	76	7 (9.2)	--	--	--
Japan	25	0 (0.0)	--	23	0 (0.0)	--	--	--
Europe/North America	36	0 (0.0)	--	30	5 (16.7)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	1 (1.0)	--	106	7 (6.6)	--	--	--
White	34	0 (0.0)	--	23	5 (21.7)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Blood and lymphatic system disorders / PT - Neutropenia

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	0 (0.0)	--	34	2 (5.9)	--	--	--
vCPS < 10%	53	1 (1.9)	--	54	8 (14.8)	--	--	--
Missing	41	0 (0.0)	--	41	2 (4.9)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	7 (9.2)	NR (13.8, NE)	69	27 (39.1)	4.1 (1.4, NE)	0.147 (0.060, 0.359)	<0.0001
>= 65 Years	63	5 (7.9)	NR (NE, NE)	60	24 (40.0)	NR (1.0, NE)	0.149 (0.057, 0.393)	<0.0001
Interaction								0.7763
Gender								
Male	118	11 (9.3)	NR (NE, NE)	106	47 (44.3)	4.1 (1.2, NE)	0.135 (0.068, 0.269)	<0.0001
Female	21	1 (4.8)	NR (3.1, NE)	23	4 (17.4)	NR (NE, NE)	0.246 (0.027, 2.203)	0.1721
Interaction								0.6964

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	11 (10.6)	NR (NE, NE)	101	42 (41.6)	NR (1.4, NE)	0.164 (0.082, 0.330)	<0.0001
Non-Smoker	35	1 (2.9)	NR (NE, NE)	28	9 (32.1)	NR (0.5, NE)	0.080 (0.010, 0.632)	0.0018
Interaction								0.3594
ICC Options								
Paclitaxel	83	6 (7.2)	NR (NE, NE)	79	24 (30.4)	NR (4.1, NE)	0.185 (0.075, 0.456)	<0.0001
Docetaxel	56	6 (10.7)	NR (13.8, NE)	50	27 (54.0)	1.0 (0.3, NE)	0.108 (0.041, 0.285)	<0.0001
Interaction								0.4747

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	4 (9.3)	NR (13.8, NE)	37	14 (37.8)	NR (1.1, NE)	0.137 (0.039, 0.484)	0.0003
1	96	8 (8.3)	NR (NE, NE)	92	37 (40.2)	NR (1.2, NE)	0.154 (0.071, 0.331)	<0.0001
Interaction								0.8519
Region #1								
Asia	103	10 (9.7)	NR (NE, NE)	99	45 (45.5)	4.1 (1.1, NE)	0.129 (0.062, 0.266)	<0.0001
Europe/North America	36	2 (5.6)	NR (NE, NE)	30	6 (20.0)	NR (NE, NE)	0.243 (0.049, 1.209)	0.0596
Interaction								0.5153

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	8 (10.3)	NR (NE, NE)	76	35 (46.1)	4.1 (1.1, NE)	0.133 (0.059, 0.303)	<0.0001
Japan	25	2 (8.0)	NR (NE, NE)	23	10 (43.5)	NR (0.5, NE)	0.125 (0.026, 0.593)	0.0018
Europe/North America	36	2 (5.6)	NR (NE, NE)	30	6 (20.0)	NR (NE, NE)	0.243 (0.049, 1.209)	0.0596
Interaction								0.7778

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	10 (9.5)	NR (NE, NE)	106	48 (45.3)	4.1 (1.1, NE)	0.128 (0.062, 0.263)	<0.0001
White	34	2 (5.9)	NR (NE, NE)	23	3 (13.0)	NR (NE, NE)	0.408 (0.068, 2.453)	0.3061
Interaction								0.2549

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	3 (6.7)	NR (NE, NE)	34	10 (29.4)	NR (4.1, NE)	0.163 (0.044, 0.604)	0.0021
vCPS < 10%	53	4 (7.5)	NR (13.8, NE)	54	26 (48.1)	2.4 (0.5, NE)	0.081 (0.024, 0.268)	<0.0001
Missing	41	5 (12.2)	NR (NE, NE)	41	15 (36.6)	NR (1.2, NE)	0.267 (0.097, 0.736)	0.0053
Interaction								0.4298

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	76	2 (2.6)	--	69	3 (4.3)	--	--	--
>= 65 Years	63	0 (0.0)	--	60	6 (10.0)	--	--	--
Interaction								--
Gender								
Male	118	2 (1.7)	NR (NE, NE)	106	8 (7.5)	NR (NE, NE)	0.210 (0.044, 0.989)	0.0285
Female	21	0 (0.0)	NR (NE, NE)	23	1 (4.3)	NR (NE, NE)	0.000 (0.000, NE)	0.3393
Interaction								0.9926

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	2 (1.9)	NR (NE, NE)	101	8 (7.9)	NR (NE, NE)	0.229 (0.049, 1.079)	0.0403
Non-Smoker	35	0 (0.0)	NR (NE, NE)	28	1 (3.6)	NR (NE, NE)	0.000 (0.000, NE)	0.2618
Interaction								0.9938
ICC Options								
Paclitaxel	83	0 (0.0)	--	79	3 (3.8)	--	--	--
Docetaxel	56	2 (3.6)	--	50	6 (12.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	1 (2.3)	--	37	3 (8.1)	--	--	--
1	96	1 (1.0)	--	92	6 (6.5)	--	--	--
Interaction								--
Region #1								
Asia	103	2 (1.9)	--	99	6 (6.1)	--	--	--
Europe/North America	36	0 (0.0)	--	30	3 (10.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Region #2								
Asia (excluding Japan)	78	2 (2.6)	--	76	4 (5.3)	--	--	--
Japan	25	0 (0.0)	--	23	2 (8.7)	--	--	--
Europe/North America	36	0 (0.0)	--	30	3 (10.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	105	2 (1.9)	--	106	7 (6.6)	--	--	--
White	34	0 (0.0)	--	23	2 (8.7)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.
System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.
Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.
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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations / PT - Lymphocyte count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	0 (0.0)	--	34	1 (2.9)	--	--	--
vCPS < 10%	53	2 (3.8)	--	54	6 (11.1)	--	--	--
Missing	41	0 (0.0)	--	41	2 (4.9)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Age								
< 65 Years	76	0 (0.0)	NR (NE, NE)	69	22 (31.9)	NR (4.1, NE)	0.000 (0.000, NE)	<0.0001
>= 65 Years	63	0 (0.0)	NR (NE, NE)	60	16 (26.7)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9999
Gender								
Male	118	0 (0.0)	NR (NE, NE)	106	35 (33.0)	NR (4.1, NE)	0.000 (0.000, NE)	<0.0001
Female	21	0 (0.0)	NR (NE, NE)	23	3 (13.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0931
Interaction								0.9997

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Smoking Status								
Former/Current Smoker	104	0 (0.0)	NR (NE, NE)	101	32 (31.7)	NR (4.1, NE)	0.000 (0.000, NE)	<0.0001
Non-Smoker	35	0 (0.0)	NR (NE, NE)	28	6 (21.4)	NR (NE, NE)	0.000 (0.000, NE)	0.0040
Interaction								0.9998
ICC Options								
Paclitaxel	83	0 (0.0)	NR (NE, NE)	79	19 (24.1)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Docetaxel	56	0 (0.0)	NR (NE, NE)	50	19 (38.0)	NR (1.0, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9998

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	0 (0.0)	NR (NE, NE)	37	12 (32.4)	NR (2.4, NE)	0.000 (0.000, NE)	<0.0001
1	96	0 (0.0)	NR (NE, NE)	92	26 (28.3)	NR (4.1, NE)	0.000 (0.000, NE)	<0.0001
Interaction								1.0000
Region #1								
Asia	103	0 (0.0)	NR (NE, NE)	99	35 (35.4)	NR (4.1, NE)	0.000 (0.000, NE)	<0.0001
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	3 (10.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0537
Interaction								0.9995

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Region #2								
Asia (excluding Japan)	78	0 (0.0)	NR (NE, NE)	76	26 (34.2)	NR (2.4, NE)	0.000 (0.000, NE)	<0.0001
Japan	25	0 (0.0)	NR (NE, NE)	23	9 (39.1)	NR (0.5, NE)	0.000 (0.000, NE)	0.0005
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	3 (10.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0537
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	105	0 (0.0)	NR (NE, NE)	106	36 (34.0)	NR (4.1, NE)	0.000 (0.000, NE)	<0.0001
White	34	0 (0.0)	NR (NE, NE)	23	2 (8.7)	NR (NE, NE)	0.000 (0.000, NE)	0.0827
Interaction								0.9995

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.
System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.
Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.
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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Baseline PD-L1 Status								
vCPS >= 10%	45	0 (0.0)	NR (NE, NE)	34	9 (26.5)	NR (4.1, NE)	0.000 (0.000, NE)	0.0001
vCPS < 10%	53	0 (0.0)	NR (NE, NE)	54	17 (31.5)	NR (2.4, NE)	0.000 (0.000, NE)	<0.0001
Missing	41	0 (0.0)	NR (NE, NE)	41	12 (29.3)	NR (NE, NE)	0.000 (0.000, NE)	0.0002
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	0 (0.0)	NR (NE, NE)	69	16 (23.2)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
>= 65 Years	63	0 (0.0)	NR (NE, NE)	60	12 (20.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0002
Interaction								0.9999
Gender								
Male	118	0 (0.0)	NR (NE, NE)	106	25 (23.6)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Female	21	0 (0.0)	NR (NE, NE)	23	3 (13.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0904
Interaction								0.9998

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	0 (0.0)	NR (NE, NE)	101	22 (21.8)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Non-Smoker	35	0 (0.0)	NR (NE, NE)	28	6 (21.4)	NR (NE, NE)	0.000 (0.000, NE)	0.0038
Interaction								1.0000
ICC Options								
Paclitaxel	83	0 (0.0)	NR (NE, NE)	79	8 (10.1)	NR (NE, NE)	0.000 (0.000, NE)	0.0029
Docetaxel	56	0 (0.0)	NR (NE, NE)	50	20 (40.0)	NR (1.0, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9994

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	43	0 (0.0)	NR (NE, NE)	37	10 (27.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0003
1	96	0 (0.0)	NR (NE, NE)	92	18 (19.6)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Interaction								0.9999
Region #1								
Asia	103	0 (0.0)	NR (NE, NE)	99	27 (27.3)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	1 (3.3)	NR (NE, NE)	0.000 (0.000, NE)	0.2733
Interaction								0.9994

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	0 (0.0)	NR (NE, NE)	76	18 (23.7)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
Japan	25	0 (0.0)	NR (NE, NE)	23	9 (39.1)	NR (0.5, NE)	0.000 (0.000, NE)	0.0005
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	1 (3.3)	NR (NE, NE)	0.000 (0.000, NE)	0.2733
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan
TEAE >= Grade 3: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Race								
Asian and other	105	0 (0.0)	NR (NE, NE)	106	28 (26.4)	NR (NE, NE)	0.000 (0.000, NE)	<0.0001
White	34	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9965

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.
System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.
Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.
[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.
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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Investigations / PT - White blood cell count decreased

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	0 (0.0)	NR (NE, NE)	34	4 (11.8)	NR (NE, NE)	0.000 (0.000, NE)	0.0191
vCPS < 10%	53	0 (0.0)	NR (NE, NE)	54	13 (24.1)	NR (NE, NE)	0.000 (0.000, NE)	0.0001
Missing	41	0 (0.0)	NR (NE, NE)	41	11 (26.8)	NR (NE, NE)	0.000 (0.000, NE)	0.0004
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Vascular disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	6 (7.9)	--	69	0 (0.0)	--	--	--
>= 65 Years	63	2 (3.2)	--	60	0 (0.0)	--	--	--
Interaction								--
Gender								
Male	118	7 (5.9)	--	106	0 (0.0)	--	--	--
Female	21	1 (4.8)	--	23	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Vascular disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	7 (6.7)	--	101	0 (0.0)	--	--	--
Non-Smoker	35	1 (2.9)	--	28	0 (0.0)	--	--	--
Interaction								--
ICC Options								
Paclitaxel	83	5 (6.0)	--	79	0 (0.0)	--	--	--
Docetaxel	56	3 (5.4)	--	50	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Vascular disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	4 (9.3)	--	37	0 (0.0)	--	--	--
1	96	4 (4.2)	--	92	0 (0.0)	--	--	--
Interaction								--
Region #1								
Asia	103	5 (4.9)	--	99	0 (0.0)	--	--	--
Europe/North America	36	3 (8.3)	--	30	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Vascular disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	5 (6.4)	--	76	0 (0.0)	--	--	--
Japan	25	0 (0.0)	--	23	0 (0.0)	--	--	--
Europe/North America	36	3 (8.3)	--	30	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Vascular disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	5 (4.8)	--	106	0 (0.0)	--	--	--
White	34	3 (8.8)	--	23	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.2.3.1.b.s:
Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

TEAE >= Grade 3: SOC - Vascular disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	4 (8.9)	--	34	0 (0.0)	--	--	--
vCPS < 10%	53	4 (7.5)	--	54	0 (0.0)	--	--	--
Missing	41	0 (0.0)	--	41	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	1 (0.7)	NR (NE, NE)	146	11 (7.5)	NR (NE, NE)	0.084 (0.011, 0.650)	0.0024
>= 65 Years	103	0 (0.0)	NR (NE, NE)	94	8 (8.5)	NR (NE, NE)	0.000 (0.000, NE)	0.0026
Interaction								0.9901
Gender								
Male	216	1 (0.5)	NR (NE, NE)	204	17 (8.3)	NR (NE, NE)	0.053 (0.007, 0.400)	<0.0001
Female	39	0 (0.0)	NR (NE, NE)	36	2 (5.6)	NR (NE, NE)	0.000 (0.000, NE)	0.1408
Interaction								0.9914

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	1 (0.5)	NR (NE, NE)	183	13 (7.1)	NR (NE, NE)	0.072 (0.009, 0.554)	0.0009
Non-Smoker	68	0 (0.0)	NR (NE, NE)	57	6 (10.5)	NR (NE, NE)	0.000 (0.000, NE)	0.0064
Interaction								0.9922

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	0 (0.0)	NR (NE, NE)	79	1 (1.3)	NR (NE, NE)	0.000 (0.000, NE)	0.3049
Docetaxel	56	1 (1.8)	NR (NE, NE)	50	9 (18.0)	NR (NE, NE)	0.093 (0.012, 0.732)	0.0043
Irinotecan	116	0 (0.0)	NR (NE, NE)	111	9 (8.1)	NR (NE, NE)	0.000 (0.000, NE)	0.0017
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	0 (0.0)	NR (NE, NE)	57	2 (3.5)	NR (NE, NE)	0.000 (0.000, NE)	0.1353
1	192	1 (0.5)	NR (NE, NE)	183	17 (9.3)	NR (NE, NE)	0.054 (0.007, 0.403)	<0.0001
Interaction								0.9933
Region #1								
Asia	201	1 (0.5)	NR (NE, NE)	191	18 (9.4)	NR (NE, NE)	0.051 (0.007, 0.380)	<0.0001
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	0.000 (0.000, NE)	0.2888
Interaction								0.9912

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	1 (0.6)	NR (NE, NE)	168	16 (9.5)	NR (NE, NE)	0.057 (0.008, 0.432)	0.0001
Japan	25	0 (0.0)	NR (NE, NE)	23	2 (8.7)	NR (NE, NE)	0.000 (0.000, NE)	0.1354
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	0.000 (0.000, NE)	0.2888
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	1 (0.5)	NR (NE, NE)	198	18 (9.1)	NR (NE, NE)	0.052 (0.007, 0.391)	<0.0001
White	52	0 (0.0)	NR (NE, NE)	42	1 (2.4)	NR (NE, NE)	0.000 (0.000, NE)	0.2601
Interaction								0.9911

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	0 (0.0)	--	60	5 (8.3)	--	--	--
vCPS < 10%	100	0 (0.0)	--	119	9 (7.6)	--	--	--
Missing	75	1 (1.3)	--	61	5 (8.2)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	19 (12.5)	NR (15.8, NE)	146	15 (10.3)	NR (NE, NE)	0.895 (0.447, 1.792)	0.7543
>= 65 Years	103	10 (9.7)	NR (30.4, NE)	94	17 (18.1)	9.2 (9.2, NE)	0.291 (0.121, 0.698)	0.0036
Interaction								0.1006
Gender								
Male	216	28 (13.0)	NR (30.4, NE)	204	28 (13.7)	NR (9.2, NE)	0.627 (0.361, 1.088)	0.0939
Female	39	1 (2.6)	NR (7.3, NE)	36	4 (11.1)	NR (NE, NE)	0.166 (0.018, 1.533)	0.0748
Interaction								0.2273

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	22 (11.8)	NR (30.4, NE)	183	27 (14.8)	NR (9.2, NE)	0.503 (0.275, 0.920)	0.0231
Non-Smoker	68	7 (10.3)	NR (NE, NE)	57	5 (8.8)	NR (4.9, NE)	0.880 (0.273, 2.836)	0.8302
Interaction								0.4425

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	11 (13.3)	NR (30.4, NE)	79	12 (15.2)	NR (NE, NE)	0.644 (0.271, 1.529)	0.3151
Docetaxel	56	7 (12.5)	NR (NE, NE)	50	7 (14.0)	NR (NE, NE)	0.700 (0.245, 2.004)	0.5040
Irinotecan	116	11 (9.5)	NR (13.8, NE)	111	13 (11.7)	NR (9.2, NE)	0.453 (0.187, 1.098)	0.0733
Interaction								0.9079

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	6 (9.5)	30.4 (15.8, NE)	57	5 (8.8)	NR (9.2, NE)	0.481 (0.126, 1.836)	0.2748
1	192	23 (12.0)	NR (NE, NE)	183	27 (14.8)	NR (NE, NE)	0.585 (0.330, 1.039)	0.0644
Interaction								0.5955
Region #1								
Asia	201	25 (12.4)	NR (30.4, NE)	191	21 (11.0)	NR (NE, NE)	0.750 (0.409, 1.376)	0.3515
Europe/North America	54	4 (7.4)	NR (NE, NE)	49	11 (22.4)	9.2 (4.9, NE)	0.259 (0.081, 0.826)	0.0143
Interaction								0.0891

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	22 (12.5)	NR (15.8, NE)	168	16 (9.5)	NR (NE, NE)	0.906 (0.466, 1.765)	0.7723
Japan	25	3 (12.0)	30.4 (NE, NE)	23	5 (21.7)	NR (3.4, NE)	0.256 (0.047, 1.398)	0.0935
Europe/North America	54	4 (7.4)	NR (NE, NE)	49	11 (22.4)	9.2 (4.9, NE)	0.259 (0.081, 0.826)	0.0143
Interaction								0.1205

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

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Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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Safety Analysis Set

Serious TEAE: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	26 (12.8)	NR (30.4, NE)	198	22 (11.1)	NR (NE, NE)	0.781 (0.432, 1.414)	0.4132
White	52	3 (5.8)	NR (NE, NE)	42	10 (23.8)	9.2 (4.9, NE)	0.187 (0.051, 0.690)	0.0050
Interaction								0.0418

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Safety Analysis Set

Serious TEAE: SOC - Infections and infestations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	7 (8.8)	NR (15.8, NE)	60	8 (13.3)	NR (NE, NE)	0.372 (0.124, 1.118)	0.0679
vCPS < 10%	100	16 (16.0)	NR (10.8, NE)	119	16 (13.4)	NR (9.2, NE)	0.884 (0.435, 1.795)	0.7323
Missing	75	6 (8.0)	NR (13.8, NE)	61	8 (13.1)	NR (NE, NE)	0.415 (0.135, 1.279)	0.1143
Interaction								0.3110

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	1 (0.7)	--	146	7 (4.8)	--	--	--
>= 65 Years	103	0 (0.0)	--	94	6 (6.4)	--	--	--
Interaction								--
Gender								
Male	216	1 (0.5)	NR (NE, NE)	204	12 (5.9)	NR (NE, NE)	0.076 (0.010, 0.583)	0.0012
Female	39	0 (0.0)	NR (NE, NE)	36	1 (2.8)	NR (NE, NE)	0.000 (0.000, NE)	0.3042
Interaction								0.9928

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	1 (0.5)	--	183	8 (4.4)	--	--	--
Non-Smoker	68	0 (0.0)	--	57	5 (8.8)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	1 (1.2)	--	79	0 (0.0)	--	--	--
Docetaxel	56	0 (0.0)	--	50	4 (8.0)	--	--	--
Irinotecan	116	0 (0.0)	--	111	9 (8.1)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	1 (1.6)	NR (NE, NE)	57	3 (5.3)	NR (NE, NE)	0.296 (0.031, 2.847)	0.2626
1	192	0 (0.0)	NR (NE, NE)	183	10 (5.5)	NR (NE, NE)	0.000 (0.000, NE)	0.0010
Interaction								0.9920
Region #1								
Asia	201	1 (0.5)	NR (NE, NE)	191	13 (6.8)	NR (NE, NE)	0.071 (0.009, 0.540)	0.0007
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9993

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Safety Analysis Set

Serious TEAE: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	1 (0.6)	NR (NE, NE)	168	13 (7.7)	NR (NE, NE)	0.071 (0.009, 0.540)	0.0007
Japan	25	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Safety Analysis Set

Serious TEAE: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	1 (0.5)	NR (NE, NE)	198	13 (6.6)	NR (NE, NE)	0.073 (0.010, 0.555)	0.0009
White	52	0 (0.0)	NR (NE, NE)	42	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9993

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Safety Analysis Set

Serious TEAE: SOC - Investigations

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	0 (0.0)	--	60	3 (5.0)	--	--	--
vCPS < 10%	100	0 (0.0)	--	119	6 (5.0)	--	--	--
Missing	75	1 (1.3)	--	61	4 (6.6)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	0 (0.0)	--	146	6 (4.1)	--	--	--
>= 65 Years	103	0 (0.0)	--	94	4 (4.3)	--	--	--
Interaction								--
Gender								
Male	216	0 (0.0)	--	204	9 (4.4)	--	--	--
Female	39	0 (0.0)	--	36	1 (2.8)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	0 (0.0)	--	183	7 (3.8)	--	--	--
Non-Smoker	68	0 (0.0)	--	57	3 (5.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	0 (0.0)	--	79	0 (0.0)	--	--	--
Docetaxel	56	0 (0.0)	--	50	4 (8.0)	--	--	--
Irinotecan	116	0 (0.0)	--	111	6 (5.4)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

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Safety Analysis Set

Serious TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	0 (0.0)	--	57	2 (3.5)	--	--	--
1	192	0 (0.0)	--	183	8 (4.4)	--	--	--
Interaction								--
Region #1								
Asia	201	0 (0.0)	NR (NE, NE)	191	10 (5.2)	NR (NE, NE)	0.000 (0.000, NE)	0.0010
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9979

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

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System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

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Safety Analysis Set

Serious TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	0 (0.0)	NR (NE, NE)	168	10 (6.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0010
Japan	25	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								1.0000

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	0 (0.0)	NR (NE, NE)	198	10 (5.1)	NR (NE, NE)	0.000 (0.000, NE)	0.0012
White	52	0 (0.0)	NR (NE, NE)	42	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9979

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Serious TEAE: SOC - Investigations / PT - Neutrophil count decreased

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	0 (0.0)	--	60	2 (3.3)	--	--	--
vCPS < 10%	100	0 (0.0)	--	119	6 (5.0)	--	--	--
Missing	75	0 (0.0)	--	61	2 (3.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.b.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	1 (1.3)	--	69	6 (8.7)	--	--	--
>= 65 Years	63	0 (0.0)	--	60	4 (6.7)	--	--	--
Interaction								--
Gender								
Male	118	1 (0.8)	NR (NE, NE)	106	9 (8.5)	NR (NE, NE)	0.096 (0.012, 0.761)	0.0056
Female	21	0 (0.0)	NR (NE, NE)	23	1 (4.3)	NR (NE, NE)	0.000 (0.000, NE)	0.3393
Interaction								0.9934

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.b.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	1 (1.0)	NR (NE, NE)	101	9 (8.9)	NR (NE, NE)	0.104 (0.013, 0.824)	0.0083
Non-Smoker	35	0 (0.0)	NR (NE, NE)	28	1 (3.6)	NR (NE, NE)	0.000 (0.000, NE)	0.2636
Interaction								0.9945
ICC Options								
Paclitaxel	83	0 (0.0)	NR (NE, NE)	79	1 (1.3)	NR (NE, NE)	0.000 (0.000, NE)	0.3049
Docetaxel	56	1 (1.8)	NR (NE, NE)	50	9 (18.0)	NR (NE, NE)	0.093 (0.012, 0.732)	0.0043
Interaction								0.9952

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.b.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	0 (0.0)	NR (NE, NE)	37	1 (2.7)	NR (NE, NE)	0.000 (0.000, NE)	0.2810
1	96	1 (1.0)	NR (NE, NE)	92	9 (9.8)	NR (NE, NE)	0.103 (0.013, 0.810)	0.0076
Interaction								0.9943
Region #1								
Asia	103	1 (1.0)	NR (NE, NE)	99	9 (9.1)	NR (NE, NE)	0.103 (0.013, 0.815)	0.0078
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	1 (3.3)	NR (NE, NE)	0.000 (0.000, NE)	0.2733
Interaction								0.9945

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.b.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	1 (1.3)	--	76	7 (9.2)	--	--	--
Japan	25	0 (0.0)	--	23	2 (8.7)	--	--	--
Europe/North America	36	0 (0.0)	--	30	1 (3.3)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.b.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	1 (1.0)	NR (NE, NE)	106	9 (8.5)	NR (NE, NE)	0.109 (0.014, 0.858)	0.0099
White	34	0 (0.0)	NR (NE, NE)	23	1 (4.3)	NR (NE, NE)	0.000 (0.000, NE)	0.2240
Interaction								0.9944

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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Table 14.3.1.2.4.1.1.b.s:
Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious TEAE: SOC - Blood and lymphatic system disorders

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	0 (0.0)	--	34	2 (5.9)	--	--	--
vCPS < 10%	53	0 (0.0)	--	54	4 (7.4)	--	--	--
Missing	41	1 (2.4)	--	41	4 (9.8)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.

Adverse events were classified based on MedDRA v25.0 and graded for severity using CTCAE version 4.03.

System organ classes or preferred terms will only be included if they have occurred in at least 5% of patients in one study arm or occurred in at least 10 patients and in at least 1% of patients in one study arm, and 2-sided p-value for the treatment effect in the main analysis < 0.05.

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on an unstratified Cox regression model with treatment, subgroup and treatment by subgroup interaction term as covariates to test for differences in treatment effect across subgroups.

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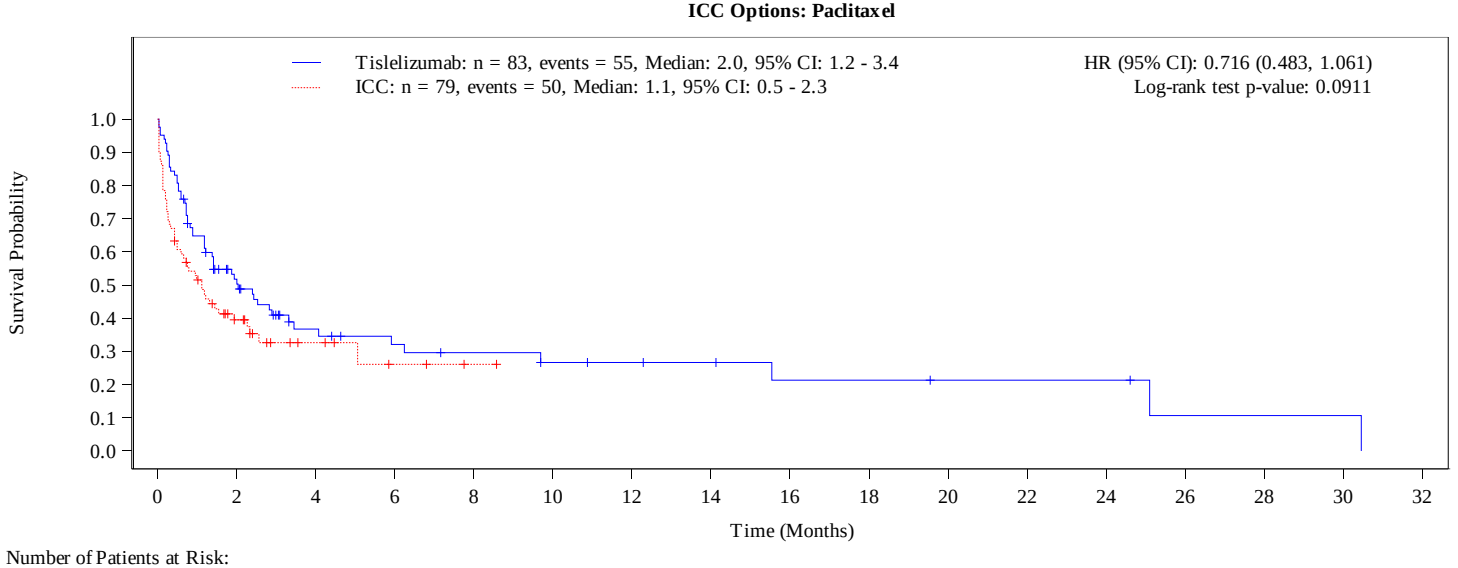
Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders

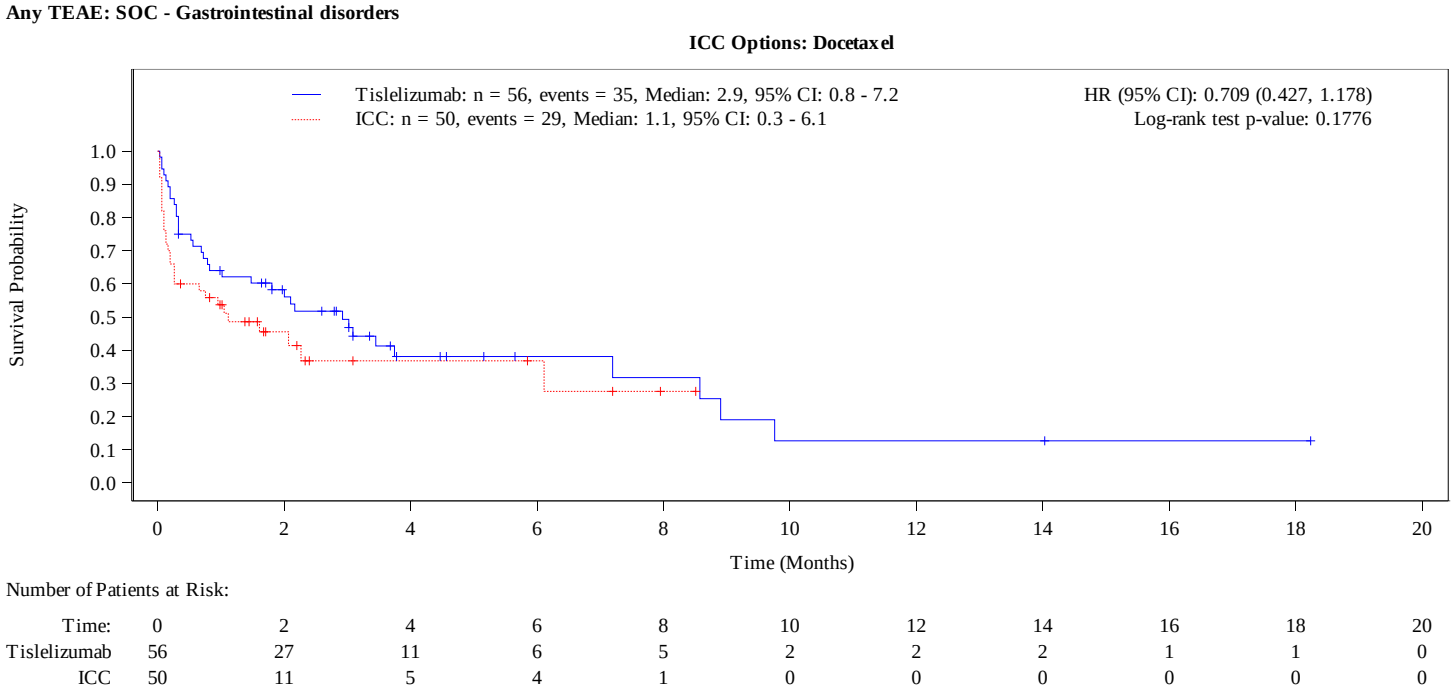


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Tislelizumab	83	35	17	13	10	8	7	6	4	4	3	3	3	1	1	1	0
ICC	79	21	8	3	1	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-s-km-socpt-sub-safety-cl.rtf

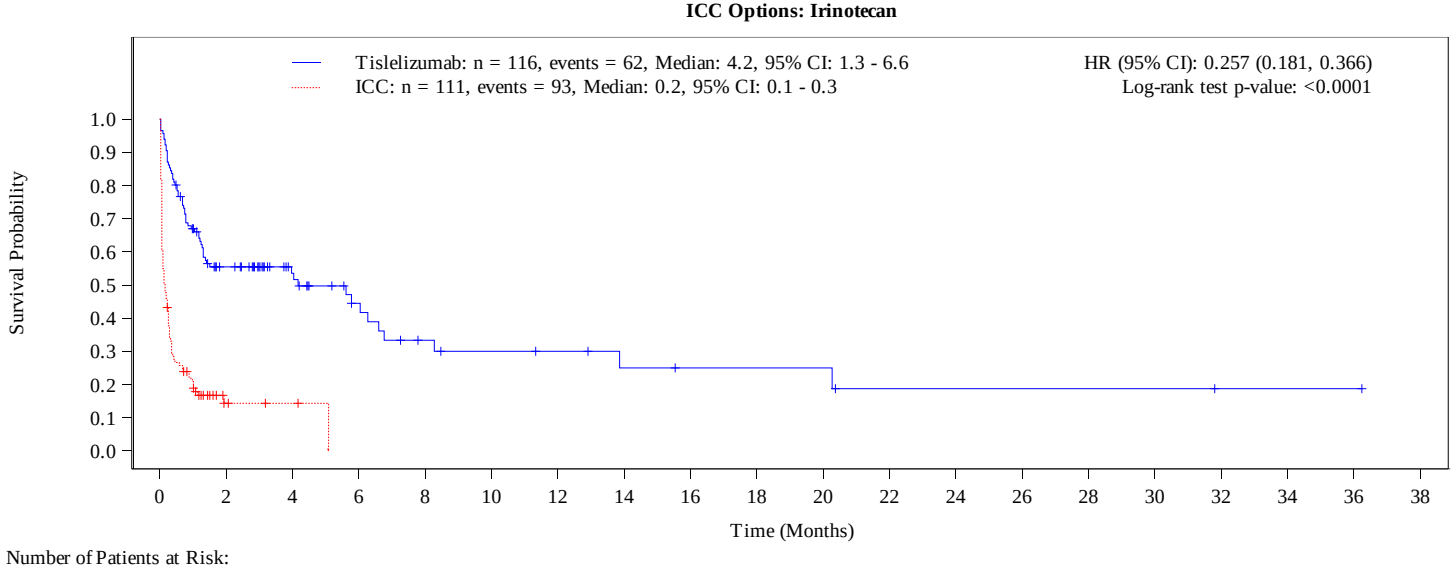
Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-s-km-socpt-sub-safety-cl.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders



Number of Patients at Risk:

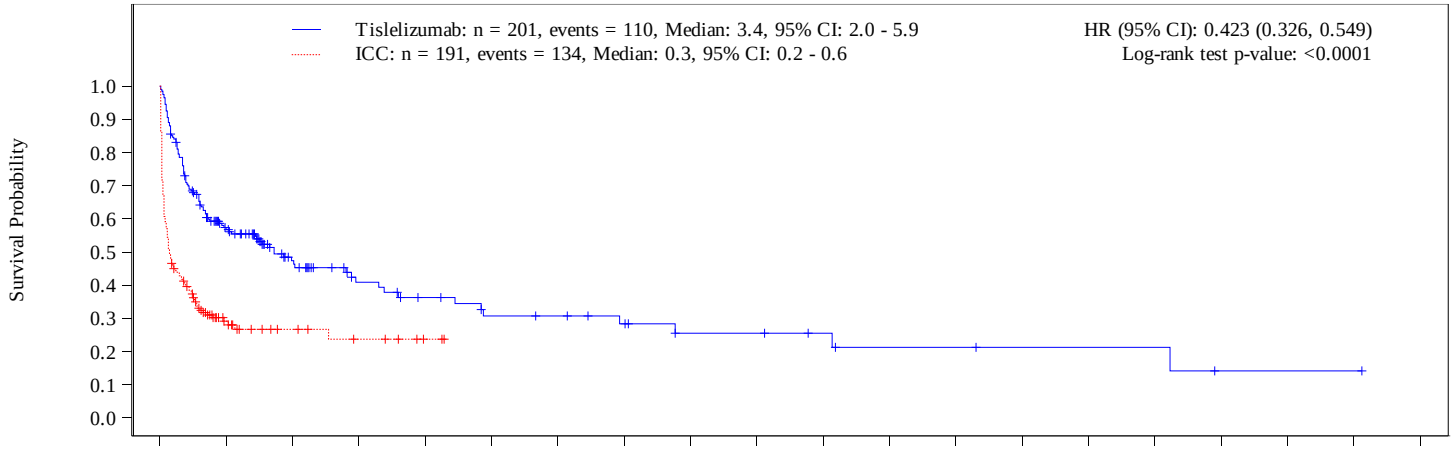
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38
Tislelizumab	116	50	28	16	10	8	7	5	4	4	4	2	2	2	2	2	1	1	1	0
ICC	111	4	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-s-km-socpt-sub-safety-cl.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders

Region #1: Asia



Number of Patients at Risk:

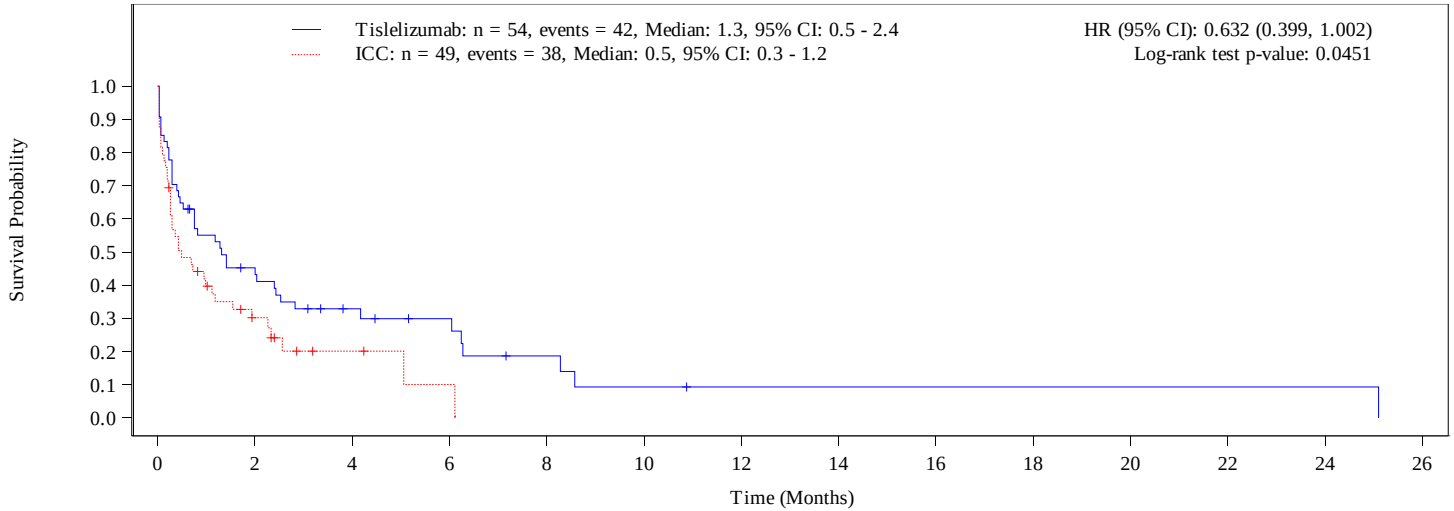
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38
Tislelizumab	201	90	45	27	21	16	15	12	8	8	6	4	4	3	3	3	1	1	1	0
ICC	191	26	12	6	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-s-km-socpt-sub-safety-cl.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders

Region #1: Europe/North America



Number of Patients at Risk:

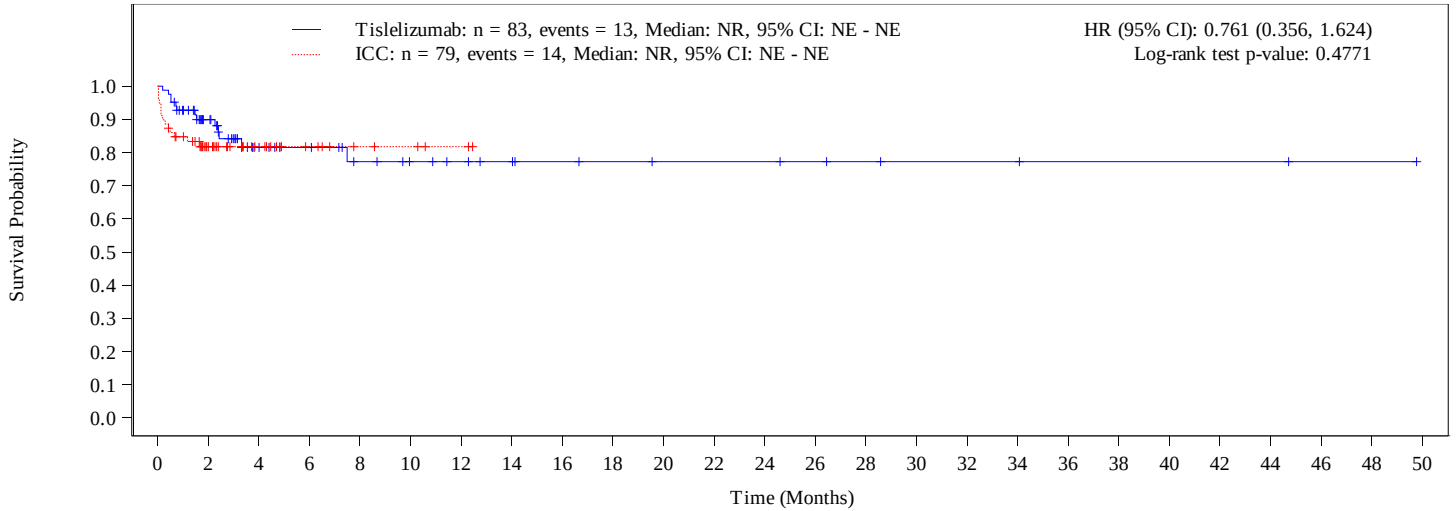
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Tislelizumab	54	22	11	8	4	2	1	1	1	1	1	1	1	0
ICC	49	10	3	1	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-s-km-socpt-sub-safety-cl.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Diarrhoea

ICC Options: Paclitaxel



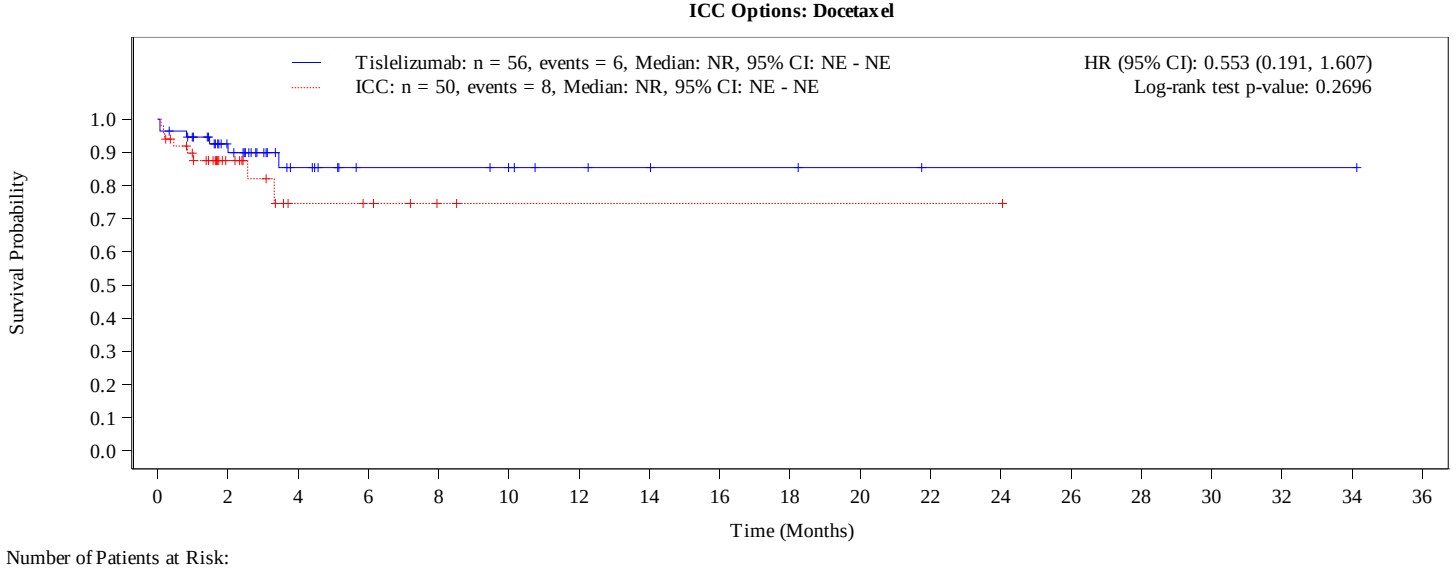
Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	83	51	27	23	17	14	12	10	8	7	6	6	6	5	4	3	3	3	2	2	2	2	2	1	1	0
ICC	79	41	17	9	5	4	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-s-km-socpt-sub-safety-cl.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Diarrhoea



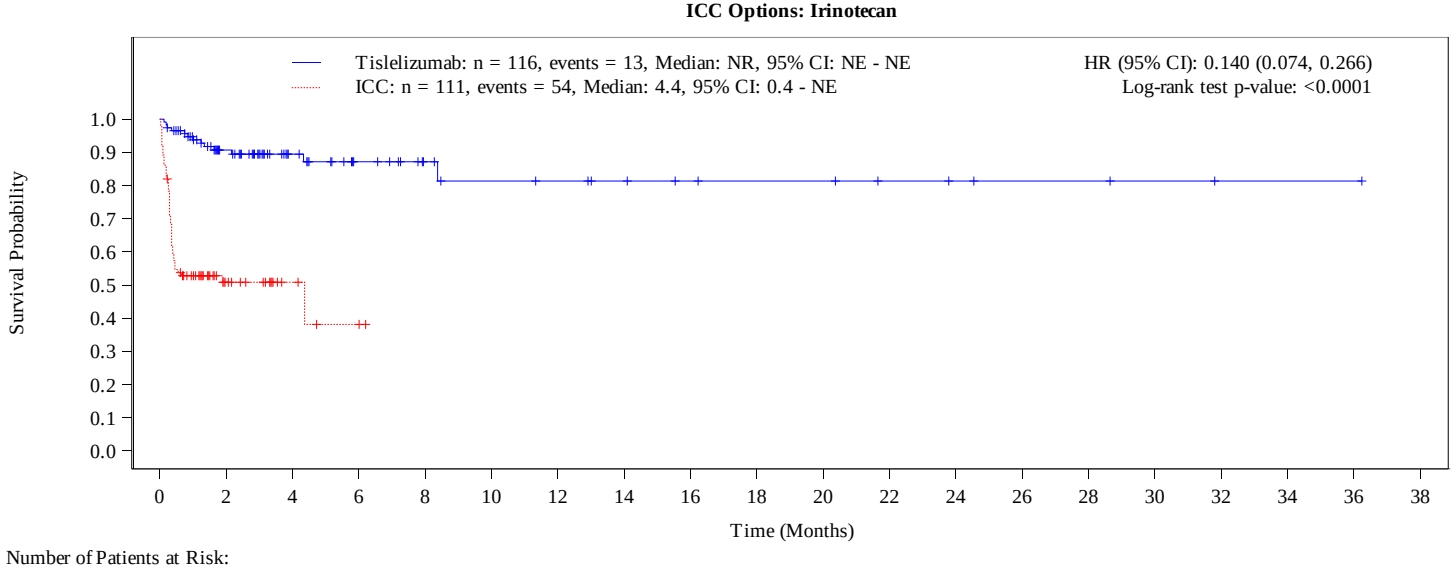
Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36
Tislelizumab	56	35	17	9	9	7	5	4	3	3	2	1	1	1	1	1	1	1	0
ICC	50	20	7	5	2	1	1	1	1	1	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-s-km-socpt-sub-safety-cl.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Diarrhoea



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38
Tislelizumab	116	73	40	24	16	13	12	10	8	7	7	5	4	3	3	2	1	1	1	0
ICC	111	20	5	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
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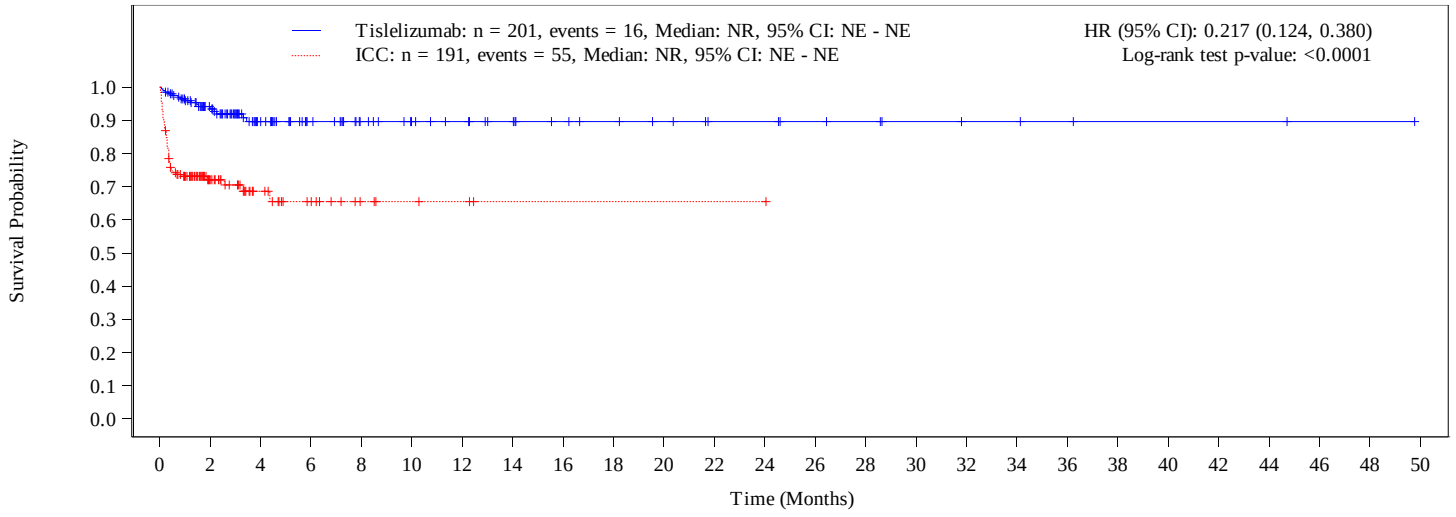
Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Diarrhoea

Region #1: Asia



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	201	128	68	46	35	29	26	22	17	15	13	10	10	8	7	5	4	4	3	2	2	2	2	1	1	0
ICC	191	62	24	13	6	4	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
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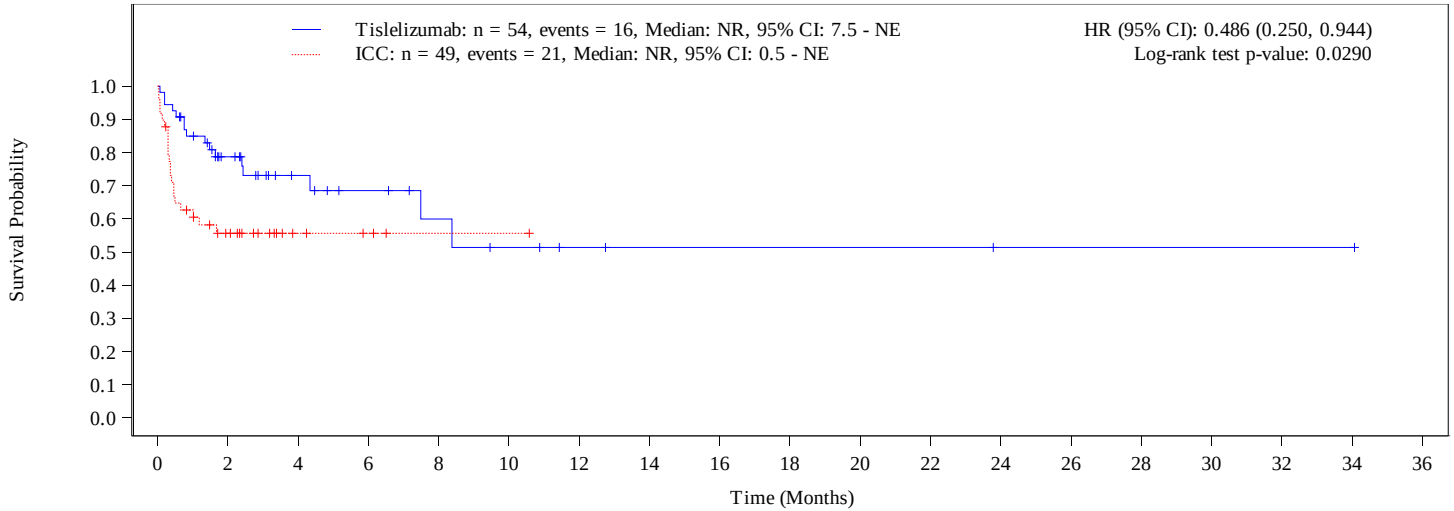
Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Diarrhoea

Region #1: Europe/North America



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36
Tislelizumab	54	31	16	10	7	5	3	2	2	2	2	2	1	1	1	1	1	1	0
ICC	49	19	5	3	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
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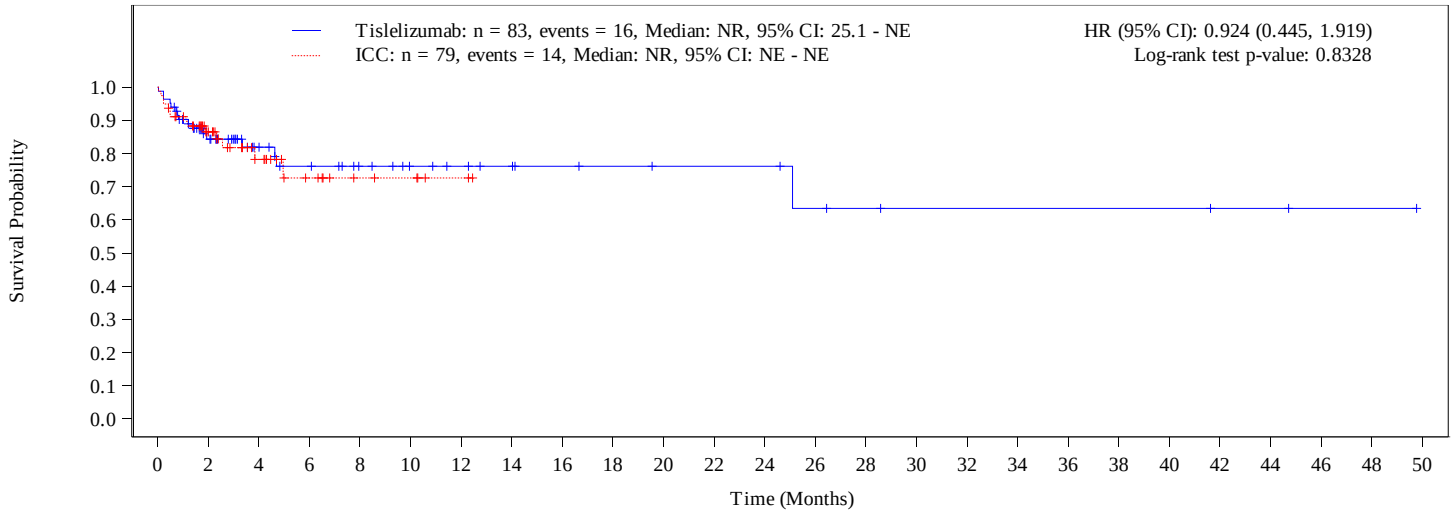
Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Nausea

ICC Options: Paclitaxel



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	83	51	31	25	19	15	13	11	9	8	7	7	7	5	4	3	3	3	3	3	3	2	2	1	1	0
ICC	79	46	21	11	6	5	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
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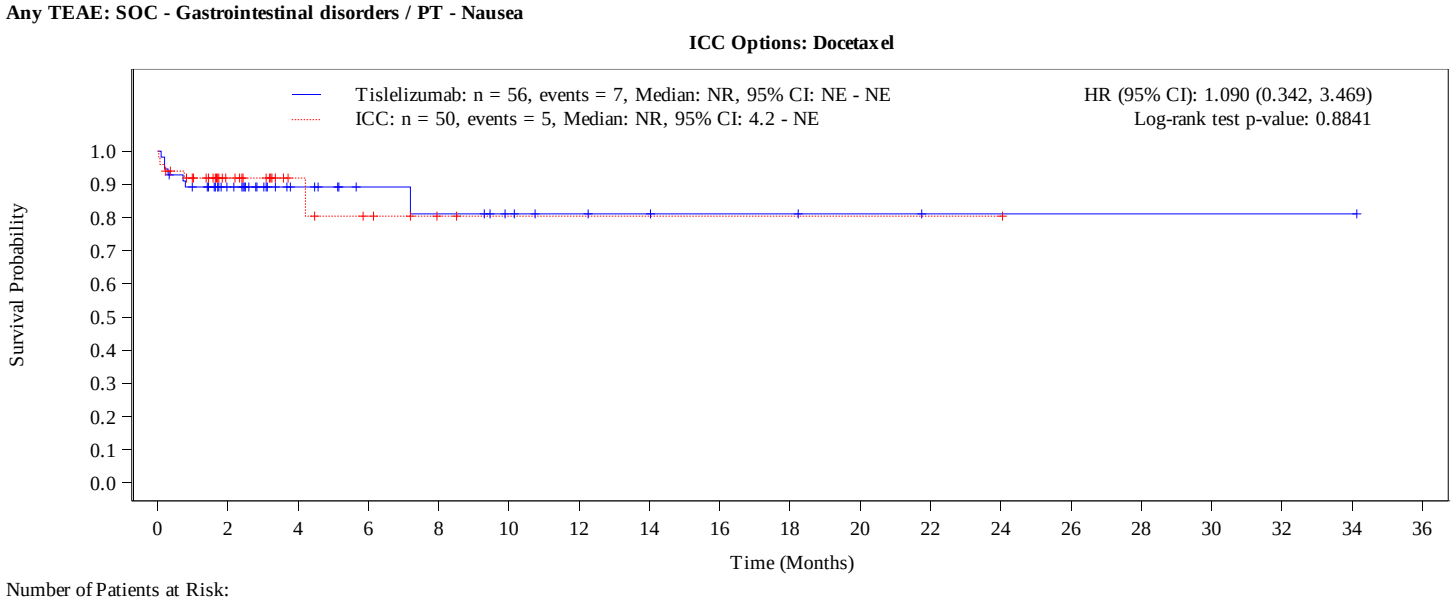
Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36
Tislelizumab	56	36	18	11	10	7	5	4	3	3	2	1	1	1	1	1	1	1	0
ICC	50	21	8	5	2	1	1	1	1	1	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
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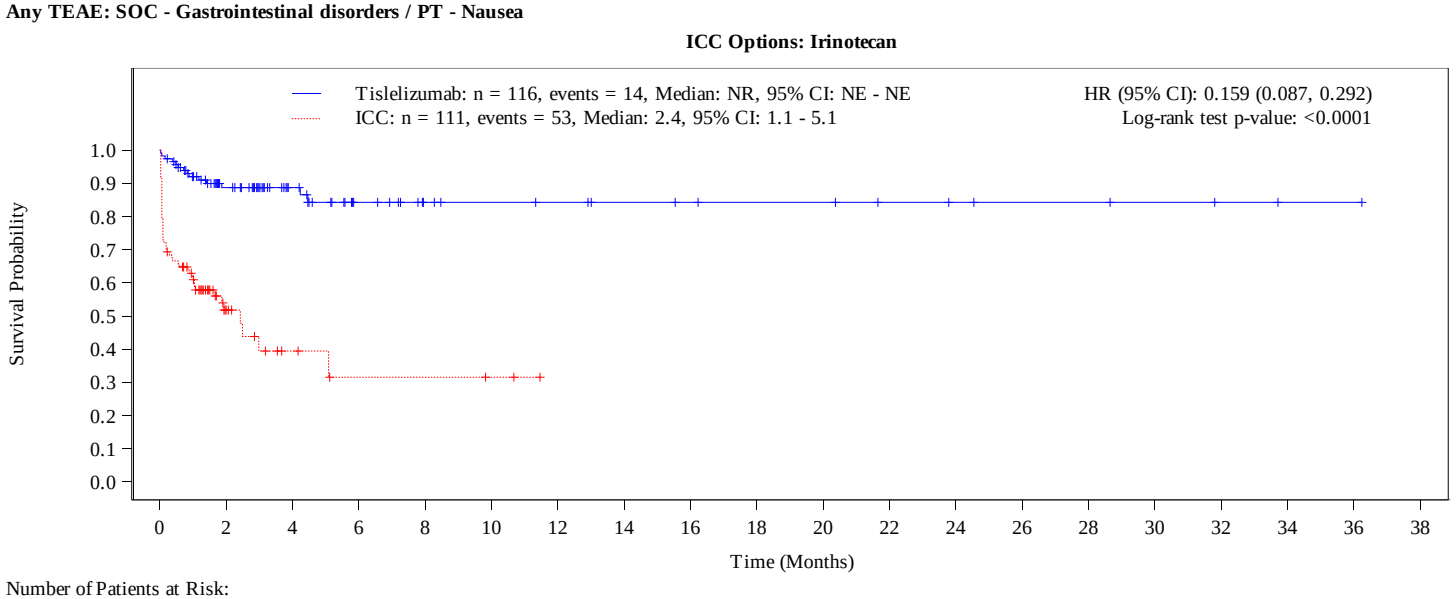
Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



Number of Patients at Risk:

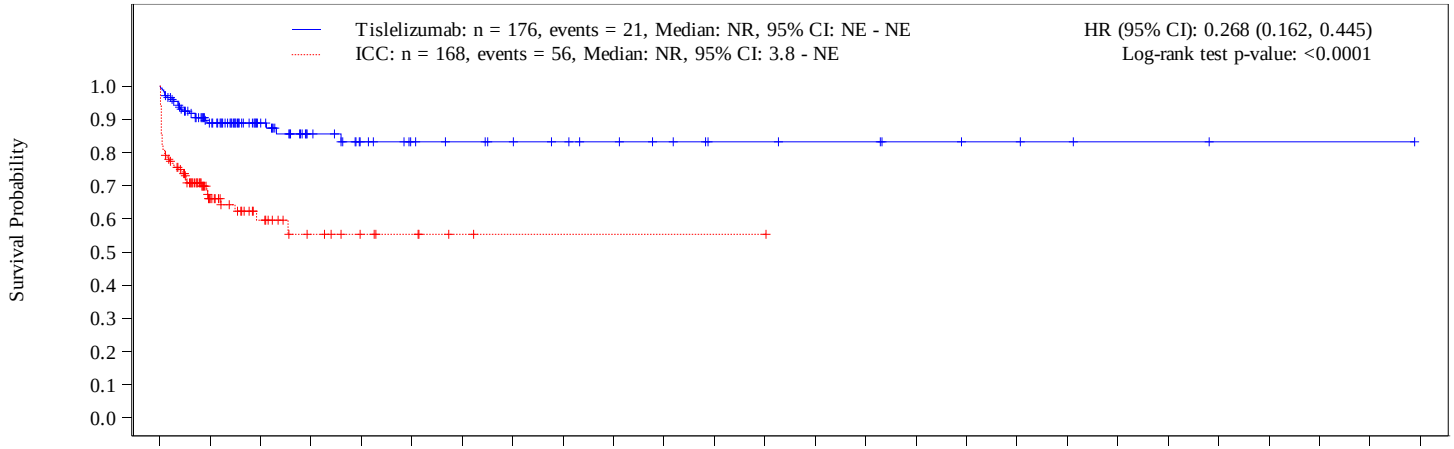
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38
Tislelizumab	116	72	42	24	16	14	12	10	9	8	8	6	5	4	4	3	2	1	1	0
ICC	111	18	6	3	3	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-s-km-socpt-sub-safety-cl.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Nausea

Region #2: Asia (excluding Japan)



Number of Patients at Risk:

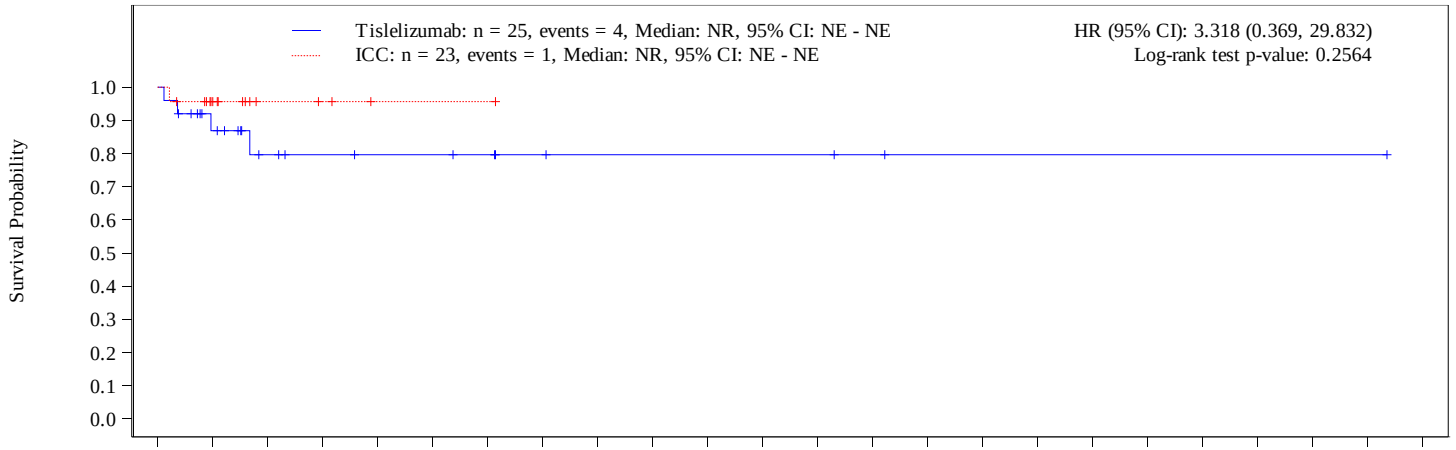
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	176	108	60	38	28	22	20	18	15	13	11	8	8	7	7	5	4	4	3	2	2	1	1	1	1	0
ICC	168	47	22	11	7	5	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-s-km-socpt-sub-safety-cl.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Nausea

Region #2: Japan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46
Tislelizumab	25	17	10	8	7	7	6	4	3	3	3	3	3	2	1	1	1	1	1	1	1	1	1	0
ICC	23	12	4	3	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
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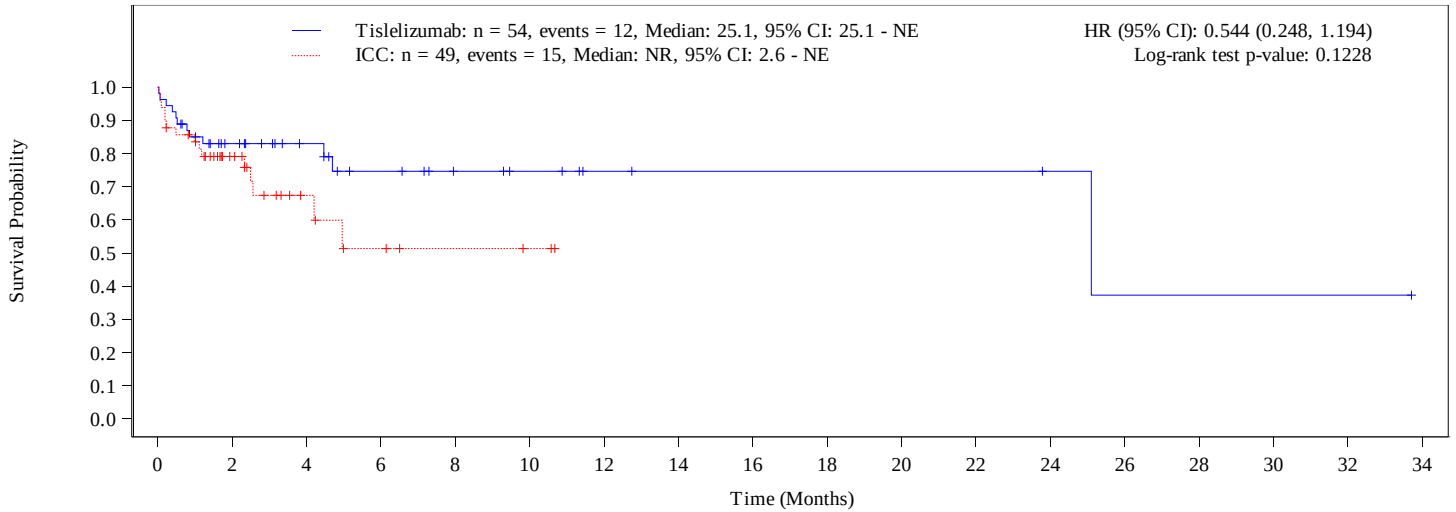
Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Nausea

Region #2: Europe/North America



Number of Patients at Risk:

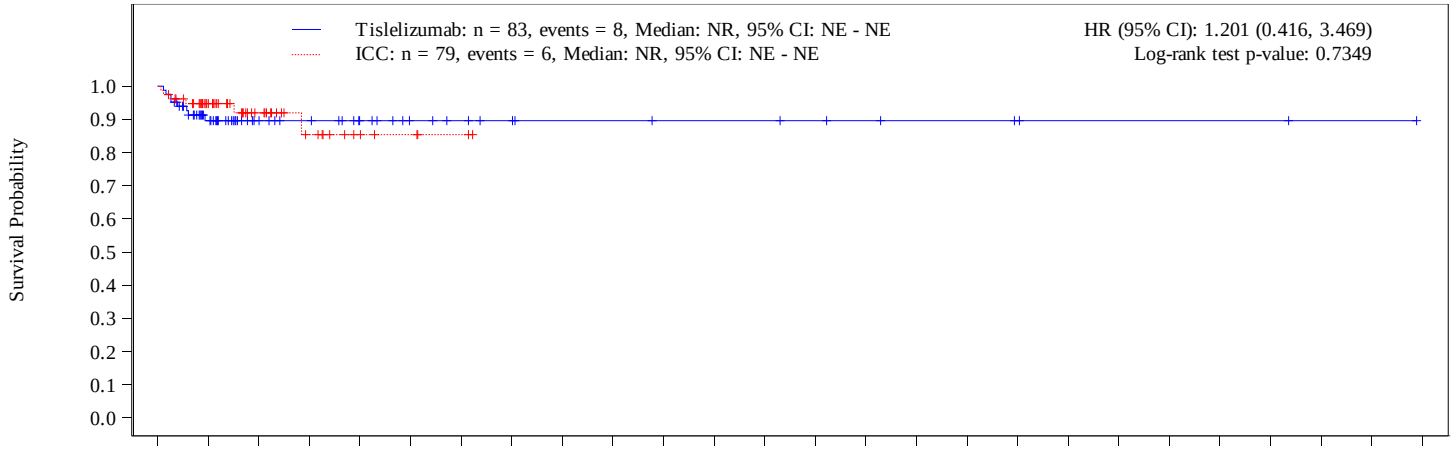
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34
Tislelizumab	54	34	21	14	10	7	4	3	3	3	3	3	2	1	1	1	1	0
ICC	49	26	9	5	3	2	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-s-km-socpt-sub-safety-cl.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Vomiting

ICC Options: Paclitaxel



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	83	53	30	26	19	14	12	10	8	8	7	7	7	6	5	4	4	3	2	2	2	2	2	1	1	0
ICC	79	51	23	12	6	4	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
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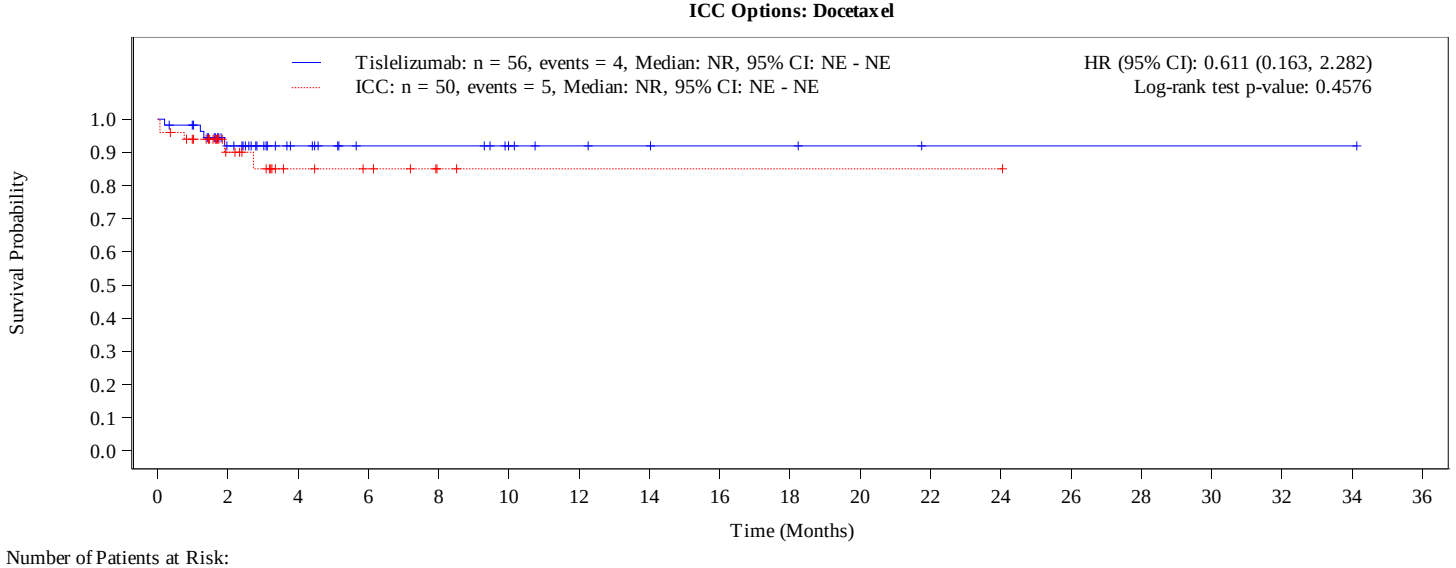
Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Gastrointestinal disorders / PT - Vomiting



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36
Tislelizumab	56	36	19	11	11	7	5	4	3	3	2	1	1	1	1	1	1	1	0
ICC	50	21	9	6	2	1	1	1	1	1	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
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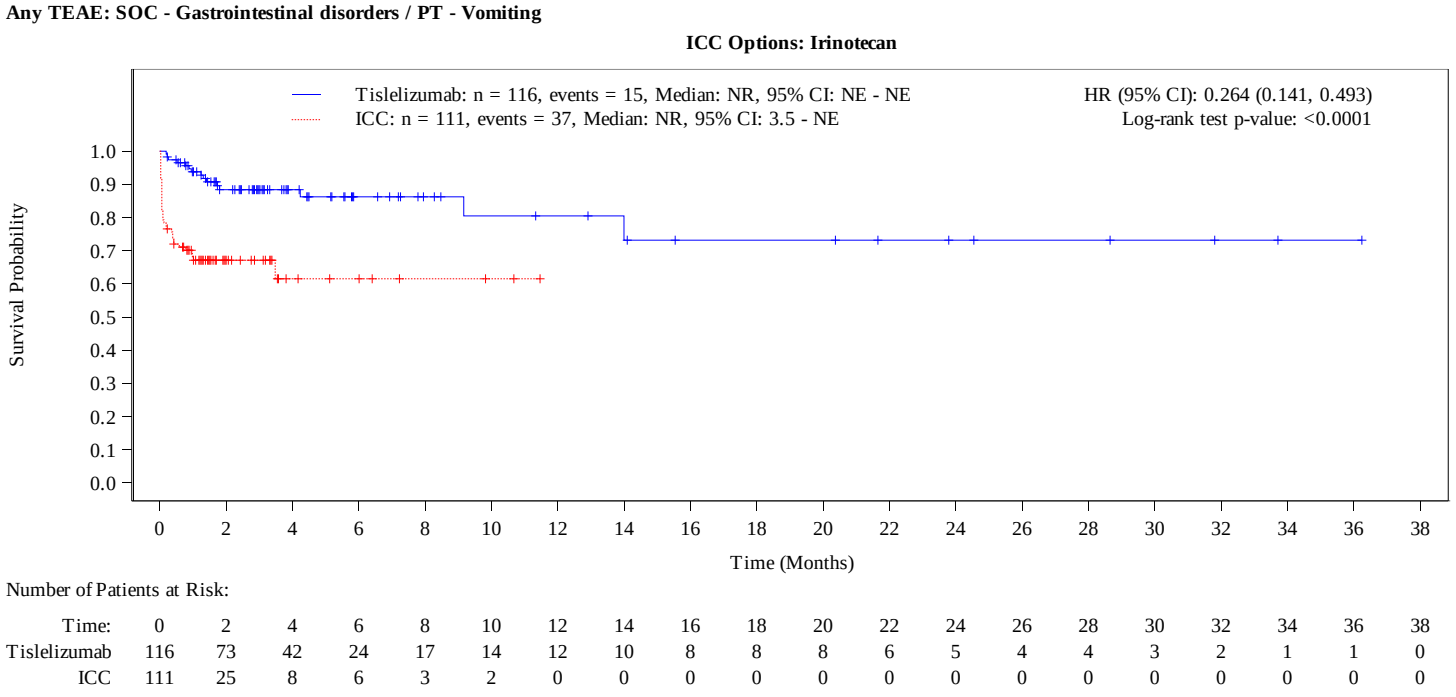
Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

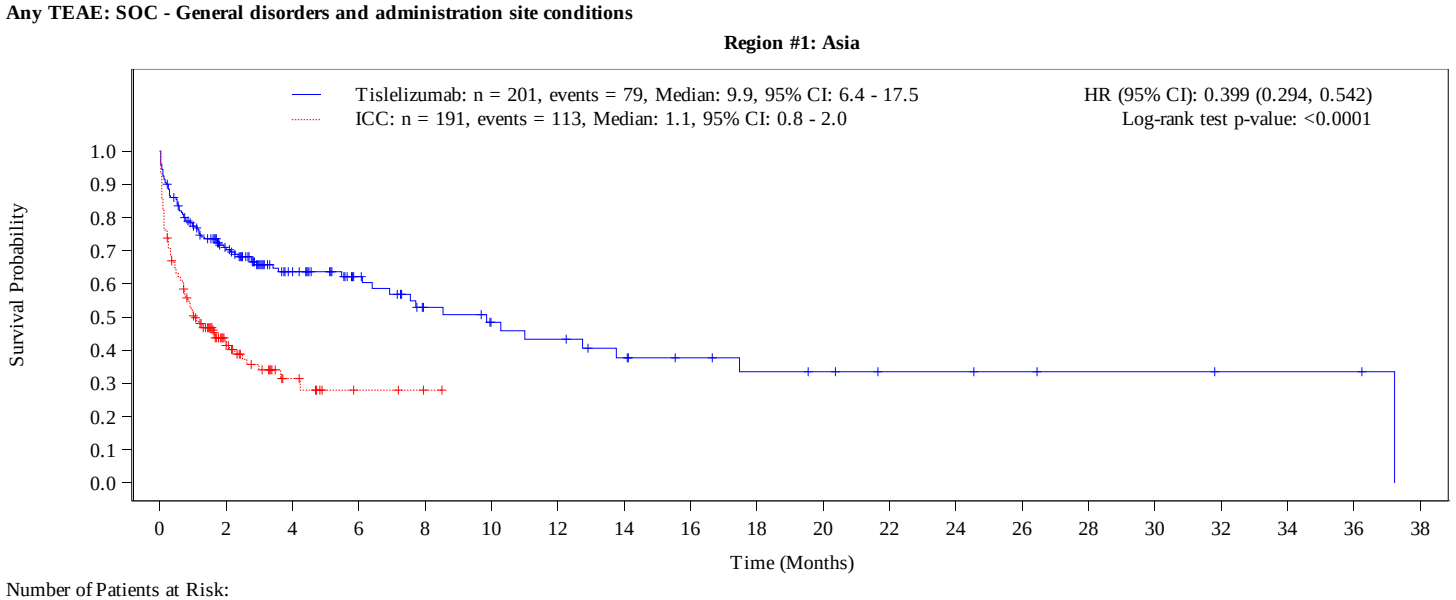


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38
Tislelizumab	116	73	42	24	17	14	12	10	8	8	8	6	5	4	4	3	2	1	1	0
ICC	111	25	8	6	3	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-s-km-socpt-sub-safety-cl.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



Number of Patients at Risk:

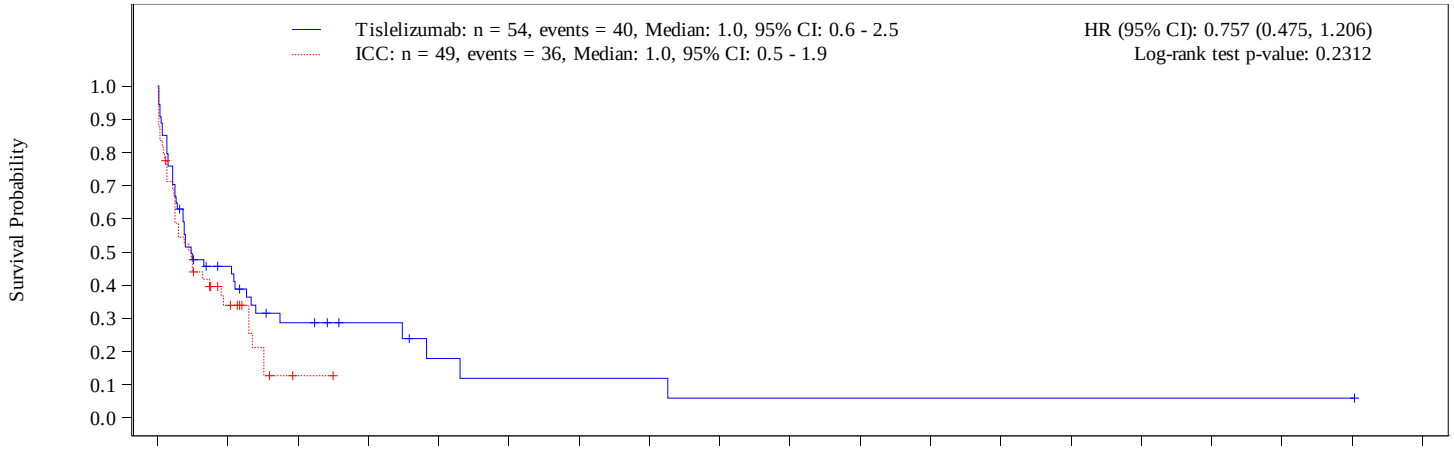
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38
Tislelizumab	201	103	55	36	24	19	17	13	10	8	7	5	5	4	3	3	2	2	2	0
ICC	191	37	10	3	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-s-km-socpt-sub-safety-cl.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions

Region #1: Europe/North America



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36
Tislelizumab	54	20	10	6	3	2	2	2	1	1	1	1	1	1	1	1	1	1	0
ICC	49	12	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
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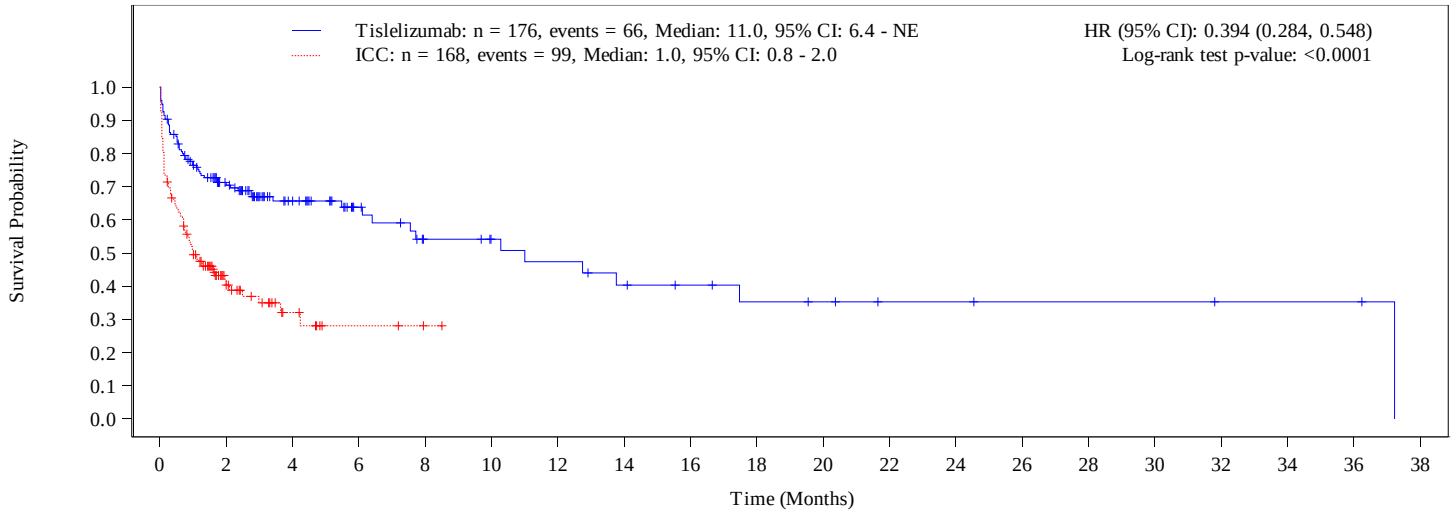
Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions

Region #2: Asia (excluding Japan)



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38
Tislelizumab	176	88	47	28	19	16	14	11	9	7	6	4	4	3	3	3	2	2	2	0
ICC	168	29	9	3	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
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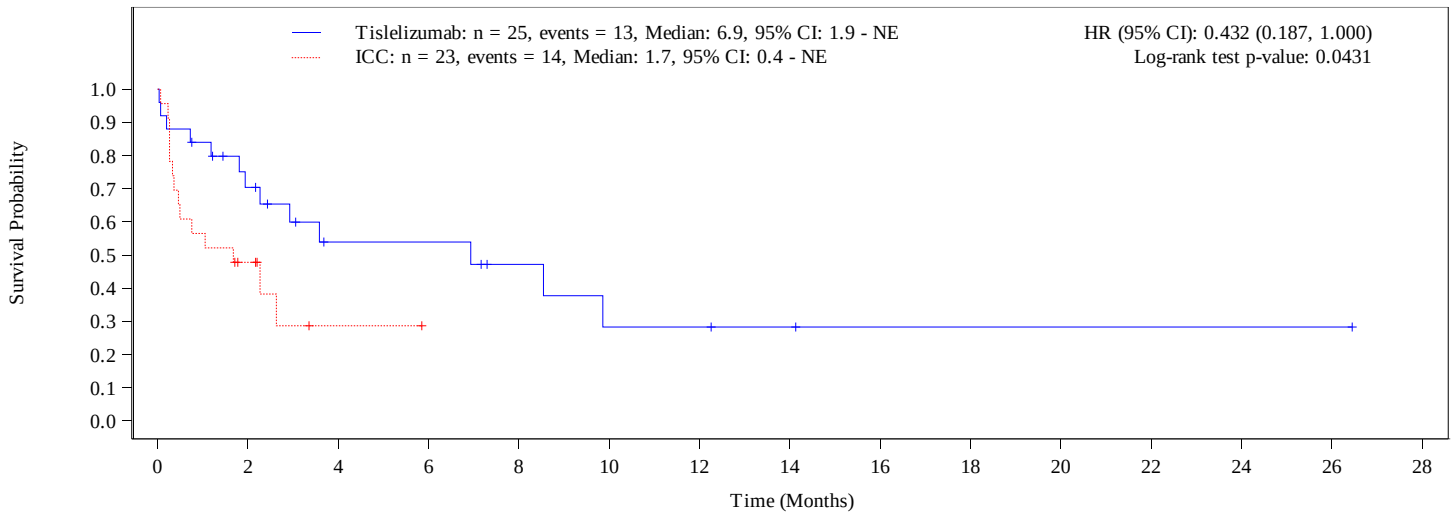
Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions

Region #2: Japan



Number of Patients at Risk:

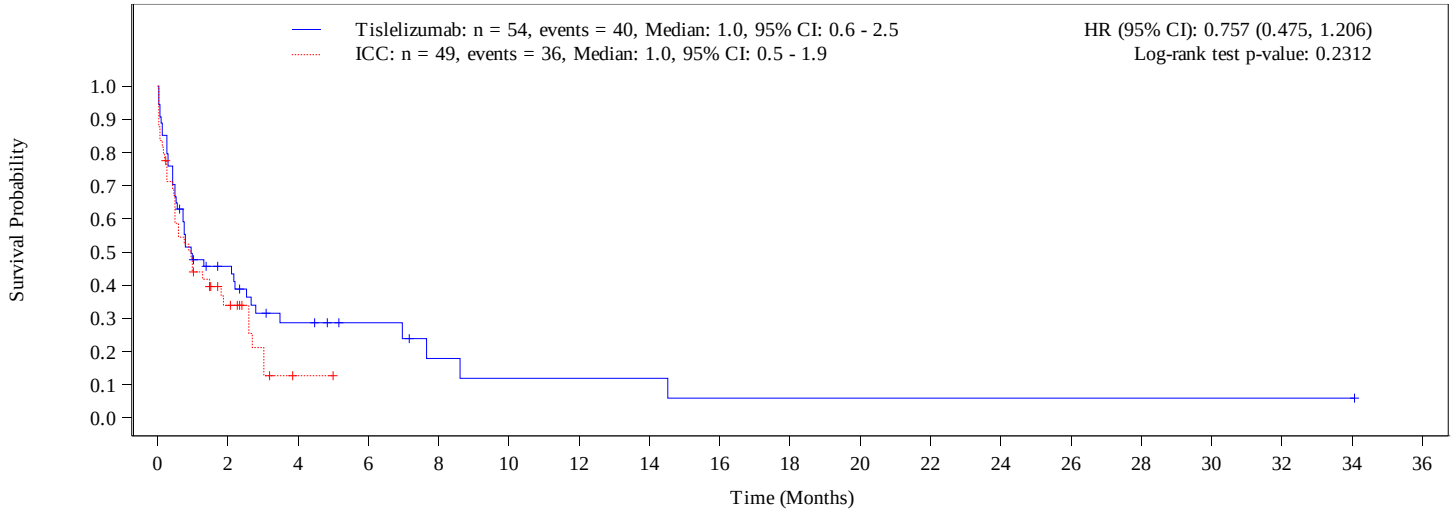
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28
Tislelizumab	25	15	8	8	5	3	3	2	1	1	1	1	1	1	0
ICC	23	8	1	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-s-km-socpt-sub-safety-cl.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions

Region #2: Europe/North America

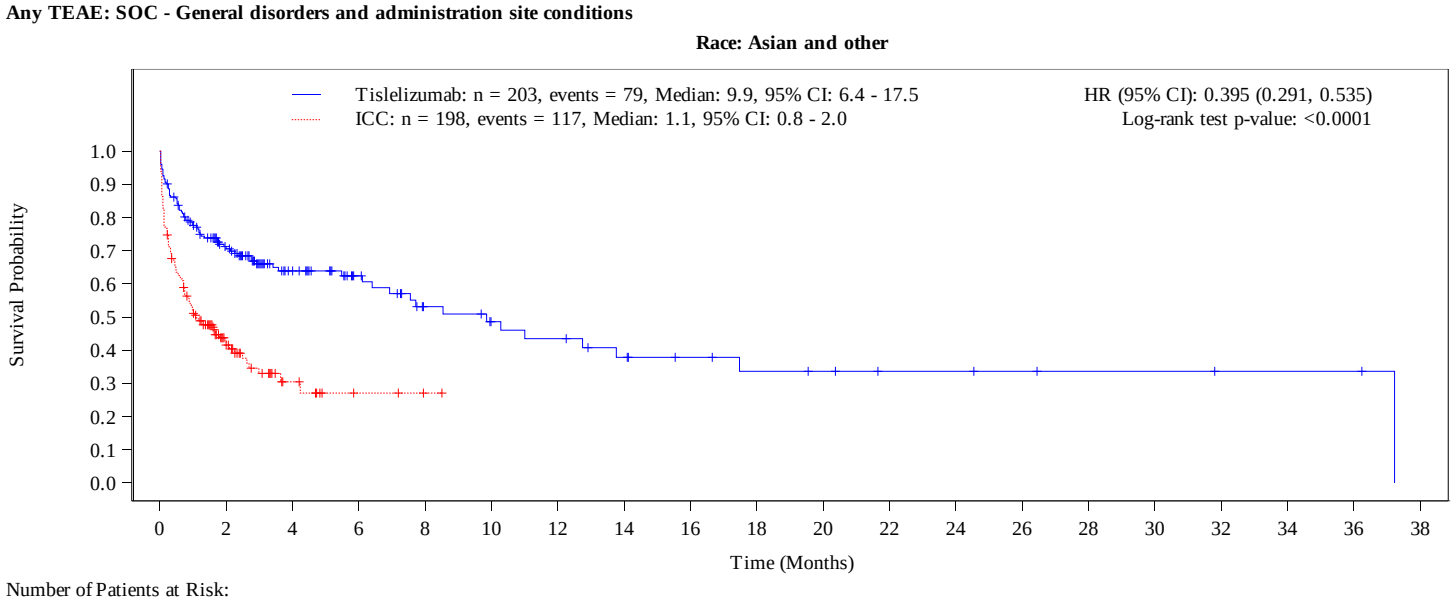


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36
Tislelizumab	54	20	10	6	3	2	2	2	1	1	1	1	1	1	1	1	1	1	0
ICC	49	12	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-s-km-socpt-sub-safety-cl.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

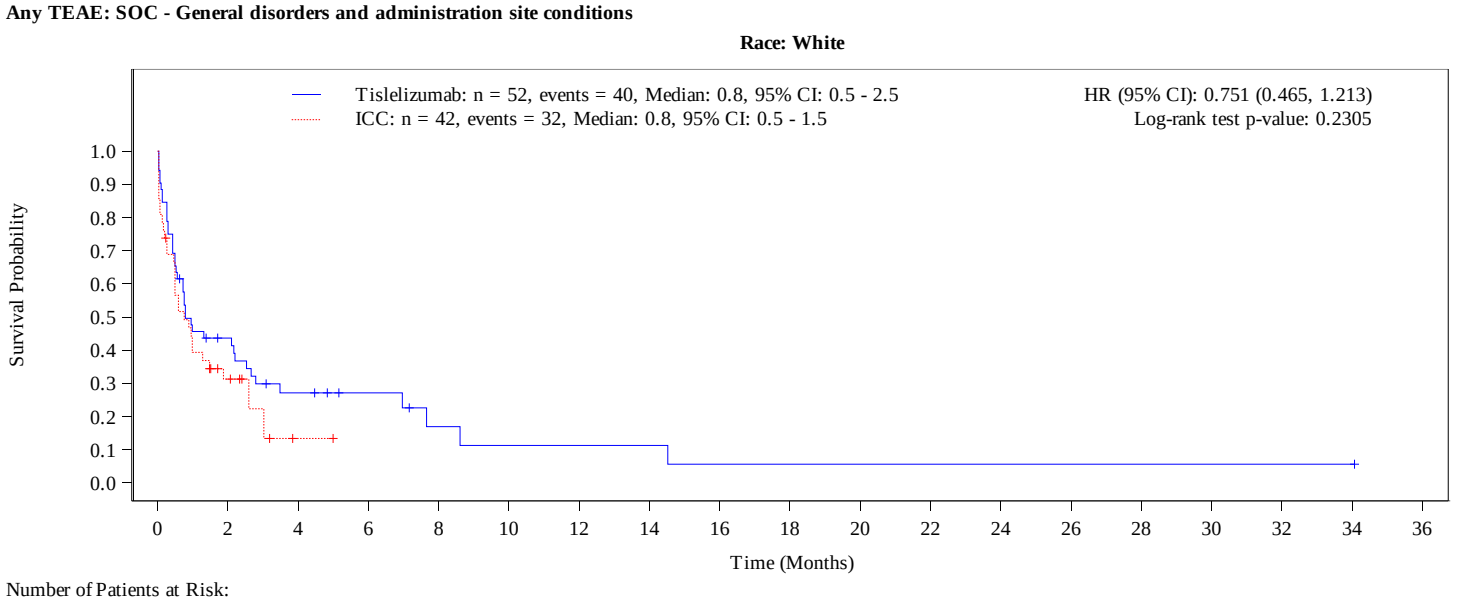


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38
Tislelizumab	203	104	55	36	24	19	17	13	10	8	7	5	5	4	3	3	2	2	2	0
ICC	198	39	10	3	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-s-km-socpt-sub-safety-cl.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

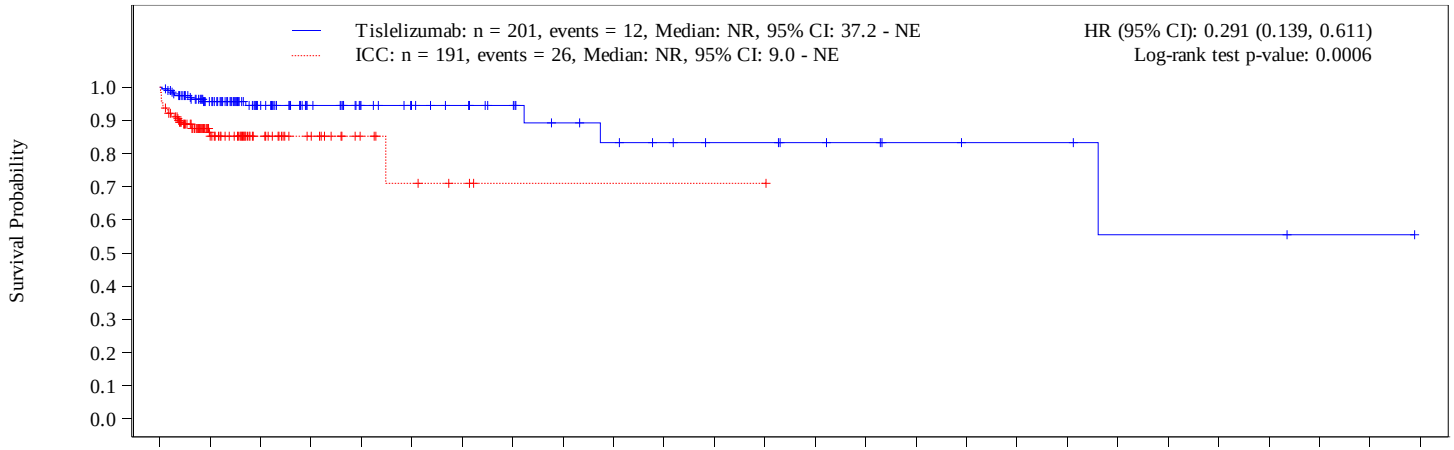


Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-s-km-socpt-sub-safety-cl.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

Region #1: Asia



Number of Patients at Risk:

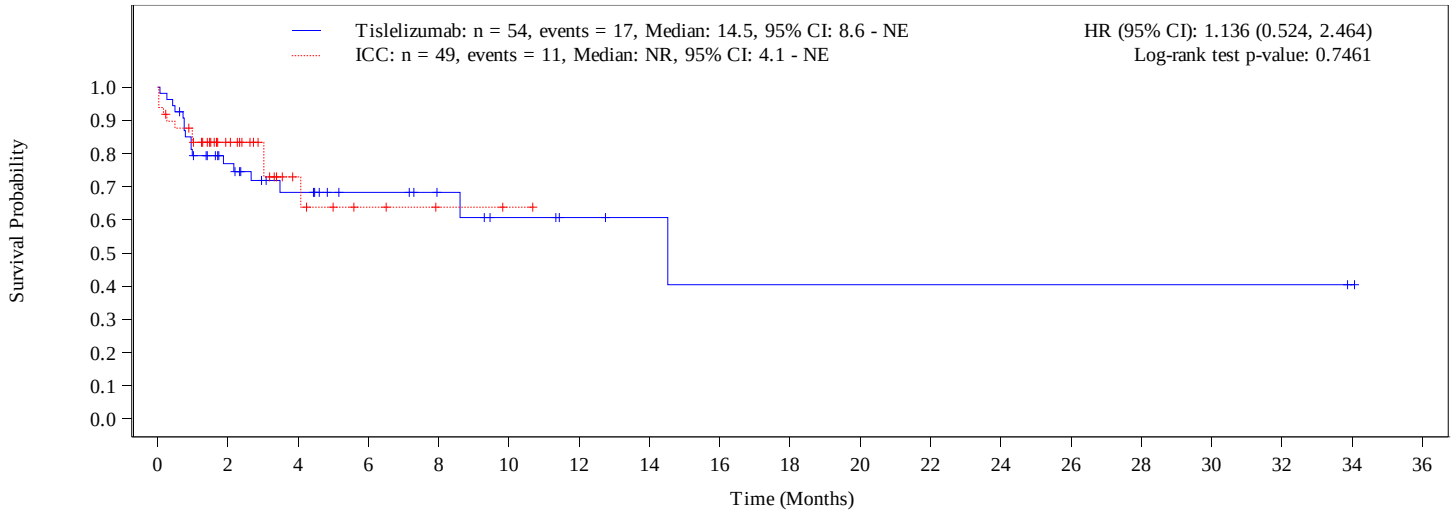
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	201	131	71	46	35	29	26	22	16	14	12	10	10	8	7	5	4	4	4	2	2	2	2	1	1	0
ICC	191	74	31	17	8	5	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-s-km-socpt-sub-safety-cl.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

Region #1: Europe/North America



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36
Tislelizumab	54	32	19	12	9	6	4	3	2	2	2	2	2	2	2	2	2	1	0
ICC	49	27	8	4	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
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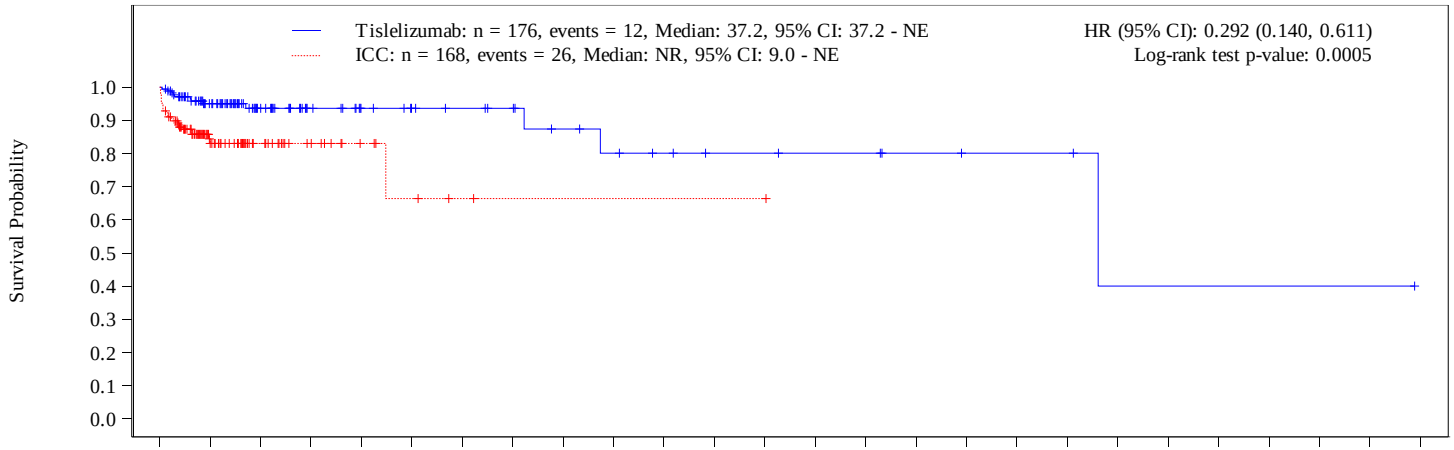
Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

Region #2: Asia (excluding Japan)

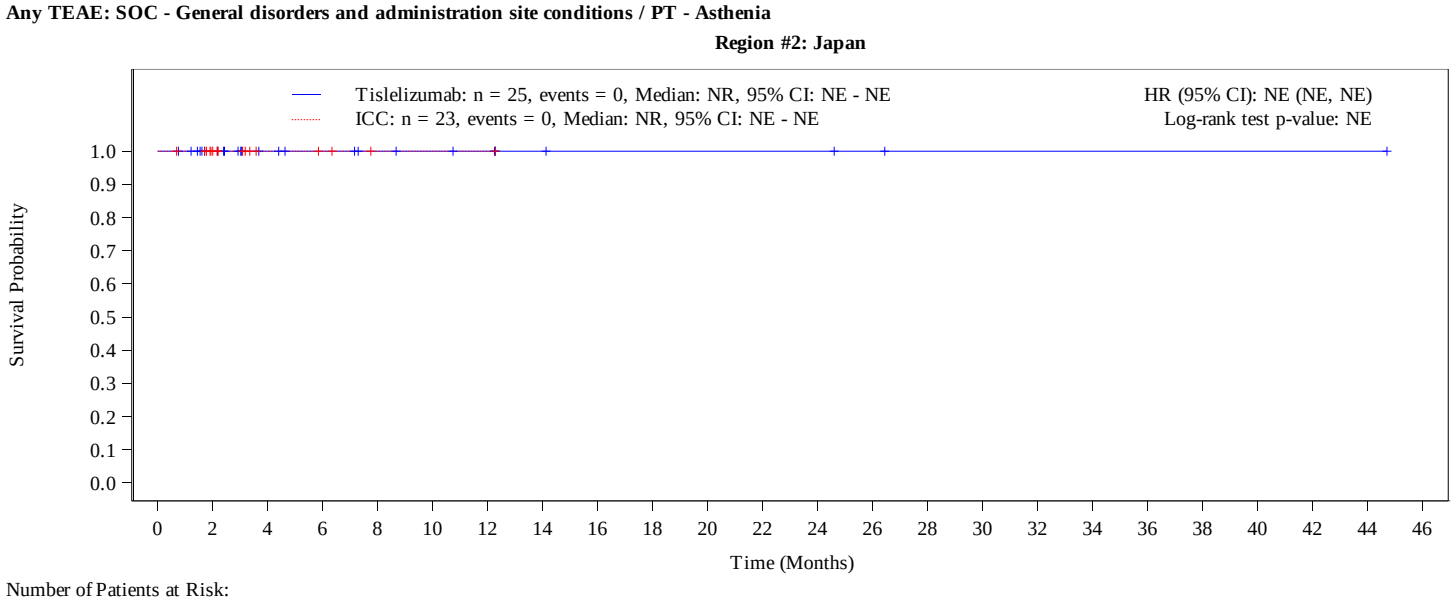


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	176	112	59	36	27	22	20	18	13	11	9	7	7	6	6	4	3	3	3	1	1	1	1	1	1	0
ICC	168	61	27	14	7	4	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-s-km-socpt-sub-safety-cl.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



Number of Patients at Risk:

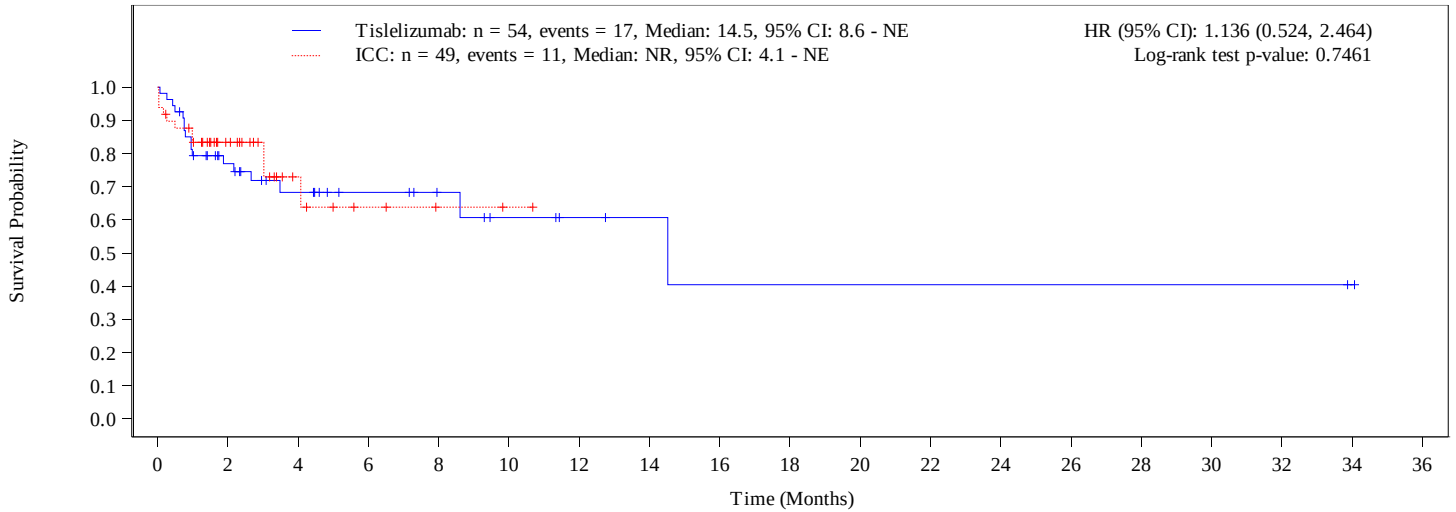
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46
Tislelizumab	25	19	12	10	8	7	6	4	3	3	3	3	3	2	1	1	1	1	1	1	1	1	1	0
ICC	23	13	4	3	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-s-km-socpt-sub-safety-cl.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

Region #2: Europe/North America



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36
Tislelizumab	54	32	19	12	9	6	4	3	2	2	2	2	2	2	2	2	2	1	0
ICC	49	27	8	4	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
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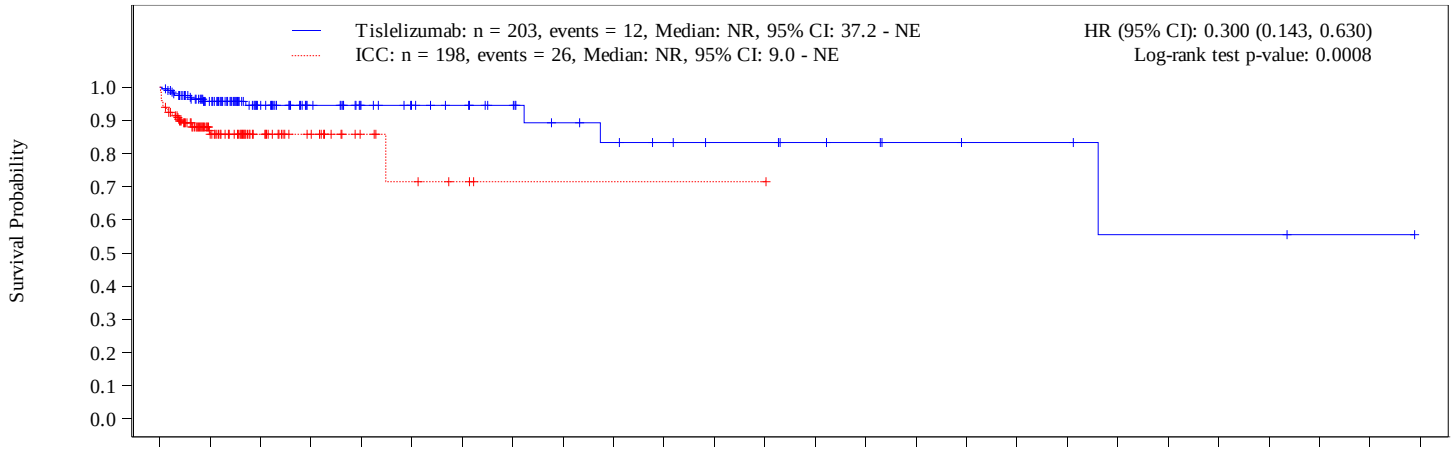
Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

Race: Asian and other



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	203	132	71	46	35	29	26	22	16	14	12	10	10	8	7	5	4	4	4	2	2	2	2	1	1	0
ICC	198	79	33	18	8	5	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
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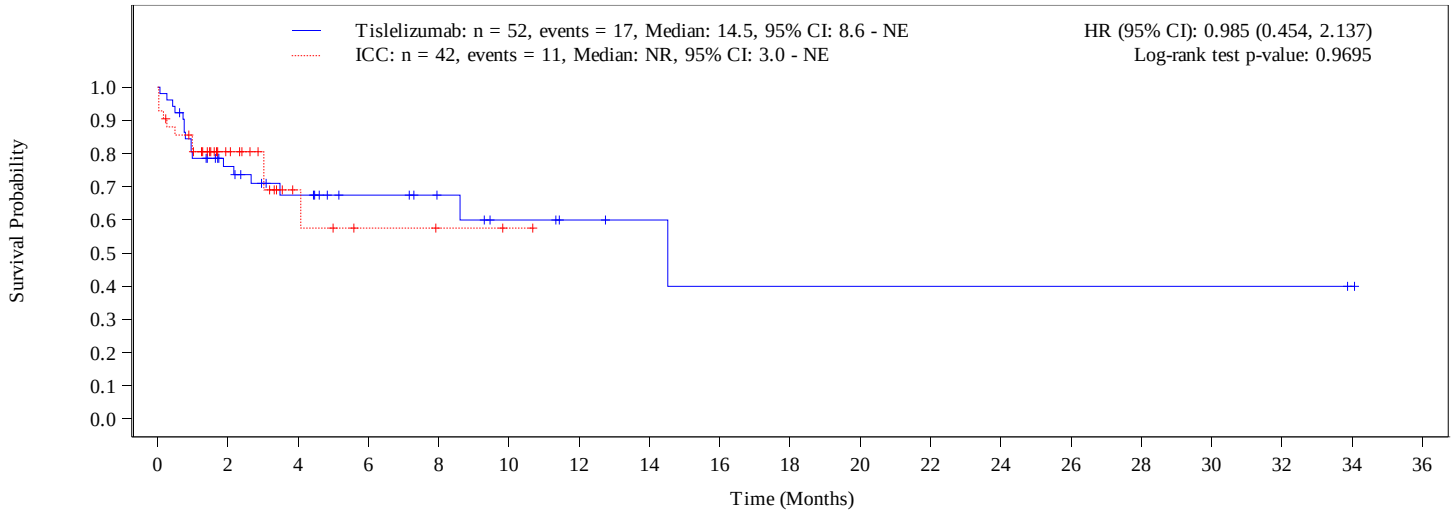
Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - General disorders and administration site conditions / PT - Asthenia

Race: White

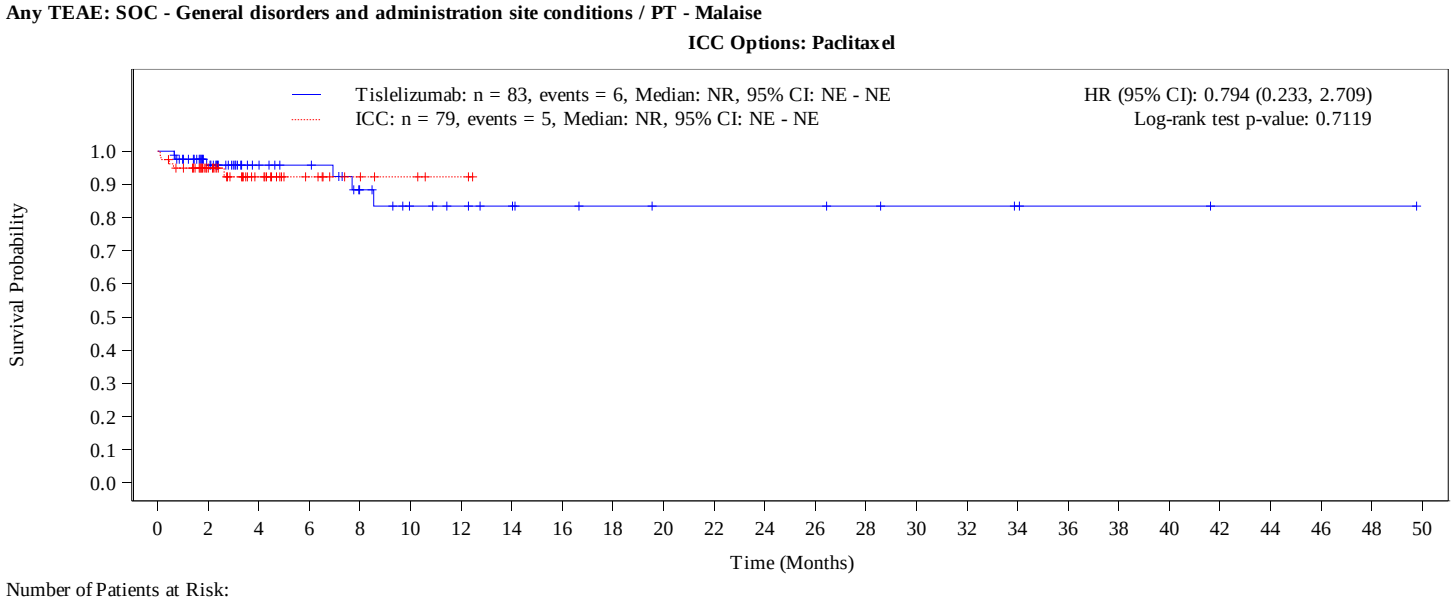


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36
Tislelizumab	52	31	19	12	9	6	4	3	2	2	2	2	2	2	2	2	2	1	0
ICC	42	22	6	3	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-s-km-socpt-sub-safety-cl.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

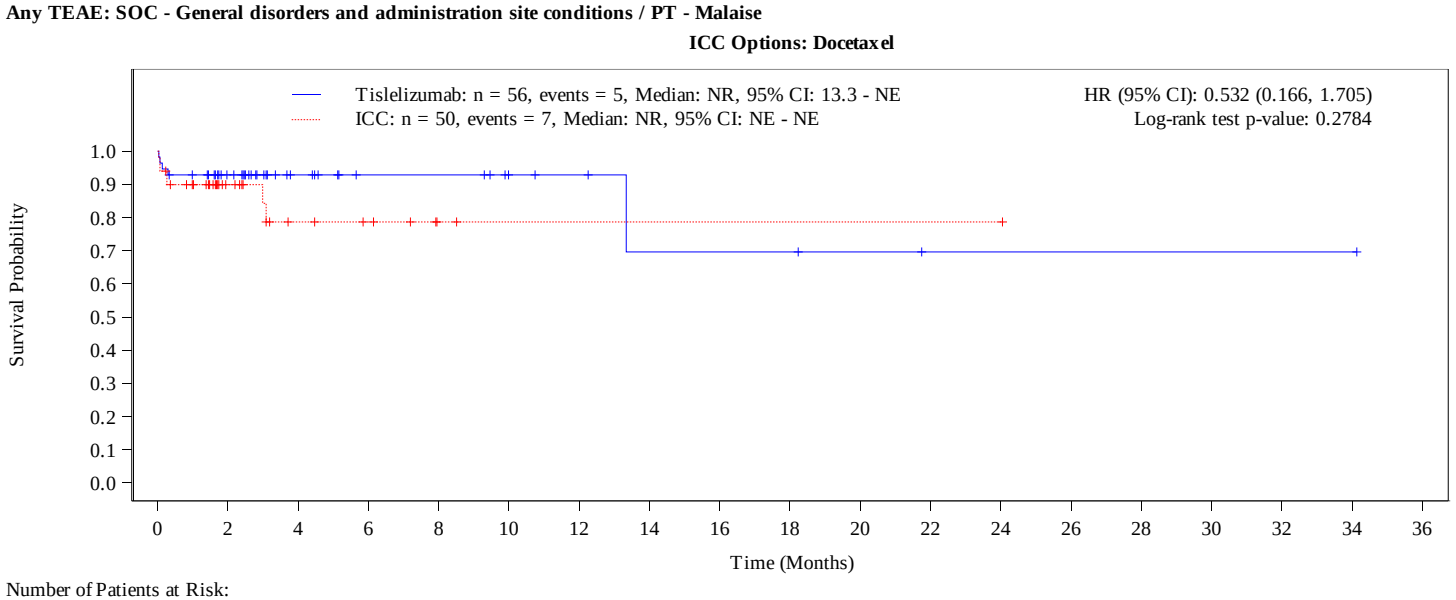


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	83	54	33	29	19	14	12	10	8	7	6	6	6	6	5	4	4	3	2	2	2	1	1	1	1	0
ICC	79	50	22	11	6	4	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-s-km-socpt-sub-safety-cl.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36
Tislelizumab	56	37	18	10	10	6	5	3	3	3	2	1	1	1	1	1	1	1	0
ICC	50	20	8	6	2	1	1	1	1	1	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
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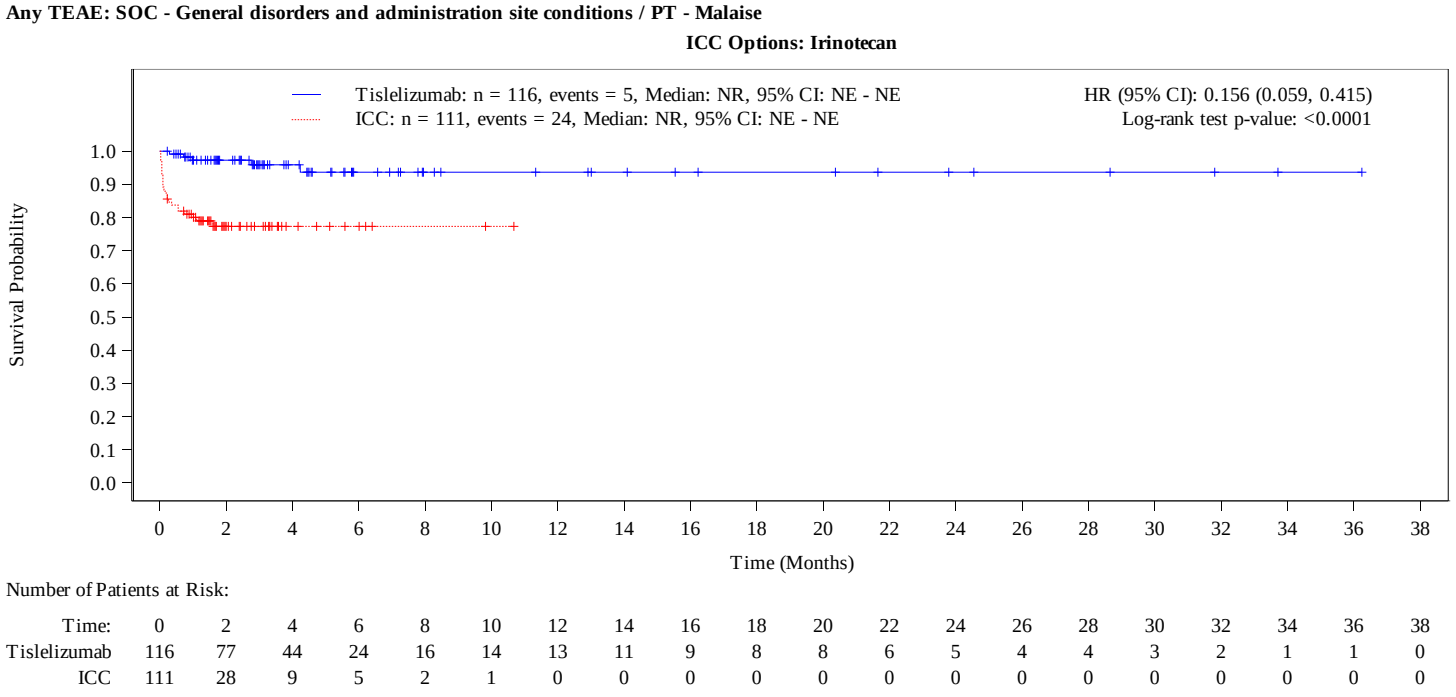
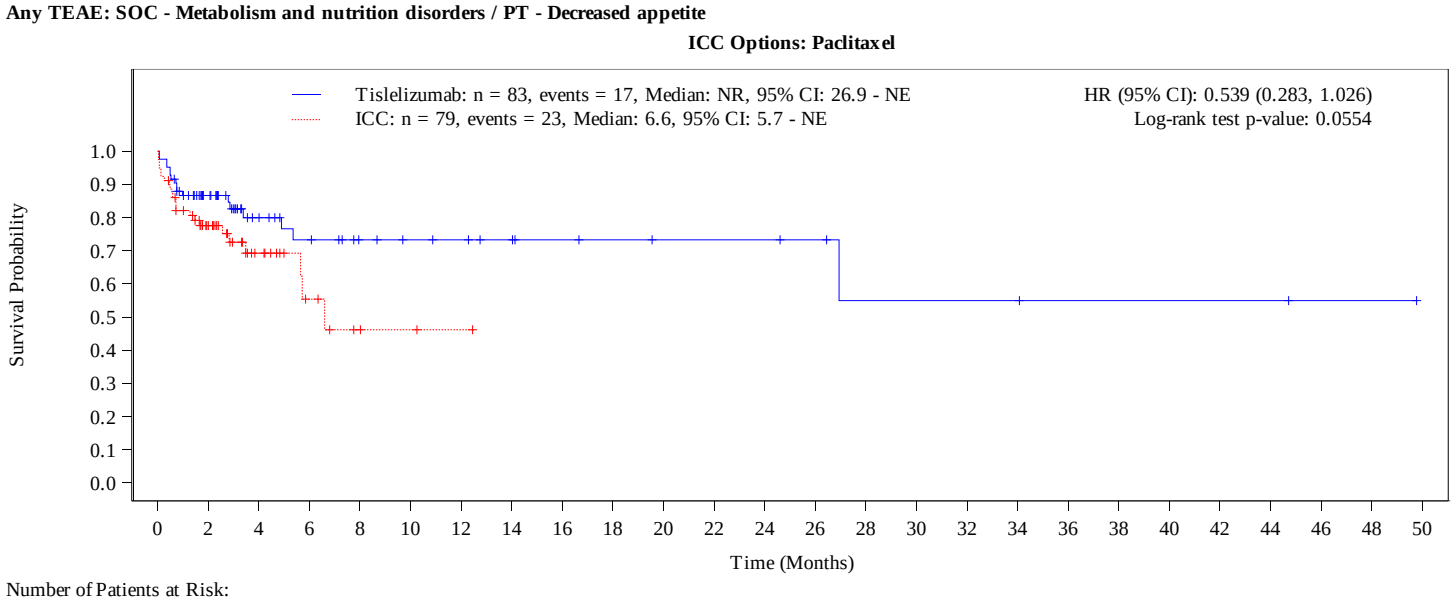
Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-s-km-socpt-sub-safety-cl.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



Number of Patients at Risk:

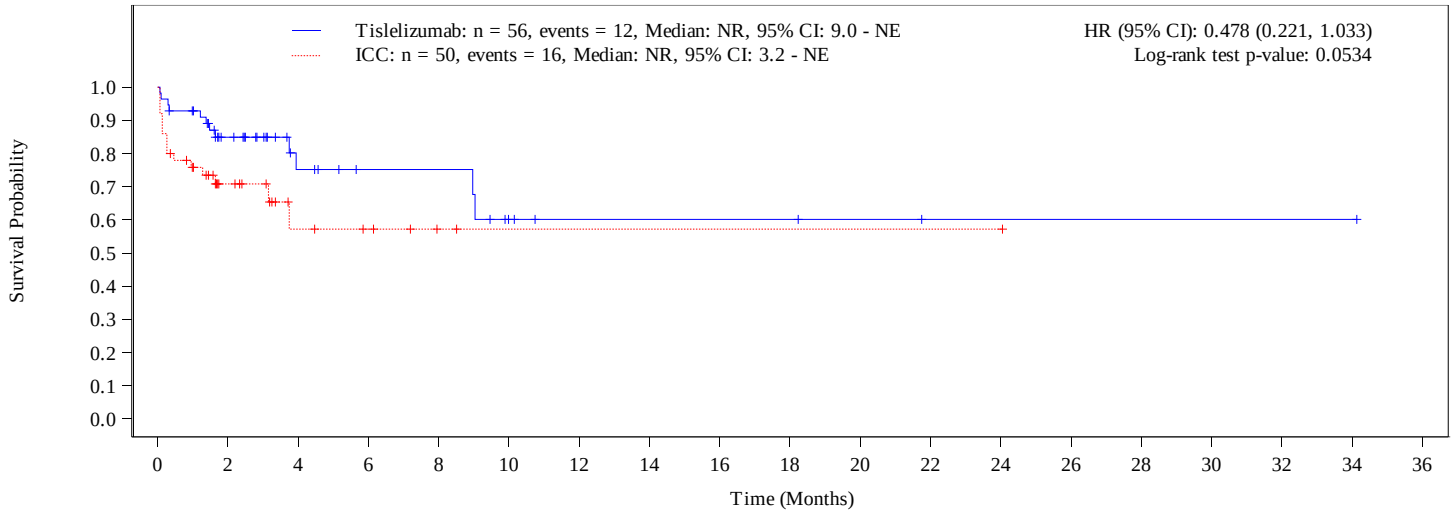
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	83	51	28	22	15	13	12	10	8	7	6	6	6	5	3	3	3	3	2	2	2	2	2	1	1	0
ICC	79	42	16	7	3	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-s-km-socpt-sub-safety-cl.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

ICC Options: Docetaxel

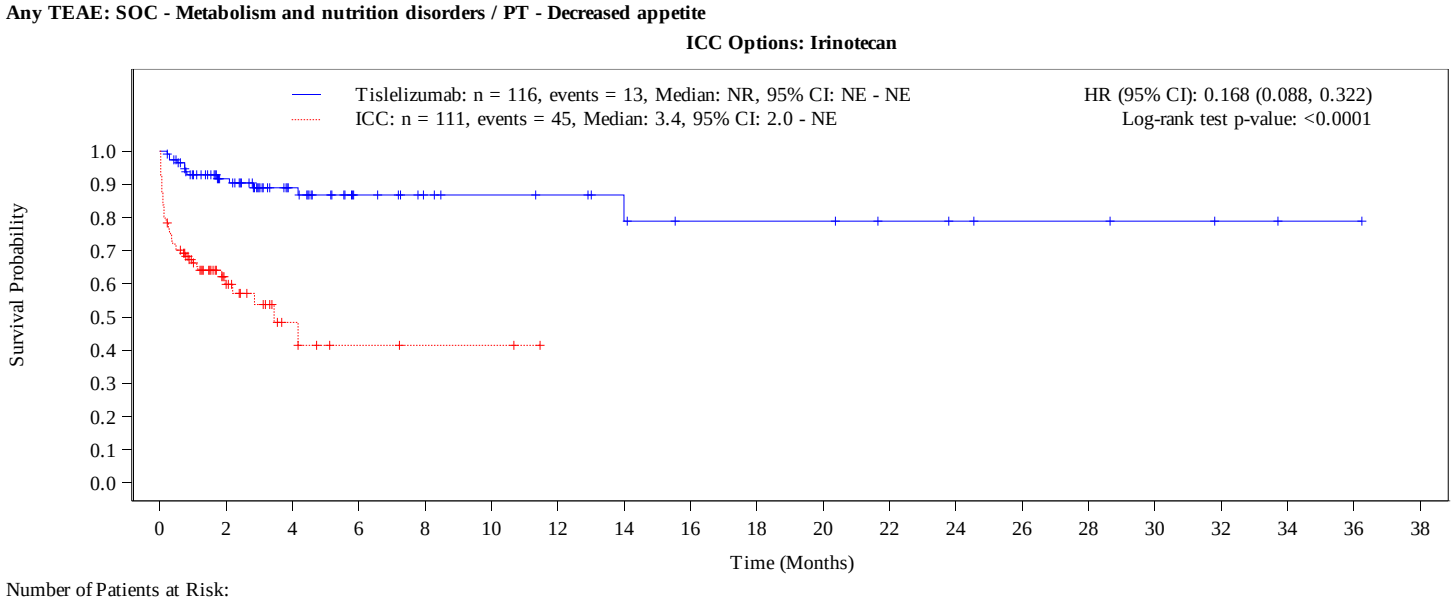


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36
Tislelizumab	56	33	15	10	10	5	3	3	3	3	2	1	1	1	1	1	1	1	0
ICC	50	19	7	5	2	1	1	1	1	1	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-s-km-socpt-sub-safety-cl.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



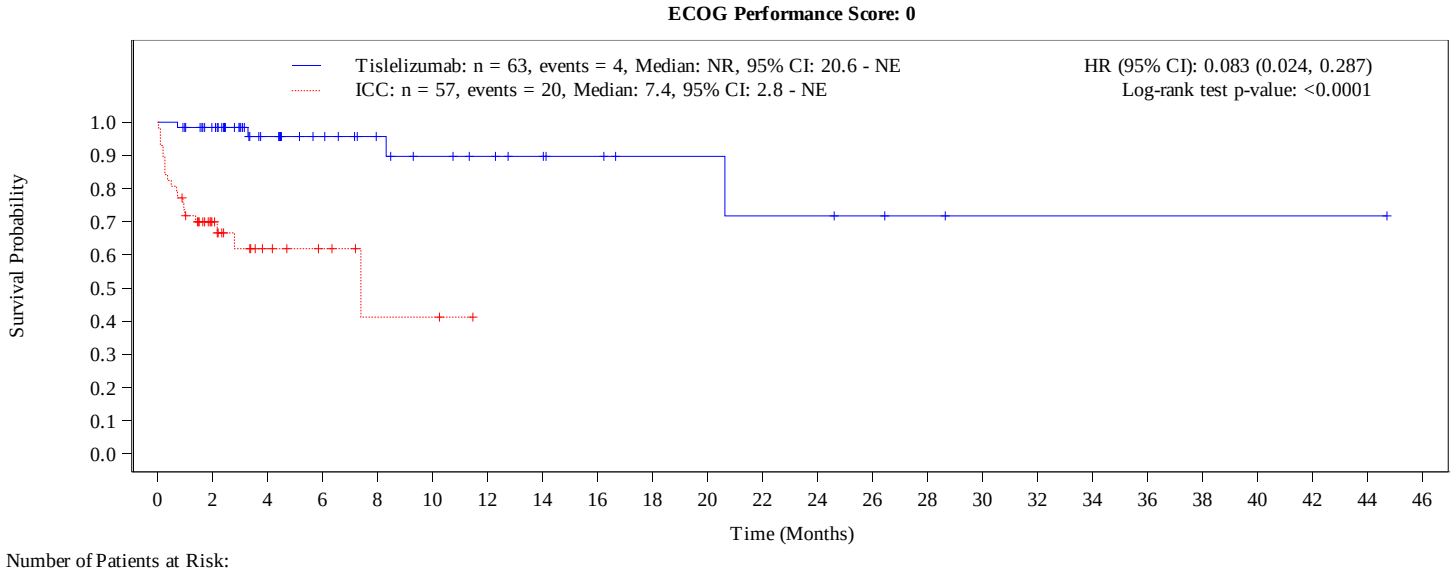
Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38
Tislelizumab	116	73	41	22	16	14	13	10	8	8	8	6	5	4	4	3	2	1	1	0
ICC	111	26	7	3	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-s-km-socpt-sub-safety-cl.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders



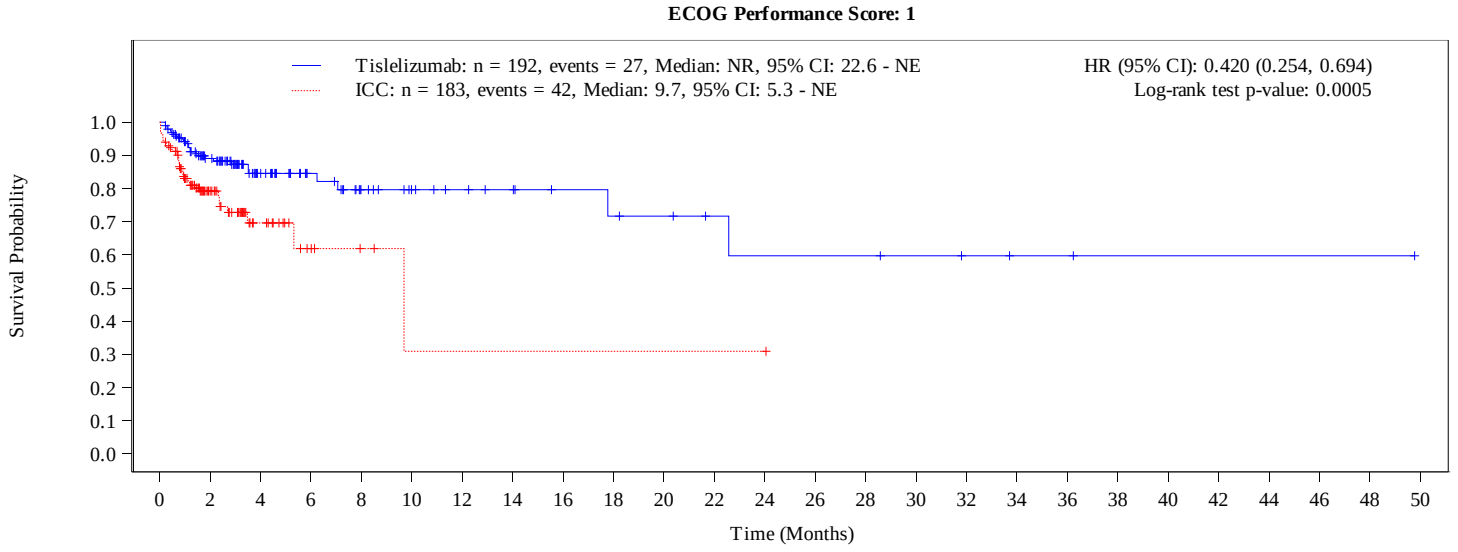
Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46
Tislelizumab	63	50	31	22	16	13	11	9	7	5	5	4	4	3	2	1	1	1	1	1	1	1	1	0
ICC	57	22	9	5	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-s-km-socpt-sub-safety-cl.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders



Number of Patients at Risk:

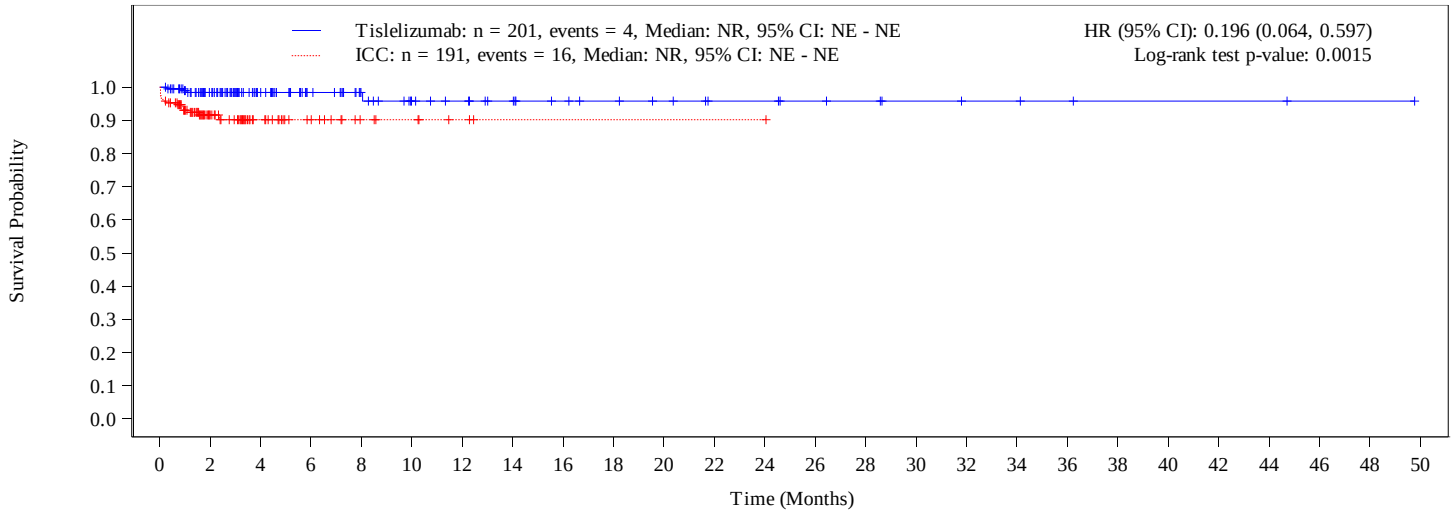
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	192	112	55	35	24	18	15	13	10	9	8	6	5	5	5	4	3	2	2	1	1	1	1	1	1	0
ICC	183	59	18	6	3	1	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-s-km-socpt-sub-safety-cl.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders / PT - Dizziness

Region #1: Asia



Number of Patients at Risk:

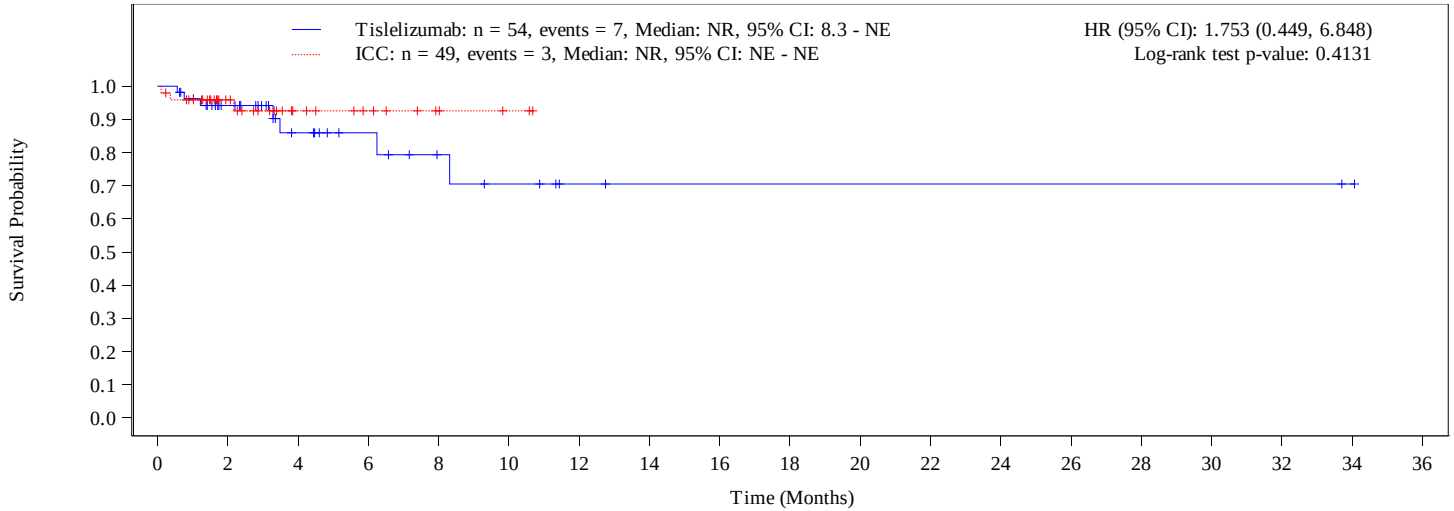
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	201	135	75	50	38	29	26	22	17	15	13	10	10	8	7	5	4	4	3	2	2	2	2	1	1	0
ICC	191	75	29	16	8	6	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-s-km-socpt-sub-safety-cl.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders / PT - Dizziness

Region #1: Europe/North America



Number of Patients at Risk:

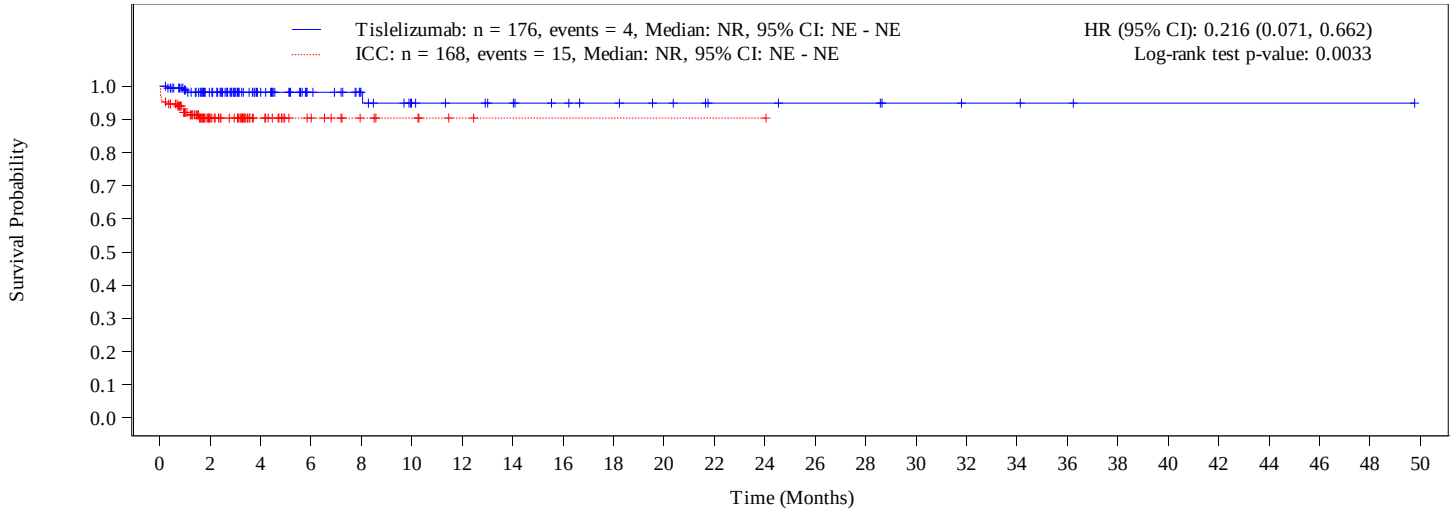
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36
Tislelizumab	54	36	19	13	9	6	3	2	2	2	2	2	2	2	2	2	2	1	0
ICC	49	30	12	8	4	2	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-s-km-socpt-sub-safety-cl.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders / PT - Dizziness

Region #2: Asia (excluding Japan)

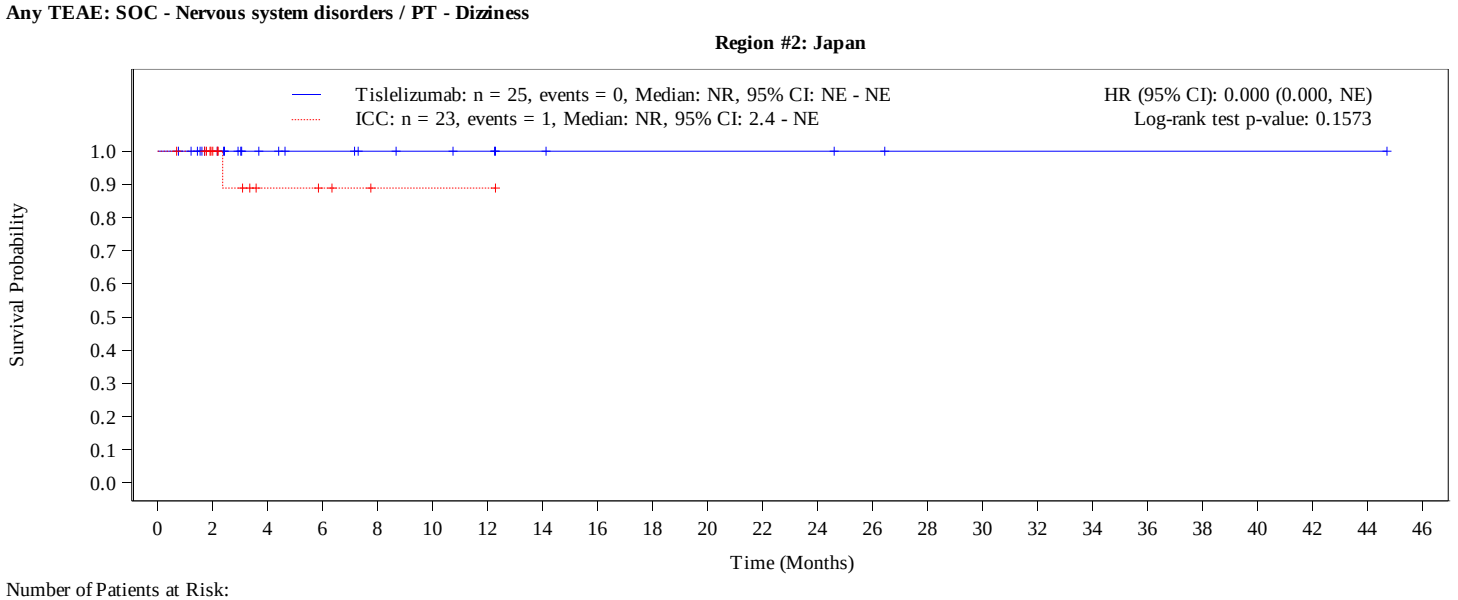


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	176	116	63	40	30	22	20	18	14	12	10	7	7	6	6	4	3	3	2	1	1	1	1	1	1	0
ICC	168	62	25	13	7	5	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-s-km-socpt-sub-safety-cl.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

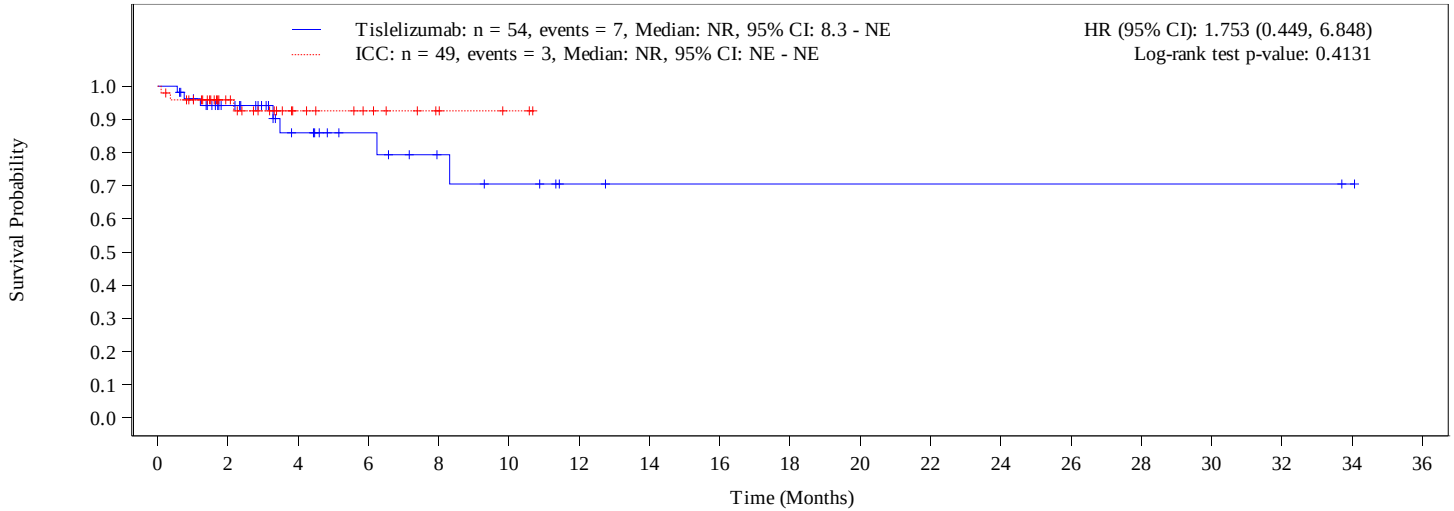


Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-s-km-socpt-sub-safety-cl.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders / PT - Dizziness

Region #2: Europe/North America



Number of Patients at Risk:

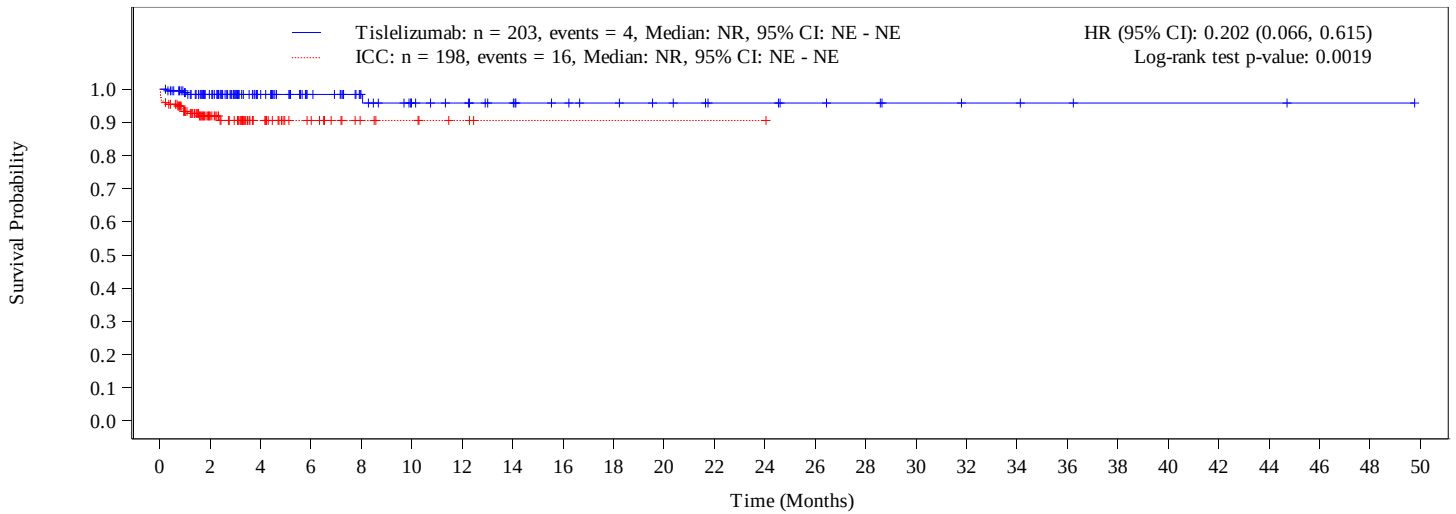
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36
Tislelizumab	54	36	19	13	9	6	3	2	2	2	2	2	2	2	2	2	2	1	0
ICC	49	30	12	8	4	2	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-s-km-socpt-sub-safety-cl.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders / PT - Dizziness

Race: Asian and other



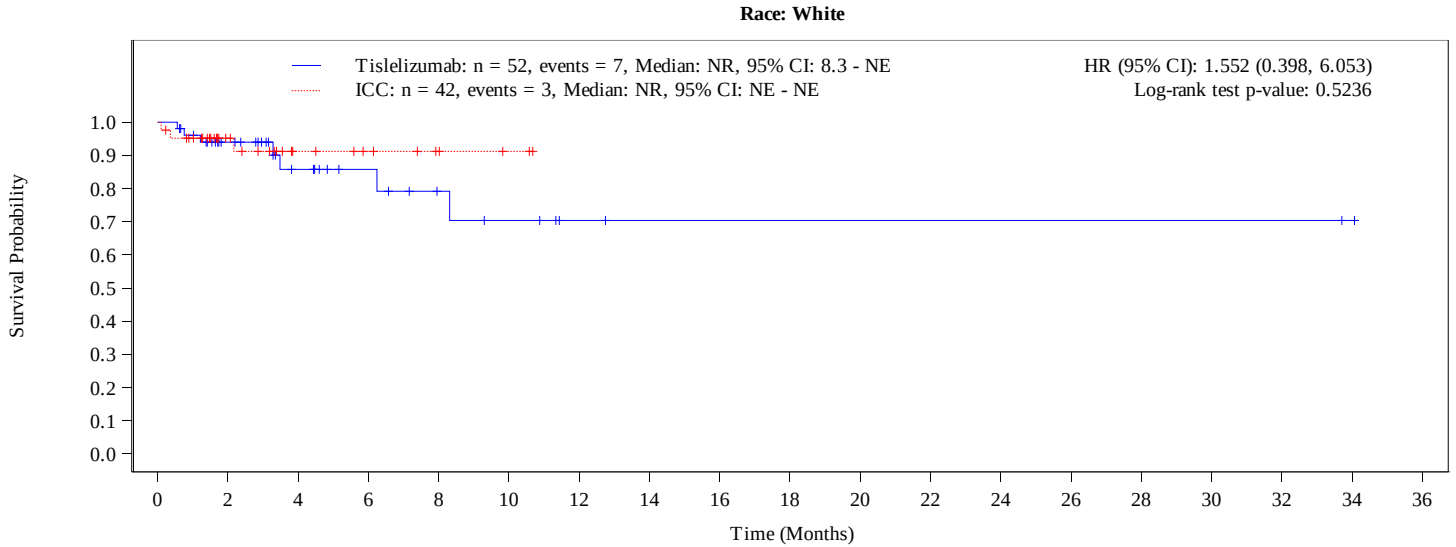
Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	203	136	75	50	38	29	26	22	17	15	13	10	10	8	7	5	4	4	3	2	2	2	2	1	1	0
ICC	198	80	31	17	8	6	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-s-km-socpt-sub-safety-cl.rtf

Figure 14.3.1.2.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

Any TEAE: SOC - Nervous system disorders / PT - Dizziness

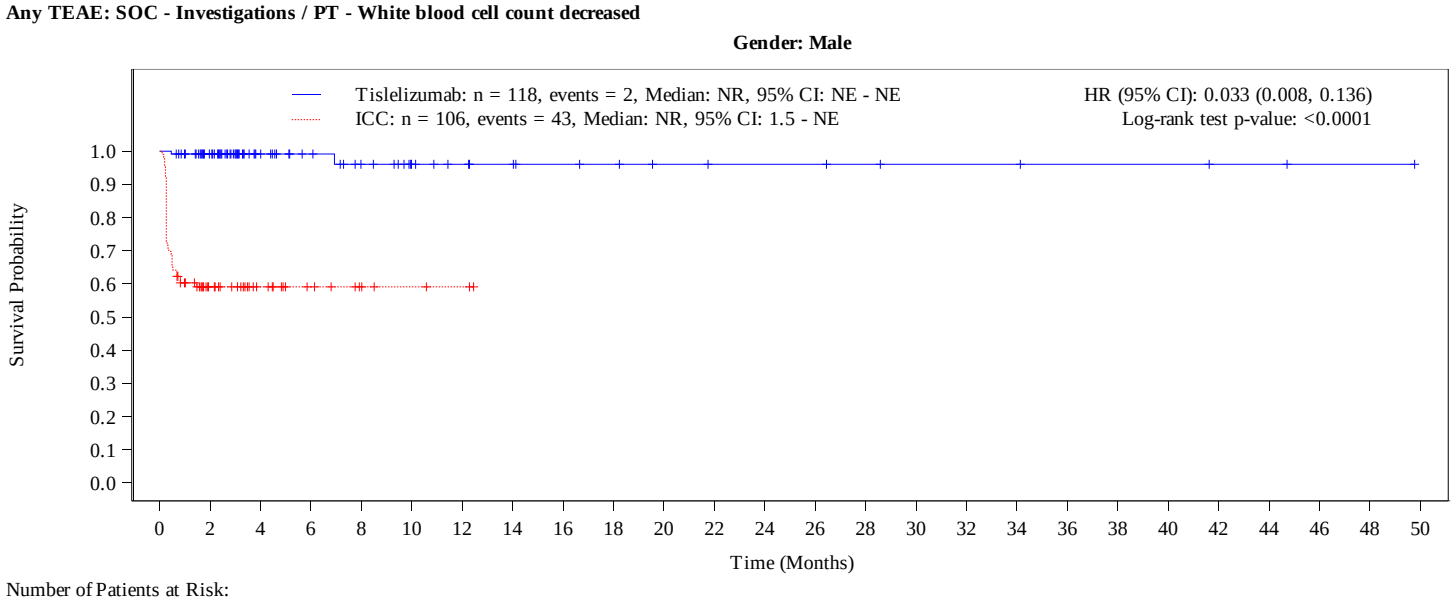


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36
Tislelizumab	52	35	19	13	9	6	3	2	2	2	2	2	2	2	2	2	2	1	0
ICC	42	25	10	7	4	2	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-s-km-socpt-sub-safety-cl.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

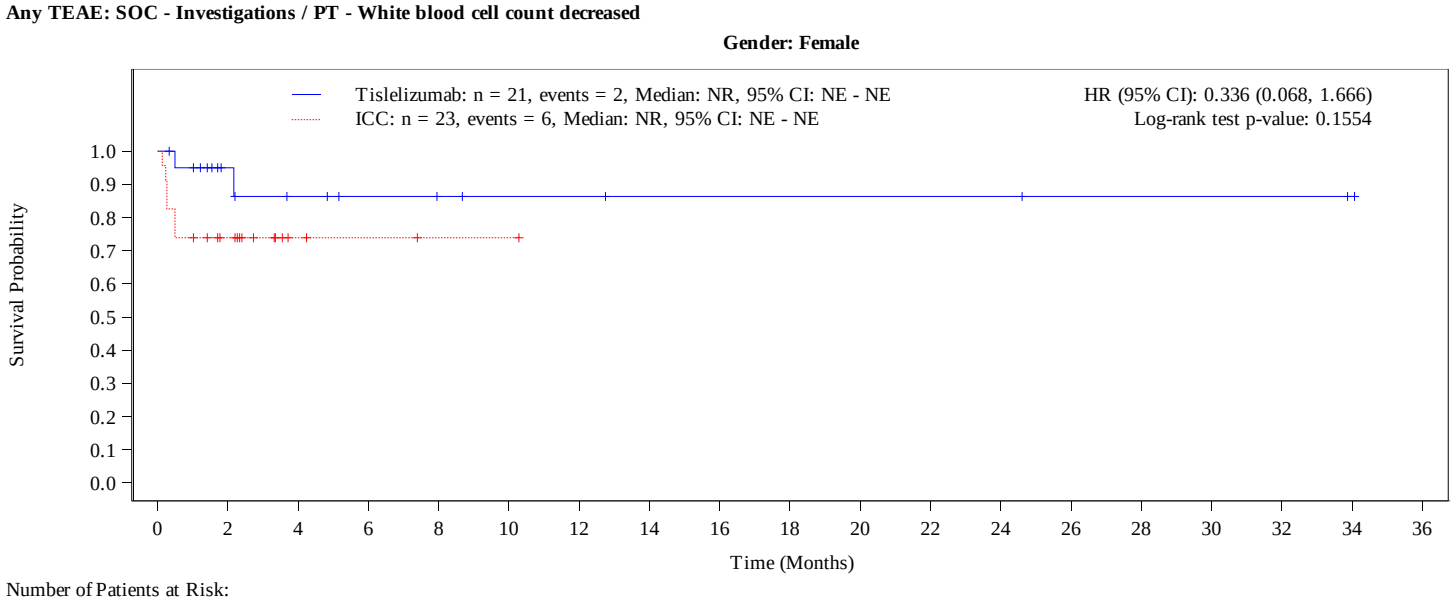


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	118	83	43	33	25	17	14	12	10	9	7	6	6	6	5	4	4	4	3	3	3	2	2	1	1	0
ICC	106	33	16	9	5	3	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-b-s-km-socpt-sub-safetys-cl.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

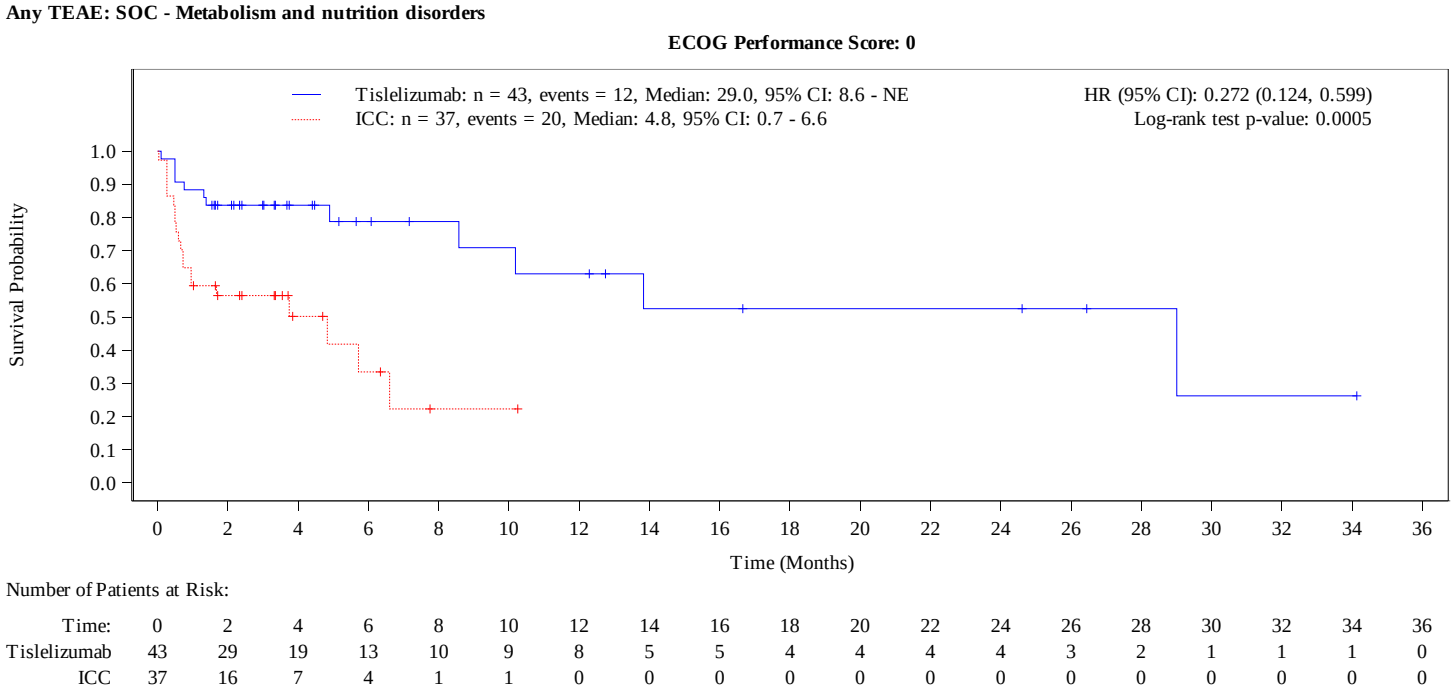


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36
Tislelizumab	21	11	8	6	5	4	4	3	3	3	3	3	3	2	2	2	2	1	0
ICC	23	12	3	2	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-b-s-km-socpt-sub-safetys-cl.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

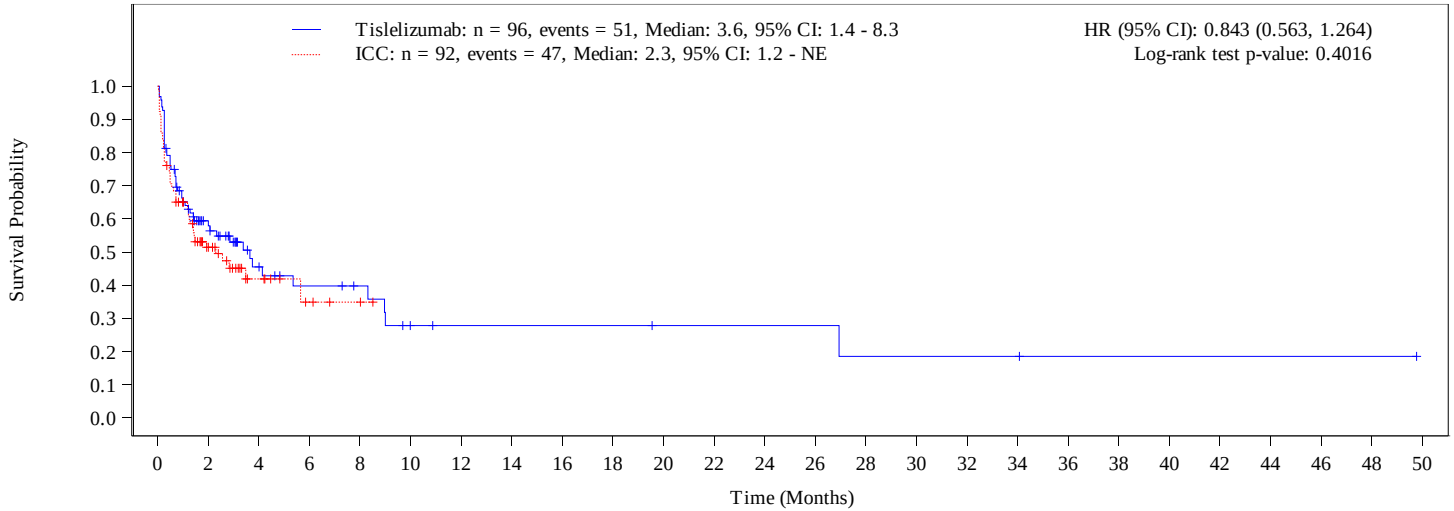


Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-b-s-km-socpt-sub-safetys-cl.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Metabolism and nutrition disorders

ECOG Performance Score: 1

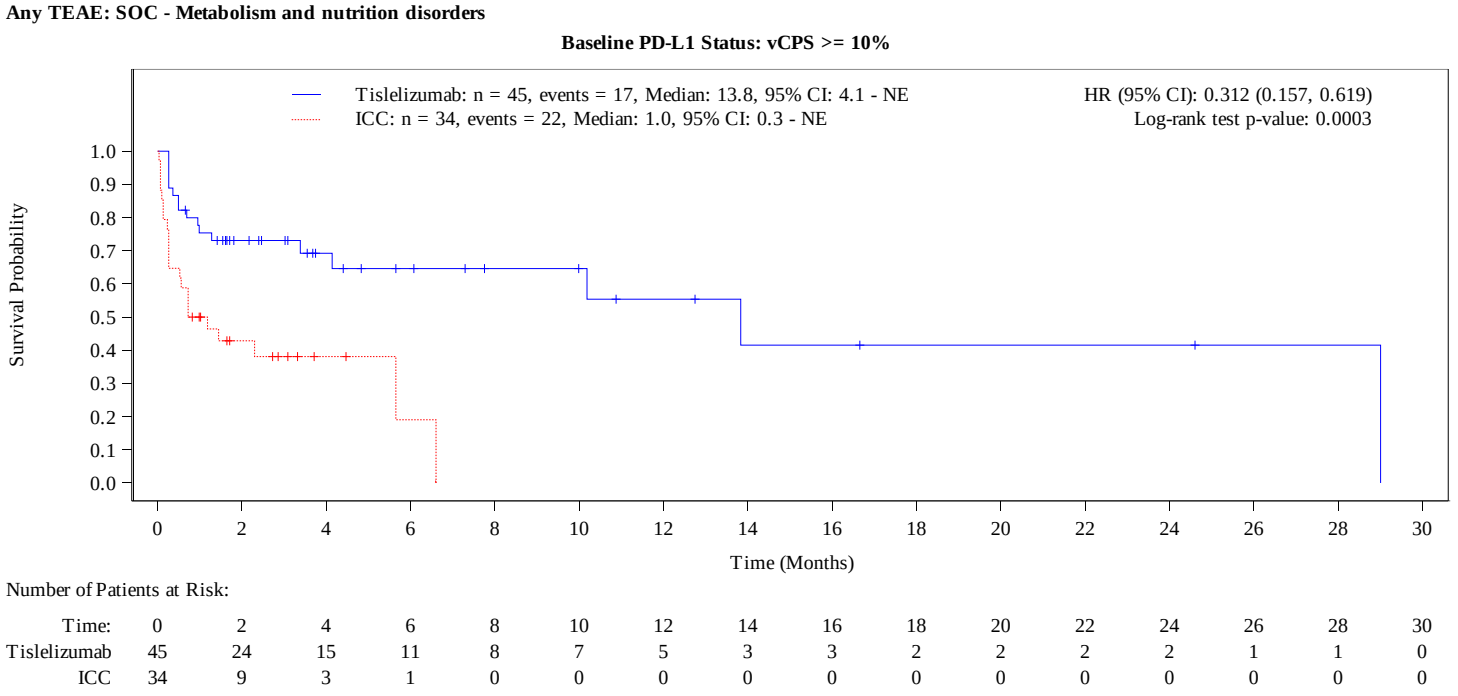


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	96	39	18	13	10	5	4	4	4	4	3	3	3	3	2	2	2	2	1	1	1	1	1	1	1	0
ICC	92	30	11	4	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-b-s-km-socpt-sub-safetys-cl.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

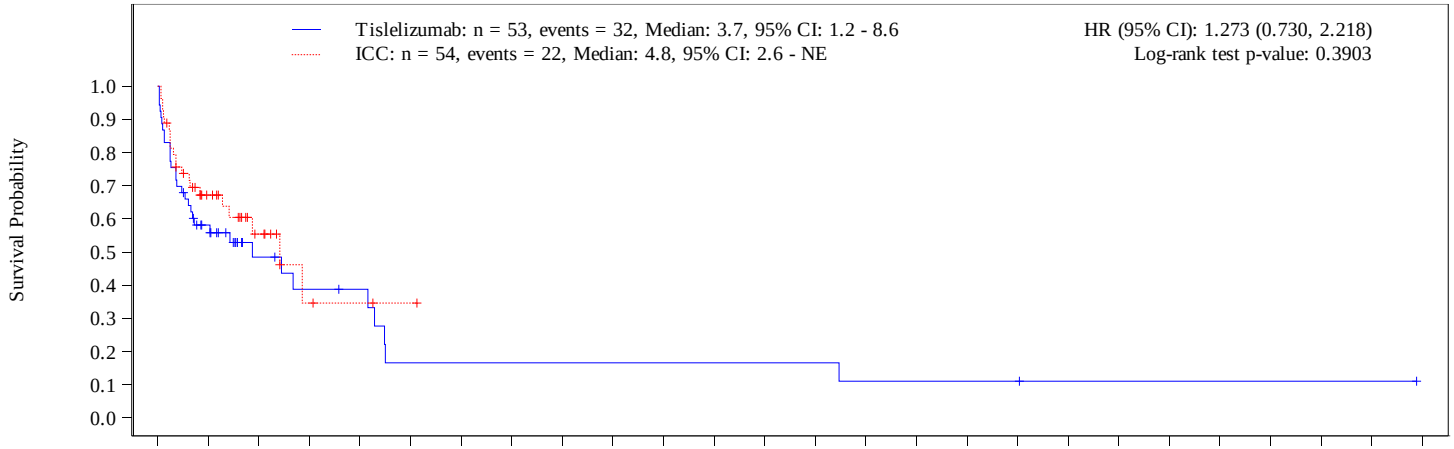


Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-b-s-km-socpt-sub-safetys-cl.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Metabolism and nutrition disorders

Baseline PD-L1 Status: vCPS < 10%

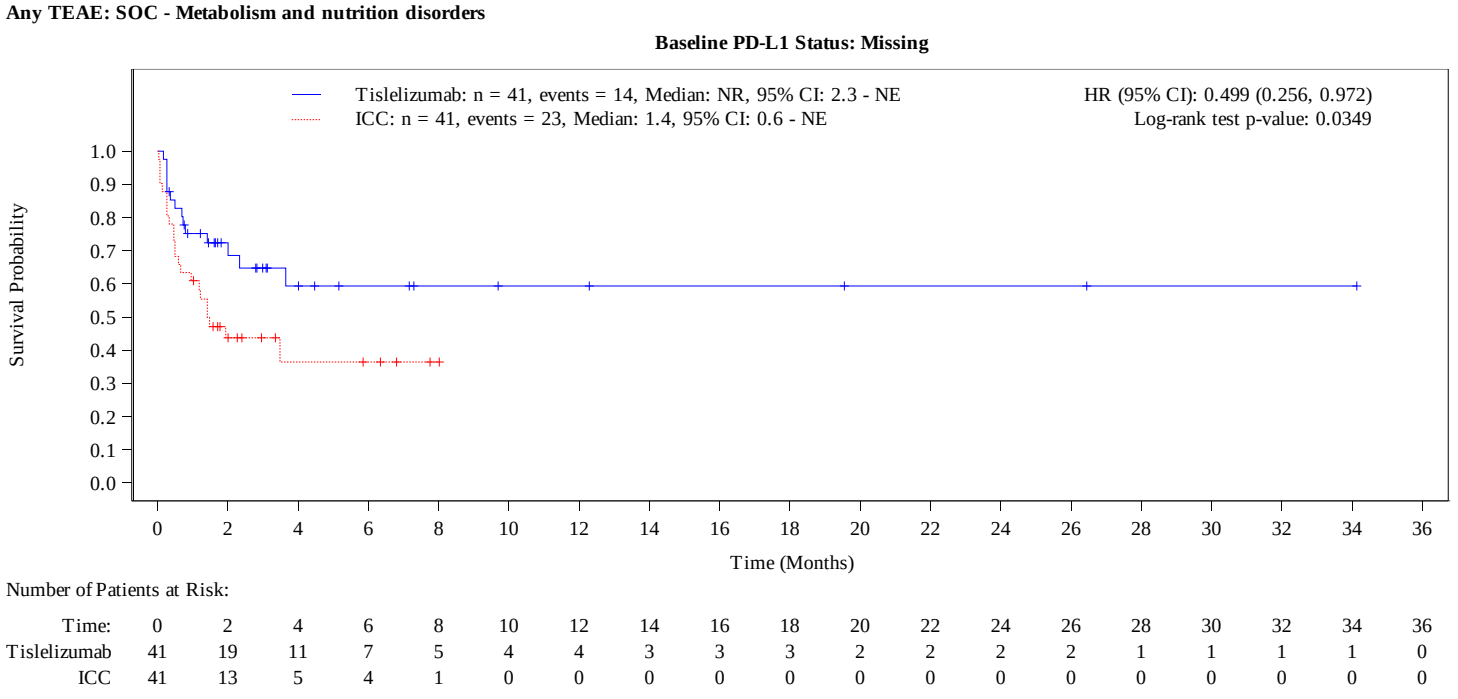


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	53	25	11	8	7	3	3	3	3	3	3	3	3	3	2	2	2	2	1	1	1	1	1	1	1	0
ICC	54	24	10	3	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

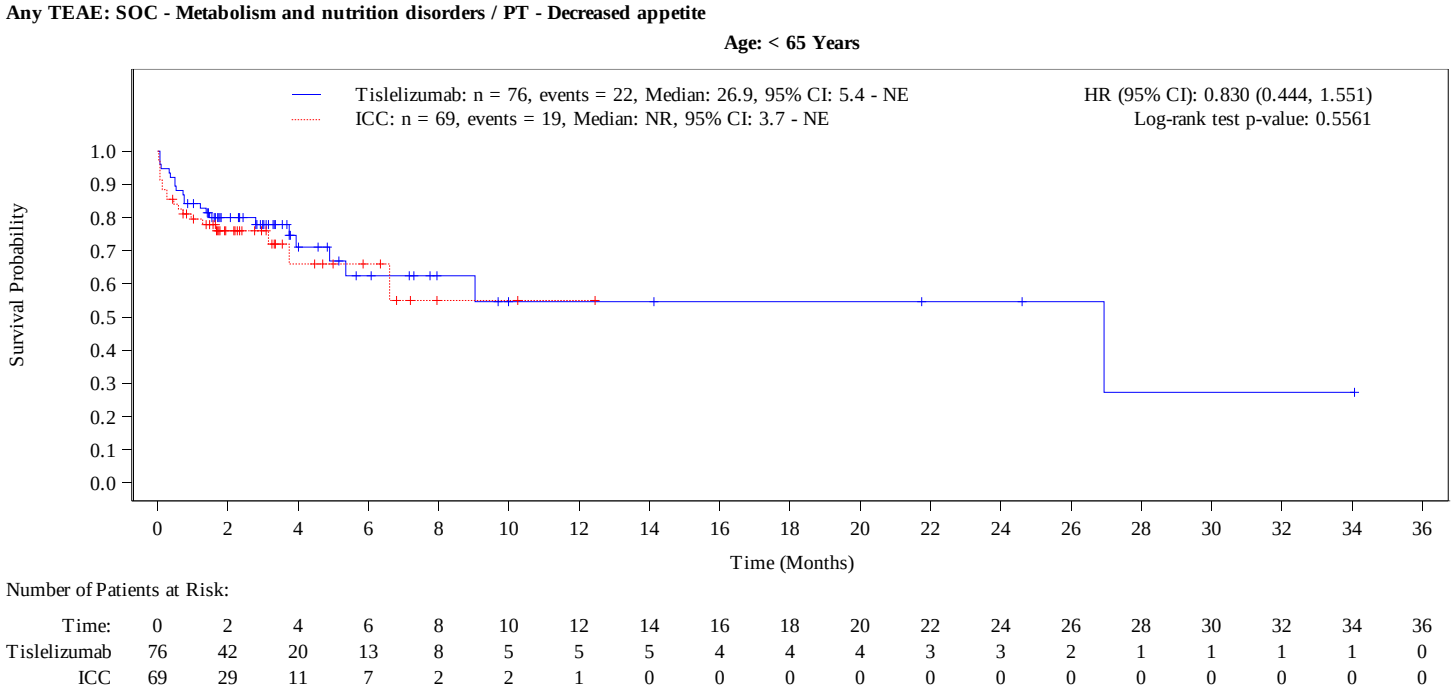
Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-b-s-km-socpt-sub-safetys-cl.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



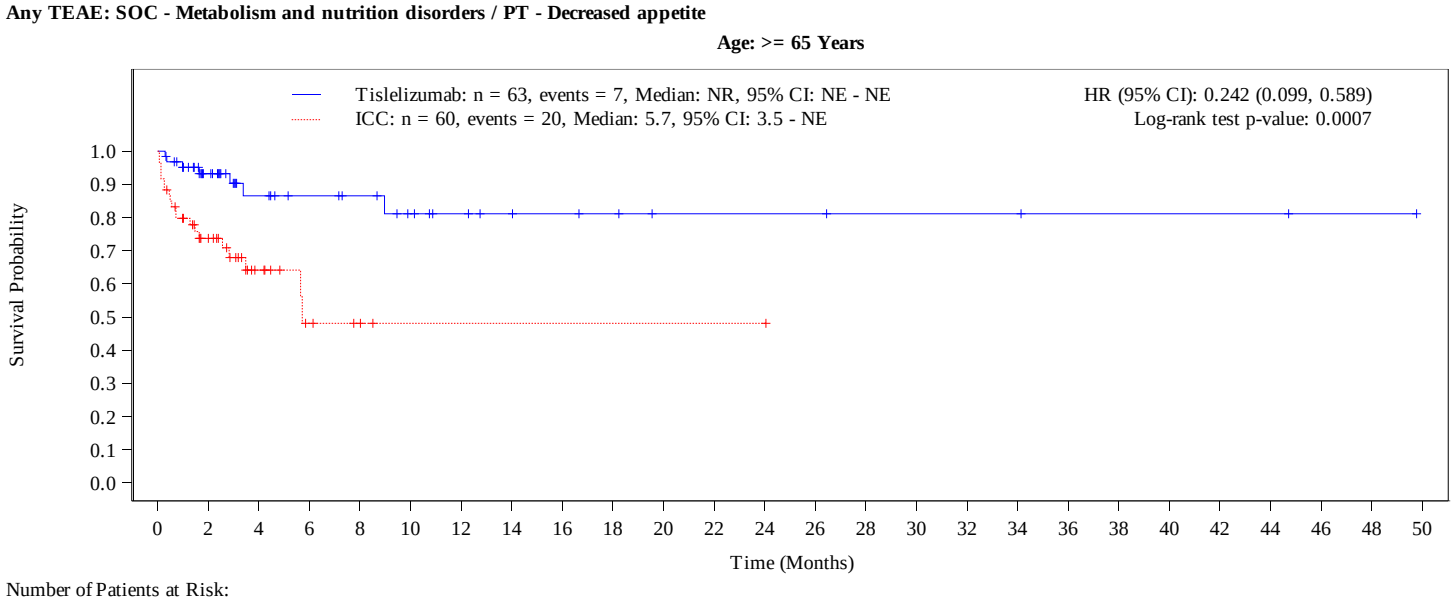
Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-b-s-km-socpt-sub-safetys-cl.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-b-s-km-socpt-sub-safetys-cl.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

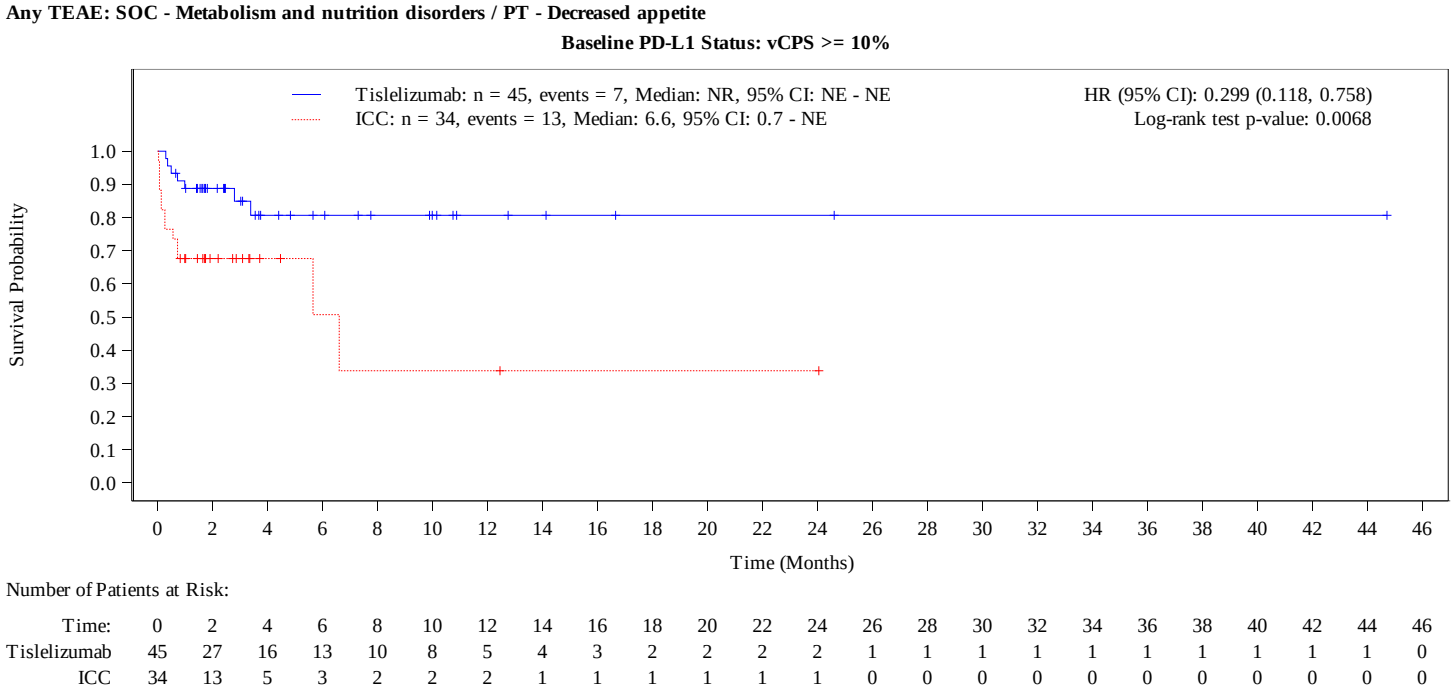


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	63	42	23	19	17	13	10	8	7	6	4	4	4	4	3	3	3	3	2	2	2	2	2	1	1	0
ICC	60	32	12	5	3	1	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-b-s-km-socpt-sub-safetys-cl.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

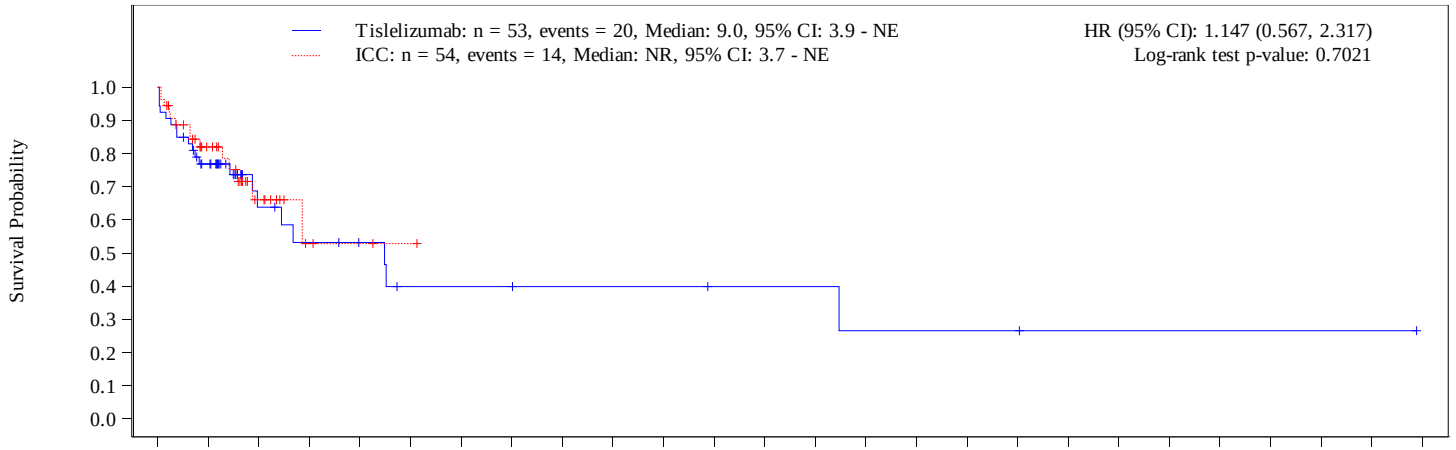
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46
Tislelizumab	45	27	16	13	10	8	5	4	3	2	2	2	2	1	1	1	1	1	1	1	1	1	1	0
ICC	34	13	5	3	2	2	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-b-s-km-socpt-sub-safetys-cl.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Metabolism and nutrition disorders / PT - Decreased appetite

Baseline PD-L1 Status: vCPS < 10%

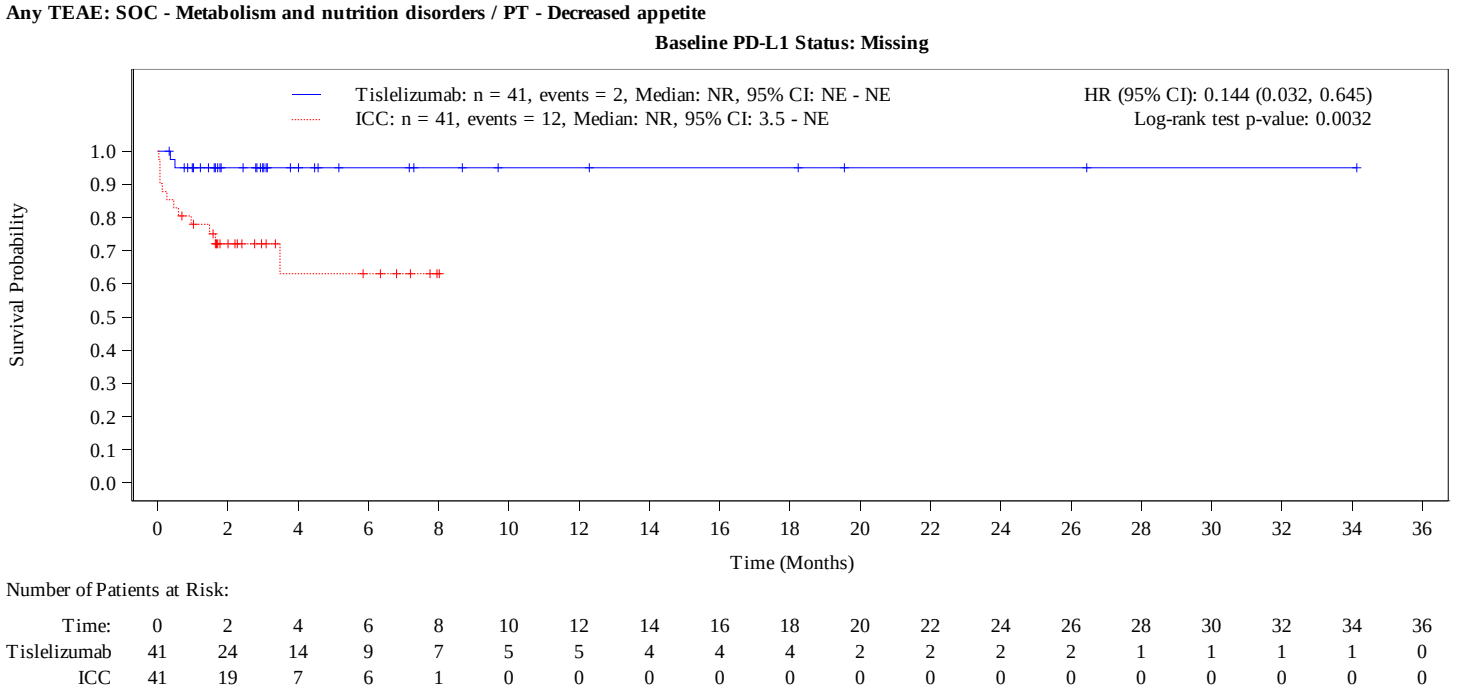


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	53	33	13	10	8	5	5	5	4	4	4	3	3	3	2	2	2	2	1	1	1	1	1	1	1	0
ICC	54	29	11	3	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

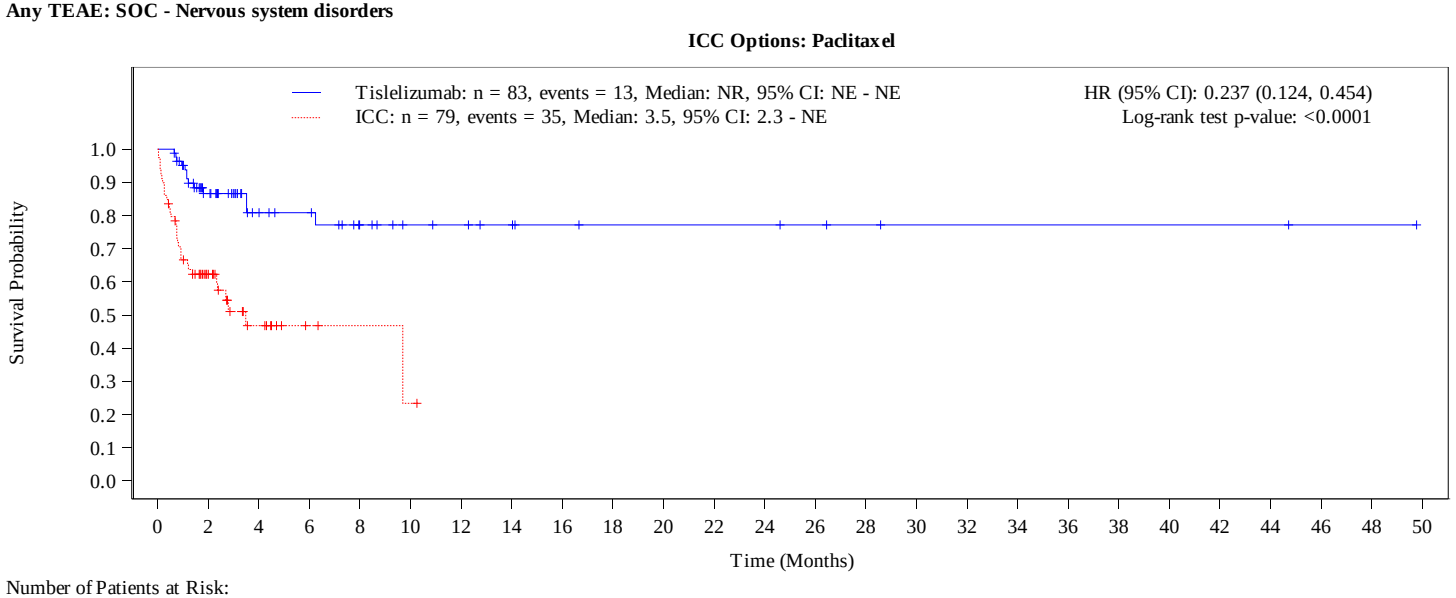
Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-b-s-km-socpt-sub-safetys-cl.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-b-s-km-socpt-sub-safetys-cl.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

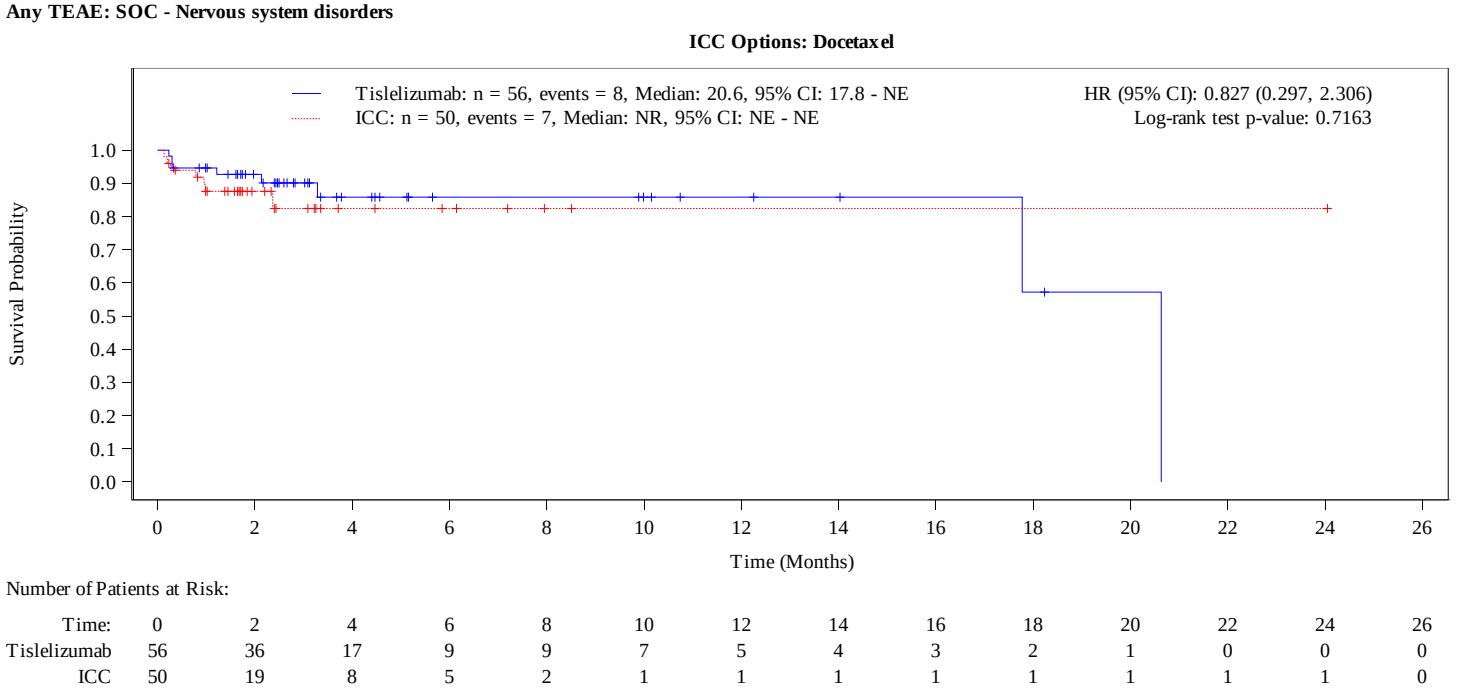


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	83	49	26	23	15	11	10	8	6	5	5	5	5	4	3	2	2	2	2	2	2	2	2	1	1	0
ICC	79	31	10	3	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

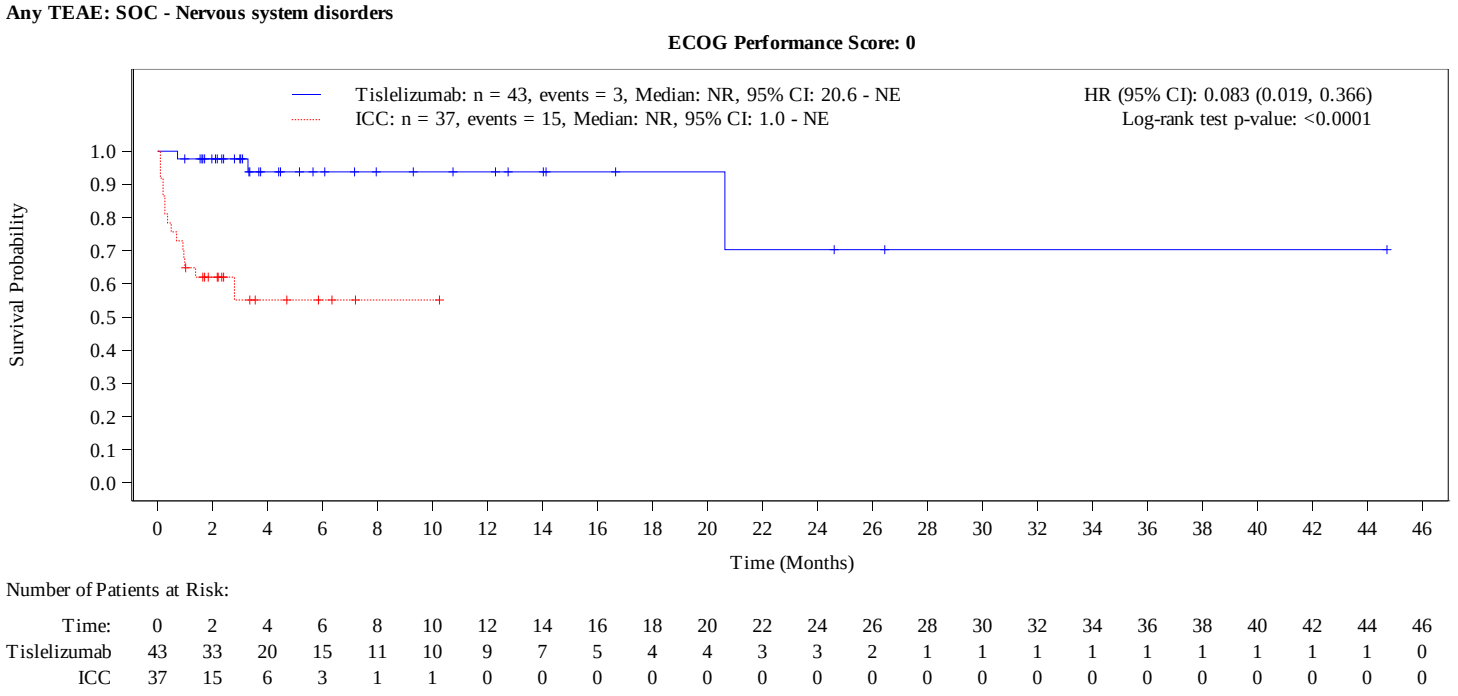
Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-b-s-km-socpt-sub-safetys-cl.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-b-s-km-socpt-sub-safetys-cl.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

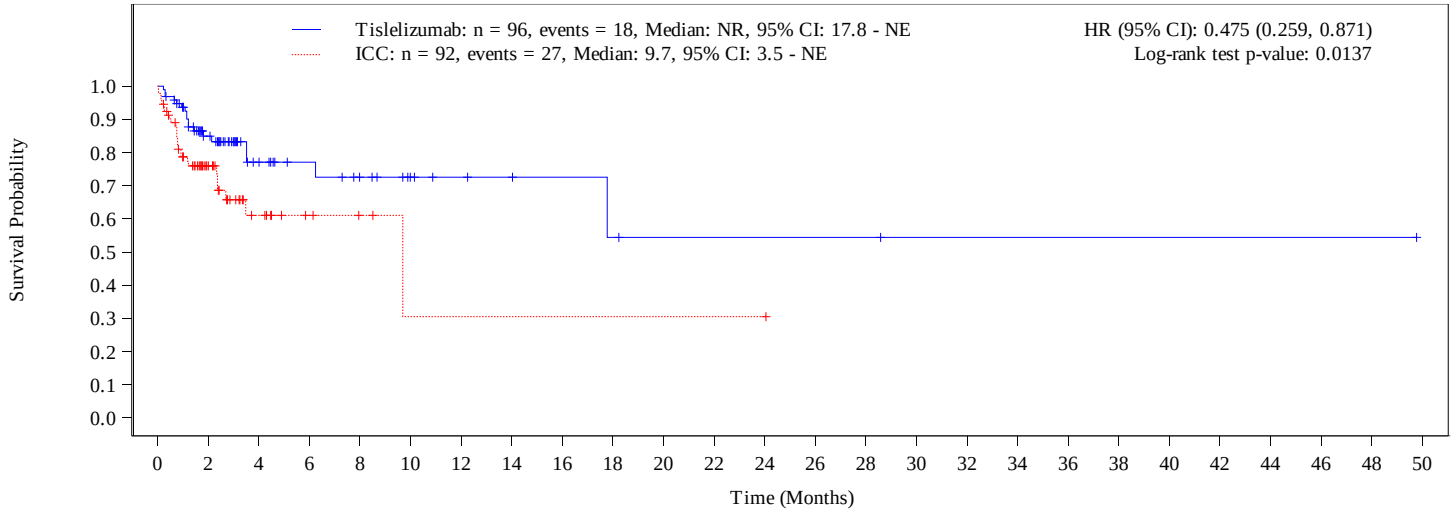


Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-b-s-km-socpt-sub-safetys-cl.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Nervous system disorders

ECOG Performance Score: 1



Number of Patients at Risk:

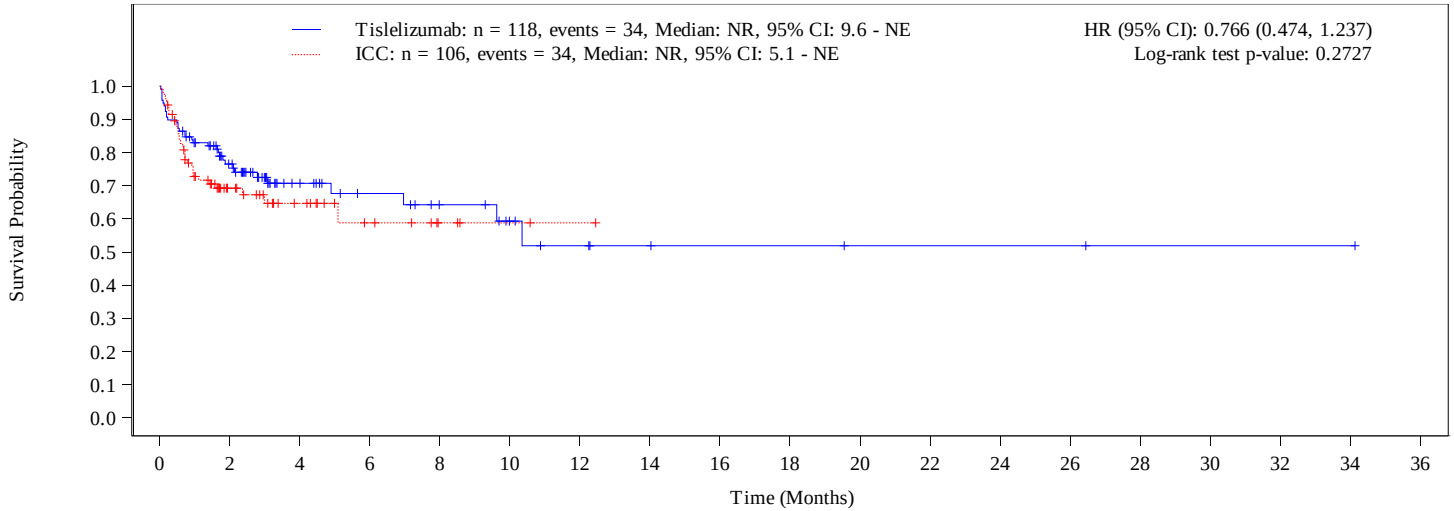
Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	96	52	23	17	13	8	6	5	4	3	2	2	2	2	2	1	1	1	1	1	1	1	1	1	1	0
ICC	92	35	12	5	3	1	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-b-s-km-socpt-sub-safetys-cl.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Skin and subcutaneous tissue disorders

Gender: Male



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36
Tislelizumab	118	63	28	20	14	9	6	4	3	3	2	2	2	2	1	1	1	1	0
ICC	106	39	17	9	4	2	1	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
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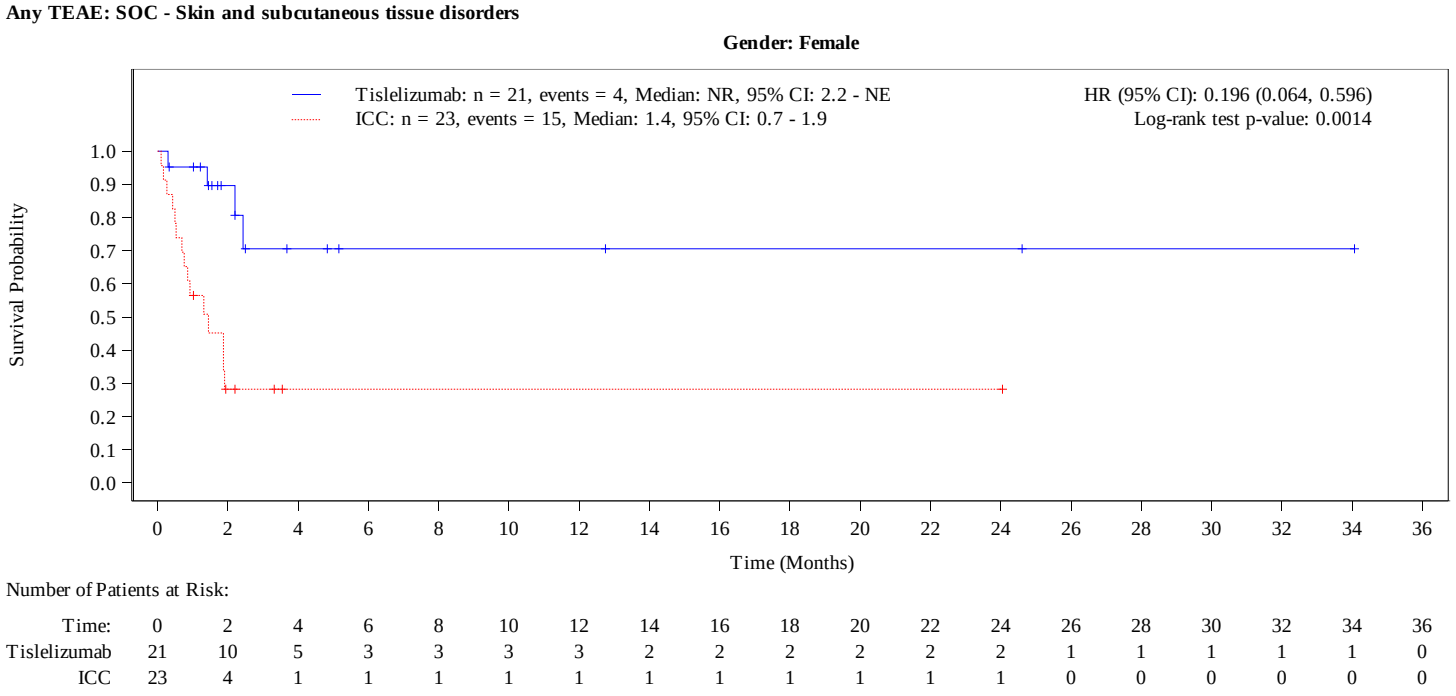
Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

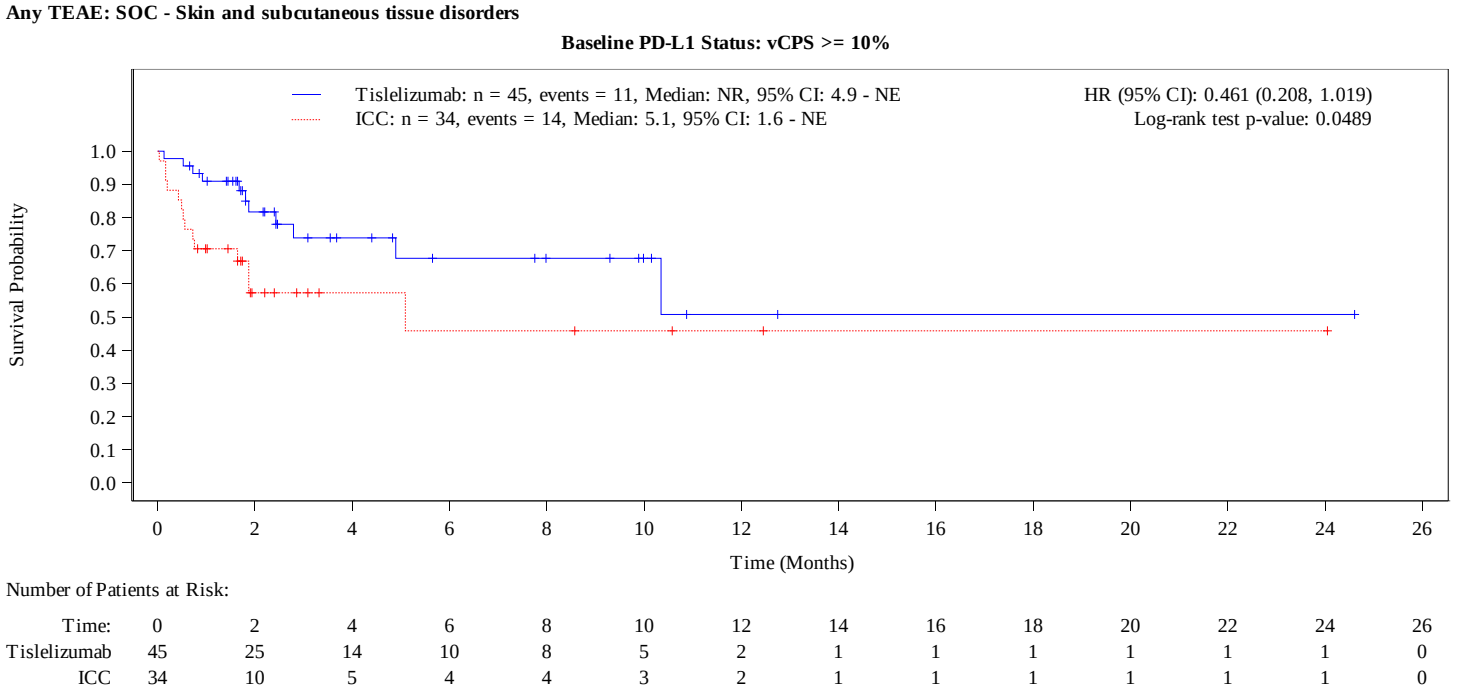


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36
Tislelizumab	21	10	5	3	3	3	3	2	2	2	2	2	2	1	1	1	1	1	0
ICC	23	4	1	1	1	1	1	1	1	1	1	1	1	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-b-s-km-socpt-sub-safetys-cl.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



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Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
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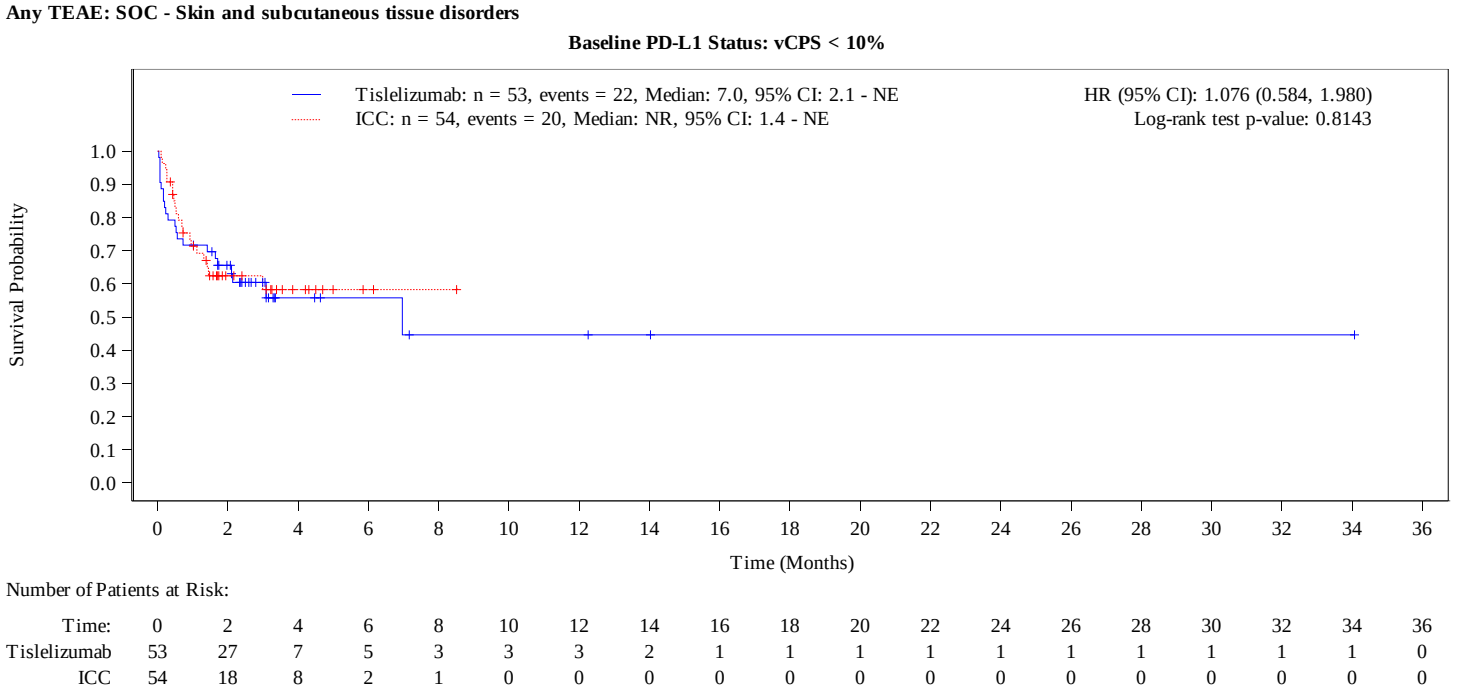
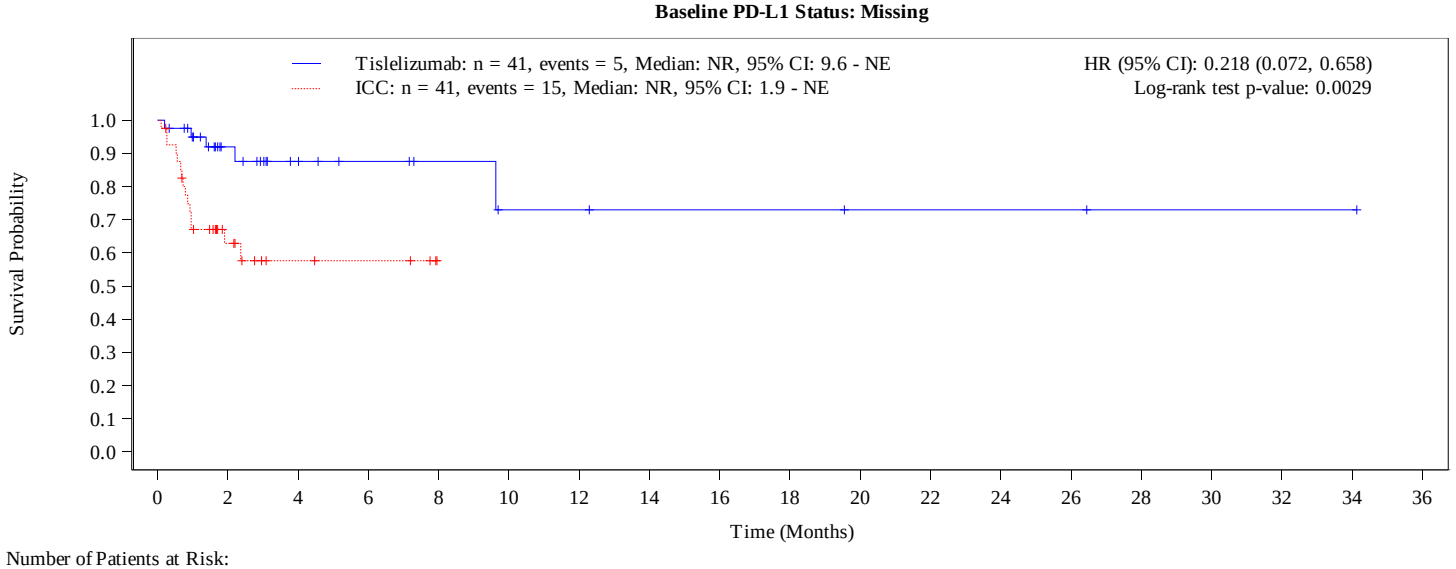
Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-b-s-km-socpt-sub-safetys-cl.rtf

Figure 14.3.1.2.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any TEAE: SOC - Skin and subcutaneous tissue disorders

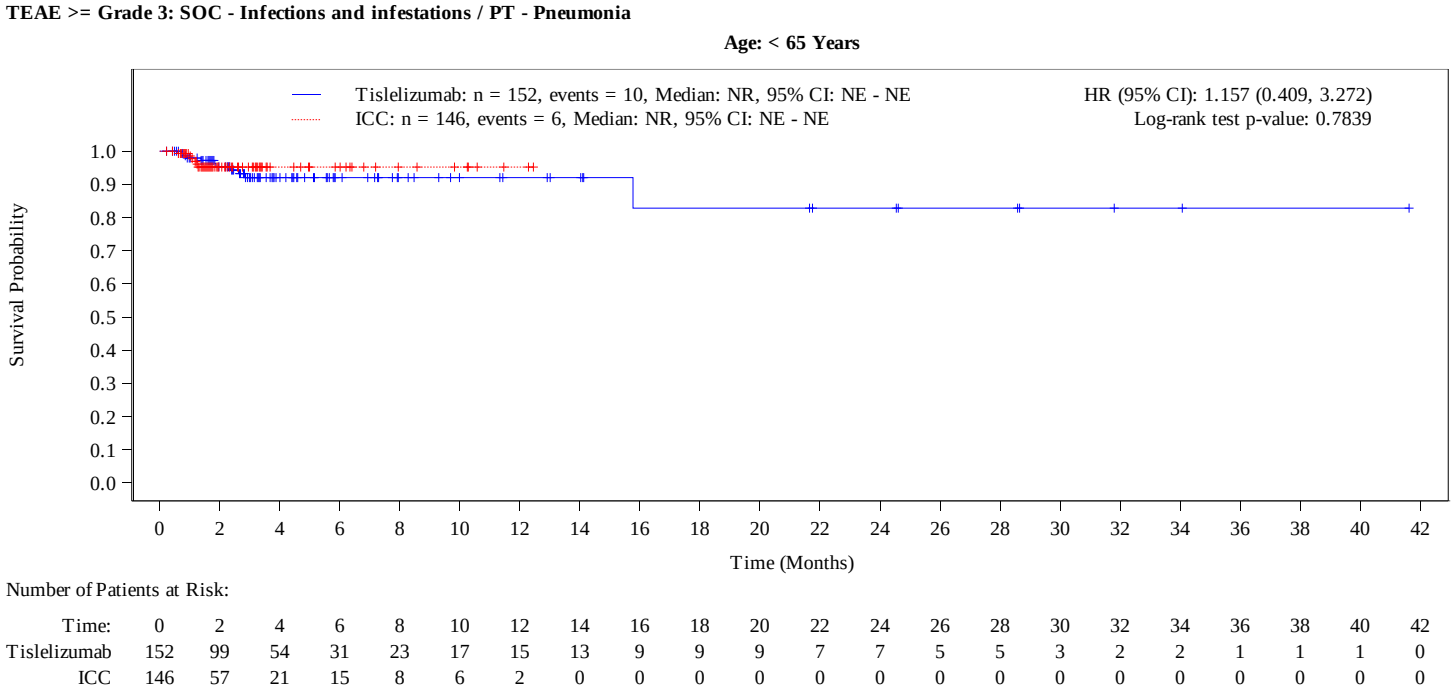


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36
Tislelizumab	41	21	12	8	6	4	4	3	3	3	2	2	2	2	1	1	1	1	0
ICC	41	15	5	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

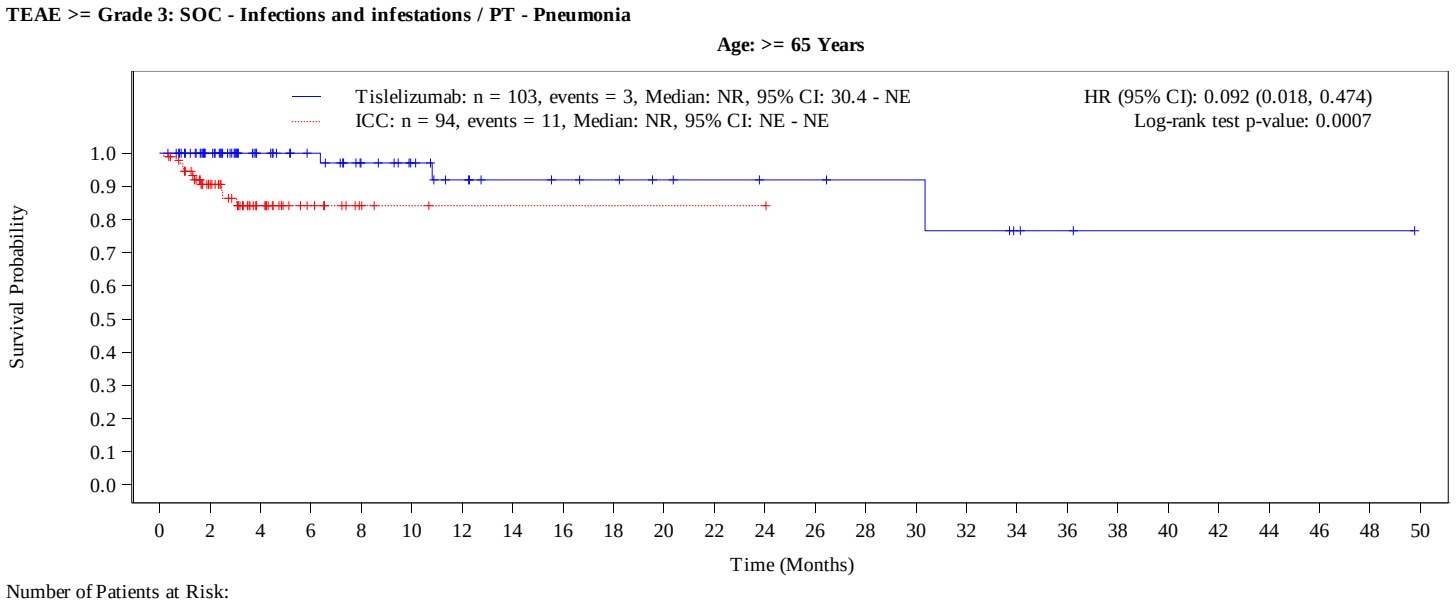
Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-02-b-s-km-socpt-sub-safetys-cl.rtf

Figure 14.3.1.3.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set



Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-03-s-km-socpt-sub-g3-safety-cl.rtf

Figure 14.3.1.3.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

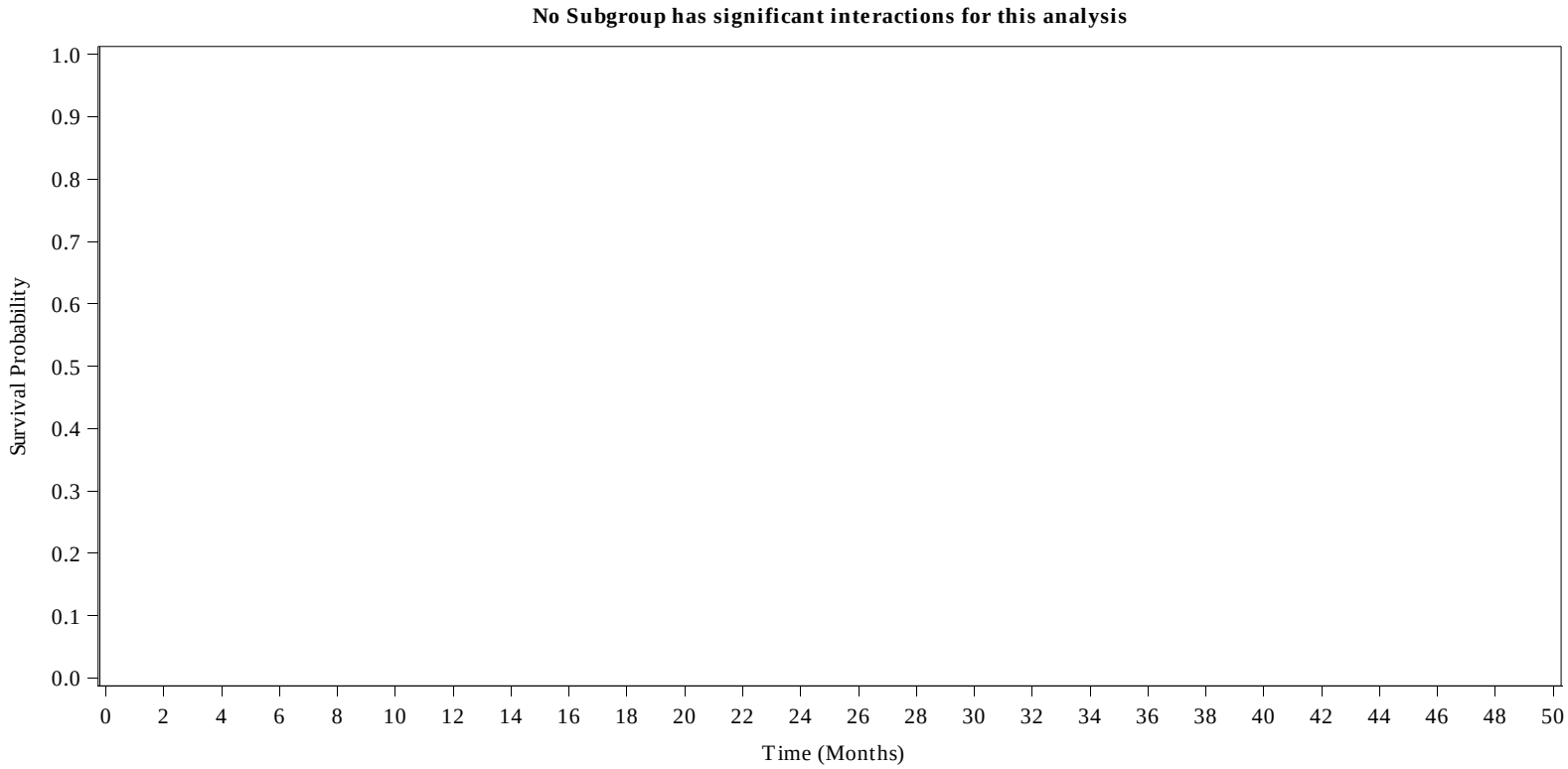


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	103	74	43	34	26	21	16	13	12	11	9	8	7	7	6	6	5	3	2	1	1	1	1	1	1	0
ICC	94	55	24	11	4	2	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-03-s-km-socpt-sub-g3-safety-cl.rtf

Figure 14.3.1.3.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events >= Grade 3 by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
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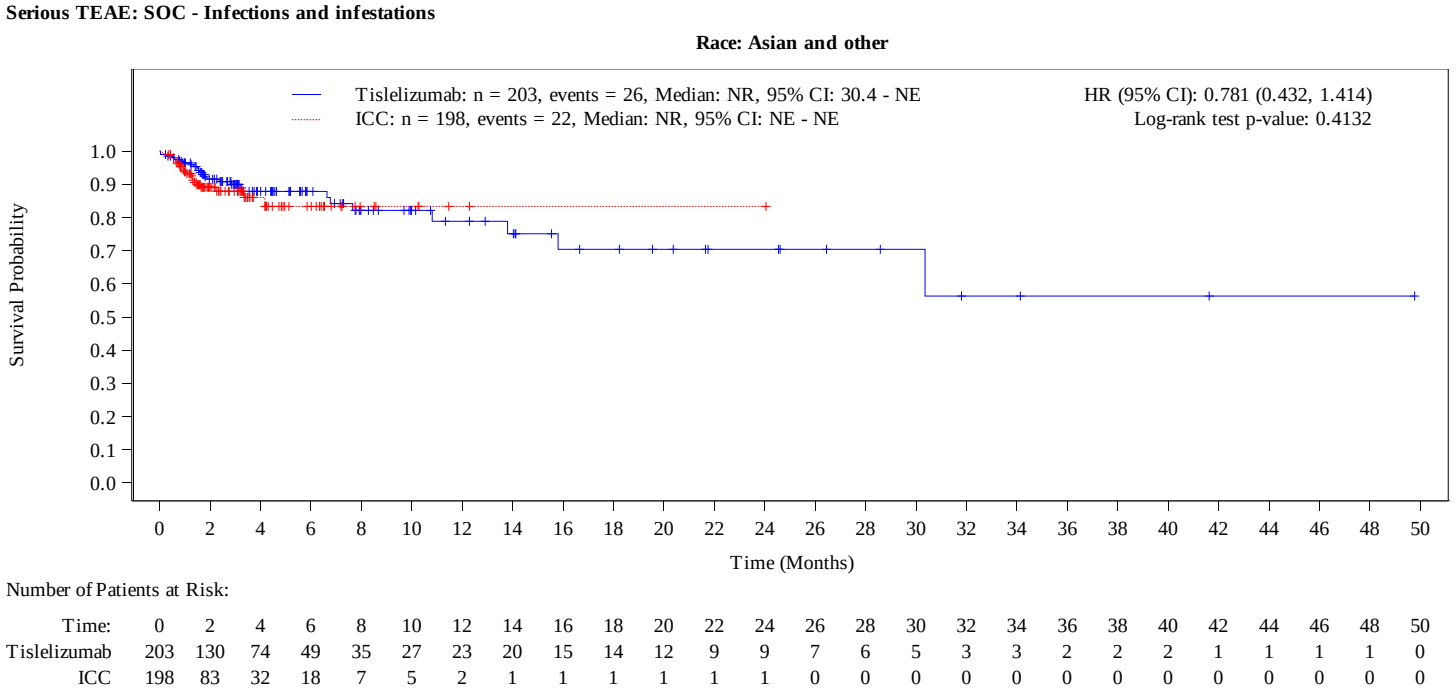
Figure 14.3.1.4.s:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

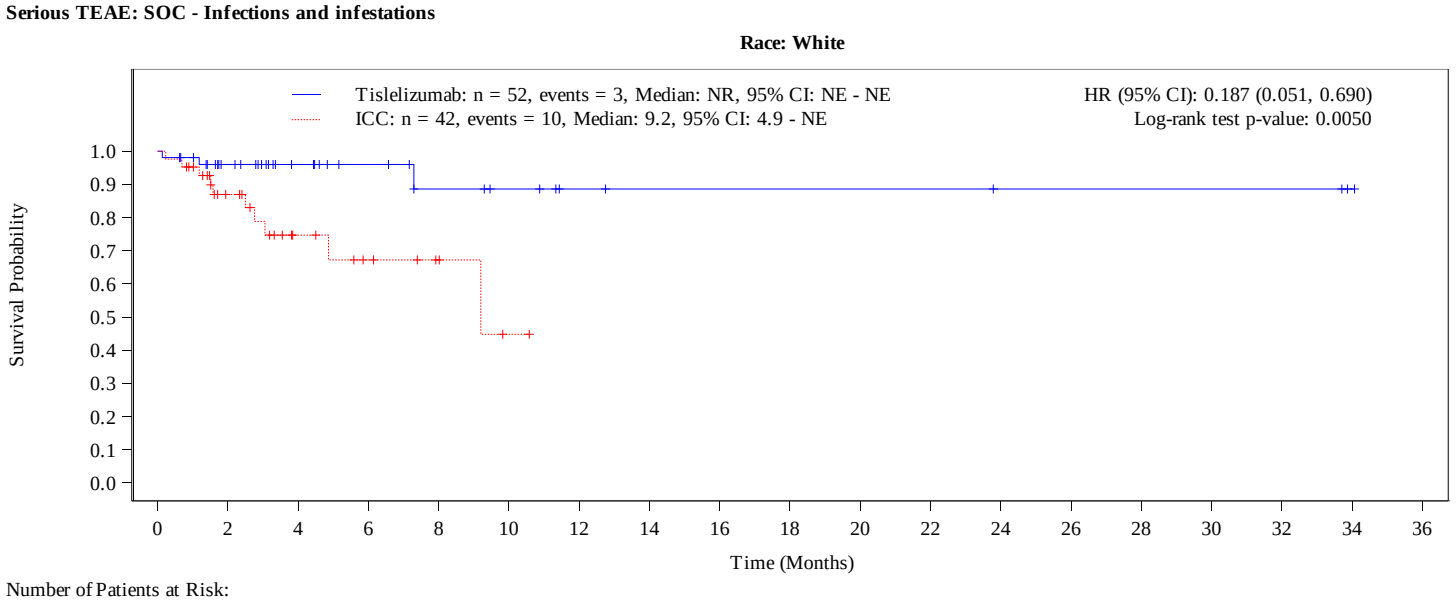


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	203	130	74	49	35	27	23	20	15	14	12	9	9	7	6	5	3	3	2	2	2	1	1	1	1	0
ICC	198	83	32	18	7	5	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-04-s-km-socpt-sub-sae-safety-cl.rtf

Figure 14.3.1.4.s:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set

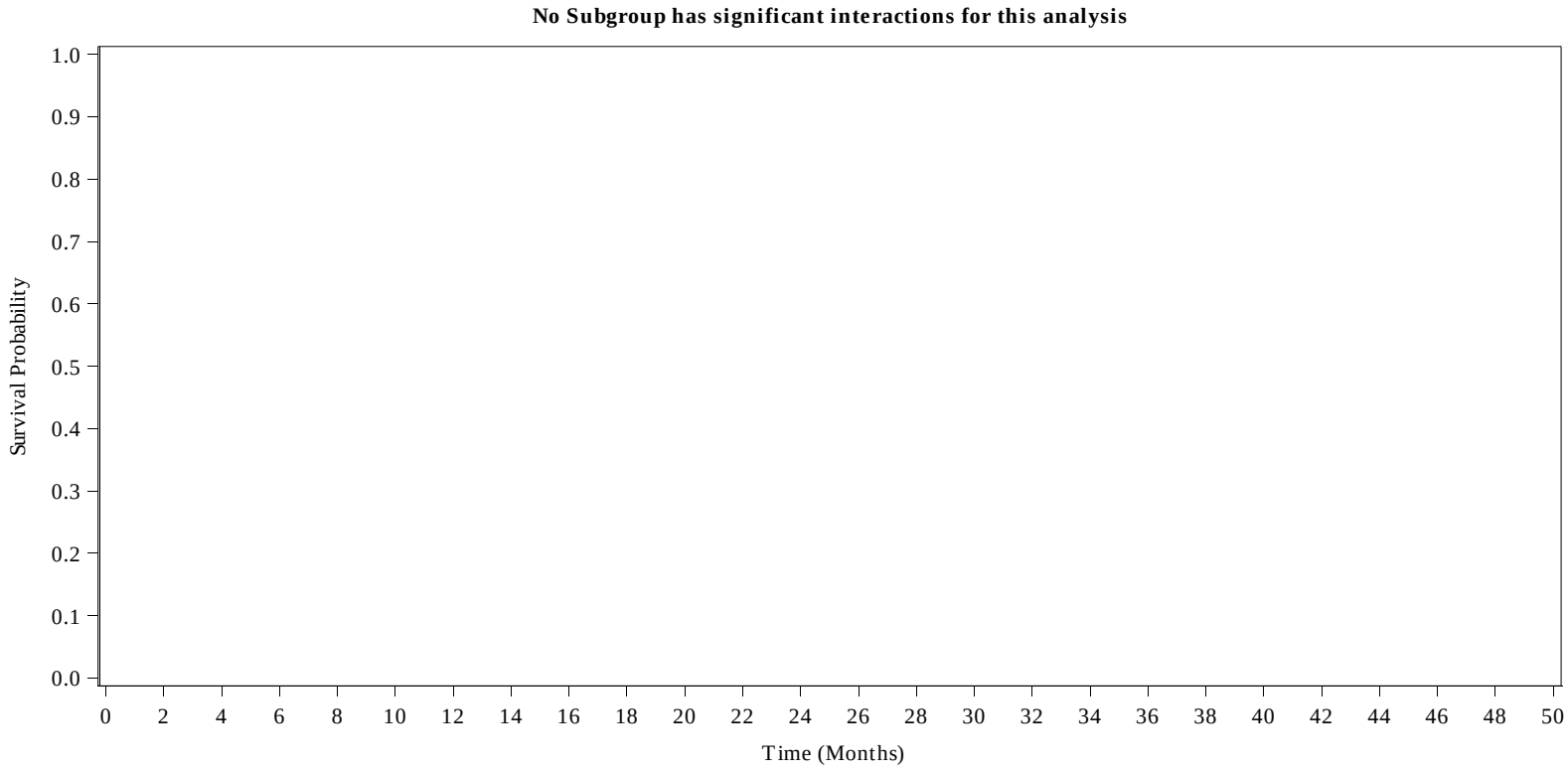


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36
Tislelizumab	52	37	22	15	11	8	5	4	4	4	4	4	3	3	3	3	3	1	0
ICC	42	26	11	7	4	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; NE = not estimable; NR = not reached.
The hazard ratio and 95% CI were estimated from an unstratified Cox regression model.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-04-s-km-socpt-sub-sae-safety-cl.rtf

Figure 14.3.1.4.b.s:
Kaplan-Meier Plot of Time to Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-socpt-sub.sas 05AUG2024 18:21 f-14-03-01-04-b-s-km-socpt-sub-sae-safetys-cl.rtf

Table 14.3.1.3.1:
Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set

	Tislelizumab (N = 255)			ICC (N = 240)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Any imAE	255	88 (34.5)	16.1 (9.0, NE)	240	19 (7.9)	NR (NE, NE)	4.330 (2.624, 7.144)	<0.0001
imAE of Grade 1 and 2	255	80 (31.4)	18.6 (10.3, NE)	240	17 (7.1)	NR (NE, NE)	4.448 (2.624, 7.541)	<0.0001
imAE >= Grade 3	255	14 (5.5)	NR (36.1, NE)	240	3 (1.3)	NR (NE, NE)	3.248 (0.898, 11.749)	0.0576
Serious imAE	255	18 (7.1)	NR (36.1, NE)	240	3 (1.3)	NR (NE, NE)	4.451 (1.282, 15.461)	0.0101

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.
Adverse events were graded for severity using CTCAE v4.03.
Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.
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Table 14.3.1.3.1:
Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set

	Tislelizumab (N = 255)			ICC (N = 240)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
IRR	255	8 (3.1)	NR (NE, NE)	240	11 (4.6)	NR (NE, NE)	0.580 (0.231, 1.459)	0.2379
IRR of Grade 1 and 2	255	8 (3.1)	NR (NE, NE)	240	11 (4.6)	NR (NE, NE)	0.580 (0.231, 1.459)	0.2379
IRR >= Grade 3	255	0 (0.0)	NR (NE, NE)	240	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Serious IRR	255	0 (0.0)	NR (NE, NE)	240	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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Table 14.3.1.3.1.b:
Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 129)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Any imAE	139	52 (37.4)	10.6 (9.0, NE)	129	15 (11.6)	NR (NE, NE)	3.393 (1.899, 6.063)	<0.0001
imAE of Grade 1 and 2	139	49 (35.3)	10.6 (9.0, NE)	129	13 (10.1)	NR (NE, NE)	3.676 (1.982, 6.818)	<0.0001
imAE >= Grade 3	139	7 (5.0)	NR (NE, NE)	129	2 (1.6)	NR (NE, NE)	2.389 (0.471, 12.122)	0.2790
Serious imAE	139	9 (6.5)	NR (NE, NE)	129	2 (1.6)	NR (NE, NE)	3.181 (0.666, 15.193)	0.1261

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.
Adverse events were graded for severity using CTCAE v4.03.
Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).
[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.
[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.
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Table 14.3.1.3.1.b:
Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation without Irinotecan

	Tislelizumab (N = 139)			ICC (N = 129)				
	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Total No. of Patients	Patients with events n (%)	Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
IRR	139	8 (5.8)	NR (NE, NE)	129	7 (5.4)	NR (NE, NE)	0.977 (0.352, 2.706)	0.9634
IRR of Grade 1 and 2	139	8 (5.8)	NR (NE, NE)	129	7 (5.4)	NR (NE, NE)	0.977 (0.352, 2.706)	0.9634
IRR >= Grade 3	139	0 (0.0)	NR (NE, NE)	129	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Serious IRR	139	0 (0.0)	NR (NE, NE)	129	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

[c] P-value for treatment effect was based on a log rank test stratified by baseline ECOG status and ICC options.

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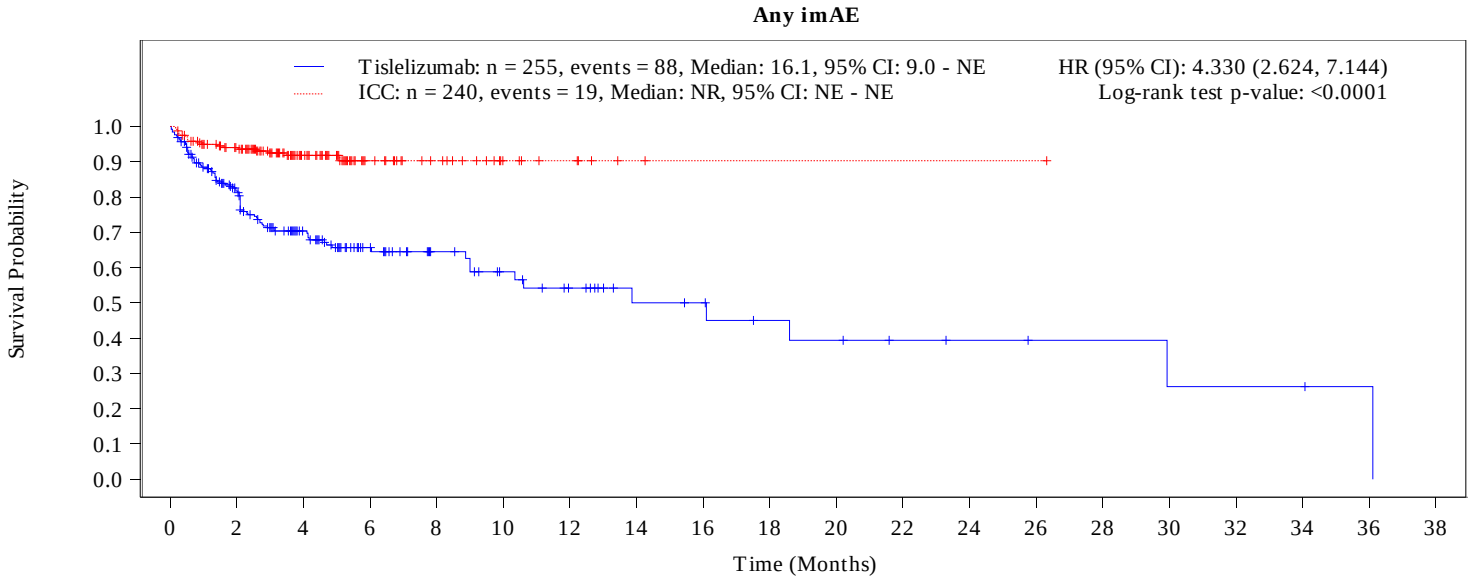
Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38
Tislelizumab	255	185	112	57	35	26	19	12	11	8	7	5	4	3	3	2	2	2	1	0
ICC	240	200	89	35	19	9	6	2	1	1	1	1	1	1	0	0	0	0	0	0

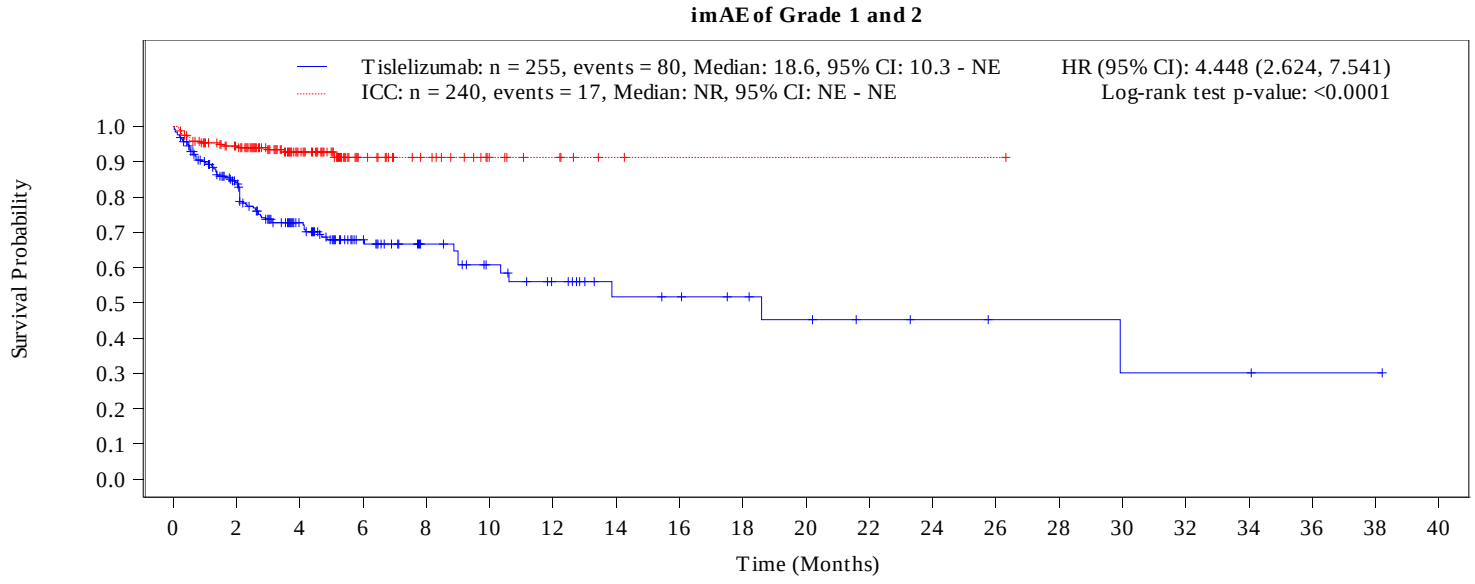
Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesi.sas 13AUG2024 19:03 f-14-03-01-05-km-aesi-safety-cl.rtf

Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set

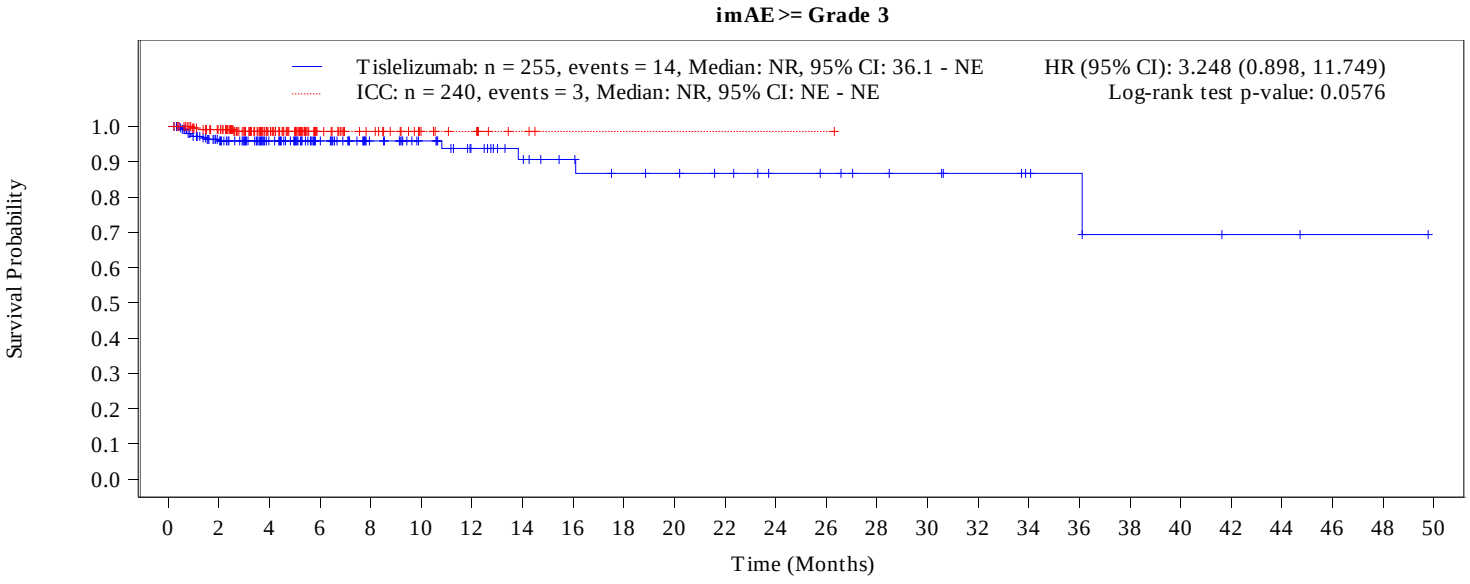


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40
Tislelizumab	255	189	113	57	35	26	19	12	11	9	7	5	4	3	3	2	2	2	1	1	0
ICC	240	201	90	35	19	9	6	2	1	1	1	1	1	1	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesi.sas 13AUG2024 19:03 f-14-03-01-05-km-aesi-safety-cl.rtf

Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	219	154	92	62	48	37	29	24	21	20	18	15	14	12	11	9	7	5	3	3	2	2	1	1	0
ICC	240	211	99	41	23	11	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0

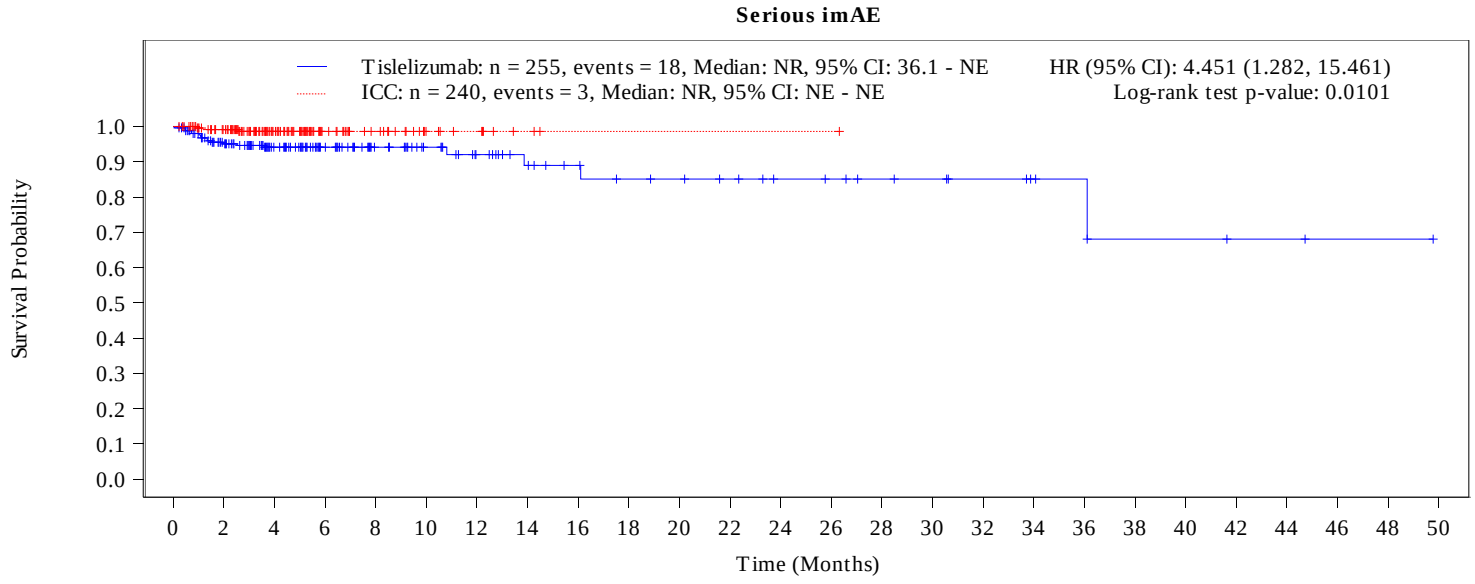
Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesi.sas 13AUG2024 19:03 f-14-03-01-05-km-aesi-safety-cl.rtf

Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set

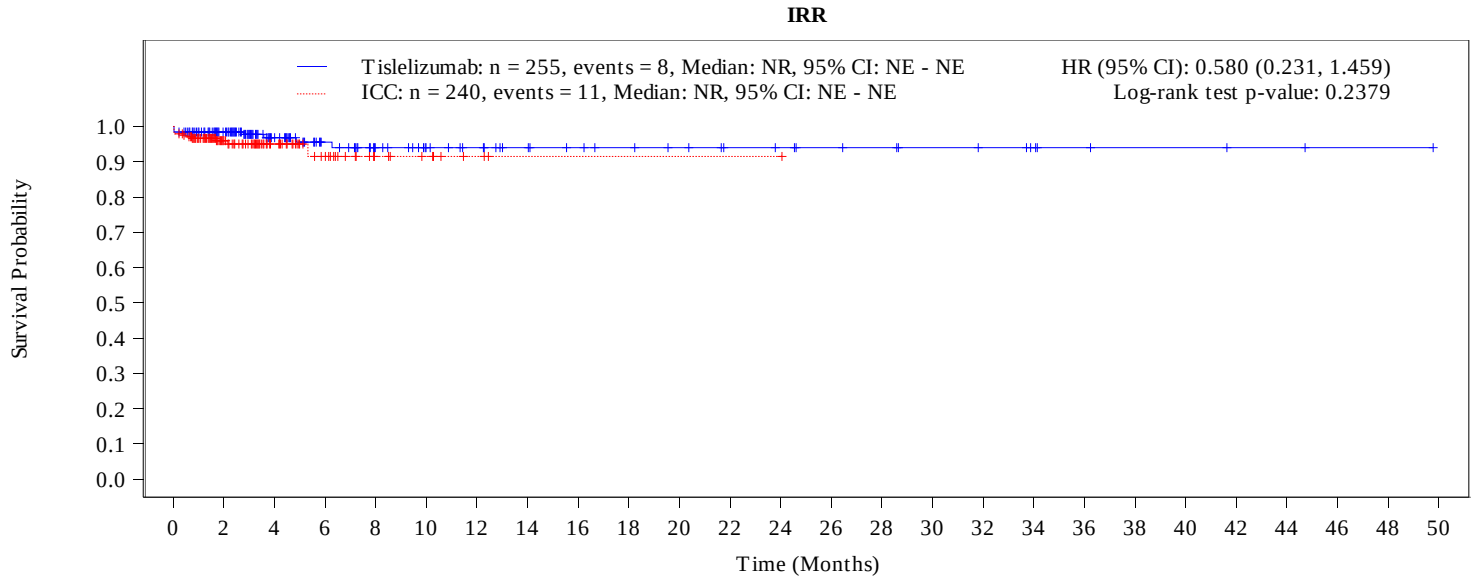


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	216	152	92	62	48	37	29	24	21	20	18	15	14	12	11	9	7	5	3	3	2	2	1	1	0
ICC	240	211	99	41	23	11	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesi.sas 13AUG2024 19:03 f-14-03-01-05-km-aesi-safety-cl.rtf

Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set

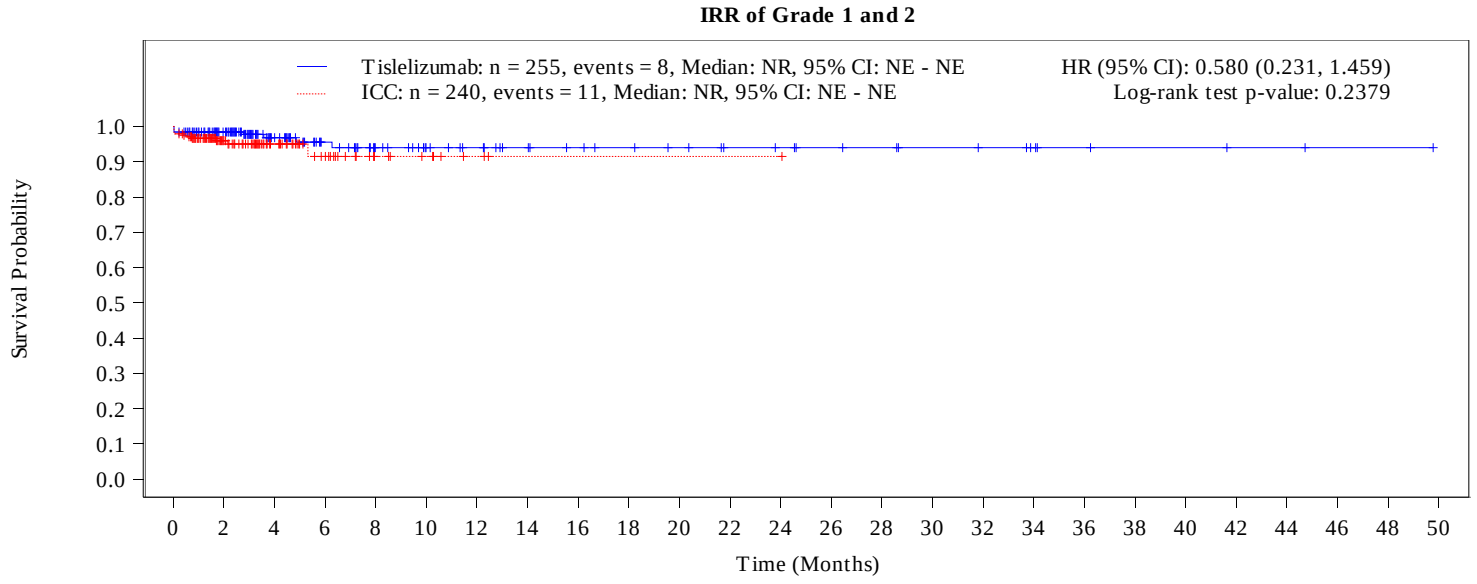


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	173	94	61	45	35	30	25	22	20	18	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	106	41	22	10	7	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesi.sas 13AUG2024 19:03 f-14-03-01-05-km-aesi-safety-cl.rtf

Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set

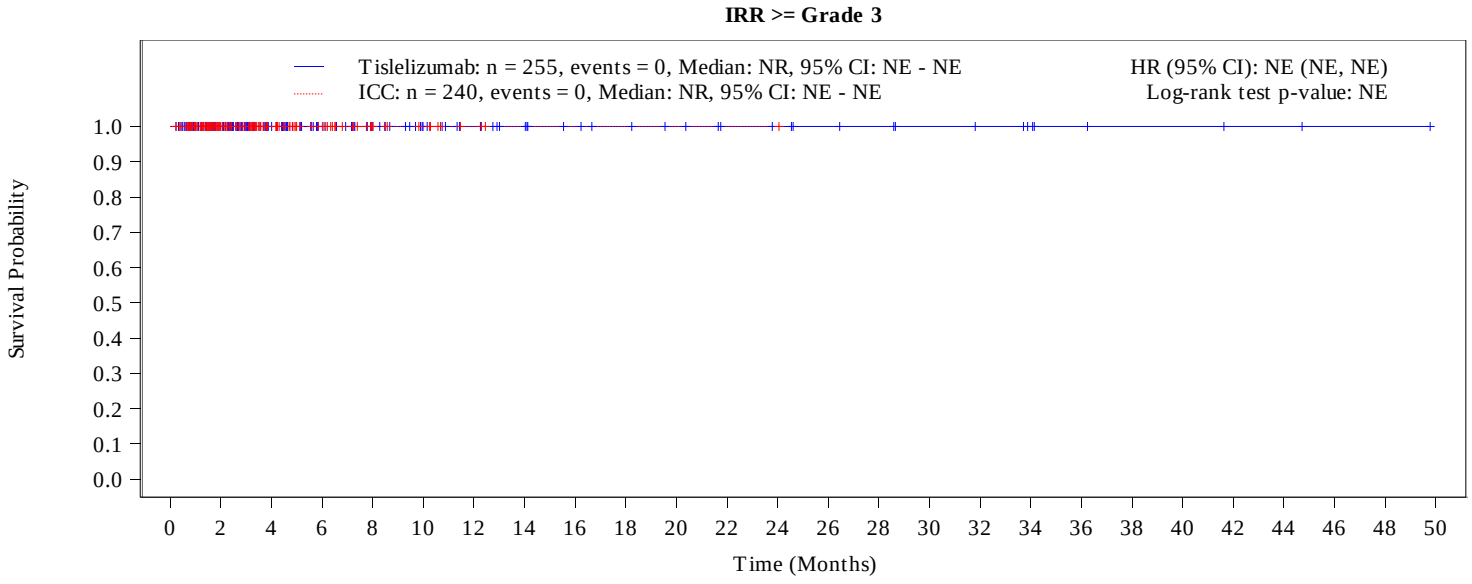


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	173	94	61	45	35	30	25	22	20	18	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	106	41	22	10	7	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesi.sas 13AUG2024 19:03 f-14-03-01-05-km-aesi-safety-cl.rtf

Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	175	97	65	49	38	32	27	22	20	18	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	113	45	26	12	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

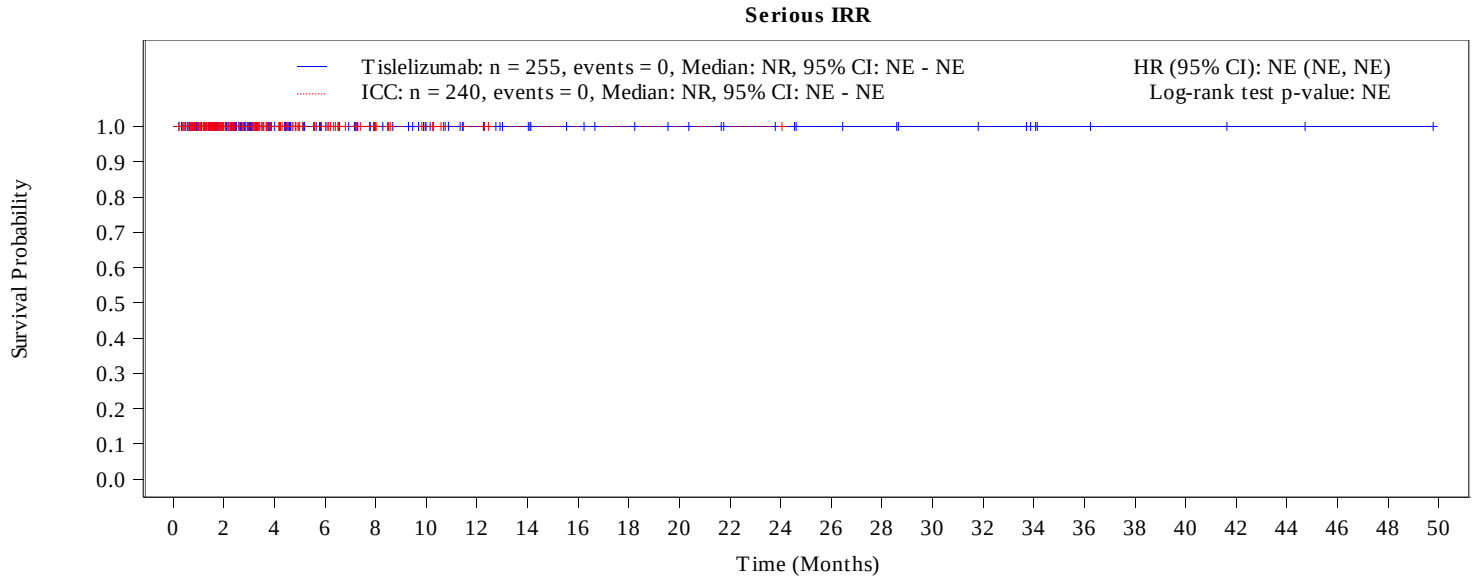
Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesi.sas 13AUG2024 19:03 f-14-03-01-05-km-aesi-safety-cl.rtf

Figure 14.3.1.5:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set

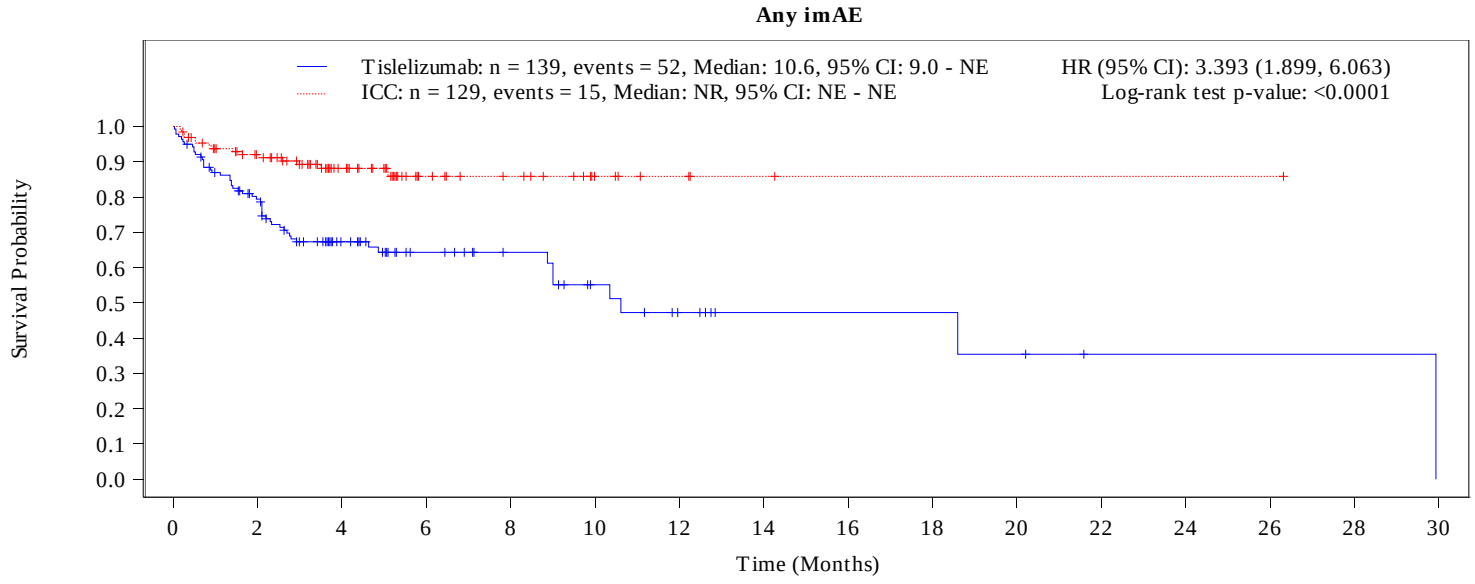


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	255	175	97	65	49	38	32	27	22	20	18	15	14	12	11	9	8	6	4	3	3	2	2	1	1	0
ICC	240	113	45	26	12	8	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesi.sas 13AUG2024 19:03 f-14-03-01-05-km-aesi-safety-cl.rtf

Figure 14.3.1.5.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation without Irinotecan

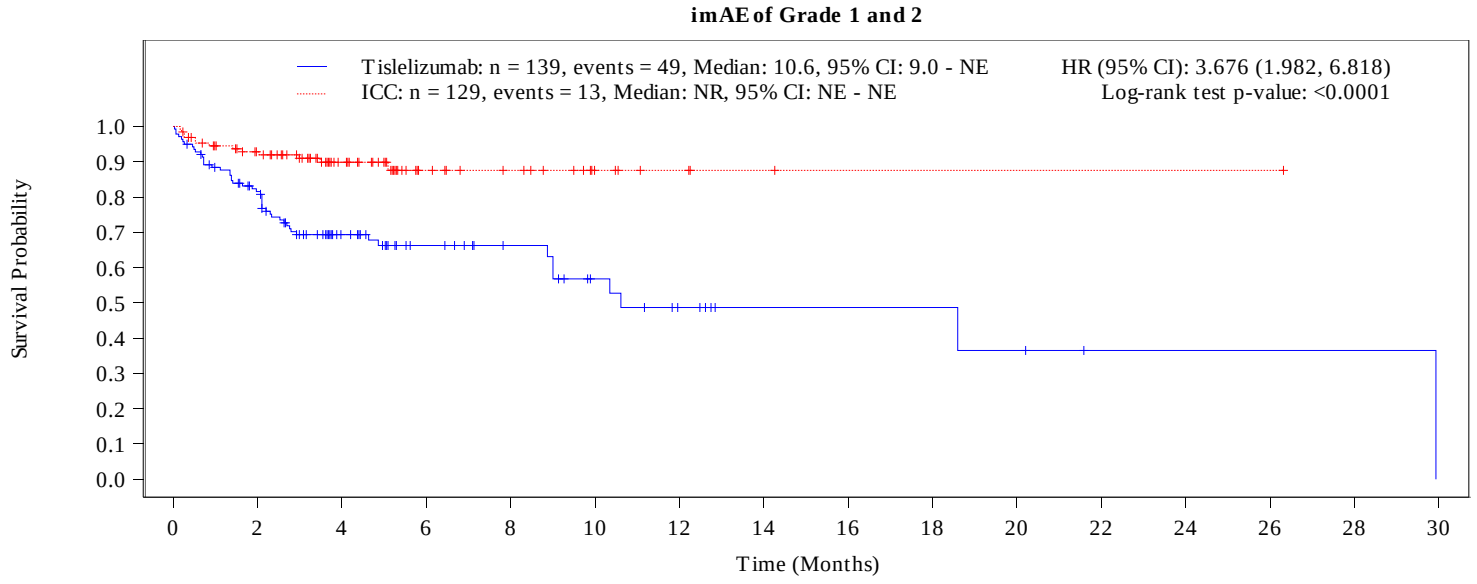


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	139	101	54	30	21	14	8	4	4	4	3	1	1	1	1	0
ICC	129	106	55	24	15	7	4	2	1	1	1	1	1	1	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesi.sas 13AUG2024 19:03 f-14-03-01-05-b-km-aesi-safetys-cl.rtf

Figure 14.3.1.5.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation without Irinotecan

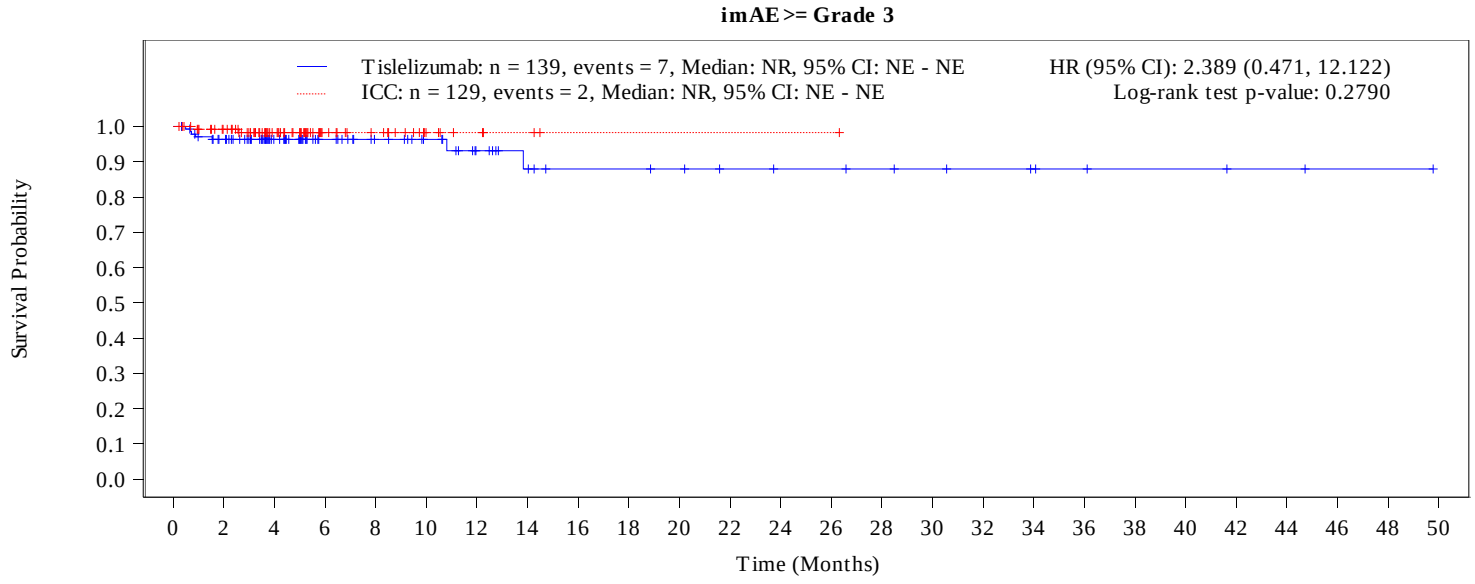


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Tislelizumab	139	103	54	30	21	14	8	4	4	4	3	1	1	1	1	0
ICC	129	107	56	24	15	7	4	2	1	1	1	1	1	1	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesi.sas 13AUG2024 19:03 f-14-03-01-05-b-km-aesi-safetys-cl.rtf

Figure 14.3.1.5.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation without Irinotecan

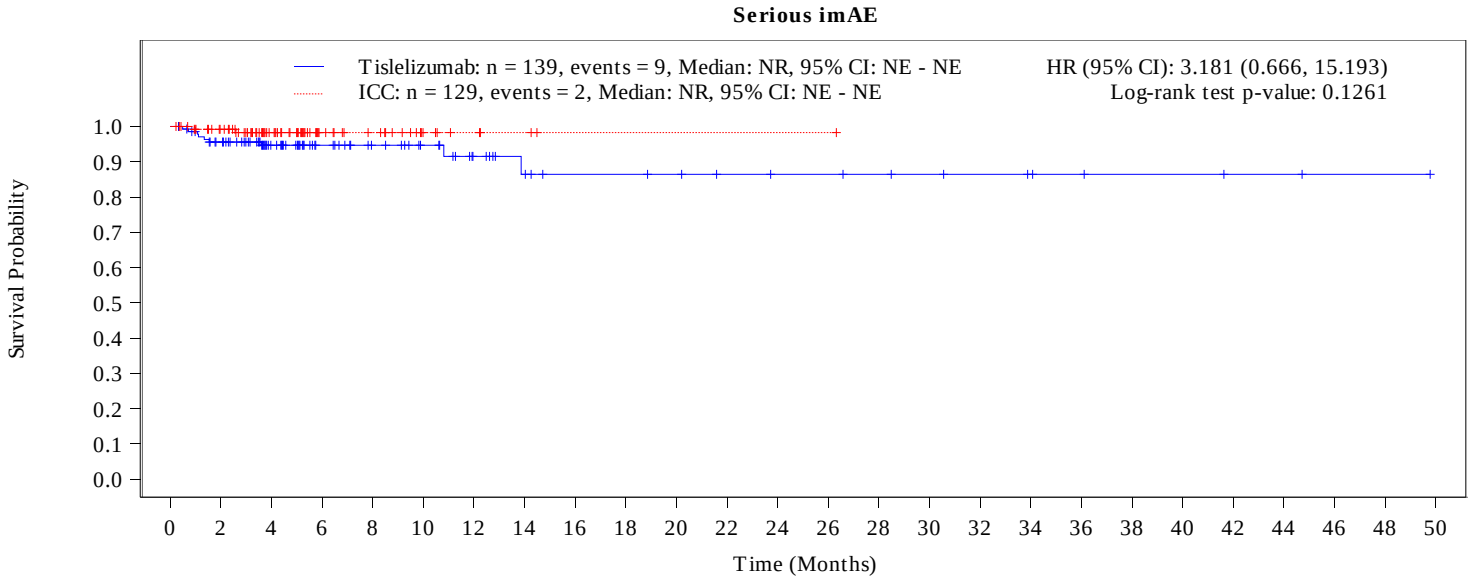


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	124	81	51	39	32	22	17	13	13	12	10	9	9	8	7	6	5	4	3	3	2	2	1	1	0
ICC	129	115	64	29	18	8	5	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesi.sas 13AUG2024 19:03 f-14-03-01-05-b-km-aesi-safetys-cl.rtf

Figure 14.3.1.5.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation without Irinotecan

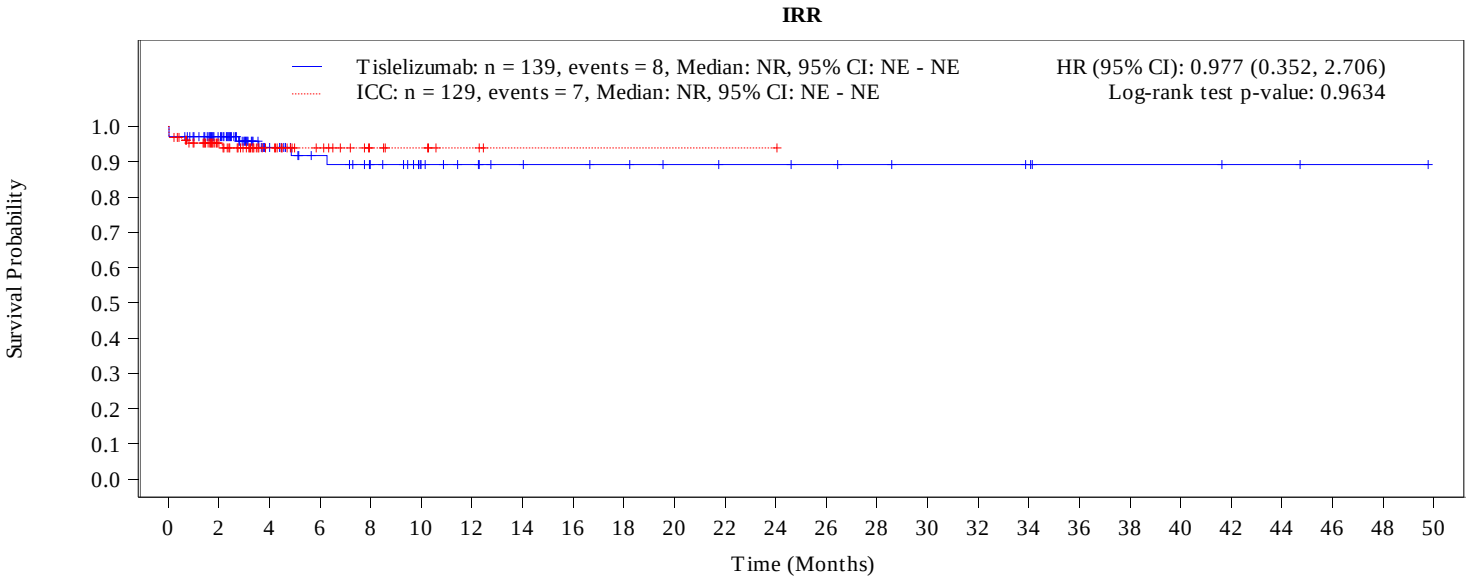


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	123	80	51	39	32	22	17	13	13	12	10	9	9	8	7	6	5	4	3	3	2	2	1	1	0
ICC	129	115	64	29	18	8	5	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesi.sas 13AUG2024 19:03 f-14-03-01-05-b-km-aesi-safetys-cl.rtf

Figure 14.3.1.5.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation without Irinotecan

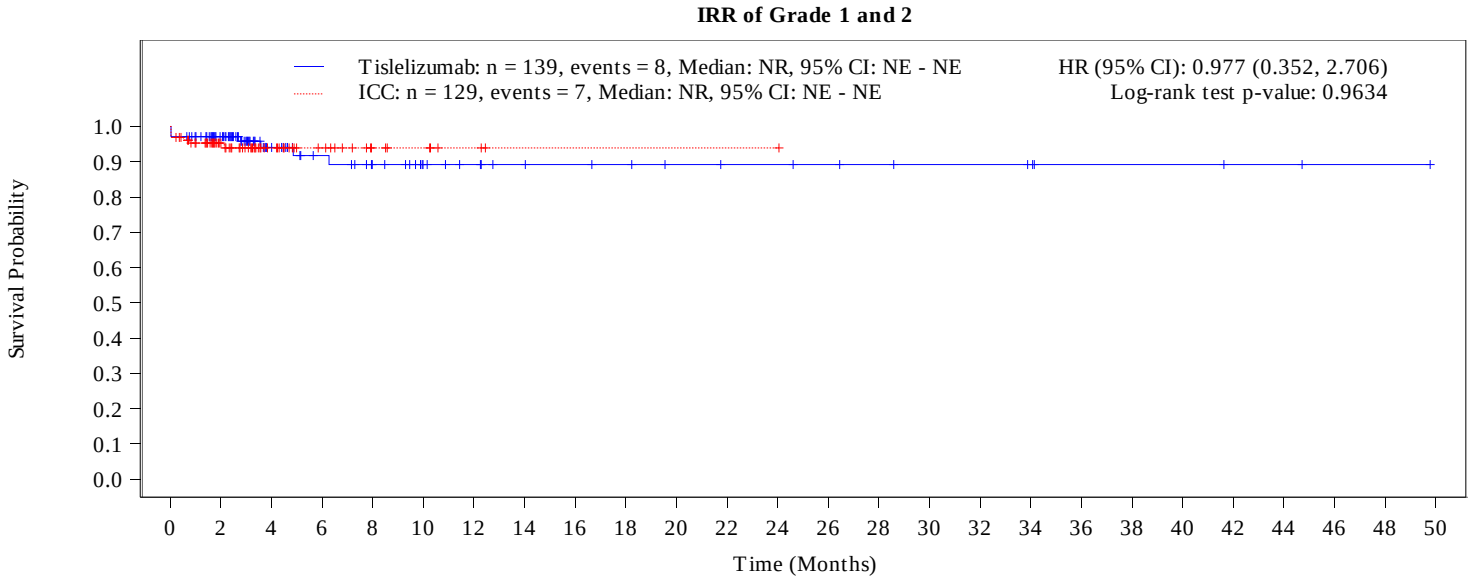


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	93	49	36	28	20	17	14	13	12	10	9	9	8	7	6	6	5	3	3	3	2	2	1	1	0
ICC	129	70	29	16	8	6	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesi.sas 13AUG2024 19:03 f-14-03-01-05-b-km-aesi-safetys-cl.rtf

Figure 14.3.1.5.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation without Irinotecan

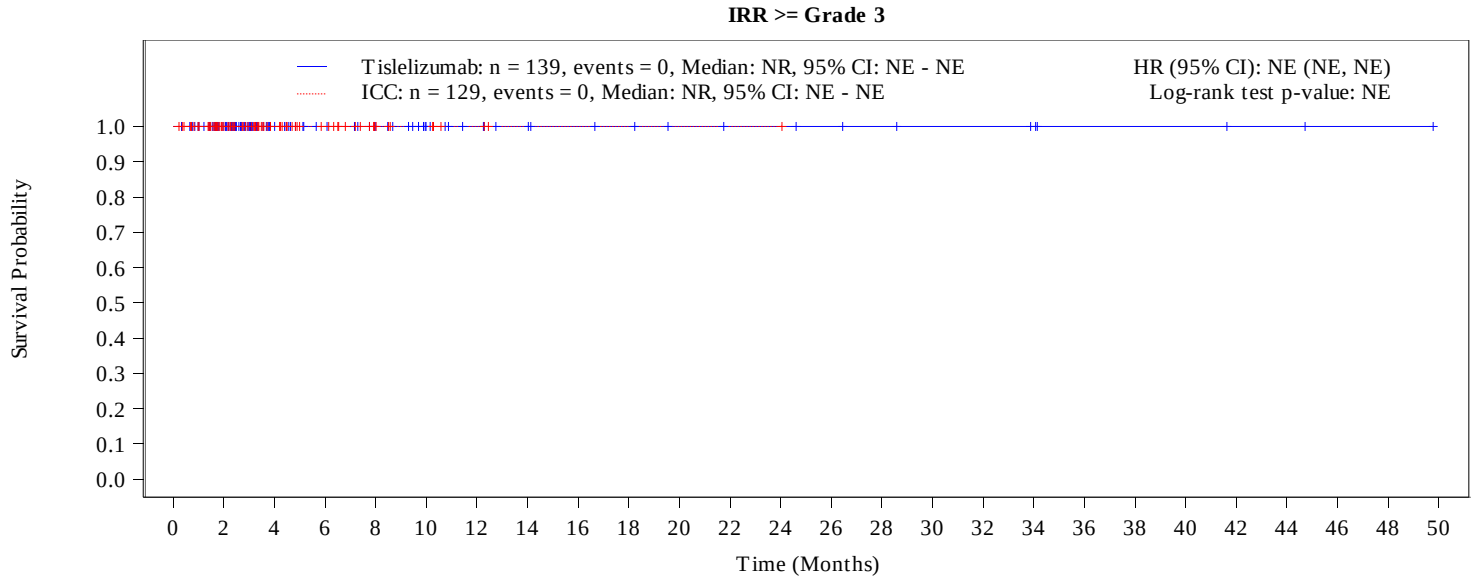


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	93	49	36	28	20	17	14	13	12	10	9	9	8	7	6	6	5	3	3	3	2	2	1	1	0
ICC	129	70	29	16	8	6	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesi.sas 13AUG2024 19:03 f-14-03-01-05-b-km-aesi-safetys-cl.rtf

Figure 14.3.1.5.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation without Irinotecan

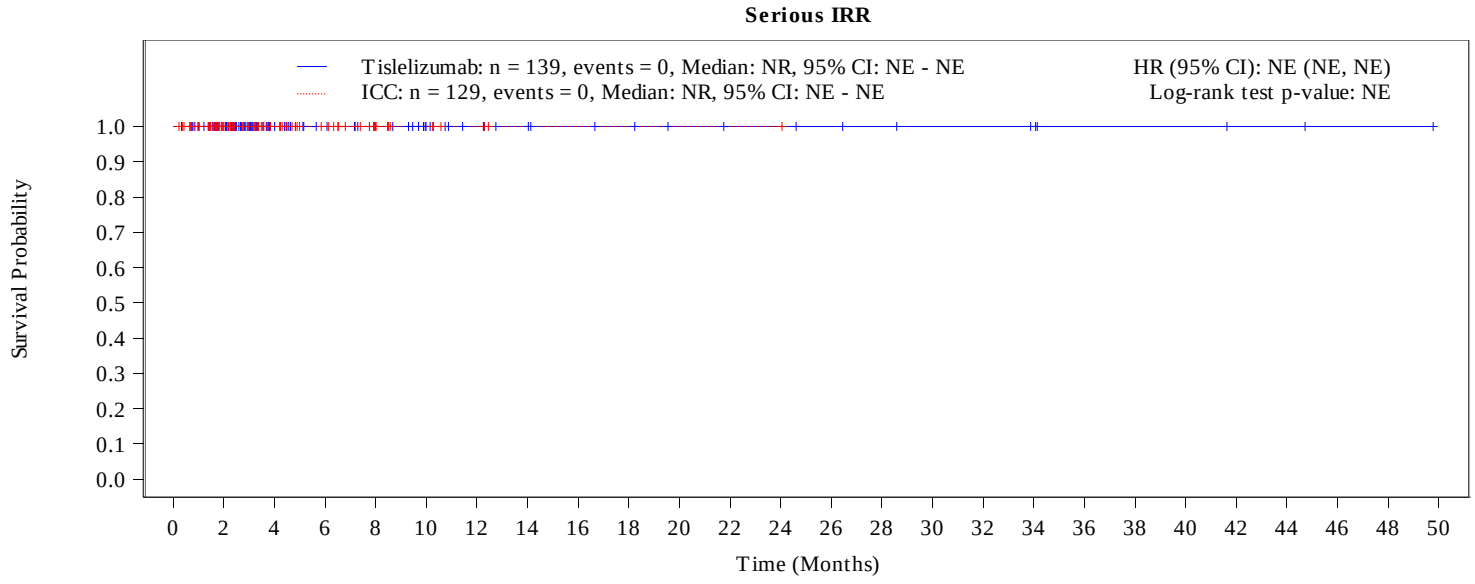


Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	95	52	40	32	23	19	16	13	12	10	9	9	8	7	6	6	5	3	3	3	2	2	1	1	0
ICC	129	75	33	19	9	6	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesi.sas 13AUG2024 19:03 f-14-03-01-05-b-km-aesi-safetys-cl.rtf

Figure 14.3.1.5.b:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest
Safety Analysis Set - Subpopulation without Irinotecan



Number of Patients at Risk:

Time:	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50
Tislelizumab	139	95	52	40	32	23	19	16	13	12	10	9	9	8	7	6	6	5	3	3	3	2	2	1	1	0
ICC	129	75	33	19	9	6	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.
The hazard ratio and its 2-sided 95% CI were based on Cox regression model including treatment as covariate, and baseline ECOG status and ICC options as strata.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesi.sas 13AUG2024 19:03 f-14-03-01-05-b-km-aesi-safetys-cl.rtf

Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

Any imAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	49 (32.2)	16.1 (9.0, NE)	146	11 (7.5)	NR (NE, NE)	4.155 (2.151, 8.027)	<0.0001
>= 65 Years	103	39 (37.9)	10.6 (8.9, NE)	94	8 (8.5)	NR (NE, NE)	4.251 (1.974, 9.154)	<0.0001
Interaction								0.9412
Gender								
Male	216	71 (32.9)	16.1 (10.3, NE)	204	15 (7.4)	NR (NE, NE)	4.281 (2.442, 7.505)	<0.0001
Female	39	17 (43.6)	9.0 (2.7, NE)	36	4 (11.1)	NR (NE, NE)	4.046 (1.351, 12.112)	0.0067
Interaction								0.9194

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

Any imAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	63 (33.7)	16.1 (9.0, NE)	183	16 (8.7)	NR (NE, NE)	3.665 (2.107, 6.374)	<0.0001
Non-Smoker	68	25 (36.8)	10.6 (4.1, NE)	57	3 (5.3)	NR (NE, NE)	7.062 (2.121, 23.518)	0.0002
Interaction								0.3257

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-aesi-subgrp.sas 01AUG2024 19:33 t-14-03-01-03-01-s-aesi-subgrp-safety-cl.rtf

Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

Any imAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	37 (44.6)	9.0 (2.9, NE)	79	10 (12.7)	NR (NE, NE)	3.952 (1.958, 7.976)	<0.0001
Docetaxel	56	15 (26.8)	18.6 (9.0, NE)	50	5 (10.0)	NR (NE, NE)	2.416 (0.872, 6.689)	0.0792
Irinotecan	116	36 (31.0)	16.1 (13.9, NE)	111	4 (3.6)	NR (NE, NE)	7.805 (2.758, 22.087)	<0.0001
Interaction								0.2794

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/t-aesi-subgrp.sas 01AUG2024 19:33 t-14-03-01-03-01-s-aesi-subgrp-safety-cl.rtf

Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

Any imAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	26 (41.3)	10.6 (9.0, 16.1)	57	5 (8.8)	NR (NE, NE)	4.236 (1.610, 11.144)	0.0014
1	192	62 (32.3)	29.9 (9.0, NE)	183	14 (7.7)	NR (NE, NE)	4.247 (2.371, 7.608)	<0.0001
Interaction								0.8150
Region #1								
Asia	201	73 (36.3)	13.9 (9.0, NE)	191	16 (8.4)	NR (NE, NE)	4.235 (2.457, 7.301)	<0.0001
Europe/North America	54	15 (27.8)	29.9 (9.0, NE)	49	3 (6.1)	NR (NE, NE)	4.138 (1.187, 14.425)	0.0150
Interaction								0.9695

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

Any imAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	60 (34.1)	16.1 (13.9, NE)	168	12 (7.1)	NR (NE, NE)	4.815 (2.581, 8.983)	<0.0001
Japan	25	13 (52.0)	9.0 (2.8, 10.6)	23	4 (17.4)	NR (NE, NE)	2.483 (0.805, 7.656)	0.1016
Europe/North America	54	15 (27.8)	29.9 (9.0, NE)	49	3 (6.1)	NR (NE, NE)	4.138 (1.187, 14.425)	0.0150
Interaction								0.7008

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

Any imAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	74 (36.5)	13.9 (9.0, NE)	198	17 (8.6)	NR (NE, NE)	4.152 (2.442, 7.058)	<0.0001
White	52	14 (26.9)	29.9 (9.0, NE)	42	2 (4.8)	NR (NE, NE)	5.133 (1.157, 22.778)	0.0161
Interaction								0.7359

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

Any imAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	26 (32.5)	16.1 (9.0, NE)	60	7 (11.7)	NR (NE, NE)	2.501 (1.081, 5.791)	0.0266
vCPS < 10%	100	37 (37.0)	9.0 (8.9, NE)	119	6 (5.0)	NR (NE, NE)	7.938 (3.340, 18.866)	<0.0001
Missing	75	25 (33.3)	13.9 (10.6, NE)	61	6 (9.8)	NR (NE, NE)	2.934 (1.183, 7.280)	0.0147
Interaction								0.1426

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

imAE of Grade 1 and 2

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	43 (28.3)	29.9 (13.9, NE)	146	10 (6.8)	NR (NE, NE)	4.004 (2.005, 7.999)	<0.0001
>= 65 Years	103	37 (35.9)	10.6 (8.9, NE)	94	7 (7.4)	NR (NE, NE)	4.708 (2.089, 10.610)	<0.0001
Interaction								0.7166
Gender								
Male	216	65 (30.1)	18.6 (10.3, NE)	204	13 (6.4)	NR (NE, NE)	4.599 (2.527, 8.369)	<0.0001
Female	39	15 (38.5)	9.0 (3.1, NE)	36	4 (11.1)	NR (NE, NE)	3.451 (1.135, 10.491)	0.0200
Interaction								0.6709

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

imAE of Grade 1 and 2

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	58 (31.0)	18.6 (10.3, NE)	183	14 (7.7)	NR (NE, NE)	3.954 (2.199, 7.109)	<0.0001
Non-Smoker	68	22 (32.4)	29.9 (9.0, NE)	57	3 (5.3)	NR (NE, NE)	5.981 (1.778, 20.119)	0.0010
Interaction								0.5157

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

imAE of Grade 1 and 2

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	35 (42.2)	9.0 (4.6, NE)	79	9 (11.4)	NR (NE, NE)	4.130 (1.977, 8.625)	<0.0001
Docetaxel	56	14 (25.0)	18.6 (9.0, NE)	50	4 (8.0)	NR (NE, NE)	2.805 (0.917, 8.580)	0.0586
Irinotecan	116	31 (26.7)	NR (13.9, NE)	111	4 (3.6)	NR (NE, NE)	6.929 (2.434, 19.723)	<0.0001
Interaction								0.5155

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

imAE of Grade 1 and 2

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	23 (36.5)	10.6 (9.0, NE)	57	4 (7.0)	NR (NE, NE)	4.769 (1.637, 13.893)	0.0016
1	192	57 (29.7)	29.9 (9.0, NE)	183	13 (7.1)	NR (NE, NE)	4.226 (2.309, 7.735)	<0.0001
Interaction								0.7075
Region #1								
Asia	201	66 (32.8)	13.9 (9.0, NE)	191	14 (7.3)	NR (NE, NE)	4.432 (2.483, 7.911)	<0.0001
Europe/North America	54	14 (25.9)	29.9 (9.0, NE)	49	3 (6.1)	NR (NE, NE)	3.793 (1.079, 13.335)	0.0247
Interaction								0.8936

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

imAE of Grade 1 and 2

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	54 (30.7)	18.6 (13.9, NE)	168	11 (6.5)	NR (NE, NE)	4.809 (2.508, 9.220)	<0.0001
Japan	25	12 (48.0)	9.0 (2.8, 10.6)	23	3 (13.0)	NR (NE, NE)	3.063 (0.859, 10.920)	0.0695
Europe/North America	54	14 (25.9)	29.9 (9.0, NE)	49	3 (6.1)	NR (NE, NE)	3.793 (1.079, 13.335)	0.0247
Interaction								0.9005

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

imAE of Grade 1 and 2

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	66 (32.5)	13.9 (9.0, NE)	198	15 (7.6)	NR (NE, NE)	4.231 (2.409, 7.431)	<0.0001
White	52	14 (26.9)	29.9 (9.0, NE)	42	2 (4.8)	NR (NE, NE)	5.133 (1.157, 22.778)	0.0161
Interaction								0.7523

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

imAE of Grade 1 and 2

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	25 (31.3)	NR (9.0, NE)	60	6 (10.0)	NR (NE, NE)	2.867 (1.171, 7.019)	0.0158
vCPS < 10%	100	34 (34.0)	29.9 (8.9, NE)	119	5 (4.2)	NR (NE, NE)	8.545 (3.331, 21.919)	<0.0001
Missing	75	21 (28.0)	18.6 (10.6, NE)	61	6 (9.8)	NR (NE, NE)	2.464 (0.977, 6.218)	0.0479
Interaction								0.1395

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

imAE >= Grade 3

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	10 (6.6)	NR (16.1, NE)	146	1 (0.7)	NR (NE, NE)	7.990 (1.003, 63.619)	0.0198
>= 65 Years	103	4 (3.9)	NR (36.1, NE)	94	2 (2.1)	NR (NE, NE)	0.980 (0.147, 6.531)	0.9838
Interaction								0.1538
Gender								
Male	216	12 (5.6)	NR (36.1, NE)	204	3 (1.5)	NR (NE, NE)	2.628 (0.707, 9.772)	0.1346
Female	39	2 (5.1)	NR (NE, NE)	36	0 (0.0)	NR (NE, NE)	29721513.991 (0.000, NE)	0.1566
Interaction								0.9904

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

imAE >= Grade 3

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	11 (5.9)	NR (36.1, NE)	183	3 (1.6)	NR (NE, NE)	2.386 (0.629, 9.054)	0.1880
Non-Smoker	68	3 (4.4)	NR (NE, NE)	57	0 (0.0)	NR (NE, NE)	26558471.879 (0.000, NE)	0.1018
Interaction								0.9924

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

imAE >= Grade 3

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	5 (6.0)	--	79	1 (1.3)	--	--	--
Docetaxel	56	2 (3.6)	--	50	1 (2.0)	--	--	--
Irinotecan	116	7 (6.0)	--	111	1 (0.9)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

imAE >= Grade 3

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	5 (7.9)	NR (16.1, NE)	57	1 (1.8)	NR (NE, NE)	2.292 (0.236, 22.221)	0.4632
1	192	9 (4.7)	NR (36.1, NE)	183	2 (1.1)	NR (NE, NE)	3.839 (0.815, 18.080)	0.0667
Interaction								0.9429
Region #1								
Asia	201	12 (6.0)	NR (36.1, NE)	191	2 (1.0)	NR (NE, NE)	4.055 (0.874, 18.826)	0.0537
Europe/North America	54	2 (3.7)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	1.829 (0.166, 20.176)	0.6165
Interaction								0.4651

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

imAE >= Grade 3

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	9 (5.1)	NR (36.1, NE)	168	1 (0.6)	NR (NE, NE)	6.888 (0.850, 55.846)	0.0360
Japan	25	3 (12.0)	NR (10.8, NE)	23	1 (4.3)	NR (NE, NE)	1.356 (0.124, 14.780)	0.8022
Europe/North America	54	2 (3.7)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	1.829 (0.166, 20.176)	0.6165
Interaction								0.5772

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

imAE >= Grade 3

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	13 (6.4)	NR (36.1, NE)	198	2 (1.0)	NR (NE, NE)	4.662 (1.019, 21.340)	0.0296
White	52	1 (1.9)	NR (NE, NE)	42	1 (2.4)	NR (NE, NE)	0.797 (0.050, 12.753)	0.8726
Interaction								0.2140

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

imAE >= Grade 3

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	5 (6.3)	--	60	1 (1.7)	--	--	--
vCPS < 10%	100	5 (5.0)	--	119	2 (1.7)	--	--	--
Missing	75	4 (5.3)	--	61	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

Serious imAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	12 (7.9)	NR (16.1, NE)	146	1 (0.7)	NR (NE, NE)	9.644 (1.238, 75.148)	0.0080
>= 65 Years	103	6 (5.8)	NR (36.1, NE)	94	2 (2.1)	NR (NE, NE)	1.905 (0.354, 10.237)	0.4451
Interaction								0.2173
Gender								
Male	216	17 (7.9)	NR (36.1, NE)	204	3 (1.5)	NR (NE, NE)	4.150 (1.189, 14.492)	0.0155
Female	39	1 (2.6)	NR (NE, NE)	36	0 (0.0)	NR (NE, NE)	31426460.578 (0.000, NE)	0.3031
Interaction								0.9906

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

Serious imAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	16 (8.6)	NR (36.1, NE)	183	3 (1.6)	NR (NE, NE)	3.949 (1.121, 13.905)	0.0211
Non-Smoker	68	2 (2.9)	NR (NE, NE)	57	0 (0.0)	NR (NE, NE)	27115615.366 (0.000, NE)	0.1765
Interaction								0.9924

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

Serious imAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	5 (6.0)	NR (NE, NE)	79	1 (1.3)	NR (NE, NE)	3.910 (0.445, 34.389)	0.1861
Docetaxel	56	4 (7.1)	NR (NE, NE)	50	1 (2.0)	NR (NE, NE)	2.616 (0.278, 24.601)	0.3833
Irinotecan	116	9 (7.8)	36.1 (NE, NE)	111	1 (0.9)	NR (NE, NE)	6.929 (0.852, 56.320)	0.0351
Interaction								0.8184

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

Serious imAE

Subgroup	Tislelizumab (N = 255) Total No. of Patients	Tislelizumab (N = 255) Patients with events n (%)	Tislelizumab (N = 255) Median time to event (95% CI) [a]	ICC (N = 240) Total No. of Patients	ICC (N = 240) Patients with events n (%)	ICC (N = 240) Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
ECOG Performance Score								
0	63	6 (9.5)	NR (16.1, NE)	57	1 (1.8)	NR (NE, NE)	3.152 (0.350, 28.410)	0.2822
1	192	12 (6.3)	NR (36.1, NE)	183	2 (1.1)	NR (NE, NE)	5.185 (1.149, 23.401)	0.0168
Interaction								0.9026
Region #1								
Asia	201	16 (8.0)	NR (36.1, NE)	191	2 (1.0)	NR (NE, NE)	5.894 (1.327, 26.173)	0.0083
Europe/North America	54	2 (3.7)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	1.765 (0.160, 19.464)	0.6383
Interaction								0.3372

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

Serious imAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	13 (7.4)	NR (36.1, NE)	168	1 (0.6)	NR (NE, NE)	10.629 (1.373, 82.270)	0.0047
Japan	25	3 (12.0)	NR (10.8, NE)	23	1 (4.3)	NR (NE, NE)	1.356 (0.124, 14.780)	0.8022
Europe/North America	54	2 (3.7)	NR (NE, NE)	49	1 (2.0)	NR (NE, NE)	1.765 (0.160, 19.464)	0.6383
Interaction								0.4066

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

Serious imAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	16 (7.9)	NR (36.1, NE)	198	2 (1.0)	NR (NE, NE)	6.043 (1.361, 26.837)	0.0072
White	52	2 (3.8)	NR (NE, NE)	42	1 (2.4)	NR (NE, NE)	1.551 (0.141, 17.108)	0.7178
Interaction								0.2872

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

Serious imAE

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	8 (10.0)	--	60	1 (1.7)	--	--	--
vCPS < 10%	100	3 (3.0)	--	119	2 (1.7)	--	--	--
Missing	75	7 (9.3)	--	61	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

IRR

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	4 (2.6)	NR (NE, NE)	146	5 (3.4)	NR (NE, NE)	0.577 (0.152, 2.189)	0.4133
>= 65 Years	103	4 (3.9)	NR (NE, NE)	94	6 (6.4)	NR (NE, NE)	0.500 (0.138, 1.806)	0.2760
Interaction								0.7569
Gender								
Male	216	6 (2.8)	NR (NE, NE)	204	8 (3.9)	NR (NE, NE)	0.500 (0.170, 1.467)	0.1977
Female	39	2 (5.1)	NR (NE, NE)	36	3 (8.3)	NR (NE, NE)	0.618 (0.103, 3.698)	0.5913
Interaction								0.8896

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

IRR

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	5 (2.7)	NR (NE, NE)	183	9 (4.9)	NR (NE, NE)	0.371 (0.122, 1.131)	0.0702
Non-Smoker	68	3 (4.4)	NR (NE, NE)	57	2 (3.5)	NR (NE, NE)	1.271 (0.212, 7.608)	0.7912
Interaction								0.4070

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

IRR

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	4 (4.8)	NR (NE, NE)	79	6 (7.6)	NR (NE, NE)	0.566 (0.159, 2.021)	0.3703
Docetaxel	56	4 (7.1)	NR (NE, NE)	50	1 (2.0)	NR (NE, NE)	2.920 (0.323, 26.438)	0.3173
Irinotecan	116	0 (0.0)	NR (NE, NE)	111	4 (3.6)	NR (5.3, NE)	0.000 (0.000, NE)	0.0100
Interaction								0.3827

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

IRR

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	4 (6.3)	NR (NE, NE)	57	2 (3.5)	NR (NE, NE)	1.145 (0.208, 6.318)	0.8764
1	192	4 (2.1)	NR (NE, NE)	183	9 (4.9)	NR (NE, NE)	0.394 (0.121, 1.283)	0.1070
Interaction								0.1514
Region #1								
Asia	201	8 (4.0)	NR (NE, NE)	191	6 (3.1)	NR (NE, NE)	0.988 (0.337, 2.899)	0.9824
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	5 (10.2)	NR (5.3, NE)	0.000 (0.000, NE)	0.0102
Interaction								0.9907

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

IRR

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	5 (2.8)	NR (NE, NE)	168	6 (3.6)	NR (NE, NE)	0.654 (0.196, 2.182)	0.4846
Japan	25	3 (12.0)	NR (4.9, NE)	23	0 (0.0)	NR (NE, NE)	55301530.201 (0.000, NE)	0.1794
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	5 (10.2)	NR (5.3, NE)	0.000 (0.000, NE)	0.0102
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

IRR

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	8 (3.9)	NR (NE, NE)	198	7 (3.5)	NR (NE, NE)	0.884 (0.315, 2.479)	0.8145
White	52	0 (0.0)	NR (NE, NE)	42	4 (9.5)	NR (5.3, NE)	0.000 (0.000, NE)	0.0132
Interaction								0.9905

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

IRR

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	3 (3.8)	--	60	2 (3.3)	--	--	--
vCPS < 10%	100	3 (3.0)	--	119	4 (3.4)	--	--	--
Missing	75	2 (2.7)	--	61	5 (8.2)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

IRR of Grade 1 and 2

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	4 (2.6)	NR (NE, NE)	146	5 (3.4)	NR (NE, NE)	0.577 (0.152, 2.189)	0.4133
>= 65 Years	103	4 (3.9)	NR (NE, NE)	94	6 (6.4)	NR (NE, NE)	0.500 (0.138, 1.806)	0.2760
Interaction								0.7569
Gender								
Male	216	6 (2.8)	NR (NE, NE)	204	8 (3.9)	NR (NE, NE)	0.500 (0.170, 1.467)	0.1977
Female	39	2 (5.1)	NR (NE, NE)	36	3 (8.3)	NR (NE, NE)	0.618 (0.103, 3.698)	0.5913
Interaction								0.8896

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

IRR of Grade 1 and 2

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	5 (2.7)	NR (NE, NE)	183	9 (4.9)	NR (NE, NE)	0.371 (0.122, 1.131)	0.0702
Non-Smoker	68	3 (4.4)	NR (NE, NE)	57	2 (3.5)	NR (NE, NE)	1.271 (0.212, 7.608)	0.7912
Interaction								0.4070

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

IRR of Grade 1 and 2

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	4 (4.8)	NR (NE, NE)	79	6 (7.6)	NR (NE, NE)	0.566 (0.159, 2.021)	0.3703
Docetaxel	56	4 (7.1)	NR (NE, NE)	50	1 (2.0)	NR (NE, NE)	2.920 (0.323, 26.438)	0.3173
Irinotecan	116	0 (0.0)	NR (NE, NE)	111	4 (3.6)	NR (5.3, NE)	0.000 (0.000, NE)	0.0100
Interaction								0.3827

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

IRR of Grade 1 and 2

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	4 (6.3)	NR (NE, NE)	57	2 (3.5)	NR (NE, NE)	1.145 (0.208, 6.318)	0.8764
1	192	4 (2.1)	NR (NE, NE)	183	9 (4.9)	NR (NE, NE)	0.394 (0.121, 1.283)	0.1070
Interaction								0.1514
Region #1								
Asia	201	8 (4.0)	NR (NE, NE)	191	6 (3.1)	NR (NE, NE)	0.988 (0.337, 2.899)	0.9824
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	5 (10.2)	NR (5.3, NE)	0.000 (0.000, NE)	0.0102
Interaction								0.9907

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

IRR of Grade 1 and 2

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	5 (2.8)	NR (NE, NE)	168	6 (3.6)	NR (NE, NE)	0.654 (0.196, 2.182)	0.4846
Japan	25	3 (12.0)	NR (4.9, NE)	23	0 (0.0)	NR (NE, NE)	55301530.201 (0.000, NE)	0.1794
Europe/North America	54	0 (0.0)	NR (NE, NE)	49	5 (10.2)	NR (5.3, NE)	0.000 (0.000, NE)	0.0102
Interaction								0.9999

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

IRR of Grade 1 and 2

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	8 (3.9)	NR (NE, NE)	198	7 (3.5)	NR (NE, NE)	0.884 (0.315, 2.479)	0.8145
White	52	0 (0.0)	NR (NE, NE)	42	4 (9.5)	NR (5.3, NE)	0.000 (0.000, NE)	0.0132
Interaction								0.9905

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

IRR of Grade 1 and 2

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	3 (3.8)	--	60	2 (3.3)	--	--	--
vCPS < 10%	100	3 (3.0)	--	119	4 (3.4)	--	--	--
Missing	75	2 (2.7)	--	61	5 (8.2)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

IRR >= Grade 3

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	0 (0.0)	--	146	0 (0.0)	--	--	--
>= 65 Years	103	0 (0.0)	--	94	0 (0.0)	--	--	--
Interaction								--
Gender								
Male	216	0 (0.0)	--	204	0 (0.0)	--	--	--
Female	39	0 (0.0)	--	36	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

IRR >= Grade 3

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	0 (0.0)	--	183	0 (0.0)	--	--	--
Non-Smoker	68	0 (0.0)	--	57	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

IRR >= Grade 3

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	0 (0.0)	--	79	0 (0.0)	--	--	--
Docetaxel	56	0 (0.0)	--	50	0 (0.0)	--	--	--
Irinotecan	116	0 (0.0)	--	111	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

IRR >= Grade 3

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	0 (0.0)	--	57	0 (0.0)	--	--	--
1	192	0 (0.0)	--	183	0 (0.0)	--	--	--
Interaction								--
Region #1								
Asia	201	0 (0.0)	--	191	0 (0.0)	--	--	--
Europe/North America	54	0 (0.0)	--	49	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

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Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

IRR >= Grade 3

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	176	0 (0.0)	--	168	0 (0.0)	--	--	--
Japan	25	0 (0.0)	--	23	0 (0.0)	--	--	--
Europe/North America	54	0 (0.0)	--	49	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

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Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

IRR >= Grade 3

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	0 (0.0)	--	198	0 (0.0)	--	--	--
White	52	0 (0.0)	--	42	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

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Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

IRR >= Grade 3

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	0 (0.0)	--	60	0 (0.0)	--	--	--
vCPS < 10%	100	0 (0.0)	--	119	0 (0.0)	--	--	--
Missing	75	0 (0.0)	--	61	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

Serious IRR

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	152	0 (0.0)	--	146	0 (0.0)	--	--	--
>= 65 Years	103	0 (0.0)	--	94	0 (0.0)	--	--	--
Interaction								--
Gender								
Male	216	0 (0.0)	--	204	0 (0.0)	--	--	--
Female	39	0 (0.0)	--	36	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

Serious IRR

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	187	0 (0.0)	--	183	0 (0.0)	--	--	--
Non-Smoker	68	0 (0.0)	--	57	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

Serious IRR

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ICC Options								
Paclitaxel	83	0 (0.0)	--	79	0 (0.0)	--	--	--
Docetaxel	56	0 (0.0)	--	50	0 (0.0)	--	--	--
Irinotecan	116	0 (0.0)	--	111	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

Serious IRR

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	63	0 (0.0)	--	57	0 (0.0)	--	--	--
1	192	0 (0.0)	--	183	0 (0.0)	--	--	--
Interaction								--
Region #1								
Asia	201	0 (0.0)	--	191	0 (0.0)	--	--	--
Europe/North America	54	0 (0.0)	--	49	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

Serious IRR

Subgroup	Tislelizumab (N = 255) Total No. of Patients	Tislelizumab (N = 255) Patients with events n (%)	Tislelizumab (N = 255) Median time to event (95% CI) [a]	ICC (N = 240) Total No. of Patients	ICC (N = 240) Patients with events n (%)	ICC (N = 240) Median time to event (95% CI) [a]	Hazard Ratio (95% CI) [b]	2-sided p-value [c]
Region #2								
Asia (excluding Japan)	176	0 (0.0)	--	168	0 (0.0)	--	--	--
Japan	25	0 (0.0)	--	23	0 (0.0)	--	--	--
Europe/North America	54	0 (0.0)	--	49	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

Serious IRR

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	203	0 (0.0)	--	198	0 (0.0)	--	--	--
White	52	0 (0.0)	--	42	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set

Serious IRR

	Tislelizumab (N = 255)			ICC (N = 240)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	80	0 (0.0)	--	60	0 (0.0)	--	--	--
vCPS < 10%	100	0 (0.0)	--	119	0 (0.0)	--	--	--
Missing	75	0 (0.0)	--	61	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel vs irinotecan; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any imAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	29 (38.2)	9.0 (4.6, NE)	69	10 (14.5)	NR (NE, NE)	2.697 (1.310, 5.554)	0.0049
>= 65 Years	63	23 (36.5)	10.6 (8.9, NE)	60	5 (8.3)	NR (NE, NE)	4.155 (1.564, 11.040)	0.0020
Interaction								0.4371
Gender								
Male	118	44 (37.3)	10.6 (8.9, NE)	106	12 (11.3)	NR (NE, NE)	3.337 (1.756, 6.341)	<0.0001
Female	21	8 (38.1)	9.0 (2.3, NE)	23	3 (13.0)	NR (NE, NE)	2.776 (0.717, 10.753)	0.1219
Interaction								0.8048

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any imAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	39 (37.5)	18.6 (8.9, NE)	101	13 (12.9)	NR (NE, NE)	2.993 (1.592, 5.625)	0.0003
Non-Smoker	35	13 (37.1)	10.6 (9.0, NE)	28	2 (7.1)	NR (NE, NE)	4.772 (1.064, 21.398)	0.0241
Interaction								0.5305
ICC Options								
Paclitaxel	83	37 (44.6)	9.0 (2.9, NE)	79	10 (12.7)	NR (NE, NE)	3.952 (1.958, 7.976)	<0.0001
Docetaxel	56	15 (26.8)	18.6 (9.0, NE)	50	5 (10.0)	NR (NE, NE)	2.416 (0.872, 6.689)	0.0792
Interaction								0.4513

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any imAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	20 (46.5)	10.3 (4.6, NE)	37	5 (13.5)	NR (NE, NE)	3.434 (1.281, 9.206)	0.0089
1	96	32 (33.3)	29.9 (8.9, NE)	92	10 (10.9)	NR (NE, NE)	3.154 (1.544, 6.441)	0.0009
Interaction								0.7771
Region #1								
Asia	103	40 (38.8)	10.3 (8.9, NE)	99	14 (14.1)	NR (NE, NE)	2.752 (1.494, 5.068)	0.0007
Europe/North America	36	12 (33.3)	29.9 (9.0, NE)	30	1 (3.3)	NR (NE, NE)	9.966 (1.284, 77.325)	0.0065
Interaction								0.2313

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any imAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	27 (34.6)	18.6 (8.9, NE)	76	10 (13.2)	NR (NE, NE)	2.788 (1.347, 5.772)	0.0039
Japan	25	13 (52.0)	9.0 (2.8, 10.6)	23	4 (17.4)	NR (NE, NE)	2.483 (0.805, 7.656)	0.1016
Europe/North America	36	12 (33.3)	29.9 (9.0, NE)	30	1 (3.3)	NR (NE, NE)	9.966 (1.284, 77.325)	0.0065
Interaction								0.4819

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any imAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	41 (39.0)	10.3 (8.9, NE)	106	15 (14.2)	NR (NE, NE)	2.760 (1.525, 4.997)	0.0005
White	34	11 (32.4)	29.9 (9.0, NE)	23	0 (0.0)	NR (NE, NE)	63157351.321 (0.000, NE)	0.0057
Interaction								0.9852

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Any imAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	14 (31.1)	10.3 (9.0, NE)	34	6 (17.6)	NR (5.1, NE)	1.759 (0.675, 4.584)	0.2415
vCPS < 10%	53	23 (43.4)	9.0 (2.1, NE)	54	3 (5.6)	NR (NE, NE)	8.589 (2.564, 28.771)	<0.0001
Missing	41	15 (36.6)	18.6 (4.6, NE)	41	6 (14.6)	NR (NE, NE)	2.157 (0.820, 5.675)	0.1099
Interaction								0.1148

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

imAE of Grade 1 and 2

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	27 (35.5)	29.9 (4.9, NE)	69	9 (13.0)	NR (NE, NE)	2.780 (1.303, 5.935)	0.0057
>= 65 Years	63	22 (34.9)	10.6 (9.0, NE)	60	4 (6.7)	NR (NE, NE)	4.908 (1.674, 14.389)	0.0014
Interaction								0.3516
Gender								
Male	118	41 (34.7)	18.6 (9.0, NE)	106	10 (9.4)	NR (NE, NE)	3.700 (1.846, 7.417)	<0.0001
Female	21	8 (38.1)	9.0 (2.3, NE)	23	3 (13.0)	NR (NE, NE)	2.776 (0.717, 10.753)	0.1219
Interaction								0.7112

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

imAE of Grade 1 and 2

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	36 (34.6)	18.6 (8.9, NE)	101	11 (10.9)	NR (NE, NE)	3.239 (1.643, 6.385)	0.0003
Non-Smoker	35	13 (37.1)	10.6 (9.0, NE)	28	2 (7.1)	NR (NE, NE)	4.772 (1.064, 21.398)	0.0241
Interaction								0.5997
ICC Options								
Paclitaxel	83	35 (42.2)	9.0 (4.6, NE)	79	9 (11.4)	NR (NE, NE)	4.130 (1.977, 8.625)	<0.0001
Docetaxel	56	14 (25.0)	18.6 (9.0, NE)	50	4 (8.0)	NR (NE, NE)	2.805 (0.917, 8.580)	0.0586
Interaction								0.5931

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

imAE of Grade 1 and 2

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	19 (44.2)	10.3 (4.6, NE)	37	4 (10.8)	NR (NE, NE)	4.074 (1.377, 12.052)	0.0058
1	96	30 (31.3)	29.9 (9.0, NE)	92	9 (9.8)	NR (NE, NE)	3.248 (1.536, 6.872)	0.0011
Interaction								0.6372
Region #1								
Asia	103	38 (36.9)	10.3 (8.9, NE)	99	12 (12.1)	NR (NE, NE)	3.054 (1.593, 5.857)	0.0004
Europe/North America	36	11 (30.6)	29.9 (9.0, NE)	30	1 (3.3)	NR (NE, NE)	8.869 (1.133, 69.406)	0.0116
Interaction								0.3257

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

imAE of Grade 1 and 2

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	26 (33.3)	18.6 (8.9, NE)	76	9 (11.8)	NR (NE, NE)	2.978 (1.392, 6.370)	0.0031
Japan	25	12 (48.0)	9.0 (2.8, 10.6)	23	3 (13.0)	NR (NE, NE)	3.063 (0.859, 10.920)	0.0695
Europe/North America	36	11 (30.6)	29.9 (9.0, NE)	30	1 (3.3)	NR (NE, NE)	8.869 (1.133, 69.406)	0.0116
Interaction								0.6025

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

imAE of Grade 1 and 2

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	38 (36.2)	10.3 (8.9, NE)	106	13 (12.3)	NR (NE, NE)	2.932 (1.558, 5.516)	0.0005
White	34	11 (32.4)	29.9 (9.0, NE)	23	0 (0.0)	NR (NE, NE)	63157351.321 (0.000, NE)	0.0057
Interaction								0.9858

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

imAE of Grade 1 and 2

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	14 (31.1)	10.3 (9.0, NE)	34	5 (14.7)	NR (5.1, NE)	2.134 (0.767, 5.934)	0.1370
vCPS < 10%	53	22 (41.5)	9.0 (2.3, NE)	54	2 (3.7)	NR (NE, NE)	11.981 (2.803, 51.204)	<0.0001
Missing	41	13 (31.7)	18.6 (4.6, NE)	41	6 (14.6)	NR (NE, NE)	1.803 (0.667, 4.875)	0.2381
Interaction								0.0950

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

imAE >= Grade 3

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	4 (5.3)	--	69	1 (1.4)	--	--	--
>= 65 Years	63	3 (4.8)	--	60	1 (1.7)	--	--	--
Interaction								--
Gender								
Male	118	7 (5.9)	--	106	2 (1.9)	--	--	--
Female	21	0 (0.0)	--	23	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

imAE >= Grade 3

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	7 (6.7)	--	101	2 (2.0)	--	--	--
Non-Smoker	35	0 (0.0)	--	28	0 (0.0)	--	--	--
Interaction								--
ICC Options								
Paclitaxel	83	5 (6.0)	--	79	1 (1.3)	--	--	--
Docetaxel	56	2 (3.6)	--	50	1 (2.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

imAE >= Grade 3

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	3 (7.0)	--	37	1 (2.7)	--	--	--
1	96	4 (4.2)	--	92	1 (1.1)	--	--	--
Interaction								--
Region #1								
Asia	103	5 (4.9)	--	99	2 (2.0)	--	--	--
Europe/North America	36	2 (5.6)	--	30	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

imAE >= Grade 3

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	2 (2.6)	--	76	1 (1.3)	--	--	--
Japan	25	3 (12.0)	--	23	1 (4.3)	--	--	--
Europe/North America	36	2 (5.6)	--	30	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

imAE >= Grade 3

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	6 (5.7)	--	106	2 (1.9)	--	--	--
White	34	1 (2.9)	--	23	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

imAE >= Grade 3

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	2 (4.4)	--	34	1 (2.9)	--	--	--
vCPS < 10%	53	3 (5.7)	--	54	1 (1.9)	--	--	--
Missing	41	2 (4.9)	--	41	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious imAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	6 (7.9)	--	69	1 (1.4)	--	--	--
>= 65 Years	63	3 (4.8)	--	60	1 (1.7)	--	--	--
Interaction								--
Gender								
Male	118	9 (7.6)	NR (NE, NE)	106	2 (1.9)	NR (NE, NE)	3.234 (0.683, 15.307)	0.1183
Female	21	0 (0.0)	NR (NE, NE)	23	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9997

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

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[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious imAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	9 (8.7)	NR (NE, NE)	101	2 (2.0)	NR (NE, NE)	3.555 (0.752, 16.803)	0.0883
Non-Smoker	35	0 (0.0)	NR (NE, NE)	28	0 (0.0)	NR (NE, NE)	NE (NE, NE)	NE
Interaction								0.9998
ICC Options								
Paclitaxel	83	5 (6.0)	--	79	1 (1.3)	--	--	--
Docetaxel	56	4 (7.1)	--	50	1 (2.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious imAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	3 (7.0)	--	37	1 (2.7)	--	--	--
1	96	6 (6.3)	--	92	1 (1.1)	--	--	--
Interaction								--
Region #1								
Asia	103	7 (6.8)	--	99	2 (2.0)	--	--	--
Europe/North America	36	2 (5.6)	--	30	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious imAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	4 (5.1)	--	76	1 (1.3)	--	--	--
Japan	25	3 (12.0)	--	23	1 (4.3)	--	--	--
Europe/North America	36	2 (5.6)	--	30	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious imAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	7 (6.7)	--	106	2 (1.9)	--	--	--
White	34	2 (5.9)	--	23	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious imAE

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	3 (6.7)	--	34	1 (2.9)	--	--	--
vCPS < 10%	53	2 (3.8)	--	54	1 (1.9)	--	--	--
Missing	41	4 (9.8)	--	41	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	4 (5.3)	--	69	2 (2.9)	--	--	--
>= 65 Years	63	4 (6.3)	--	60	5 (8.3)	--	--	--
Interaction								--
Gender								
Male	118	6 (5.1)	NR (NE, NE)	106	5 (4.7)	NR (NE, NE)	0.878 (0.266, 2.904)	0.8310
Female	21	2 (9.5)	NR (NE, NE)	23	2 (8.7)	NR (NE, NE)	1.111 (0.156, 7.887)	0.9149
Interaction								0.9889

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	5 (4.8)	NR (NE, NE)	101	6 (5.9)	NR (NE, NE)	0.617 (0.185, 2.053)	0.4247
Non-Smoker	35	3 (8.6)	NR (NE, NE)	28	1 (3.6)	NR (NE, NE)	2.432 (0.253, 23.387)	0.4207
Interaction								0.3361
ICC Options								
Paclitaxel	83	4 (4.8)	NR (NE, NE)	79	6 (7.6)	NR (NE, NE)	0.566 (0.159, 2.021)	0.3703
Docetaxel	56	4 (7.1)	NR (NE, NE)	50	1 (2.0)	NR (NE, NE)	2.920 (0.323, 26.438)	0.3173
Interaction								0.1739

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	4 (9.3)	NR (NE, NE)	37	0 (0.0)	NR (NE, NE)	54390180.131 (0.000, NE)	0.1138
1	96	4 (4.2)	NR (NE, NE)	92	7 (7.6)	NR (NE, NE)	0.527 (0.154, 1.804)	0.2930
Interaction								0.9901
Region #1								
Asia	103	8 (7.8)	NR (NE, NE)	99	4 (4.0)	NR (NE, NE)	1.623 (0.485, 5.434)	0.4237
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	3 (10.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0567
Interaction								0.9901

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	5 (6.4)	--	76	4 (5.3)	--	--	--
Japan	25	3 (12.0)	--	23	0 (0.0)	--	--	--
Europe/North America	36	0 (0.0)	--	30	3 (10.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	8 (7.6)	NR (NE, NE)	106	5 (4.7)	NR (NE, NE)	1.383 (0.449, 4.259)	0.5672
White	34	0 (0.0)	NR (NE, NE)	23	2 (8.7)	NR (NE, NE)	0.000 (0.000, NE)	0.0892
Interaction								0.9903

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

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[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	3 (6.7)	--	34	2 (5.9)	--	--	--
vCPS < 10%	53	3 (5.7)	--	54	1 (1.9)	--	--	--
Missing	41	2 (4.9)	--	41	4 (9.8)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR of Grade 1 and 2

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	4 (5.3)	--	69	2 (2.9)	--	--	--
>= 65 Years	63	4 (6.3)	--	60	5 (8.3)	--	--	--
Interaction								--
Gender								
Male	118	6 (5.1)	NR (NE, NE)	106	5 (4.7)	NR (NE, NE)	0.878 (0.266, 2.904)	0.8310
Female	21	2 (9.5)	NR (NE, NE)	23	2 (8.7)	NR (NE, NE)	1.111 (0.156, 7.887)	0.9149
Interaction								0.9889

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR of Grade 1 and 2

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	5 (4.8)	NR (NE, NE)	101	6 (5.9)	NR (NE, NE)	0.617 (0.185, 2.053)	0.4247
Non-Smoker	35	3 (8.6)	NR (NE, NE)	28	1 (3.6)	NR (NE, NE)	2.432 (0.253, 23.387)	0.4207
Interaction								0.3361
ICC Options								
Paclitaxel	83	4 (4.8)	NR (NE, NE)	79	6 (7.6)	NR (NE, NE)	0.566 (0.159, 2.021)	0.3703
Docetaxel	56	4 (7.1)	NR (NE, NE)	50	1 (2.0)	NR (NE, NE)	2.920 (0.323, 26.438)	0.3173
Interaction								0.1739

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

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Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR of Grade 1 and 2

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	4 (9.3)	NR (NE, NE)	37	0 (0.0)	NR (NE, NE)	54390180.131 (0.000, NE)	0.1138
1	96	4 (4.2)	NR (NE, NE)	92	7 (7.6)	NR (NE, NE)	0.527 (0.154, 1.804)	0.2930
Interaction								0.9901
Region #1								
Asia	103	8 (7.8)	NR (NE, NE)	99	4 (4.0)	NR (NE, NE)	1.623 (0.485, 5.434)	0.4237
Europe/North America	36	0 (0.0)	NR (NE, NE)	30	3 (10.0)	NR (NE, NE)	0.000 (0.000, NE)	0.0567
Interaction								0.9901

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

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Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR of Grade 1 and 2

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	5 (6.4)	--	76	4 (5.3)	--	--	--
Japan	25	3 (12.0)	--	23	0 (0.0)	--	--	--
Europe/North America	36	0 (0.0)	--	30	3 (10.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR of Grade 1 and 2

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	8 (7.6)	NR (NE, NE)	106	5 (4.7)	NR (NE, NE)	1.383 (0.449, 4.259)	0.5672
White	34	0 (0.0)	NR (NE, NE)	23	2 (8.7)	NR (NE, NE)	0.000 (0.000, NE)	0.0892
Interaction								0.9903

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR of Grade 1 and 2

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	3 (6.7)	--	34	2 (5.9)	--	--	--
vCPS < 10%	53	3 (5.7)	--	54	1 (1.9)	--	--	--
Missing	41	2 (4.9)	--	41	4 (9.8)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR >= Grade 3

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	0 (0.0)	--	69	0 (0.0)	--	--	--
>= 65 Years	63	0 (0.0)	--	60	0 (0.0)	--	--	--
Interaction								--
Gender								
Male	118	0 (0.0)	--	106	0 (0.0)	--	--	--
Female	21	0 (0.0)	--	23	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR >= Grade 3

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	0 (0.0)	--	101	0 (0.0)	--	--	--
Non-Smoker	35	0 (0.0)	--	28	0 (0.0)	--	--	--
Interaction								--
ICC Options								
Paclitaxel	83	0 (0.0)	--	79	0 (0.0)	--	--	--
Docetaxel	56	0 (0.0)	--	50	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR >= Grade 3

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	0 (0.0)	--	37	0 (0.0)	--	--	--
1	96	0 (0.0)	--	92	0 (0.0)	--	--	--
Interaction								--
Region #1								
Asia	103	0 (0.0)	--	99	0 (0.0)	--	--	--
Europe/North America	36	0 (0.0)	--	30	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

Patients with events of Grade 1 and 2 imAE (IRR) included all patients with any Grade 1 or Grade 2 imAE (IRR).

Subgroup was included in this table only if each of its subgroups has at least 10 patients. If one or more subgroup had at least 10 events, subgroup analyses would be performed and displayed. Otherwise, number of patients and number of patients with events are displayed.

[a] Median time to event (month) was estimated by Kaplan-Meier method with 95% CI estimated using the method of Brookmeyer and Crowley.

[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR >= Grade 3

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	0 (0.0)	--	76	0 (0.0)	--	--	--
Japan	25	0 (0.0)	--	23	0 (0.0)	--	--	--
Europe/North America	36	0 (0.0)	--	30	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

[c] P-value for treatment effect in each subgroup was based on an unstratified log rank test. P-value for the interaction was based on a Cox regression model stratified by subgroup with a treatment-by-subgroup interaction term to test for differences in treatment effect across subgroups.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR >= Grade 3

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	0 (0.0)	--	106	0 (0.0)	--	--	--
White	34	0 (0.0)	--	23	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

IRR >= Grade 3

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	0 (0.0)	--	34	0 (0.0)	--	--	--
vCPS < 10%	53	0 (0.0)	--	54	0 (0.0)	--	--	--
Missing	41	0 (0.0)	--	41	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious IRR

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Age								
< 65 Years	76	0 (0.0)	--	69	0 (0.0)	--	--	--
>= 65 Years	63	0 (0.0)	--	60	0 (0.0)	--	--	--
Interaction								--
Gender								
Male	118	0 (0.0)	--	106	0 (0.0)	--	--	--
Female	21	0 (0.0)	--	23	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious IRR

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Smoking Status								
Former/Current Smoker	104	0 (0.0)	--	101	0 (0.0)	--	--	--
Non-Smoker	35	0 (0.0)	--	28	0 (0.0)	--	--	--
Interaction								--
ICC Options								
Paclitaxel	83	0 (0.0)	--	79	0 (0.0)	--	--	--
Docetaxel	56	0 (0.0)	--	50	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious IRR

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
ECOG Performance Score								
0	43	0 (0.0)	--	37	0 (0.0)	--	--	--
1	96	0 (0.0)	--	92	0 (0.0)	--	--	--
Interaction								--
Region #1								
Asia	103	0 (0.0)	--	99	0 (0.0)	--	--	--
Europe/North America	36	0 (0.0)	--	30	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

Adverse events were graded for severity using CTCAE v4.03.

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[b] The hazard ratio and its 2-sided 95% CI were estimated from an unstratified Cox regression model.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious IRR

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Region #2								
Asia (excluding Japan)	78	0 (0.0)	--	76	0 (0.0)	--	--	--
Japan	25	0 (0.0)	--	23	0 (0.0)	--	--	--
Europe/North America	36	0 (0.0)	--	30	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious IRR

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Race								
Asian and other	105	0 (0.0)	--	106	0 (0.0)	--	--	--
White	34	0 (0.0)	--	23	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

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Table 14.3.1.3.1.b.s:
Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan

Serious IRR

	Tislelizumab (N = 139)			ICC (N = 129)				
Subgroup	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Total No. of Patients**	**Patients with events n (%)**	**Median time to event (95% CI) [a]**	**Hazard Ratio (95% CI) [b]**	**2-sided p-value [c]**
Baseline PD-L1 Status								
vCPS >= 10%	45	0 (0.0)	--	34	0 (0.0)	--	--	--
vCPS < 10%	53	0 (0.0)	--	54	0 (0.0)	--	--	--
Missing	41	0 (0.0)	--	41	0 (0.0)	--	--	--
Interaction								--

Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.

Abbreviations: ICC = investigator chosen chemotherapy: paclitaxel vs docetaxel; imAE = immune-mediated adverse event; IRR = infusion-related reaction; NE = not estimable; NR = not reached.

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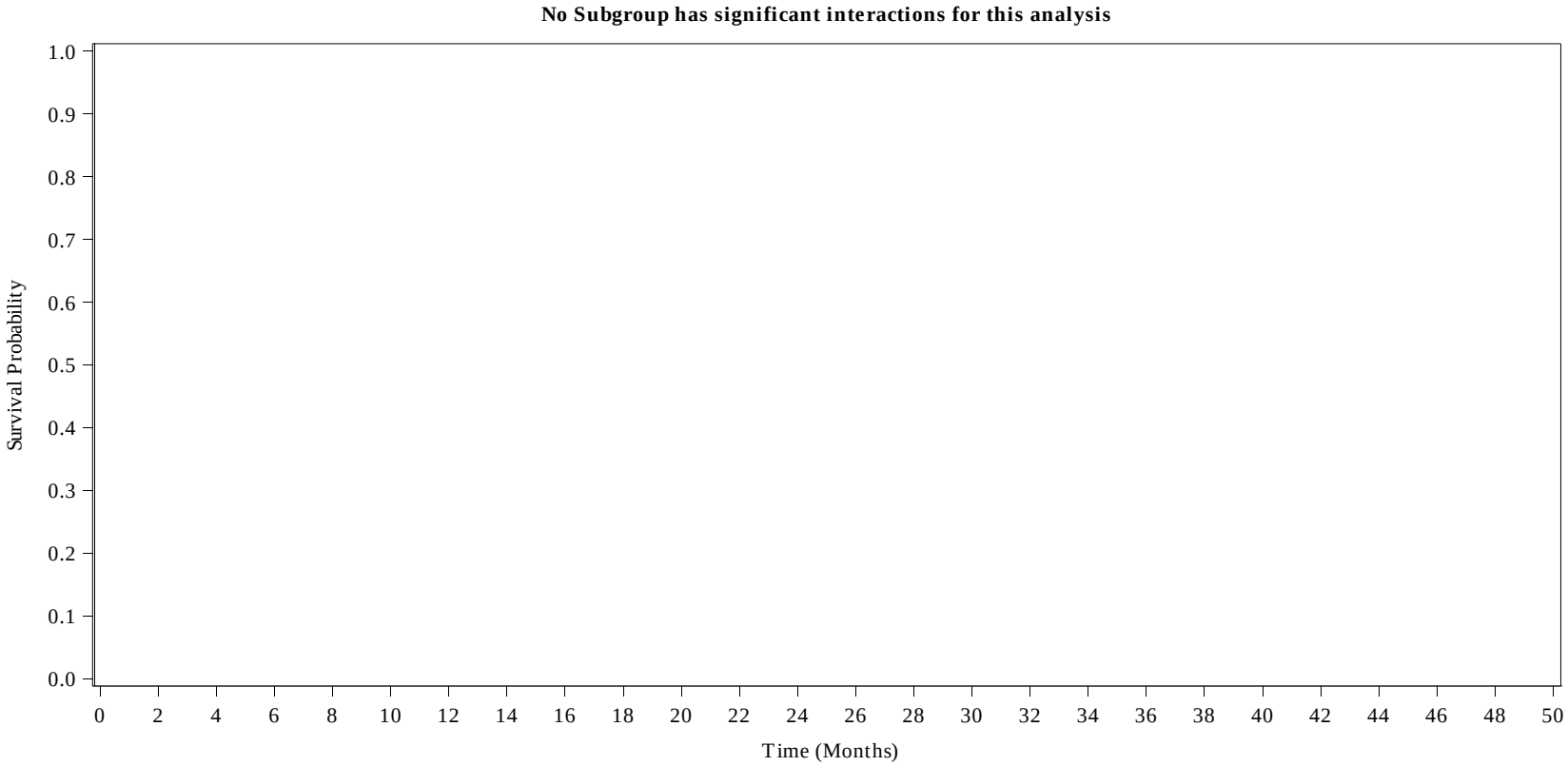
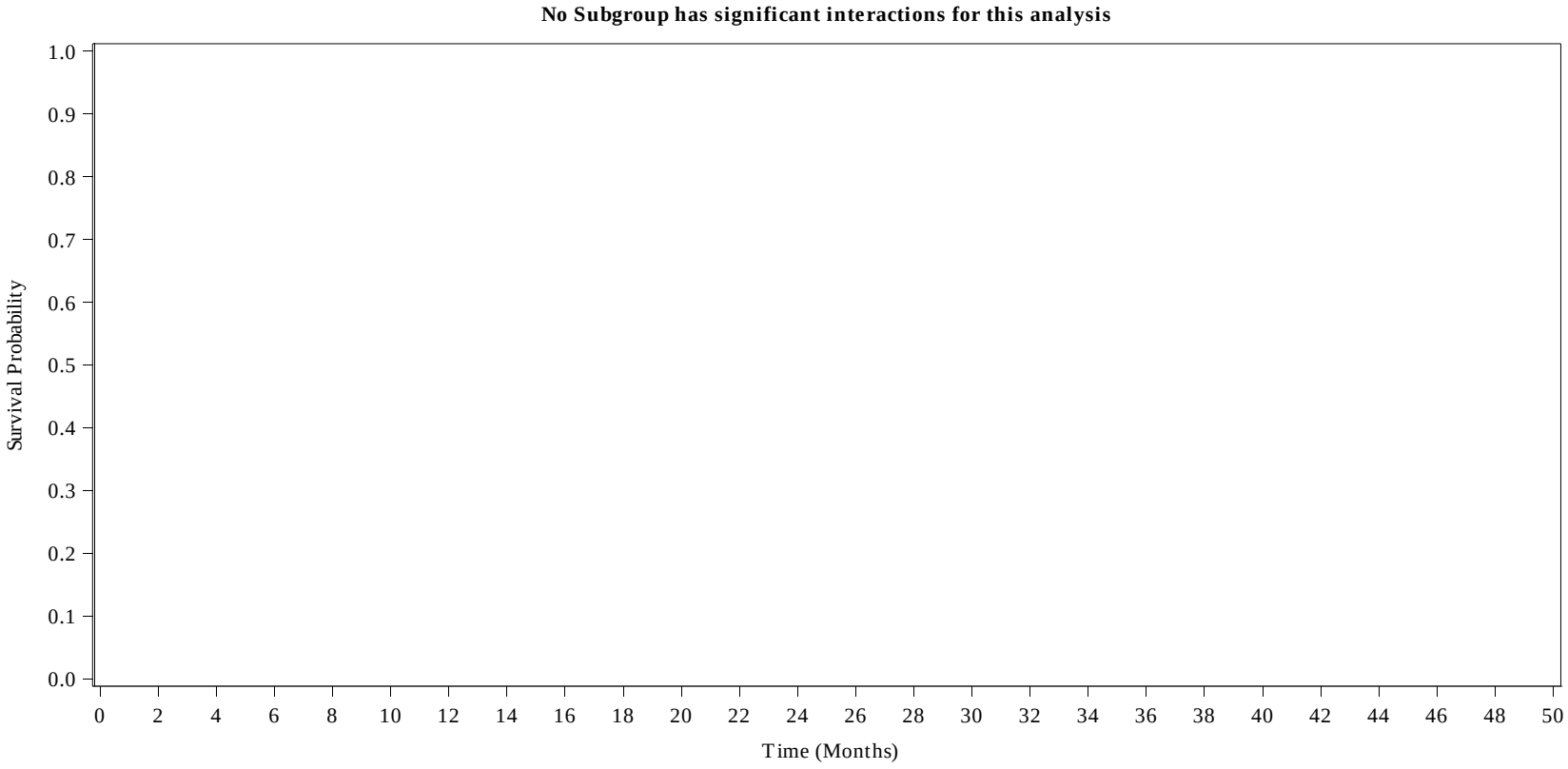
Figure 14.3.1.5.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set



Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesi-subgrp.sas 13AUG2024 18:58 f-14-03-01-05-s-km-aesi-subgrp-safety-cl.rtf

Figure 14.3.1.5.b.s:
Kaplan-Meier Plot of Time to Treatment-Emergent Adverse Events of Special Interest - Subgroup Analysis
Safety Analysis Set - Subpopulation without Irinotecan



Source: ADSL, ADTTEAE1. Data cutoff: 28DEC2022. Data extraction: 13FEB2023.
unblind/bgb_a317/bgb_a317_302/csr_close_gba/dev/pgm/tlfs/f-km-aesi-subgrp.sas 13AUG2024 18:58 f-14-03-01-05-b-s-km-aesi-subgrp-safetys-cl.rtf